

## Editor's Choice — Mid-term Outcomes of Endovenous Laser Ablation in Patients with Active and Healed Venous Ulcers: A Follow-up Study

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### WHAT THIS PAPER ADDS

To the authors' knowledge this is the largest follow-up study with the longest follow-up time of a cohort of patients with an active and healed venous ulcer treated with endovenous laser for superficial venous incompetence. While waiting for randomised controlled studies comparing compression, conventional venous surgery and endovenous treatments in this patient group, the study confirms the findings of other studies that endovenous treatment can be safely offered to patients with active and healed venous ulcers, even the elderly with significant comorbidities, achieving low ulcer recurrence rates after more than three years.

**Objectives:** The aim of this study was to assess the mid-term ulcer recurrence rate in patients with healed or active venous ulcers treated with endovenous laser ablation (EVLA) for incompetent superficial axial veins and to search for possible risk factors for non-healing and recurrence.

**Methods:** Consecutive patients treated with EVLA because of a healed or active venous ulcer between 2006 and 2013 were identified in the medical records and quality registry and invited to follow-up, including clinical history, study examination, Duplex ultrasound scanning, ankle brachial pressure, photoplethysmography, venous clinical severity score (VCSS), and health related quality of life (HRQoL) measured with EQ5D. Of 228 patients, 170 (195 legs) fulfilled the inclusion criteria. Twenty patients were interviewed by phone, 27 were unreachable and 11 were excluded. Univariate and multivariate regression analyses were performed to identify possible risk factors for recurrence.

**Results:** The mean follow-up time was 41 months (range 14–89 months). The average age was 66.6 years (range 36–87 years). All 86 legs operated on for an active ulcer had this ulcer healed sometime between the operation and the study examination, but thereafter it recurred in 14 patients (16%). In 109 legs operated on for a healed ulcer, the ulcer recurred in 17 legs (16%). Complications such as permanent sensory loss were seen in 16 legs (8%) and deep venous thrombosis in two legs (1%). Thirty legs (15%) were re-treated for superficial venous incompetence (SVI). Reduced ankle mobility was a risk factor for recurrence in both univariate and multivariate analysis ( $p = .048$ ).

**Conclusions:** These midterm results demonstrate that endovenous laser ablation of SVI in patients with healed or active venous ulcers achieves good healing and low ulcer recurrence rates, with a low rate of complications and an acceptable re-intervention rate.

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### INTRODUCTION

Chronic venous disease (CVD) is one of the most common pathologies in the general population of adults in both industrialised and developing countries.<sup>1</sup> The most severe form of CVD is venous ulceration with a prevalence of about

1%.<sup>2</sup> Venous ulcers are often painful and affect quality of life negatively.<sup>3</sup> Overall annual costs of CVD represent 1–2% of total healthcare expenditure in Western European countries and in the United States.<sup>2</sup>

The standard treatment for a venous ulcer (VU) is compression, but the recurrence rate is high.<sup>4</sup> The ESCHAR study showed that when VU patients were treated by compression and superficial venous surgery, the recurrence rate of VU was reduced with an absolute risk reduction of 25% compared with compression only.<sup>5</sup> In the authors' clinical experience many patients with VU are not referred for surgical treatment as they are considered either too old,

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with too many comorbidities or the doctor waits for the ulcer to heal before referral. However, with the new endovenous methods that can be performed under local anesthetic it may be possible to treat more patients.

Currently, there are no published randomised trials comparing endovenous methods with superficial venous surgery or compression in VU patients, but the methods have been studied in patients without VU.<sup>6,7</sup> When endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were compared with high ligation and stripping in treating varicose veins (VVs), treatments were found to be as effective and safe 5 years after treatment.<sup>8</sup> In clinical practice EVLA and RFA are increasingly used to treat patients with VU and there are several reports of low recurrence rates but with small groups and short follow-up.<sup>9,10</sup>

The aim of this study was to assess the ulcer recurrence rate after a longer follow-up in a larger cohort of patients with healed or active VU treated with EVLA for superficial venous incompetence (SVI) and to search for possible risk factors for non-healing or recurrence.<sup>11</sup>

## MATERIAL AND METHODS

### Setting

The study was a single centre follow-up study conducted at a private clinic in Stockholm, Sweden, between April 2013 and February 2015. The clinic is dedicated to treating VVs and Stockholm County Council pays for the treatment. The main methods at the original treatment were EVLA, ambulatory phlebectomies, and ultrasound guided foam sclerotherapy (UGFS). Pre-operative duplex ultrasound scanning (DUS) was done by the surgeon in the majority of cases; in some cases the patient was referred to a vascular laboratory. The policy at the clinic was to treat all SVI found on DUS, which meant that all patients with few exceptions underwent concomitant phlebectomies. Treated veins included the great saphenous vein (GSV), below and above the knee, small saphenous vein (SSV), the anterior accessory saphenous vein (AASV), and perforator vein incompetence (PVI). Low molecular weight heparin was given selectively. VU patients were not treated differently from others; follow-up was routinely scheduled after 1 year, but patients were told to come back earlier in the event of any complication, residual varices, or non-healing ulcer. The patient's district or community nurse administered compression therapy pre- and post-operatively, with varying quality depending on the level of training.

### Patients

Consecutive, eligible patients were identified from the quality registry, from procedure codes for EVLA, and from diagnosis codes for venous ulceration in the medical records. Patients treated with EVLA for SVI and who at the time of treatment had a healed or open VU of clinical class C5 and C6 according to the CEAP classification (Clinical—Etiology—Anatomy—Pathophysiology) were invited to participate in the study.<sup>12</sup> PVI was treated at the discretion

of the surgeon, in a few cases with EVLA and in some cases with UGFS or phlebectomies. Medical records for the identified patients were studied and patients who had received treatment other than EVLA or who had another aetiology of leg ulcer were excluded (Fig. 1). The excluded 11 patients included three deaths unrelated to the EVLA treatment and occurred more than a year post-operatively. The remaining patients were invited by means of a written letter, and a repeat invitation was sent to patients who did not answer the first invitation, then attempts were made to make contact by telephone. Those who answered by telephone and chose not to participate were asked for a short interview about their current ulcer status and recurrence. The final sample included in the analysis comprised only the patients who were examined clinically, 170 patients (195 legs).

### Medical history and clinical examination

Medical records and the quality registry were studied for pre-operative C class, DUS findings, anatomical locations treated with EVLA, post-operative complications, and repeat treatments.

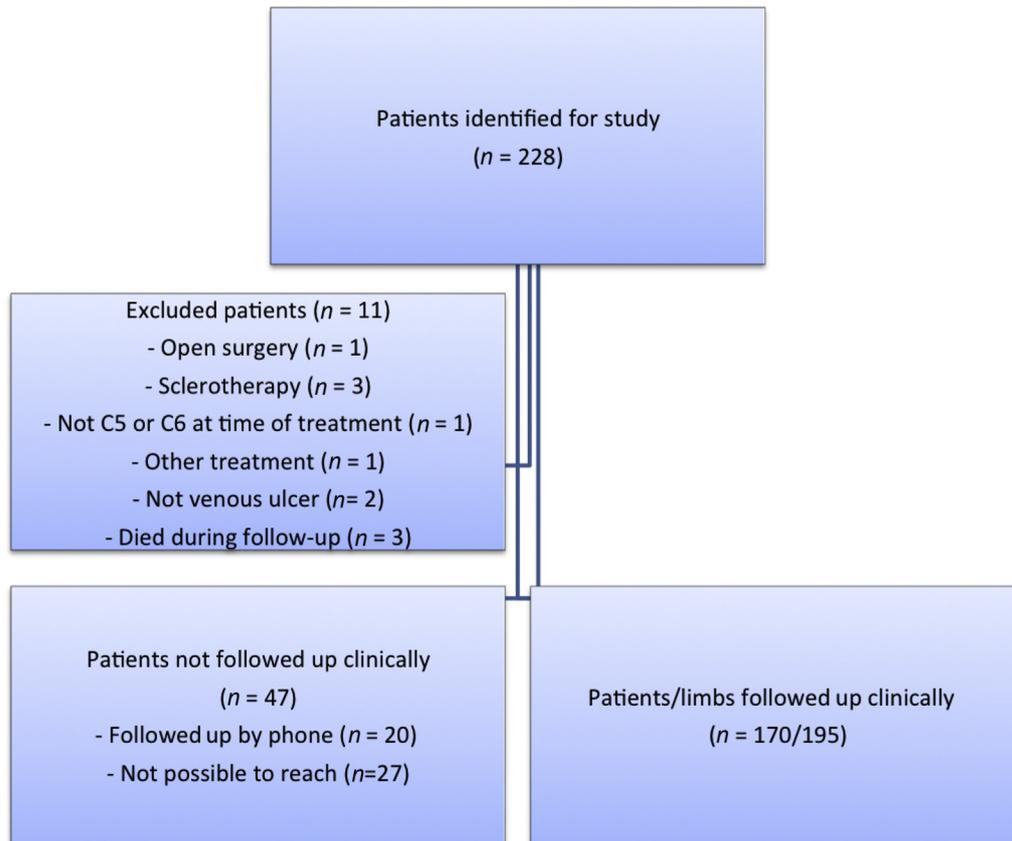
At follow-up a medical history was taken including the presence of cardiovascular disease (coronary heart disease or congestive heart failure), diabetes mellitus (DM), smoking (currently or ceased within the last 5 years), VV treatment before and after EVLA, history of deep venous thrombosis (DVT), non-healing or recurrent VU, and post-operative complications such as DVT, infection, and nerve injury. Ulcer recurrence was defined as any ulcer recurrence on the same lower leg. Patients with a body mass index (BMI, kg/m<sup>2</sup>) of 30 or above were considered obese in accordance with the World Health Organization criteria.<sup>13</sup>

Generic health related quality of life (HRQoL) scoring was measured using the EuroQOL five dimensions questionnaire (EQ-5D)<sup>14</sup> as there is currently no disease specific HRQoL questionnaire for VV or VU in Swedish.

Clinical examination included the C class of CEAP, venous clinical severity score (VCSS), ankle brachial pressure index (ABPI), and ankle mobility.<sup>15</sup> An ABPI < .85 was considered pathological. Ankle mobility was evaluated in conjunction with photoplethysmography (PPG) that required the patient to perform a series of controlled dorsiflexions of the foot. As non-impaired ankle mobility was a prerequisite for the PPG; the examination was also used as a measure of ankle mobility. Stiffness of the ankle and failure to dorsiflex sufficiently for reproducible refilling times and pump volumes was considered impaired mobility.

### Duplex ultrasound scanning

DUS was performed by an experienced vascular sonographer using a colour flow duplex imager (Logic S8, GE Healthcare Global Headquarters, Chalfont St Giles, Buckinghamshire, UK). The femoral and popliteal veins were scanned for post-thrombotic changes by testing compressibility. Valvular function was evaluated in the femoral, popliteal, tibial, fibular, perforating, and superficial veins



**Figure 1.** Chart showing the flow of patients through the study.

after manual distal compression. Reflux was considered significant if longer than 0.5 seconds for superficial and popliteal veins and longer than 1 second for the femoral veins.<sup>16</sup> Perforating veins near the ulcer area (former or current) were considered incompetent if there was outward flow after manual compression and if they had a diameter > 3 mm.<sup>17</sup> For the data analysis, the GSV was evaluated separately in the thigh and lower leg, and the SSV over its entire length. If reflux was present in more than half of these segments it was considered incompetent. The ulcer area was also examined for varicose or insufficient veins with reflux more than 0.5 seconds after manual compression.

### Statistics

All analyses were performed using IBM SPSS version 22 (SPSS Inc., Chicago, IL, USA) software. The chi-square test, Fisher exact test, and *t* test were used to compare proportions between the original C5 and C6 groups, and to compare patients with and without recurrent VU at follow-up. A *p* value < .05 was considered to be statistically significant. Logistic regression was used in the multivariate analysis to identify independent risk factors for ulcer recurrence.

### Ethics

The study was performed in accordance with the Declaration of Helsinki. The Regional Ethics Review Board in Stockholm approved the study under the protocol number

2011/4:7. Patients followed up clinically provided written informed consent.

## RESULTS

### Patient demographics and characteristics

Ninety-four patients (109 legs) were treated for a healed ulcer and 76 patients (86 legs) for an active ulcer. The mean age at the time of operation was  $62.4 \pm 11.2$  years (mean  $\pm$  standard deviation) in the C5 group and  $64.1 \pm 10.5$  years in the C6 group ( $p = .265$ ). The male/female ratio was 42:52 in C5 and 30:46 in C6 group ( $p = .761$ ). No significant difference was seen regarding CVD, BMI, ABPI, PPG, and the anatomical locations of venous incompetence as seen with DUS between the original C5 and C6 legs (Tables 1 and 2).

The only significant differences between the original C5 and C6 legs were a slightly longer follow-up (18 days) ( $p = .013$ ) in the C6 group and more legs operated with EVLA to the SSV ( $p = .049$ ).

### Ulcer healing and recurrence

The mean follow-up time was 41 months (range 14–89 months) and 164 of 195 legs (84%) had a healed ulcer without recurrence after EVLA. In the subgroups, 72 (84%) of pre-operative C6 and 92 (84%) of pre-operative C5 legs had no recurrence ( $p = .897$ ). In all C6 legs at some time between operation and study examination the ulcer had healed, to recur in 14 legs. Information about the time to

**Table 1.** Demographics and characteristics, comparing subjects with healed and open ulcer at the time of EVLA treatment.

	Total	C5 group	C6 group	<i>p</i>
<b>Patients</b>	<b>170</b>	<b>94</b>	<b>76</b>	
Age, mean years ± SD	66.6 ± 10.9	65.8 ± 11.4	67.6 ± 10.4	.491
Male/female	72/98	42/52	30/46	.761
Follow-up, mean months (range)	41 (14–89)	40.6 (14 – 73)	41.2 (17 – 89)	.013
DM	14 (8%)	7 (7%)	7 (9%)	.797
CVD	35 (21%)	17 (18%)	18 (24%)	.414
Smoker	13 (8%)	5 (5%)	8 (11%)	.307
History of DVT	27 (16%)	14 (15%)	13 (17%)	.600
<b>No. of legs</b>	<b>195</b>	<b>109</b>	<b>86</b>	
Previous venous intervention	69 (35%)	41 (38%)	28 (33%)	.259
EVLA of GSV	158 (81%)	91 (83%)	67 (78%)	.324
EVLA of SSV	50 (26%)	22 (20%)	28 (33%)	.049
EVLA of AASV	16 (8%)	11 (10%)	5 (6%)	.280
EVLA of PV	2 (1%)	2 (2%)	0 (0%)	.504
Ulcer recurrence	31 (16%)	17 (16%)	14 (16%)	.897
New EVLA same leg	16 (8%)	10 (9%)	6 (7%)	.579
Same segment	8 (4%)	5 (4.5%)	3 (3%)	
Other VV treatment same leg	15 (8%)	8 (7%)	7 (8%)	.835
VCSS score, mean (SD)	5.59 (3.9)	5.12 (3.8)	6.19 (3.9)	.054

C5 = CEAP clinical class 5 (healed ulcer) at the time of EVLA treatment; C6 = CEAP clinical class 6 (open ulcer) at the time of EVLA treatment; AASV = anterior accessory saphenous vein; CVD = cardiovascular disease; DM = diabetes mellitus; DVT = deep venous thrombosis; EVLA = endovenous laser ablation; GSV = great saphenous vein; PV = perforator vein; SD = standard deviation; SSV = small saphenous vein; VV = varicose vein; VCSS = Venous Clinical Severity Score.

complete healing of the VU was not available, as information from district and community nurses could not be retrieved and many patients could not remember the exact length of time. Of the 31 legs with recurrence 11 had an active ulcer at the time of study examination. The size was

< 2 cm in eight cases and 2–6 cm in three cases. In five cases, the duration was < 3 months in three cases > 3 months < 1 year, and in three cases > 1 year.

Among the 20 patients (20 legs) solely interviewed by telephone, 17 reported a healed VU without recurrence

**Table 2.** Comparison at follow-up in patients and legs with and without recurrent venous ulcer.

	Univariate analysis		<i>p</i>	Multivariate analysis	
	Recurrence (%)	No recurrence (%)		Odds ratio 95% CI	<i>p</i>
Patients, <i>N</i> = 170	27	143			
Age, mean years ± SD	68.8 ± 11.9	66.2 ± 10.8	0.621		
Male/Female	17/10	55/88	0.026		
BMI (kg/m <sup>2</sup> ) < 30/≥ 30	20/7	113/30	0.694		
DM	3 (11)	11 (8)	0.368		
CVD	5 (19)	30 (21)	0.984		
Smoker	0 (0)	13 (8)	0.070		
No. of legs, <i>N</i> = 195	31	164			
GSV (above knee) reflux	1 (3)	13 (8)	0.352		
GSV (below knee) reflux	4 (13)	29 (18)	0.515		
SSV reflux	5 (16)	12 (7)	0.111		
ABPI < 0.85 <sup>a</sup>	3	7	0.197		
EQ-5D index score, mean ± SD	0.68 ± 0.2	0.76 ± 0.2	0.037		
VCSS score, mean ± SD	9.29 ± 4.4	4.89 ± 3.3	0.000		
RT, mean ± SD <sup>b</sup>	13.4 ± 6.3	17.4 ± 9.2	0.029		
Perforator incompetence in ulcer area	18 (58)	44 (27)	0.001	2.42 (0.9–6.2)	.067
VV in ulcer area	25 (81)	96 (59)	0.022	1.96 (0.6–6.0)	.234
Deep vein incompetence	12 (39)	31 (19)	0.015	1.99 (0.8–4.8)	.130
Reduced ankle mobility <sup>c</sup>	7 (23)	16 (10)	0.047	2.92 (1.0–8.5)	.048

ABPI = ankle brachial pressure index; BMI = body mass index; CI = confidence interval; CVD = cardiovascular disease; DM = diabetes mellitus; EQ-5D = EuroQOL-5D; GSV = great saphenous vein; RT = refill time as measured with photoplethysmography; SD = standard deviation; SSV = small saphenous vein; VCSS = Venous Clinical Severity Score; VV = varicose veins.

<sup>a</sup> Values calculated with 18 missing values.

<sup>b</sup> Values calculated with three missing values.

<sup>c</sup> Values calculated with six missing values.

(85%) and the remaining three had had a recurrence after EVLA that healed with compression treatment.

### Post-operative complications and re-treatments

Post-operative complications in the form of persistent sensory loss in the lower leg was reported in 16 cases, all without clinical significance. No major nerve injury was reported and there were two cases of post-operative DVT, both in the lower leg. One of the DVT patients was diagnosed by ultrasound scan by a sonographer a few days post-operatively, and the other was diagnosed at the follow-up DUS examination. Both patients had no symptoms of post-thrombotic syndrome at the follow-up study examination. Thirty legs (15%) had been re-treated for SVI (Table 1). Of the 16 legs that were treated again with EVLA, six were in a new segment. The different segments treated were the GSV (10 legs), SSV (4 legs), AASV (1 leg), and PVI (1 leg). The indication for re-treatment was not explicitly stated in the medical records, thus it is not known if it was done due to a slow healing venous ulcer or due to residual or recurrent VVs.

### Comparison between legs with and without recurrent venous ulcer

The patient characteristics, the treated veins, and the ulcer recurrence rate (15.6% respectively 16.3%;  $p = .897$ ) did not differ between the C5 and C6 groups (Table 1). Therefore legs from both groups were grouped together to compare parameters according to ulcer recurrence (Table 2). Legs with recurrent VU had a statistically significant association with male sex, lower HRQoL, higher VCSS, reduced ankle mobility, and impaired venous function with lower venous refill times in the univariate analysis. There was no significant difference between legs with and without recurrent VU with respect to DM, cardiovascular disease, or smoking.

DUS findings at follow-up in legs with and without recurrence are also shown in Table 2. Deep venous reflux, PVI, and VV in the ulcer area were significantly more common in legs with recurrent VU in the univariate analysis.

Further analysis was conducted to assess risk factors for recurrence with logistic regression. Variables included were PVI, VV in the ulcer area, deep venous reflux, and reduced ankle mobility. The only variable significantly associated with ulcer recurrence was reduced ankle mobility (Table 2).

## DISCUSSION

The aim of this study was to report the mid-term treatment outcomes for a larger cohort of patients with healed or active VU treated with EVLA for SVI: the endpoint was ulcer recurrence. The results are encouraging, 84% of the treated legs (still) had a healed ulcer without recurrence after 3.5 years in a group of 170 patients where 16% were lost to follow-up. Complications were mostly minor and 15% had undergone repeat treatment of VVs. The study thus confirms the findings of previous smaller studies with shorter

follow-up.<sup>18</sup> Many of the patients included were elderly with concomitant diseases, and it is hoped that the results of this and similar studies can encourage treating this particular group of patients more actively.

Complications such as DVT can occur after endovenous treatments, and in this cohort there were two, of minor clinical importance. There were no major nerve injuries, permanent sensory loss occurred in 8% and this may be explained by the treatment of the GSV below the knee.

Concerns have been raised about the durability of endovenous methods, and one cause of recurrence is incompetence of the AASV.<sup>19</sup> In this study, 30 legs (15%) had a new treatment for SVI within 3.5 years, but only one leg in the AASV, and the most common segment was the GSV below the knee, which is similar to open surgery.<sup>20</sup> Unfortunately indications for retreatment were not recorded.

Deep venous reflux, presence of PVI and/or VVs in the ulcer area and reduced ankle mobility are considered risk factors for ulcer recurrence<sup>21,22</sup> and in this study this was confirmed in the comparison of groups but not in the logistic regression except for reduced ankle mobility. The reason for the difference between the univariate and multivariate analysis is probably multifactorial. Collinearity between predictors in the multivariate logistic regression and lack of power to detect a statistically significant association are two possible reasons. Peripheral arterial disease and recurrent superficial venous reflux are other risk factors in previous studies but this was not confirmed here.

One of the limitations with the study is that it is not known how much the added treatments of local varicosities and PVI improved the long-term results in terms of ulcer healing and recurrence, and in the medical records it was not specified exactly how many perforators and VVs in the ulcer area were treated. Possibly, patients with active or healed VU are more vulnerable to continuing deep, superficial, or perforator venous reflux in the area and thus could benefit more from radical treatment than VV patients without skin changes. This was also the tradition of the clinic and one of the reasons that in some cases the GSV was also treated with EVLA below the knee, which is controversial as it may cause more nerve injuries.

The role of PVI remains uncertain, there are no randomised trials with long-term follow-up showing that treating PVI reduces VU recurrence, even though several other studies have shown low recurrence rates after meticulous treatment of PVI.<sup>23–27</sup> The finding of a significant PVI association with ulcer recurrence may be that PVI increases with impaired global venous function and thus PVI may not reach significance in the multivariate analysis when other duplex findings are included.

A remarkable finding in this study was that all C6 legs had healed their original VU at some time before the study examination, after which it recurred in 14 patients. In most reports a certain percentage will not heal without complete eradication of venous reflux and ongoing ambulatory compression therapy. This result may be due to patient selection, presumably patients with giant ulcers of long-

standing duration were not referred to the clinic and few patients with a history of DVT were included.

Certainly a randomised controlled study may better answer the question about the efficacy of endovenous methods in treating patients with healed or active venous ulcers. Nevertheless the strength of this study is that EVLA was performed in clinical practice with no special care or follow-up for VU patients and even so the recurrence rate was low.

## CONCLUSION

Endovenous laser ablation of superficial venous insufficiency in patients with healed or active venous ulcers confers both ulcer healing and low recurrence rates in a majority of patients with a low rate of complications and a modest rate of re-interventions.

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## CONFLICT OF INTEREST

None.

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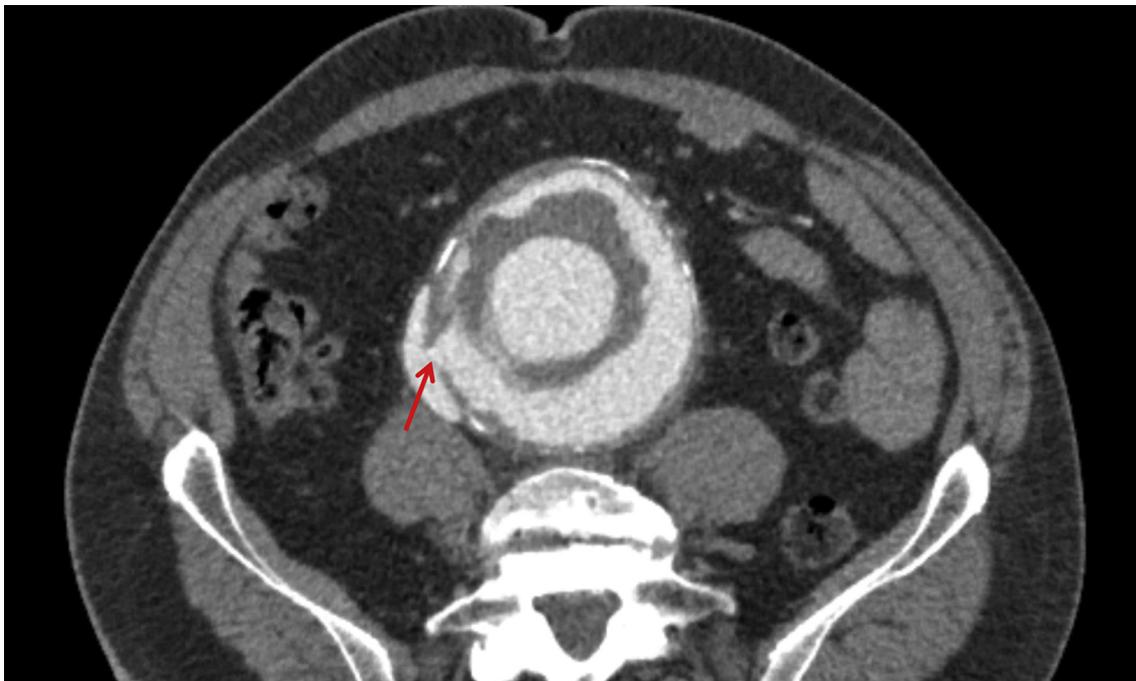
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## COUP D'OEIL

### Bull's Eye of the Abdominal Aorta

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A 64 year old man presented with acute abdominal pain, tachycardia, and a pulsatile abdominal mass. Computed tomography angiography illustrated an unusual manifestation of intracaval rupture of abdominal aortic aneurysm (AAA) causing an aortocaval fistula (ACF; arrow). Intravascular contrast can be visualised in a bilaminar configuration within the aortic lumen and also within intraluminal thrombus, resulting in the presentation of a bull's eye appearance, with contrast notable in the inferior vena cava. The patient underwent an open repair of the AAA with primary closure of the ACF. Post-operative recovery was uneventful.

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