

Post-ablation thrombus extension [PATE] as a complication of endovenous catheter procedures

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Keywords

Post-ablation thrombus, EHIT, PASTE, PATE, endovenous therapy, varicose veins, thrombosis, laser, RFA, radiofrequency

Summary

With a prevalence of 0.2–6%, appositional thrombi (post-ablation thrombi extensions) are not an uncommon complication after endovenous catheter procedures. Potential risk factors have not been adequately investigated to date and there is a lack of standards for appropriate prophylaxis and a consistent treatment regimen. We undertook a retrospective analysis of the prevalence and possible risk factors for the occurrence of an appositional thrombus after endovenous procedures carried out in the Freiburg Vein Centre from 2015–2017. The risk factors described in the literature such as vessel diameter > 7.5mm, simultaneous miniphlebectomy and an elevated BMI could not be confirmed. The staging and designations of the appositional thrombus in international use such as EHIT (endovenous heat-induced thrombosis) and PASTE (post-ablation super-

ficial thrombus extension) are misleading, because this complication can also occur with non-thermal methods and involves a thrombus extension into the deep venous system. We therefore recommend the modified name PATE (post-ablation thrombus extension). PATE grade 0 corresponds to a planar occlusion and therefore a successful therapeutic outcome. PATE I describes a thrombus extension with narrowing of the lumen of the deep vein of up to 25%, PATE II up to 50% and PATE III >50%. For PATE II upwards, the authors recommend therapeutic anticoagulation until the post-ablation thrombus has disappeared.

Schlüsselwörter

Appositionsthrombus, EHIT, PASTE, PATE, endovenöse Therapie, Varikosis, Thrombose, Laser, RFA, Radiofrequenz

Zusammenfassung

Appositionsthromben sind mit einer Prävalenz von 0,2–6% eine nicht seltene Komplikation nach endovenösen Katheterverfahren. Mögli-

che Risikofaktoren wurden bislang noch nicht ausreichend untersucht, außerdem fehlen Standards für eine angemessene Prophylaxe und ein einheitliches Therapieschema. Wir haben eine retrospektive Analyse von 2015–2017 bezüglich der Prävalenz sowie möglicher Risikofaktoren für das Auftreten eines Appositionsthrombus nach endovenösen Verfahren im Venenzentrum Freiburg durchgeführt. Die in der Literatur beschriebenen Risikofaktoren wie, Gefäßdurchmesser > 7,5mm, simultane Miniphlebektomien sowie ein erhöhter BMI konnten nicht verifiziert werden. Die Stadieneinteilung und die Bezeichnungen des Appositionsthrombus im internationalen Gebrauch wie EHIT (endovenöse hitzeinduzierte Thrombose) und PASTE (post ablation superficial thrombus extension) sind irreführend, da diese Komplikation auch bei nicht-thermischen Verfahren auftreten kann und es sich um eine Thrombusextension ins tiefe Venensystem handelt. Daher empfehlen wir die modifizierte Bezeichnung PATE (post ablation thrombus extension). Ein PATE 0 entspricht einem planen Verschluss und ist somit ein Therapieerfolg. PATE I beschreibt eine Thrombusextension mit Einengung des Lumens der tiefen Vene bis zu 25%, PATE II bis 50% und PATE III >50%. Eine therapeutische Antikoagulation empfehlen die Autoren ab PATE II mit einer Dauer bis zum Verschwinden des Appositionsthrombus.

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Appositionsthrombus als Komplikation endovenöser Katheterverfahren (Post ablation thrombus extension [PATE])

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According to the current literature, endovenous heat-induced thrombosis (EHIT) – or preferably also named post-ablation superficial thrombus extension (PASTE) – is observed as a complication of endoven-

ous catheter procedures in 0.9% – 6.0% of patients treated with laser ablation and approx. 0.2% of those treated by radiofrequency ablation. PASTE is characterised by the appositional growth of a thrombus into

the deep vein (2, 3, 5, 6). Unfortunately, the terms in international use are misleading, because the thrombus extends into the deep vein system and is not a superficial extension. We therefore recommend the

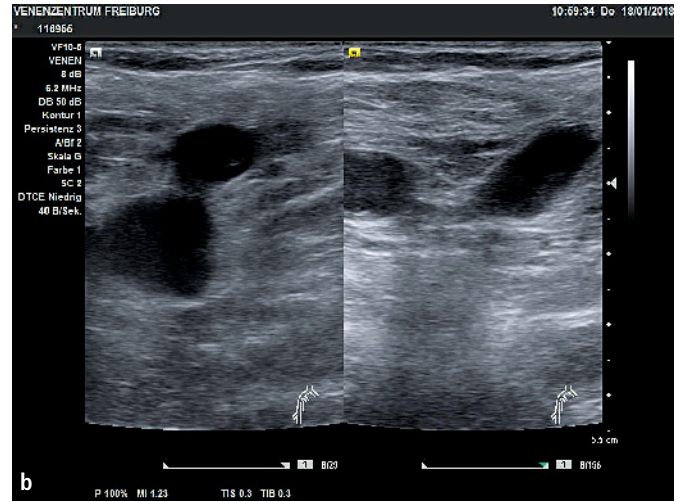
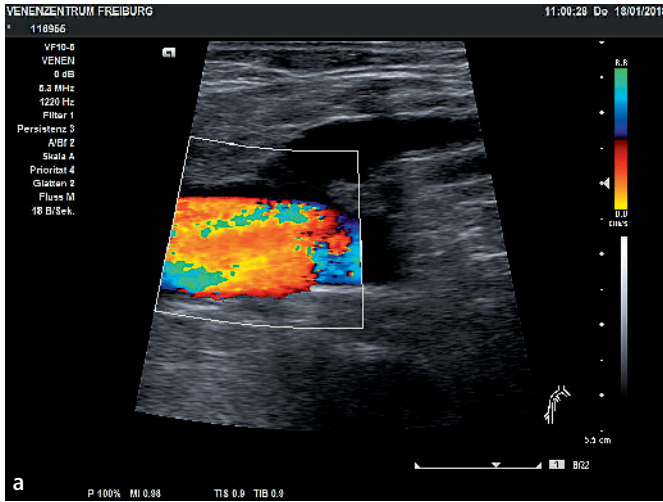


Fig. 1 a and b: Patient 0, showing the desired therapeutic outcome of a PATE grade 0 ten days after laser ablation of the great saphenous vein (GSV). The thrombus extends only up to the deep vein, corresponding to a planar occlusion of the GSV.

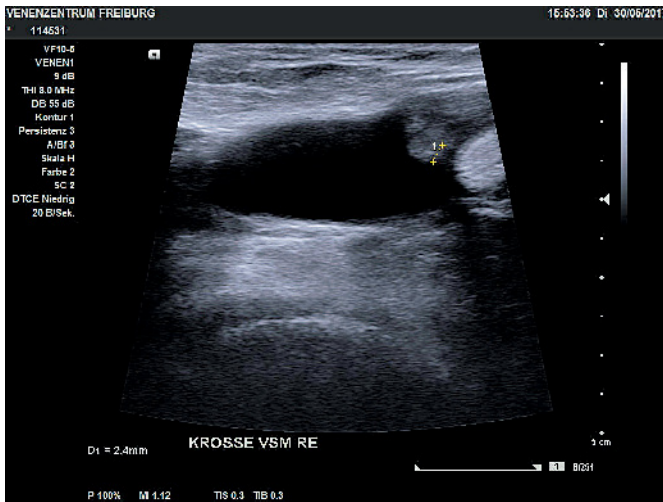


Fig. 2 Patient 1, PATE I ten days after Venefit® of the GSV and anterior accessory saphenous vein (AASV) combined with foam sclerotherapy of the right leg. A miniphlebectomy was not performed.

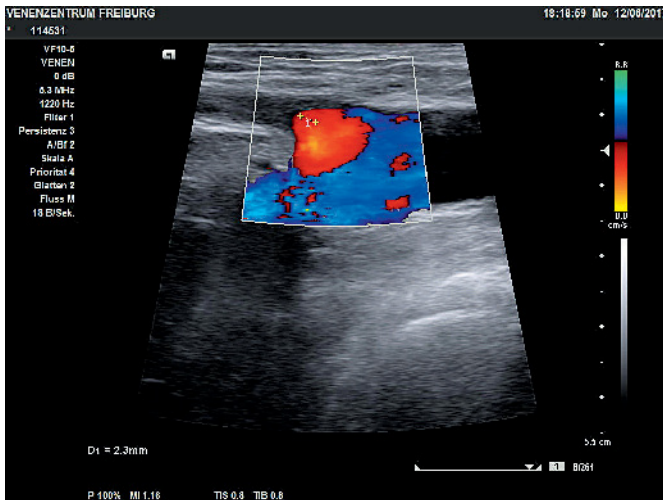


Fig. 3 Patient 1, follow-up after 12 days. The thrombus was no longer visible; pharmacotherapy was not carried out.

modified name PATE: post-ablation thrombus extension (in the style of PASTE).

According to the current literature, the main risk factors that play a significant role in the occurrence of a PATE are a large venous diameter >7.5mm, simultaneous phlebectomies and high-grade CEAP classes. The literature concerning the male sex as a risk factor is contradictory (5, 6). These parameters could not be confirmed as risk factors in our centre and an elevated BMI, concomitant treatment of the AASV or the duration of post-interventional anti-coagulation also do not appear to have a significant influence on PATE occurrence (▶ Tab. 4). According to the literature, the risk can be reduced through the use of laser systems in the wavelength region of 1470 nm, which have a high absorption spectrum in the range of water (2, 5).

A total of four grades of severity of PATE have been differentiated (1, 4).

We recommend the following modified classification:

- PATE 0: extension of thrombus only up to the deep vein (=planar occlusion = desired outcome of treatment).
- PATE I: extension of thrombus a few millimetres into the deep vein with up to 25% narrowing of the lumen.

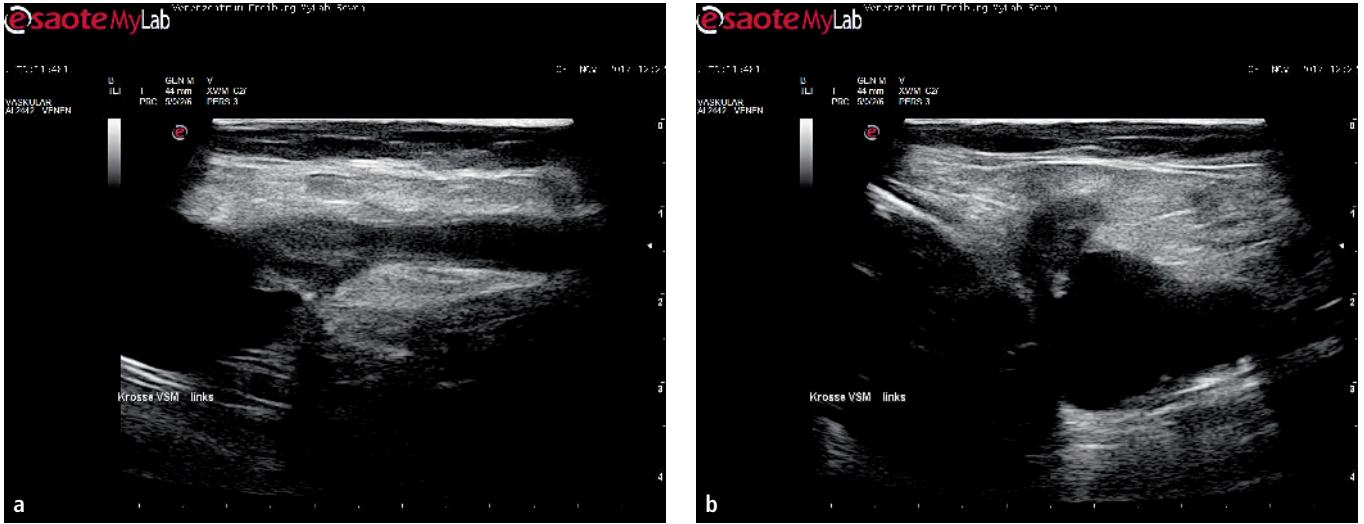


Fig. 4 a and b: Patient 2, PATE I-II (left leg) ten days after laser ablation of both GSV and miniphelebectomy combined with foam sclerotherapy. Anticoagulation with weight-adjusted tinzaparin was initiated.

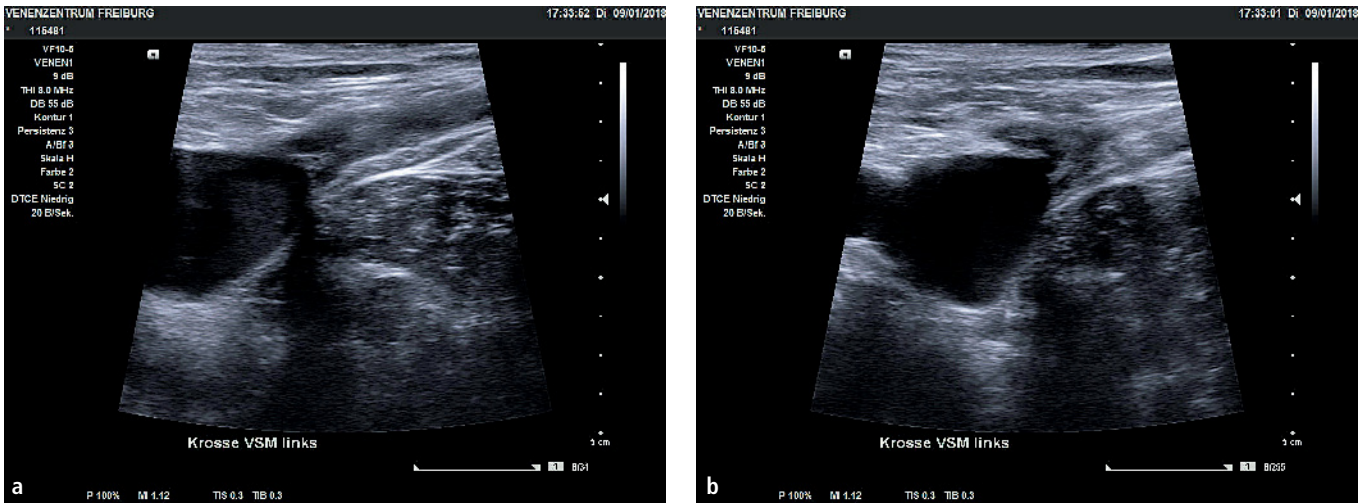


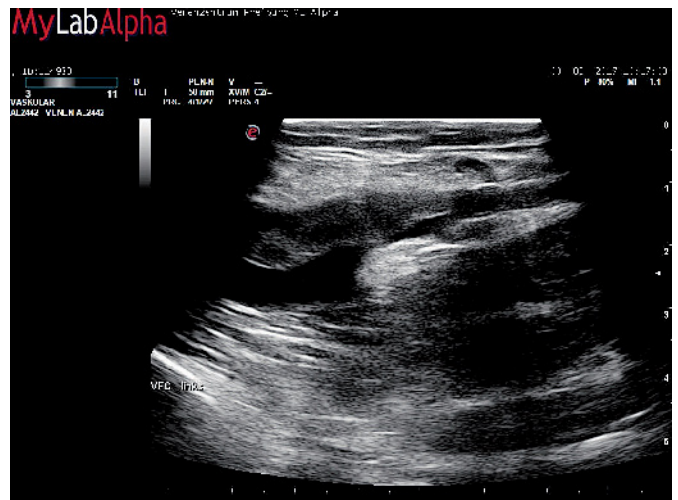
Fig. 5 a and b: Patient 2, follow-up after 10 days of treatment with weight-adjusted tinzaparin; the thrombus was no longer visible and the LMWH treatment was ended after 10 days.

- PATE II: extension into the deep vein with up to 50% narrowing of the lumen.
- PATE III: > 50% narrowing of the deep vein
- PATE IV: complete short occlusion of the deep vein

A PATE 0 is a desired effect of treatment.

A PATE I is followed-up within one to two weeks until the protrusion in the deep vein has regressed; drug treatment is not necessary. Exceptions are cone-like apposition thrombi that could exert a significant

Fig. 6 Patient 3, PATE II ten days after laser ablation of GSV and AASV. No foam sclerotherapy or miniphelebectomy was performed. Weight-adjusted tinzaparin treatment was initiated.



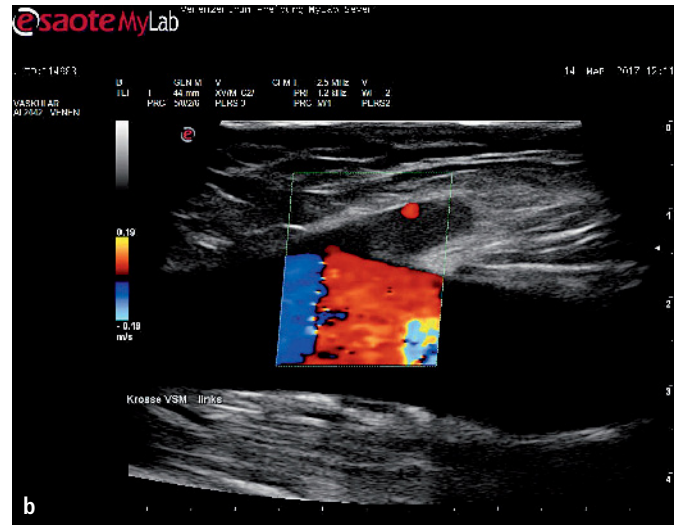
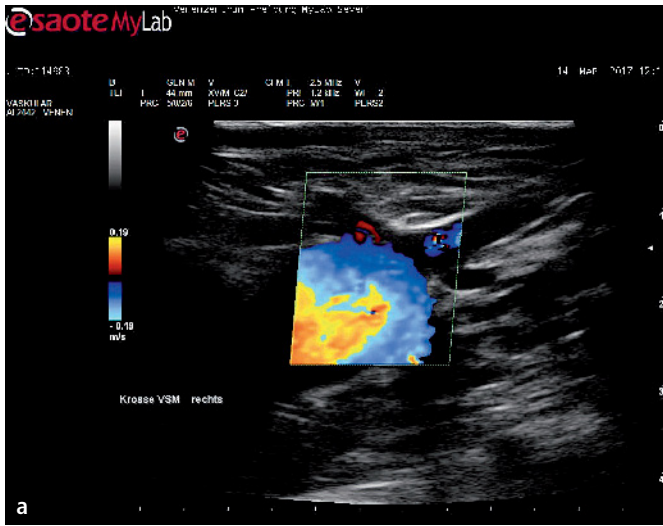


Fig. 7 a and b: Patient 3, since the post-ablation thrombus had still not dissolved after 14 days of LMWH, the weight-adjusted tinzaparin treatment was extended to a total of 30 days. Thereafter the thrombus was no longer visible and tinzaparin could be discontinued.

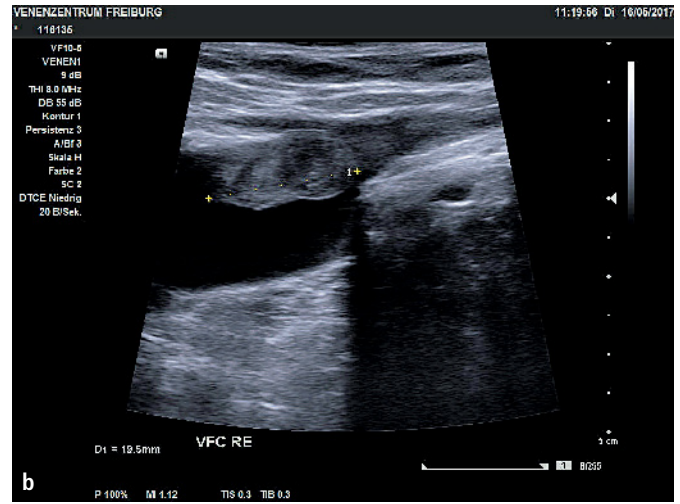
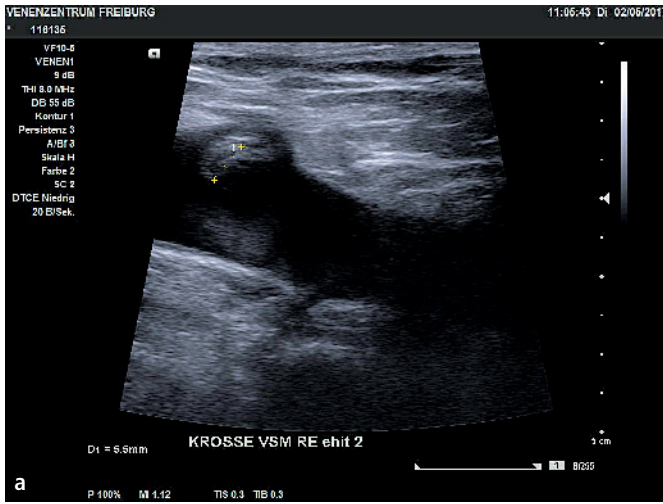


Fig. 8 a and b: Patient 4, PATE II (right leg) ten days after laser ablation of both GSV, combined with foam sclerotherapy. Weight-adjusted tinzaparin treatment was initiated.

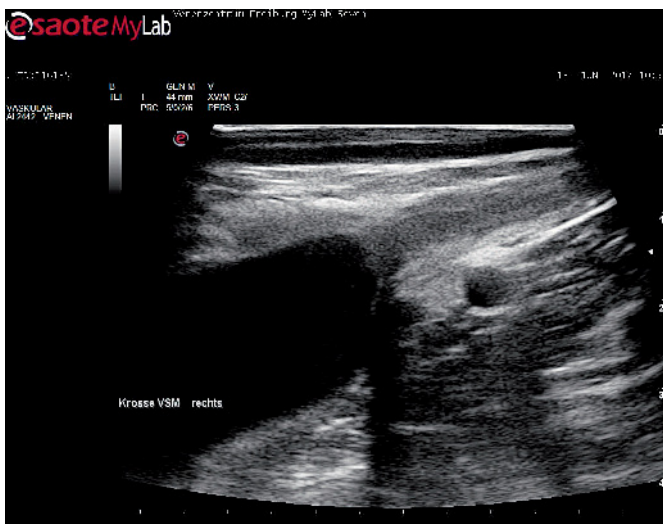


Fig. 9 Patient 4, also in this case, the post-ablation thrombus had not dissolved after 14 days treatment with LMWH, so the treatment was extended to a total of 30 days. After this, the thrombosis was no longer visible and tinzaparin could be discontinued.

influence on haemodynamics. The authors always treat these with therapeutic doses of LMWH (even when luminal narrowing is <25%).

From PATE II upwards, the authors recommend therapeutic anticoagulation until the appositional thrombus has disappeared. A follow-up check is also indicated within two weeks.

These are merely recommendations. Naturally, the treating physician retains the right to extend the treatment of a PATE,

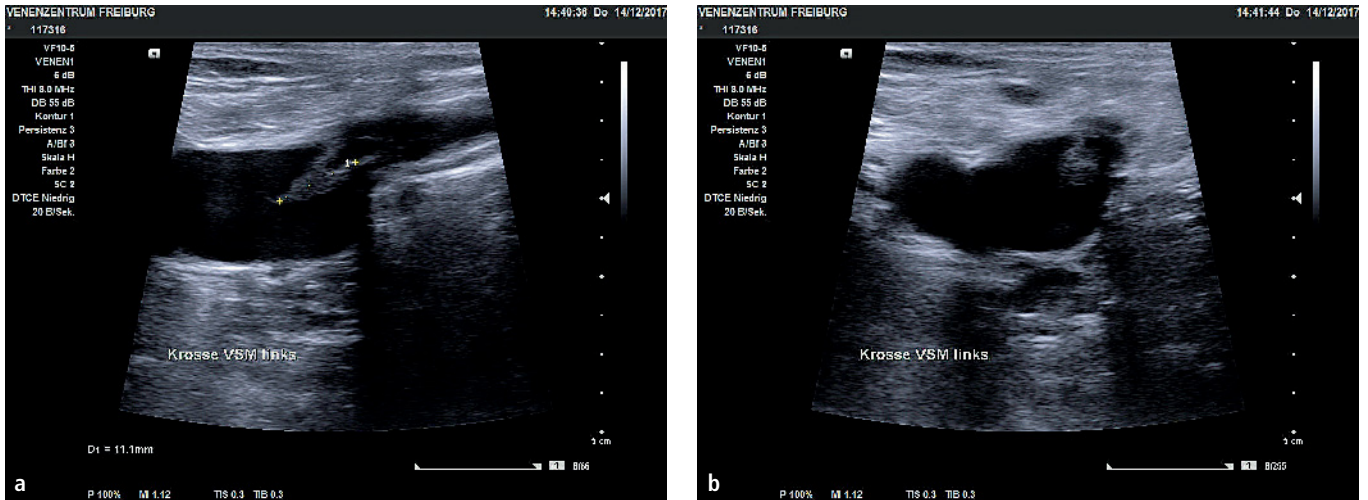


Fig. 10 a and b: Patient 5, PATE II (left leg) after laser ablation of GSV and AASV combined with a miniphlebectomy and foam sclerotherapy. Weight-adjusted tinzaparin treatment was initiated.



Fig. 11 Patient 5, follow-up after 14 days of weight-adjusted tinzaparin treatment. The thrombus has dissolved and the LMWH was discontinued.

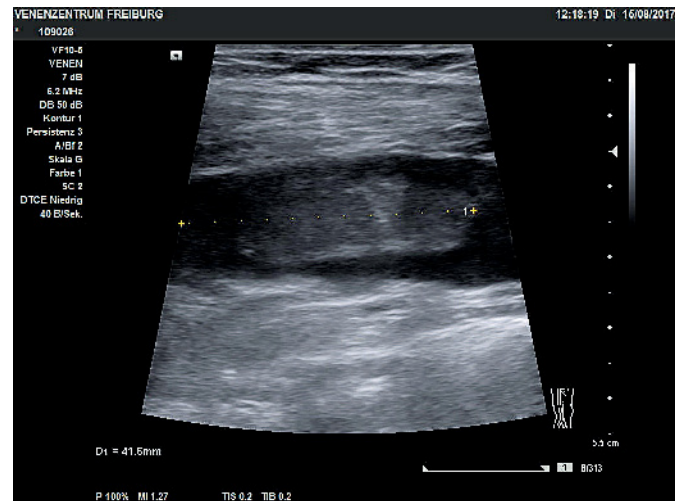


Fig. 12 Patient 6, PATE III (left leg) ten days after laser ablation of left GSV and AASV and of right GSV (recurrence). No miniphlebectomy or foam sclerotherapy was performed. Oral anticoagulation (OAC) with therapeutic doses of rivaroxaban was initiated.

adapted to the individual risk profile of the patient.

Discussion of the modified PATE classification and treatment recommendations:

38 (2.19%) PATE occurred at the Freiburg Vein Centre after laser ablation and 9 (1.65%) PATE after segmental radiofrequency ablation (RFA) (Closure Fast©) in 2017, with a total of 1732 and 53 procedures respectively. In 2015, there were only 7 (0.42%) after laser and 4 (0.59%) after RFA (► Tab. 1, ► Tab. 2, ► Tab. 3).

The difference in numbers of PATE after laser or RFA in our centre in 2015 and 2017 can be explained by the number of postoperative duplex ultrasound follow-up scans that were carried out. In 2017, all patients were asked to attend a follow-up after about 7–14 days, whereas in 2016 this routine check was only carried out in approx. 50% of patients. In 2015, the patients were not seen again until approx. 6 weeks after the procedure, by which time any PATE could have regressed. This suspicion is also suggested by the current literature, where

progression rates of an untreated EHIT I-II (= modified PATE I-II) of only about 3% have been reported (5, 6).

If the protrusion is small, the majority of PATE – especially PATE 1 – certainly regress in the weeks after the endovenous treatment. The authors therefore recommend a modified classification and a delay in starting treatment, if the venous narrowing is less than 25%, with regular scans until the appositional thrombus has regressed. However, there is the danger of thrombus progression and/or a pulmonary

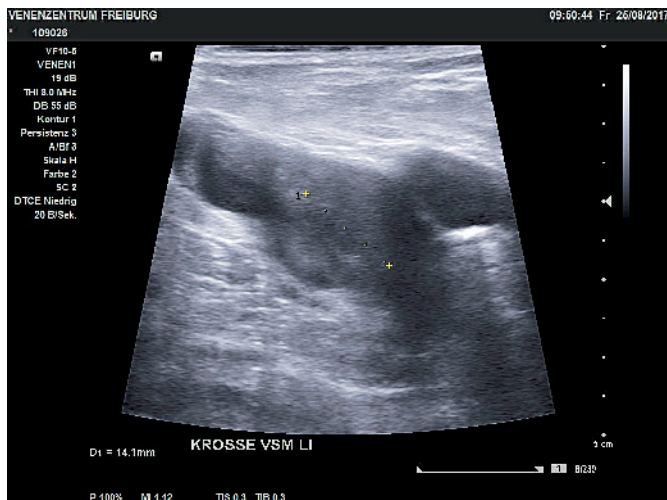


Fig. 13 Patient 6, after ten days treatment with therapeutic doses of rivaroxaban, the thrombus continued to fill more than 50% of the common femoral vein (CFV). The OAC with therapeutic doses of rivaroxaban was continued.

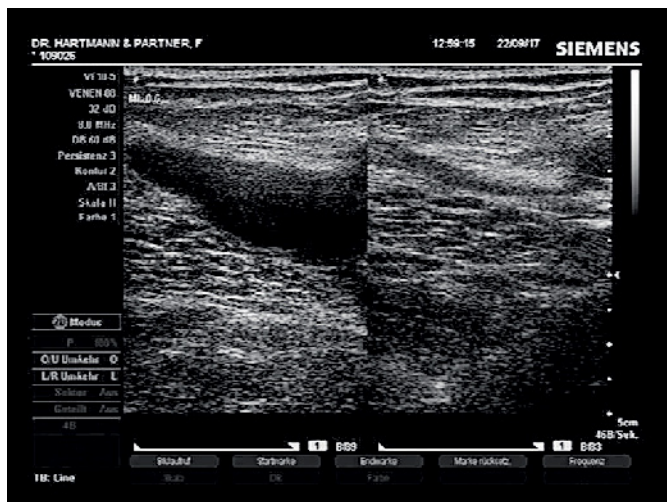


Fig. 14 Patient 6, follow-up after 39 days of therapeutic doses of rivaroxaban. The CFV was patent once again, rivaroxaban was discontinued.

embolism with PATE 2 or higher – or with cone-shaped (fluctuating) appositional thrombi – and hence the authors recommend (in contrast to the international use) therapeutic anticoagulation until the thrombus has regressed.

We adapt the prophylactic postoperative administration of LMWH to the respective risk profile of the patients. Therefore no conclusions can be drawn from our data as to whether long-term postoperative administration of LMWH can prevent the occurrence of a PATE.

In some cases, several weeks' treatment with therapeutic doses of LMWH were necessary, but in other cases, the anticoagulation could be discontinued after ten days (▶ Tab. 4). This underlines the need for duplex ultrasound follow-up scans at regular intervals until the appositional thrombus has completely dissolved.

In 2017, there were gratifyingly no thromboses after endovenous catheter procedures in our centre. In 2015, one patient developed a DVT after such treatment and in 2016 two patients were affected (▶ Tab.

5). In two patients, duplex ultrasound follow-ups were not undertaken until after four or eight weeks. One patient presented with thrombosis as early as the follow-up check on the tenth post-operative day.

Two of the three affected patients also developed a pulmonary embolism and had severe post-thrombotic changes, with deep truncal vein incompetence, also at the subsequent follow-ups, so long-term oral anticoagulation was indicated. A DVT (no PATE IV!), which occurs as early as 10 days after the intervention, should be classified

Tab. 1 Number (n) of post-ablation thrombi as complication of endovenous catheter procedures in Freiburg Vein Centre in 2017

| | Total n (%) | Laser n (%) | RFA n (%) |
|------------|-------------|-------------|-----------|
| Procedures | 2275 | 1732 | 543 |
| PATE total | 47 (2.06) | 38 (2.19) | 9 (1.65) |
| PATE I | 22 (0.97) | 17 (0.98) | 5 (0.92) |
| PATE II | 19 (0.84) | 18 (1.04) | 1 (0.18) |
| PATE III | 5 (0.22) | 2 (0.12) | 3 (0.55) |
| PATE IV | 1 (0.04) | 1 (0.06) | 0 |

Tab. 2 Number (n) of post-ablation thrombi as complication of endovenous catheter procedures in Freiburg Vein Centre in 2016.

| | Total n (%) | Laser n (%) | RFA n (%) |
|------------|-------------|-------------|-----------|
| Procedures | 1911 | 1238 | 673 |
| PATE total | 32 (1.67) | 17 (1.37) | 13 (1.93) |
| PATE I | 9 (0.47) | 4 (0.32) | 5 (0.74) |
| PATE II | 17 (0.89) | 10 (0.80) | 6 (0.89) |
| PATE III | 4 (0.20) | 2 (0.16) | 1 (0.15) |
| PATE IV | 2 (0.20) | 1 (0.08) | 1 (0.15) |

Tab. 3 Number (n) of post-ablation thrombi as complication of endovenous catheter procedures in Freiburg Vein Centre in 2015

| | Total n (%) | Laser n (%) | RFA n (%) |
|------------|-------------|-------------|-----------|
| Procedures | 1635 | 831 | 804 |
| PATE total | 7 (0.42) | 3 (0.36) | 4 (0.59) |
| PATE I | 3 (0.18) | 1 (0.12) | 2 (0.29) |
| PATE II | 3 (0.18) | 2 (0.24) | 1 (0.12) |
| PATE III | 0 | 0 | 0 |
| PATE IV | 1 (0.06) | 0 | 1 (0.12) |

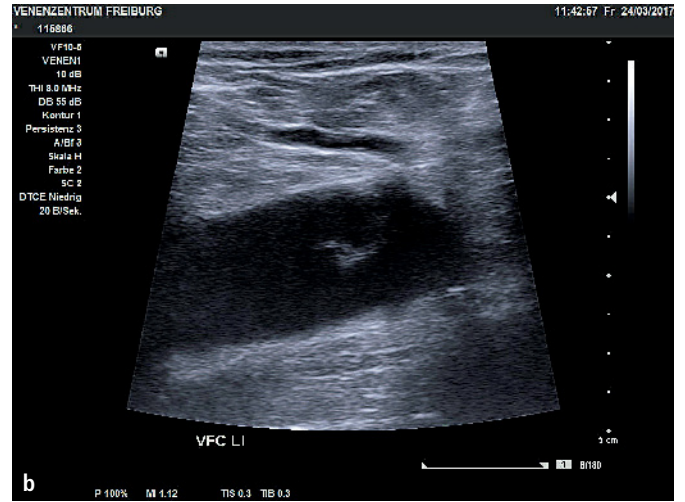
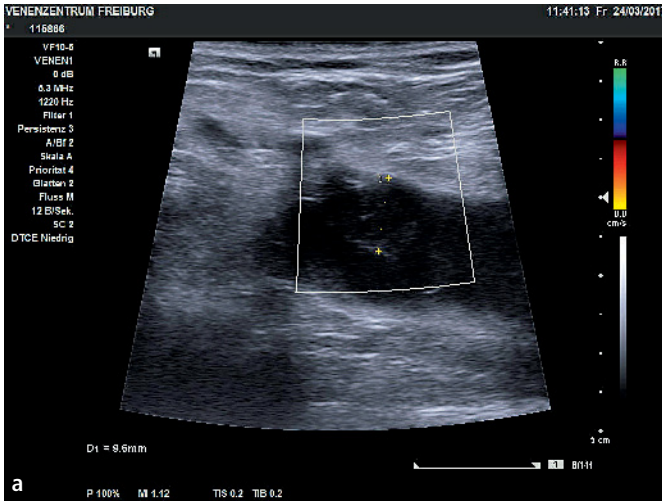


Fig. 15 a and b: Patient 7, PATE III left leg ten days after laser ablation of the left GSV combined with a miniphlebectomy and foam sclerotherapy. Weight-adjusted treatment with tinzaparin was initiated.

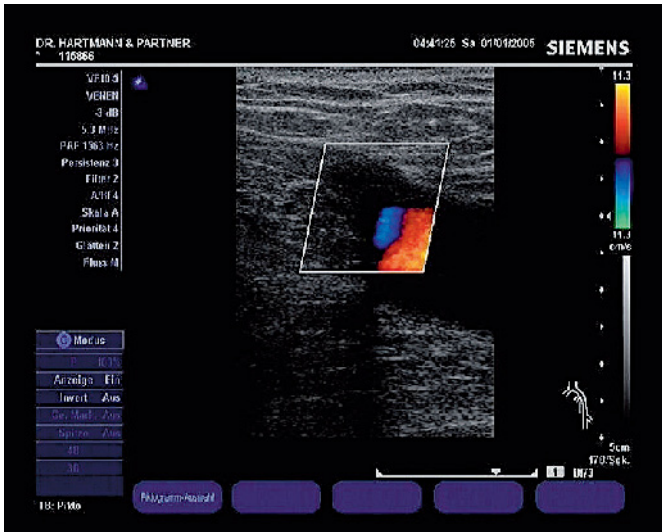


Fig. 16 Patient 7, follow-up after ten days of weight-adjusted tinzaparin. The thrombus was no longer visible; tinzaparin was discontinued after a total of 10 days.

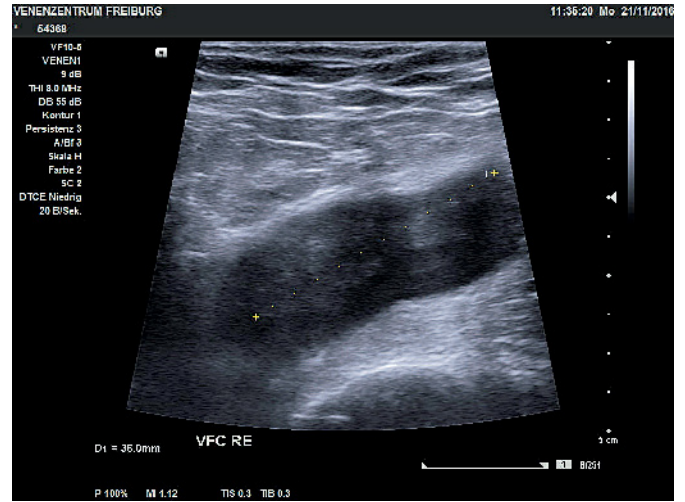


Fig. 17 Patient 8, PATE IV (right leg) (corresponds to a deep vein thrombosis (DVT) follow-up 10 days after sealing of the right GSV with vein glue (VenaSeal®) combined with a miniphlebectomy and foam sclerotherapy. OAC with rivaroxaban was initiated.

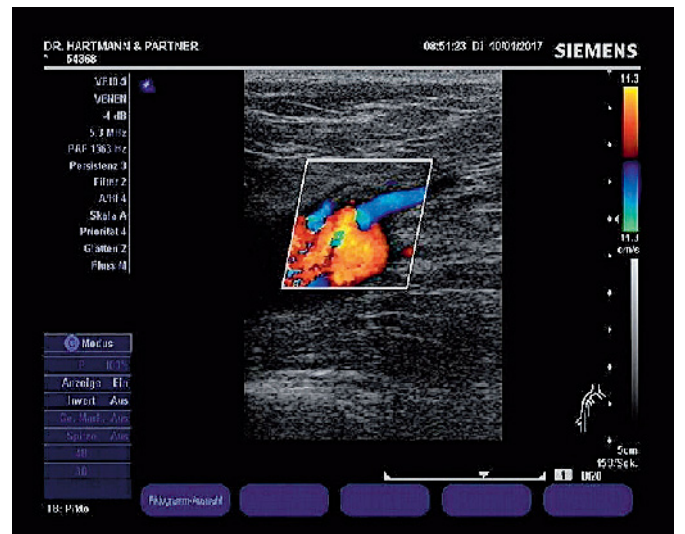
as a direct side effect of therapy and, according to the literature, occurs in 0.6%-1% of treated veins (3, 7).

In conclusion, through regular follow-ups and consistent treatment of PATE, we were able to prevent potential DVTs in 2017. However, evaluation of the data showed that mild cases of PATE (PATE 1) do not always need to be treated and regression can take place even without LMWH.

Further prospective and retrospective studies are certainly necessary to ensure

Fig. 18

Patient 8, after seven weeks treatment with rivaroxaban, the vein is patent once again. The oral anticoagulation was continued for three months, according to the guidelines for treatment of a DVT.



Tab. 4 Risk profile of patients who developed a PATE after endovenous catheter procedures in the Freiburg Vein Centre 2015–2017.

| | 2015 | 2016 | 2017 |
|-------------------------|----------|-----------|-----------|
| PATE I | | | |
| Female (%) | 0 | 6 (66.7) | 11 (50) |
| Male (%) | 3 (100) | 3 (33.3) | 11 (50) |
| BMI | 32 ± 0 | 33 ± 6 | 26 ± 5 |
| Laser (%) | 1 (33.3) | 0 | 17 (77.3) |
| RFA (%) | 2 (66.7) | 4 (44.4) | 5 (22.7) |
| Miniphlebectomy (%) | 3 (100) | 5 (55.6) | 18 (81.8) |
| GSV (%) | 3 (100) | 9 (100) | 19 (86.4) |
| SSV (%) | 0 | 0 | 2 (9.0) |
| AASV co-treated (%) | 0 | 0 | 4 (18.2) |
| Bilateral procedure (%) | 1 (33.3) | 4 (44.4) | 8(36.7) |
| Heparin post OP (days) | 6 ± 0 | 11 ± 6 | 6 ± 7 |
| LMWH therapy (days) | 9 ± 2 | 13 ± 14 | 8± 8 |
| PATE II | | | |
| Female (%) | 1 (33.3) | 5 (27.8) | 8 (42.1) |
| Male (%) | 2 (66.7) | 13 (72.2) | 11 (57.9) |
| BMI | | 29 ± 3 | 28 ± 4 |
| Laser (%) | 2 (66.6) | 11 (61.1) | 18 (94.7) |
| RFA (%) | 1 (33.3) | 6 (33.3) | 1 (5.3) |
| Other | | 1 (5.6) | |
| Miniphlebectomy (%) | 1 (33.3) | 11 (61.1) | 11 (57.9) |
| GSV (%) | 3 (100) | 15 (83.3) | 17 (89.5) |
| SSV (%) | 1 (33.3) | 3 (16.7) | 1 (5.3) |
| AASV co-treated (%) | 0 | 4 (22.2) | 5 (26.3) |
| Bilateral procedure (%) | 1 (33.3) | 3 (16.7) | 8 (42.1) |
| Heparin post OP (days) | 6 ± 0 | 8 ± 5 | 7 ± 10 |
| LMWH therapy (days) | 16 ± 8 | 23 ± 18 | 19 ± 8 |

| | 2015 | 2016 | 2017 |
|-------------------------|---------|-----------|---------|
| PATE III | | | |
| Female (%) | 0 | 3 (75) | 2 (40) |
| Male (%) | 0 | 1 (25) | 3 (60) |
| BMI | | 25 ± 3 | 26 ± 2 |
| Laser (%) | 0 | 2 (50) | 2 (40) |
| RFA (%) | 0 | 1 (25) | 3 (60) |
| Other | | 1 (25) | |
| Miniphlebectomy (%) | 0 | 3 (75) | 3 (60) |
| GSV (%) | 0 | 4 (100) | 3 (60) |
| SSV (%) | 0 | 0 | 2 (40) |
| AASV co-treated (%) | 0 | 0 | 0 |
| Bilateral procedure (%) | 0 | 0 | 1 (20) |
| Heparin post OP (days) | 0 | 12 ± 9 | 6 ± 6 |
| LMWH therapy (days) | 0 | 74 ± 41 | 17 ± 5 |
| PATE IV | | | |
| Female (%) | 0 | 1 (50) | 1 (100) |
| Male (%) | 1 | 1 (50) | 0 |
| BMI | | 32 ± 3 | |
| Laser (%) | 0 | 1 (50) | 1 (100) |
| RFA (%) | 1 (100) | 1 (50) | 0 |
| Miniphlebectomy (%) | 1 (100) | 2 (100) | 0 |
| GSV (%) | 1 (100) | 1 (50) | 1 (100) |
| SSV (%) | 1 (100) | 1 (50) | 0 |
| AASV co-treated (%) | 0 | 0 | 1 (100) |
| Bilateral procedure (%) | 1 (100) | 1 (50) | 0 |
| Heparin post OP (days) | 6 ± 0 | 17 ± 15 | 2 ± 0 |
| LMWH therapy (days) | 84 ± 0 | Long-term | 30 ± 0 |

| Year | DVTs total | DVTs n (%) after laser | DVTs n (%) after VNUS |
|------|------------|------------------------|-----------------------|
| 2017 | 0 | 0 | 0 |
| 2016 | 2 (0.1) | 1 (0.08) | 1 (0.14) |
| 2015 | 1 (0.06) | 0 | 1 (0.12) |

Tab. 5 Number (n) of DVTs after endovenous catheter procedures in Freiburg Vein Centre 2015–2017.

that, in future, a good and safe standard can be developed regarding the postoperative care of patients treated with endovenous procedures.

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