



CardioVascular  
Learning Network

CME

# Electrophysiologists & EP Lab Staff in Germany

Supported by an educational grant from Haemonetics Corporation.

# Faculty

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Germany

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Germany

# Faculty Disclosures

- **Roland R. Tilz:** Advisory board – Abbott, Boston Scientific, Philips, Biosense Webster, Medtronic; lectures – Abbott, AstraZeneca, Biosense Webster, Boston Scientific, C.T.I., Doctrina Med, Medtronic, Pfizer; research/grant support – Abbott, Biotronik, Medtronic, Lifetech, Johnson & Johnson; clinical trials – Abbott, Biotronik, Boston Scientific, Medtronic; other material support – Abbott, Biosense Webster, Boston Scientific, C.T.I., Doctrina Med, Medtronic, Philips
- **Christian-Hendrik Heeger:** Advisory board – Boston, J&J, Heamonetics, Lifetech; research/grant support – Boston, Medtronic, CTI, Pfizer, Lifetech, J&J, Heamonetics; honoraria – Boston, J&J, Medtronic, CTI, Pfizer, DoctrinaMed, Lifetech; clinical trials – Boston, J&J, Medtronic, Heamonetics, Lifetech; other financial support – Boston, Lifetech, Pfizer, J&J, CTI, DoctrinaMed, CME4U

# Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from Haemonetics Corporation

# Learning Objectives

- Analyze the current implementation of same day discharge (SDD) practices in Germany, including procedure eligibility, workflow changes, and patient selection
- Evaluate recent regulatory changes in Germany that impact same day discharge protocols for electrophysiology procedures
- Explore future directions of same day discharge and assess the role of vascular closure devices in improving workflow efficiency and patient outcomes



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# Current Landscape of Same Day Discharge in Germany

Roland R. Tilz

Klinik für Rhythmologie, UHZ Lübeck

# Outpatient Procedures

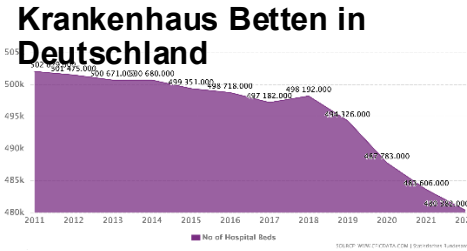
- Not required
- Costs are not relevant – I am a doctor, not a businessman
- No data available
- Dangerous
- Not feasible in Germany
- Summary

# Outpatient Procedures

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# Not Required?

- An aging society, fewer healthcare professionals, fewer hospitals and capacities, and less funding in the healthcare system



# Cost Reduction: Expansion of Capacities



- ✓ Mean cost reduction due to use of hospital resources:  
62% vs. 64% (CB vs. RF)
- ✓ Average saving per procedure: 859 €

# Cost Reduction: Expansion of Capacities Access to Healthcare and AF Ablation to All Pts



# Outpatient Procedures

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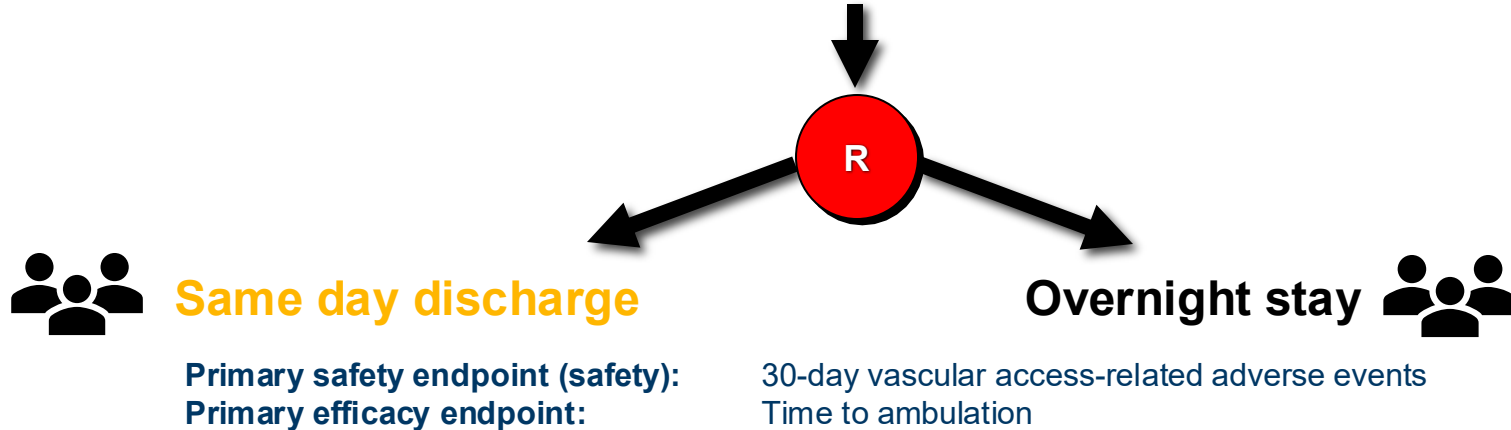
# No Data for SDD AF Ablation?

- Fabriccatore D, et al. *Europace*. 2023; 25:1361–1368.
- Jiminez-Candil J, et al. *Europace*. 2023;25:1–9.
- Honarbakhsh S, et al. *Europace*. 2023;25:1–9 (**prospective**)
- Sahashi Y, et al. *J Interv Card Electrophysiol* 2022;63(2):251-258.
- Rajendra A, et al. *JACC Clin Electrophysiol*. 2023;9(8 Pt 2):1515-1526.
- Rajendra A, et al. *J Interv Card Electrophysiol*. 2021;62:419–25.
- Dyell MW, et al. *Europace* 2023;25:400–407
- Dyell MW, et al. *JACC EP*. 2020;6:609–619
- Sangrigoli R, et al. *Journal of Interventional Cardiac Electrophysiology* (2023) 66:1601–1607
- Creta A, et al. *J Cardiovasc Electrophysiol* 2020;31:3097–3103.
- Baily SA, et al. *J Atr Fibrillation* 2021;14:20200499.
- König S, et al. *Europace* 2022;24:701–2.
- Castro-Urda C, et al. *PACE*. 2023;46:598-606 (RPOFA trial) (**prospective**)
- Zylla M, et al. *Europace*. 2024;26.

# SHAzAM AF Study

Same-day discharge versus overnight stay following pulmonary vein isolation for Atrial Fibrillation

AF ablation with 1-2 femoral venous access sites (6 to 14 Fr sheath) independent of energy source (n=290, 1:1 randomization)



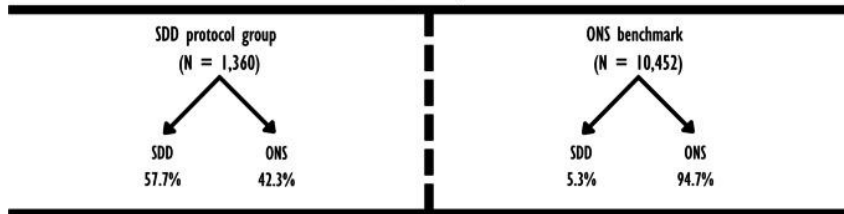
# Outpatient Procedures

- Not required
- Costs are not relevant – I am a doctor, not a businessman
- No data available
- **Dangerous**
- Not feasible in Germany
- Summary

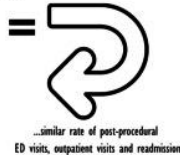
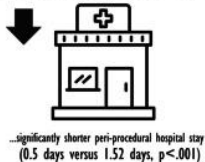
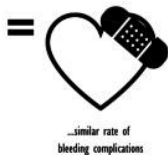
# SDD Vs Overnight Stay after PVI: Similar Complication Rates And Lower Healthcare Utilization

## Same-day discharge (SDD) versus overnight stay (ONS) after pulmonary vein isolation: an assessment on clinical outcomes and healthcare utilization

Total N = 11,812



The SDD cohort compared to the ONS cohort has...



	SDD protocol group	ONS benchmark	p-value
<i>Clinical outcomes</i>			
	N = 1360	N = 10,452	
30-days mortality (n, %)	0 (0.0)	0 (0.0)	n/a
Bleeding complication during hospital stay (n, %)	6 (0.5)	42 (0.5)	0.830
Thromboembolic complication (< 72 h) (n, %)	2 (0.2)	17 (0.2)	0.893
Vascular complication (< 30 days) (n, %)	14 (1.2)	119 (1.5)	0.720
Cardiac tamponade (< 30 days) (n, %)	5 (0.4)	48 (0.6)	0.634
Phrenic nerve injury during admission (n, %)	15 (1.3)	49 (0.6)	0.005
<i>Healthcare utilization</i>			
	N = 1150	N = 8391	
Peri-procedural hospital stay (days), (mean, SD)	0.50 (1.13)	1.52 (2.51)	< 0.001
ED visit within 7 days after PVI (n, %)	52 (3.82)	495 (4.73)	0.132
Outpatient visits within 14 months, average visits (mean, SD)	2.61 (2.34)	2.74 (2.72)	0.092
Readmission within 4 months (n, %)	214 (15.74)	1780 (17.03)	0.230

# Safety of SDD following PFA vs Radiofrequency Ablation

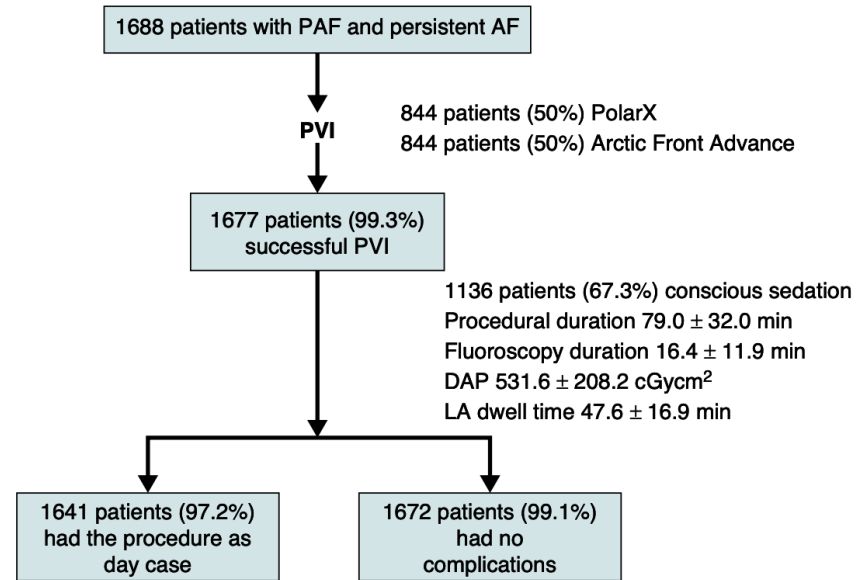
- SDD in the PFA cohort predictor lower CHA2DS2-VASc score (OR = 0.754, 95% CI: 0.663–0.858,  $p < 0.001$ )
- Being octogenarian reduced the likelihood of SDD (OR = 0.265, 95% CI: 0.105–0.666,  $p = 0.005$ )



	PFA SDD	PFA non-SDD	p value (PFA)	RFA SDD	RFA non-SDD	p value (RFA)	p value (PFA SDD vs. RFA SDD)
Major complications:	0 (0)	8 (0.5)	0.292	0 (0)	10 (1.1)	0.244	
Vascular	0 (0)	8 (0.5)		0 (0)	4 (0.42)		
CVA/TIA	0 (0)	0 (0)		0 (0)	2 (0.21)		
Phrenic nerve injury	0 (0)	0 (0)		0 (0)	3 (0.32)		
Pericardial effusion requiring intervention	0 (0)	0 (0)		0 (0)	1 (0.20)		
Minor complications	1 (0.5)	8 (1.1)	0.440	2 (1.6)	15 (1.6)	0.992	0.305
Readmission rates	3 (1.4)	10 (1.3)	0.902	3 (2.4)	29 (3.1)	0.660	0.542
All-cause mortality	0 (0)	0 (0)		0 (0)	0 (0)		

# Same Day Discharge Cryo Ablation

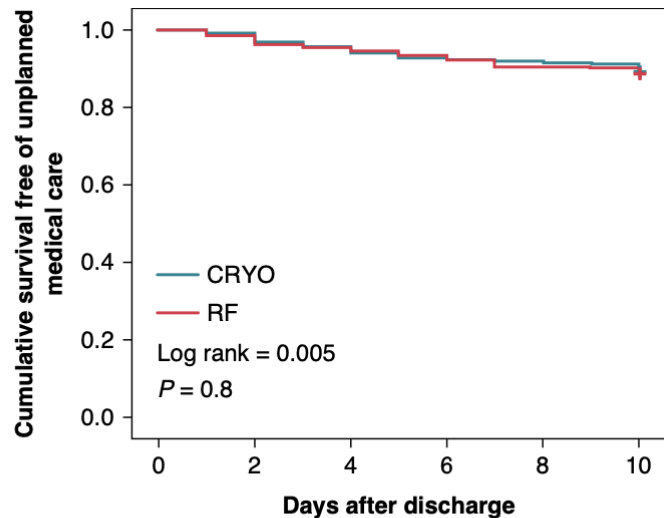
- Multi-center study across 12 centers
- No exclusion criteria for SDD



# Same Day Discharge Cryo Ablation: Safety

Procedural and cryoablation metrics	PolarX cohort <i>n</i> = 844	AFA cohort <i>n</i> = 844	P-value
Procedural metrics			
Procedural duration, min, mean ± SD	78.6 ± 38.1	79.4 ± 25.8	0.55
Fluoroscopy time, min, mean ± SD	16.1 ± 12.3	16.7 ± 11.4	0.68
Dose area product, cGycm <sup>2</sup> , mean ± SD	531.2 ± 216.3	532 ± 200.1	0.45
Complications, <i>n</i> (%)	7 (0.8)	9 (1.1)	0.80
Immediate complications, <i>n</i> (%)	6 (0.7)	8 (0.9)	0.79
Cardiac tamponade, <i>n</i> (%)	3 (0.4)	3 (0.4)	1.00
Groin haematoma, <i>n</i> (%)	3 (0.4)	4 (0.5)	1.00
Phrenic nerve palsy, <i>n</i> (%)	0 (0)	1 (0.1)	1.00
30-day complications, <i>n</i> (%)	1 (0.1)	1 (0.1)	1.00
Gastroparesis, <i>n</i> (%)	1 (0.1)	0 (0)	1.00
Phrenic nerve palsy, <i>n</i> (%)	0 (0)	1 (0.1)	1.00
Cryoablation metrics			
Number of cryoablations to achieve PVI per patient, <i>n</i> , mean ± SD	5.9 ± 2.2	6.0 ± 2.0	0.65
Number of cryoablations to achieve PVI per vein, <i>n</i> , mean ± SD	1.5 ± 0.9	1.6 ± 1.0	0.72

# Unplanned Medical Care Post SDD PVI



## Patients at risk

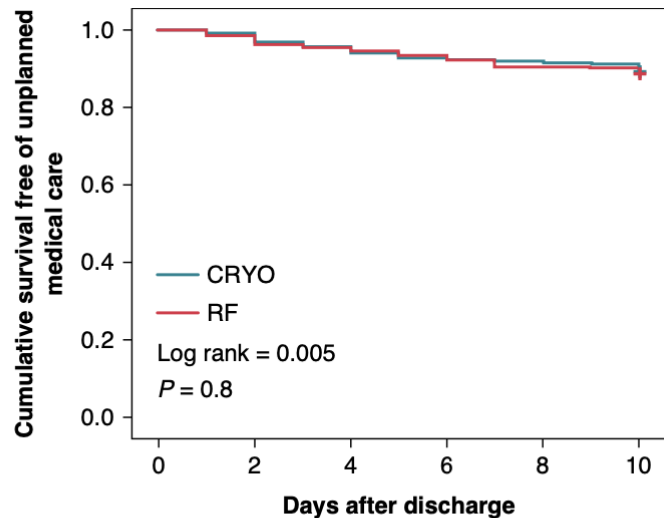
	0	2	4	6	8	10
RF	229	226	218	212	210	207
CRYO	356	350	339	332	321	320

Causes of urgent/unplanned medical care within 10 days

	<b>CRYO</b> <i>n</i> = 42	<b>RF</b> <i>n</i> = 27
AF/flutter recurrence	16	14
Vascular complications	10	5
Inguinal haematoma	7	4
Severe inguinal haematoma	3 <sup>a</sup>	1 <sup>a</sup>
Urticaria	3	1
Pericarditis	8 <sup>a</sup>	5 <sup>a</sup>
Gastroparesis	1	0
Symptomatic sinus node dysfunction	1 <sup>a</sup>	1 <sup>a</sup>
Vasovagal syncope/pre-syncope	2	1
Ecchymosis	1	0

## References

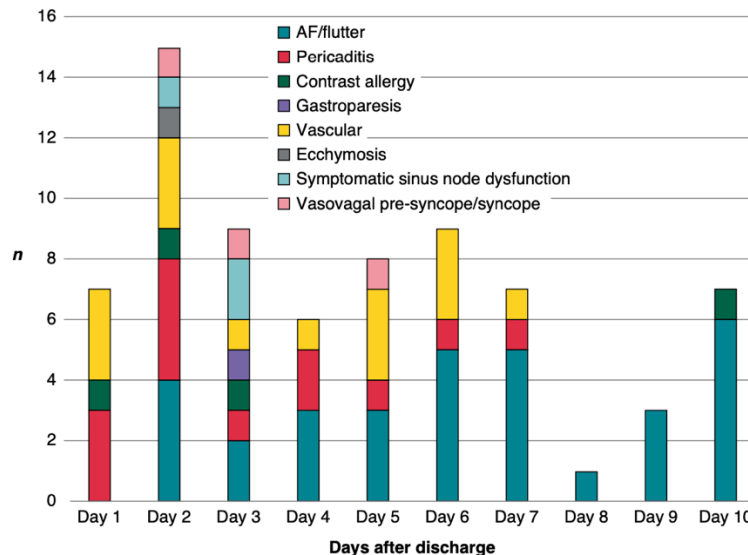
# Unplanned Medical Care Post SDD PVI



## Patients at risk

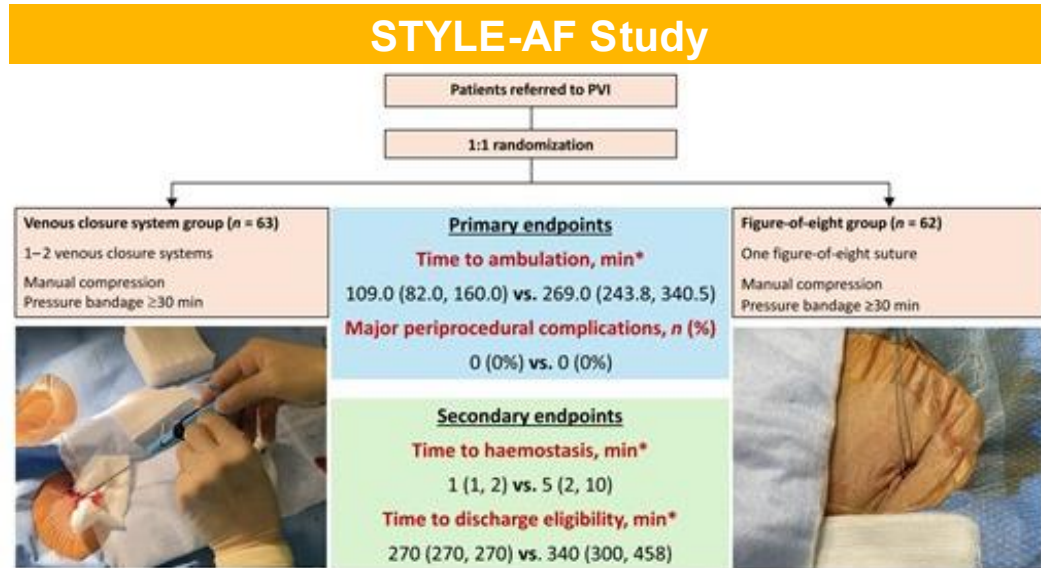
	0	2	4	6	8	10
RF	229	226	218	212	210	207
CRYO	356	350	339	332	321	320

## Causes and timing of urgent or unplanned medical care within 10 days of discharge



## References

# Optimize “Vascular Access Management”



**Time: 1) to hemostasis ↓↓; 2) to ambulation ↓↓; 3) to discharge ↓↓**

# Outpatient Procedures

- Not required
- Costs are not relevant – I am a doctor, not a businessman
- No data available
- Dangerous
- **Not feasible in Germany**
- Summary

# Standard Operating Procedures and Checklists: SDD PVI

	SOP
M	

- Zielsetzung**  
Reibungsloser Ablauf und die Gewährleistung
- Geltungsbereich/Z**  
Alle Mitarbeiter
- Voraussetzungen**  
Einschlusskriterien:
  - <80 Jahre
  - Wohnort
  - Single Shot
  - geklärte Postop

Eingriffe müssen bei Patientenchekliste

- Maßnahmen nach**
  - Monitoring für
  - Druckverban
  - Mobilisation
  - vor Entlassung
  - Dokumentation
  - PVK entfernen
  - Gespräch nach
  - Verordnete Maßnahmen
  - Entlassung durch
  - Arztbrief wird
  - Patientenmündig
  - abholende Person

Siehe Anlagen:  
Checkliste: geeignet für tagesstationäre Eingriffe  
Patientenmerkblatt: Verhalten nach tagesstationären Eingriffen  
Patientenchekliste Eingriffstag  
Dokumentation Entlassung MIC  
Patientenmerkblatt: Verhalten nach

	<b>Checkliste: geeignet für tagesstationären Eingriff</b>
Minimalinvasives-Centrum Lübeck	

Die Checkliste dient der Vorbereitung auf tagesstationäre Eingriffe in Sie beantwortet werden können, kann die Planung für ein tagesstationäres

<b>Auswahl Intervention</b>
Minimales Risiko einer Nachblutung
Minimales Risiko postoperativ auftretender respiratorischer Komplikation
Keine spezielle postoperative Nachsorge (Verbände etc.) erforderlich
Keine spezielle postoperative Pflegebedürftigkeit
Rasche Flüssigkeits- und Nahrungsaufnahme möglich

<b>Patientenauswahl</b>
<b>Soziale Aspekte</b>
Bereitschaft des Pat., sich ambulant operieren zu lassen
Verantwortliche volljährige Person für den Heimtransport vorhanden
Verantwortliche volljährige Person zur postoperativen Betreuung f. 24 h
Betreuende Person ist in der Lage, Instruktionen zu verstehen und Ent treffen
Vorhandene telefonische Verbindung
Wohnung mit Minimalstandard (Heizung, Licht, Küche, Bad, Toilette) vorhanden
Wohnt weniger als 50 km entfernt

<b>Medizinische Aspekte</b>
Einsicht in den geplanten Eingriff und in die Nachsorge
Psychisch stabiler Patient
Keine höhergradige Adipositas (= BMI <40)
Kein OSAS oder gute OSAS-Einstellung mit CPAP-Gerät

Datum	Name	Unterschrift
-------	------	--------------

	<b>Patientenmerkblatt: Verhalten nach tagesstationären</b>
Minimalinvasives-Centrum Lübeck	

- lockere und unempfindliche Kleidung an.
- Bitte verzichten Sie auf Creme, Nagellack
- Lassen Sie Wertgegenstände zu Hause.
  - Bitte seien Sie rechtzeitig da (lieber etwas zu Wartezeit ein (leider ist kein Eingriff auf die Minute möglich))
  - Sollte sich etwas an Ihrem Gesundheitszustand ändern, informieren Sie uns bitte umgehend.
  - gegessen oder getrunken haben gilt dasselbe
  - Nehmen Sie am Morgen des Eingriffs die im Gespräch besprochenen Medikamente ein.
  - Besonderheiten:

Sie helfen uns mit der Einhaltung dieser Vorsichtsmaßnahmen und der Sedierung auf ein Minimum zu

**Haben Sie noch Fragen?** Dann rufen Sie uns

Wir sind Montag bis Freitag von 7:00-15:00 Uhr

Telefon: 0451 – 51

Mit freundlichen Grüßen  
Das Team des Minimalinvasives

	<b>Patientenmerkblatt: Verhalten nach tagesstationären Eingriffen</b>
Minimalinvasives-Centrum Lübeck	

Sehr geehrte Patientin, sehr geehrter Patient,

Sehr geehrte Patientin, sehr geehrter Patient, Sie haben es geschafft. Den Eingriff haben Sie gut überstanden und Ihr Heim hat Sie wieder.

**Wann Sie**  
...gegessen  
...getrunken  
...geraucht

**Welche**  
Erkältung  
Fieber  
Durchfall  
Schmerzmittel

**Wer** holt

**Name:**

**Wer** betet

**Name:**

**Datum:**

Vor der Entlassung des Patienten persönlich vom Zustand und Sie bekommt ein Merkblatt

<b>Entlasskriterien aus d</b>
Pat. ist wach + orientiert
Schmerzen gering, NRS
Übelkeit, Erbrechen nicht
Spontane Miktion möglich
Pat. kann stehen + in B. verbändert, trocken oder
Schmerztherapie erlaubt
<input type="checkbox"/> Rezept <input type="checkbox"/> Patient
Patientenmerkblatt „Ver“
Arztbrief aus ORBIS auf
Abschlussgespräch MIC

<b>Entlasskriterien aus d</b>
Abschlussgespräch mit
Arztbrief geschrieben, g
Patient kennt nächsten
Maßnahmen vor Entlassung
Druckverband entfernt?
Miktion erfolgt?
PVK entfernen vor Entlassung

<b>Begleitende Person</b>
Name:
<b>Postoperative Erreich</b>
Dürfen wir Sie anrufen?

<b>Erneute Aufklärung d</b>
24 h fehlende Verkehrt
Keine Einnahme von Al
Entlassung nur in Begle

Datum/Uhrzeit

	<b>Patientenmerkblatt: Verhalten nach tagesstationären Eingriffen</b>	Seite 1 von 1 Revision: 004/08.2019 ID: 240635
Minimalinvasives-Centrum Lübeck		

Sehr geehrte Patientin, sehr geehrter Patient, Sie haben es geschafft. Den Eingriff haben Sie gut überstanden und Ihr Heim hat Sie wieder.

Trotzdem gibt es noch Einiges zu beachten. Bitte bewahren Sie dieses Merkblatt gut auf und sorgen Sie dafür, dass auch die Sie betreuende Person jeder Zeit Zugriff darauf hat.

- Sorgen Sie dafür, dass Sie für die nächsten Stunden nicht allein sind. Außerdem sollte ein Telefon in greifbarer Nähe sein.
- Bedenken Sie, dass Sie nach einer Narkose für 24 Stunden nicht allein am Straßenverkehr teilnehmen dürfen, keine Fahrzeuge oder Maschinen führen oder Verträge abschließen dürfen.
- Essen Sie nur leichte Mahlzeiten und verzichten Sie auf den Genuss von Alkohol.
- Wenn Sie Ihr Kind stillen, sollten Sie dies erst wieder nach 6 – 8 Stunden tun. Wir empfehlen Ihnen die erste Portion abzupumpen und zu verworfen.
- Nehmen Sie nur die verordneten Medikamente ein.
- Treiben Sie keinen Sport und vermeiden Sie Anstrengungen.

Nach einem Eingriff kann es zu Symptomen wie Halsschmerzen, Heiserkeit, Übelkeit, allgemeine Müdigkeit, Kreislaufstörungen, kleinen Nachblutungen oder Schmerzen kommen. Diese Empfindungen benötigen normalerweise keiner Behandlung und lassen nach 12 bis 24 Stunden nach. Gegen die Schmerzen starten Sie bitte rechtzeitig mit der Einnahme der verordneten Schmerzmittel.

Bei folgenden Symptomen nehmen Sie bitte umgehend mit uns Kontakt auf 0451/500-47000 auf.

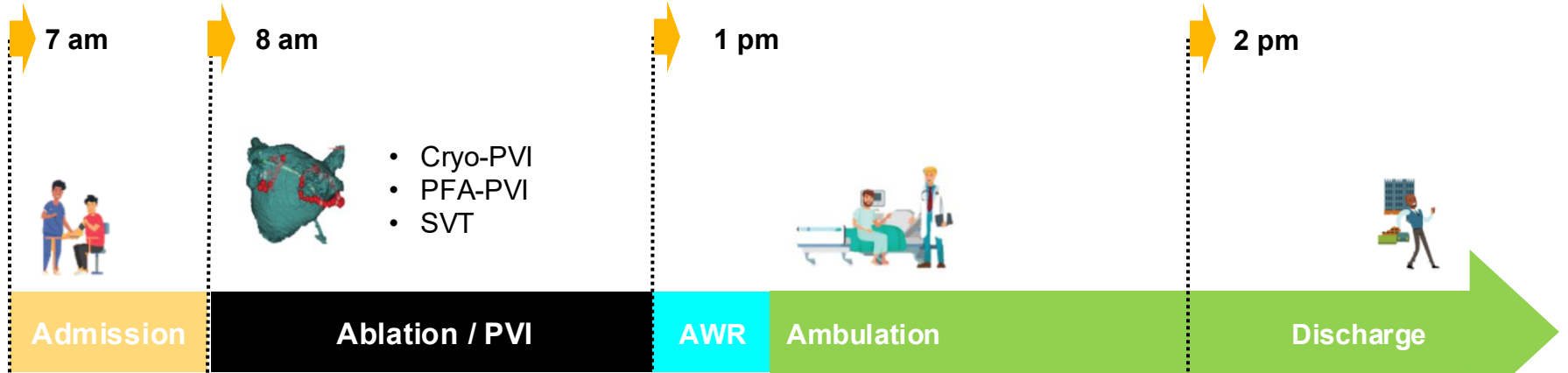
- starke Schmerzen oder Übelkeit trotz der von uns verordneten Medikamente
- stark durchgebluteter Verband
- starke Schwellung mit Gefühlsstörung (z.B. Kribbeln, Taubheitsgefühl) im Bereich der Punktionsstelle oder Blau- und Weißfärbung von Fingern und Zehen.
- Fieber über 38 Grad Celsius oder Schüttelfrost
- Starke Kopfschmerzen oder Nackensteife

Bei starker Blutung im Operationsgebiet, akuter Atemnot, Schmerzen in der Brust, Bewusstseinsstörung oder neu aufgetretene Lähmungen oder Sprachstörungen rufen Sie bitte umgehend den Rettungsdienst unter 112.

Wir wünschen Ihnen gute Besserung.

Mit freundlichen Grüßen  
Das Team des Minimal-invasiven-Centrums am UKSH

# Late Procedural Finish → SDD Protocol in Lübeck in 2025



- ✓ > 18 years old
- ✓ Residence < 50 km from the hospital
- ✓ Phone connection
- ✓ Mentally stable
- ✓ BMI < 40
- ✓ No OSAS or OSAS therapy

Compression bandage for 1-4 hours

Food and liquid intake

Discharge home: 4-6 hours after PVI

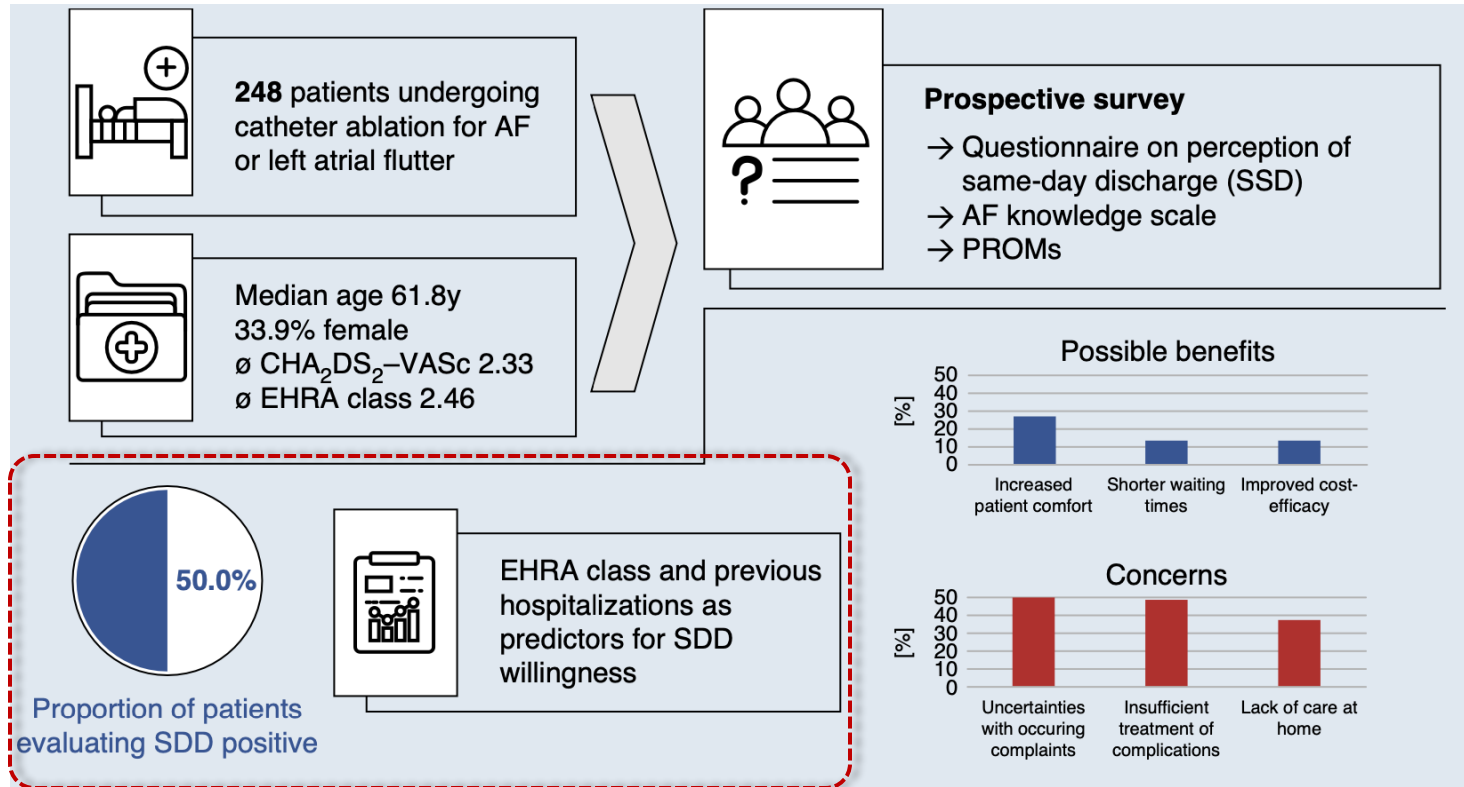
OSAS = obstructive sleep apnea syndrome; BMI = body-mass index.

# Wakeup Room

- MIC physician until 18:30
- DV 1 hr (closure device)
- DV 4 hrs (figure of 8 stitch)
- TTE after one hr



# Patient's Perspective (FAST AFA Trial)



# Outpatient Procedures

- Not required
- Costs are not relevant – I am a doctor, not a businessman
- No data available
- Dangerous
- Not feasible in Germany
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# Current Landscape of Same Day Discharge in Germany

- Costs are relevant, because I am a doctor
- We have data, data, and more data
- Safe
- Feasible in Germany
- With the introduction of hybrid DRGs, they will be required

# SDD PVI: The Smartphone Discussion with Kids





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CME

# Future Outlook and Impact of Vascular Closure Devices

Christian-Hendrik Heeger  
Asklepios Klinik Hamburg Altona, Germany

# Background

- Vascular access-related complications
  - One of the most frequent complications and the leading cause of delayed discharge
  - Standard of care to achieve haemostasis after PVI: Manual compression with or without figure of eight suture

**Table 16** Procedure-related complications in catheter ablation and thorascopic ablation of AF<sup>771</sup>

Complication severity	Complication type	Complication rate	
		Catheter ablation	Thorascopic ablation
Life-threatening complications	Periprocedural death	<0.1%	<0.1%
	Oesophageal perforation/fistula	<0.5%	N/A
	Periprocedural thromboembolic event	<1.0%	<1.5%
	Cardiac tamponade	≈1%	<1.0%
Severe complications	Pulmonary vein stenosis	<1.0%	N/A
	Persistent phrenic nerve palsy	<1.0%	N/A
	Vascular complications	2-4%	N/A
	Conversion to sternotomy	N/A	<1.7%
Moderate or minor complications	Pneumothorax	N/A	<6.5%
	Various	1 - 2%	1 - 3%
Complications of unknown significance	Asymptomatic cerebral embolism	5 - 15%	N/A

NA = not available.

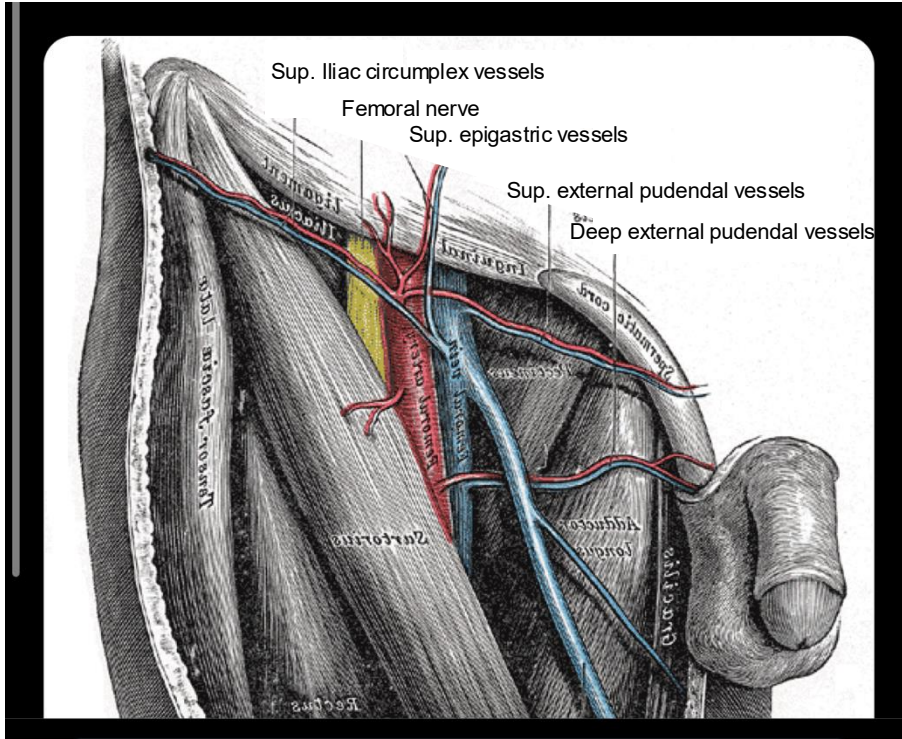
© ESC 2020



**PVI = pulmonary vein isolation; AF = atrial fibrillation.**

**Gupta A, et al. *Circ Arrhythm Electrophysiol.* 2013;6(6):1082-8. Aytemir K, et al. *Europace.* 2016;18(10):1545-1550.**

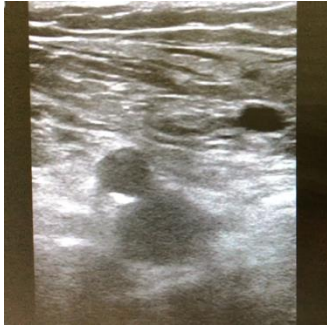
# Anatomy: Regio Femoralis



- Potential complications
  - Hematoma
  - Arterial puncture
  - AV-fistula
  - Pseudoaneurysm
  - Retroperitoneal hematoma
  - N. femoralis injury

# Reduction of Vascular Complications

## US-Guided Puncture



## Venous Closure Systems

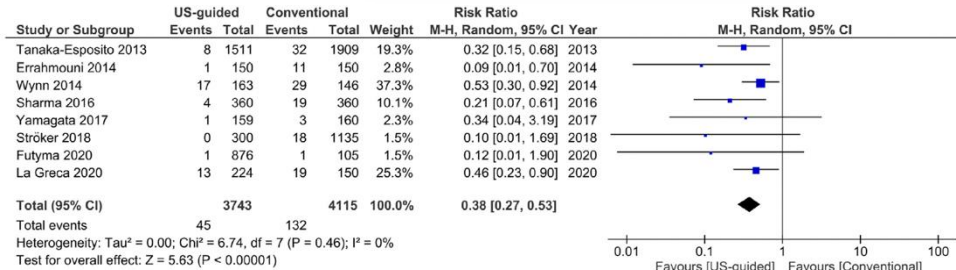


Fig. 2. Forest plot of comparison: US-guided vs. Conventional, outcome: Total vascular complications.

- AMBULATE trial
- PRO-PVI study
- STYLE-AF study

US = ultrasound.

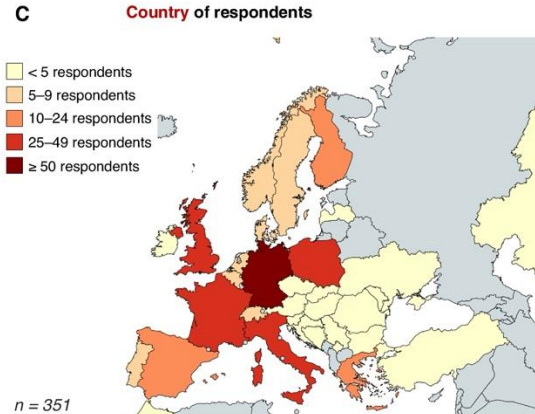
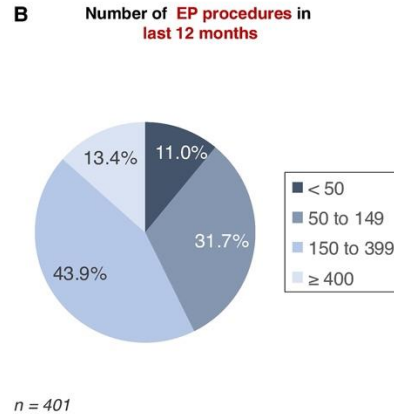
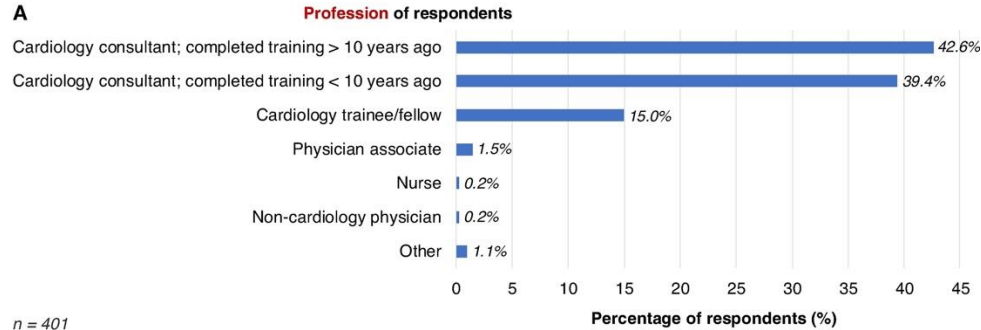
Triantafyllou K, et al. *Indian Pacing Electrophysiol J.* 2022;22(3):145-153. Tilz RR, et al. *Europace.* 2024;26(5):euae105. Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. Fabbricatore D, et al. *Europace.* 2023;25(4):1361-1368.

# Latest Survey on Vascular Access Management EHRA-Scientific Initiative Committee

## **Vascular access site management during electrophysiology procedures: a European Heart Rhythm Association survey**

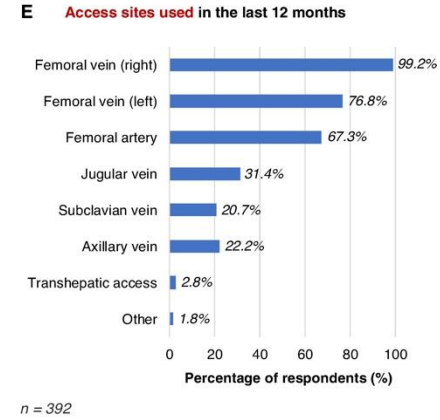
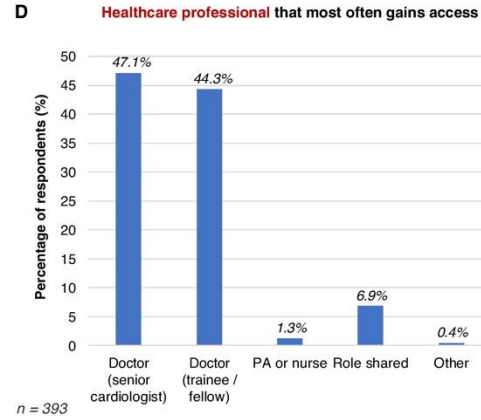
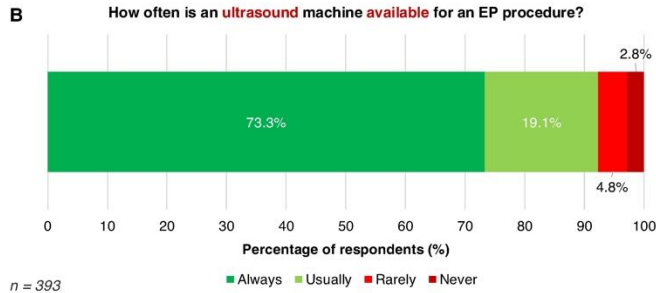
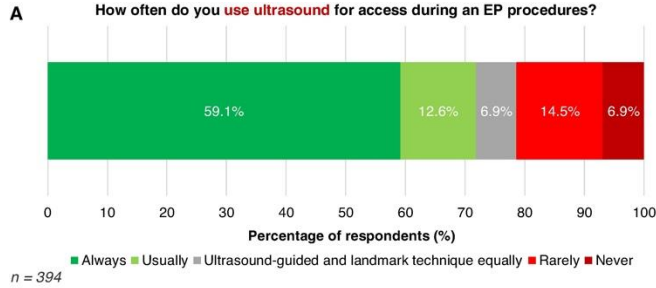
**Mark T. Mills** <sup>1,2\*</sup>, **Dhiraj Gupta** <sup>1,2</sup>, **Vishal Luther** <sup>1,2</sup>, **Maura M. Zylla** <sup>3</sup>,  
**Piotr Futyma** <sup>4</sup>, **Laura Perrotta** <sup>5</sup>, **Michal Mazurek** <sup>6</sup>,  
**Christian-Hendrick Heeger** <sup>7</sup>, **Lina Marcantoni** <sup>8</sup>, **Andreas Metzner** <sup>9</sup>, and  
**Julian K. R. Chun** <sup>10</sup>

# Demographics of Respondents



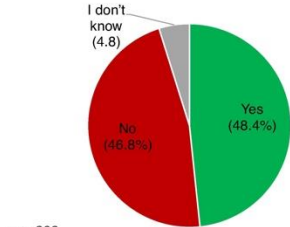
EP = electrophysiology.  
Mills MT, et al. *Europace*. 2025 ;27(7):euaf117.

# Vascular Access Management

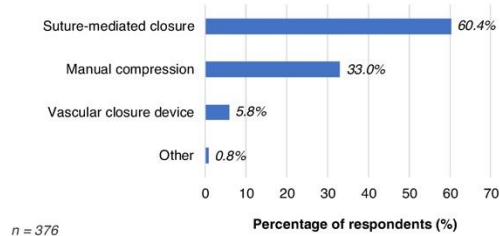


# Vascular Haemostasis and Closure

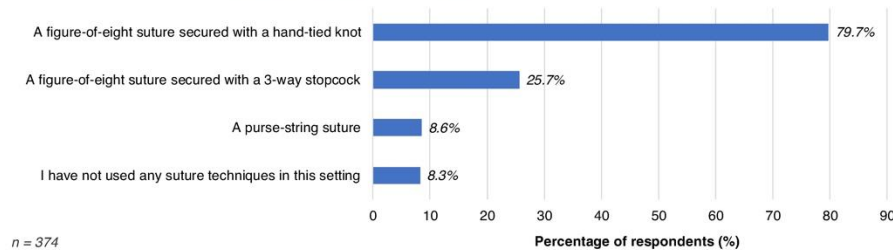
**A** Does your institution have a **standardised policy** for vascular haemostasis / closure?



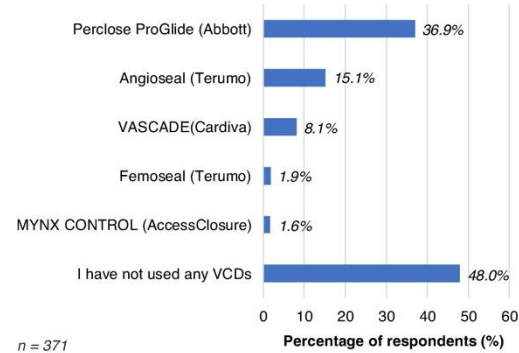
**B** Following EP procedures, which vascular haemostasis **technique** do you **most commonly** use?



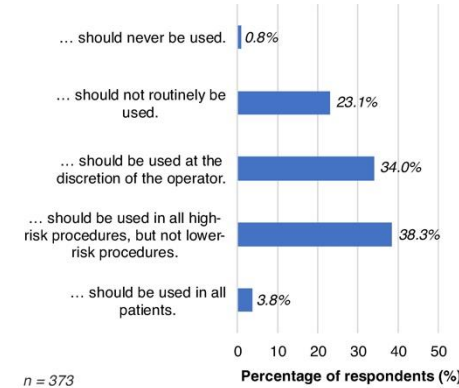
**C** Which of the following **suture techniques** have you **used** in clinical practice? **Select all that apply.**



**D** Which of the following **vascular closure devices** have you **used** in clinical practice during electrophysiology procedures? **Select all that apply.**

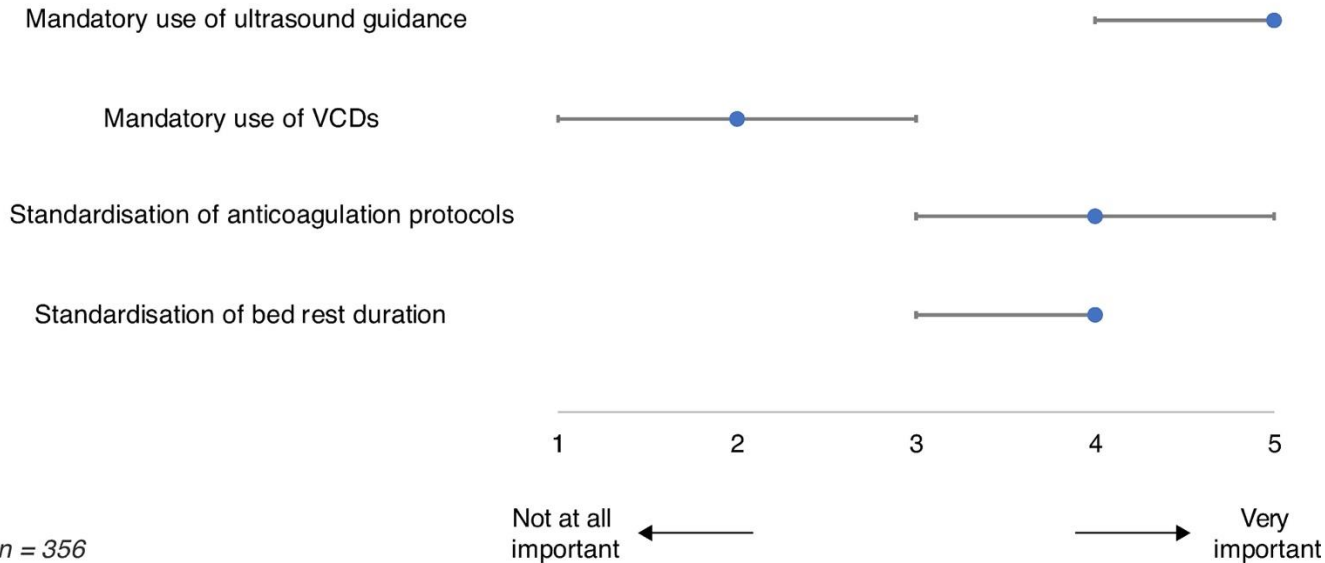


**E** In EP procedures, **vascular closure devices**...



# Importance of Factors in Reducing Vascular Access Site Complications

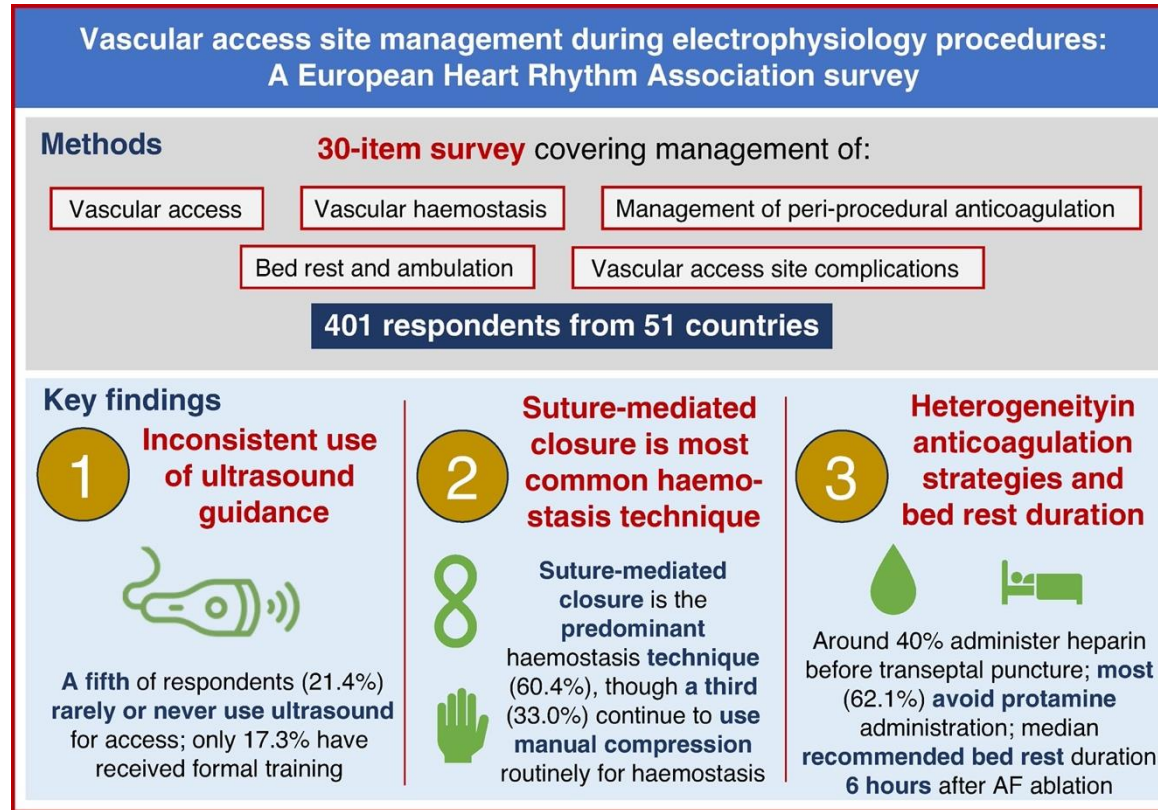
Rate the **importance** of the **following factors** for reducing the incidence of access site complications following EP procedures



VCD = vascular closure device.

Mills MT, et al. *Europace*. 2025 ;27(7):euaf117.

# Vascular Access Management: Survey



# Suture-Mediated Closure and Repair Device

- Sutures-based closure system
- A. femoralis communis and V. femoralis communis
- Immediate closure of the puncture site
- Robust data: 12 million patients have been treated
- Non-resorbable suture

Arterial usage: 5-26F OD

Venous usage: 5-29F OD



# PRO-PVI Study

- Vascular complications 2-4%
- Ambulation PVI (→ same day discharge)

## What's new?

- There is still lack of knowledge on the use of vascular devices in the EP field; this paper provides evidence supporting the use of suture-mediated vascular closure in PVI procedures.
- A shorter post-operative supine position was preferred by patients.
- Analysis of costs showed a neutral economical impact of vascular closure device use in PVI.

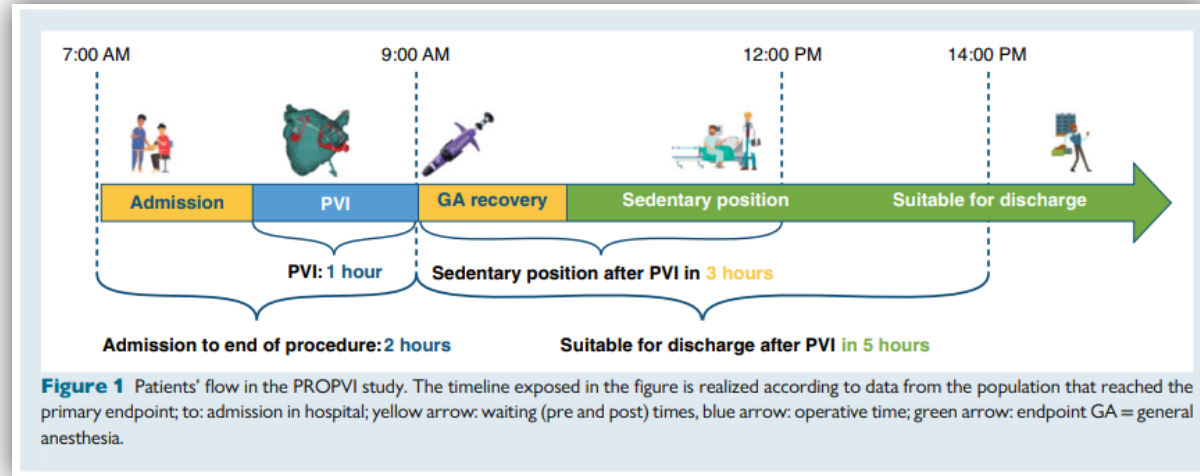
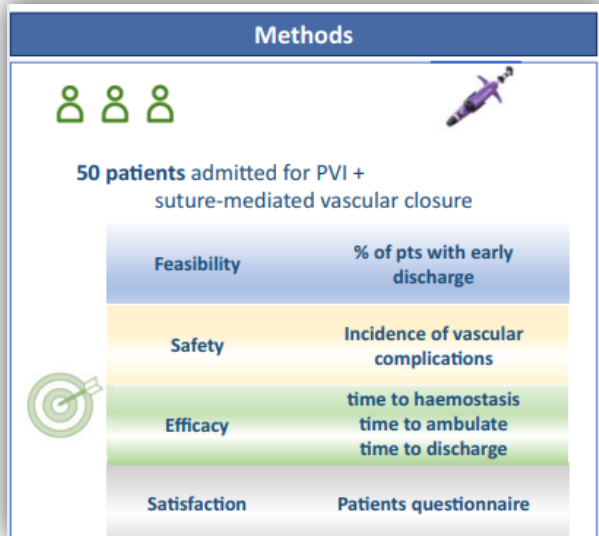
## US-Guided Puncture Femoral Groin



## Vascular Closure Device



# Methods: PRO-PVI Study



# Results: PRO-PVI Study

**Table 1** Patient demographic, clinical, and procedural characteristics (overall population)

Patient demographic, clinical and procedural characteristics	
Total population, n (%)	50 (100)
Median age (IQR)	64 (28–80)
Male sex, n (%)	38 (76)
Median BMI (IQR)	26.3 (21–42)
Hypertension, n (%)	20 (40)
DM, n (%)	11 (22)
Smokers, n (%)	4 (8)
Necessity of protamine administration (%)	2 (4)
Median ACT (s)	318 (225–355)



Feasibility

% of pts with early discharge

Efficacy

time to haemostasis  
time to ambulate  
time to discharge

Safety

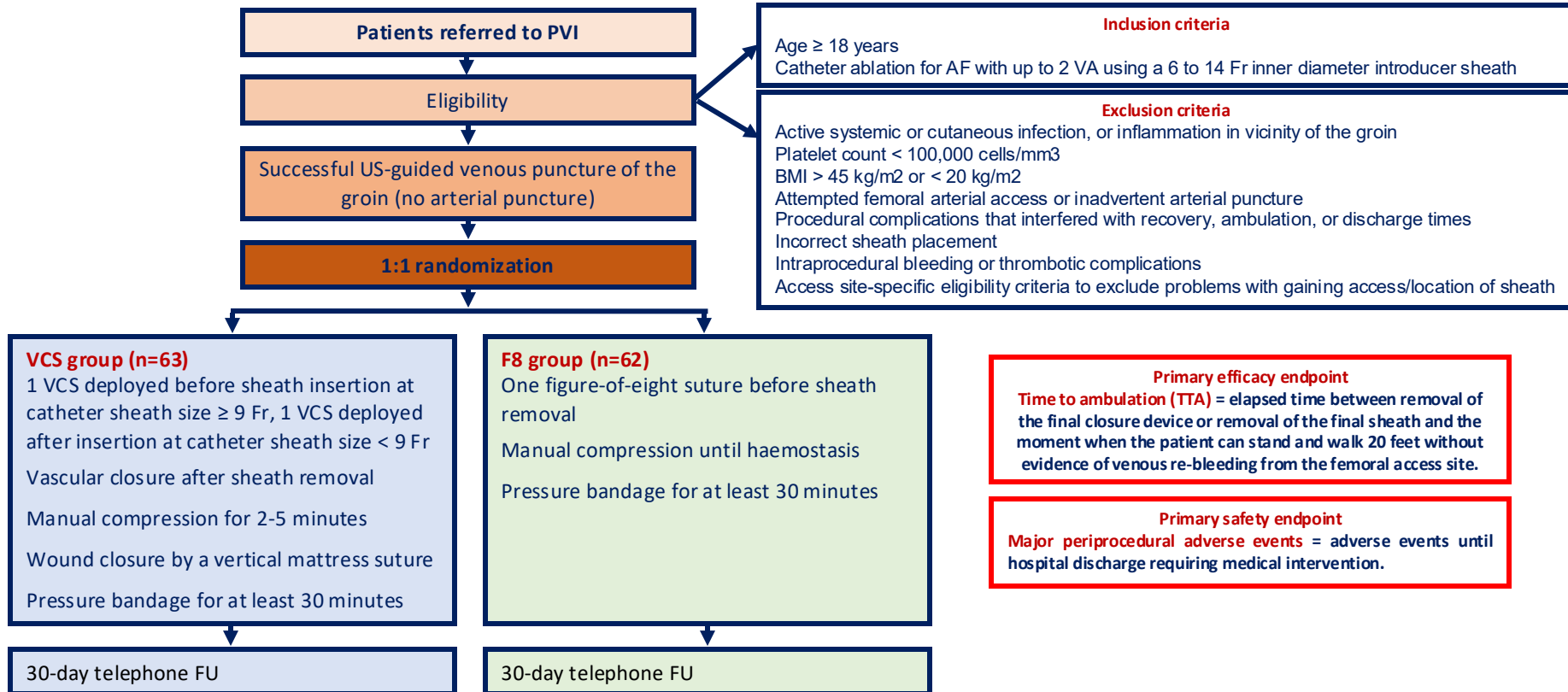
Incidence of vascular complications

**Table 2** Endpoints and outcomes

Total population, n (%)	50 (100%)
Primary endpoint	
Discharge in the same day, n (%)	48 (96) <sup>a</sup>
Outcomes	
Success of device deployment, n (%)	96 (100)
Necessity of post-deployment manual compression > 1 min, n (%)	20 (41.7)
Late recurrence of bleeding, n (%)	2 (4.16)
Mean/median time to reach haemostasis (mm:ss) <sup>b</sup>	4:35 (± 3:27)/3:00 (2:00–15:00)
Mean/median time to ambulation (hh:mm)—IQR	3:18 (± 1:05)/3:11 (1:26–6:23)
Mean and median time to be deemed suitable for discharge	4:55 (±00:54)/4:48 (2:50–7:30)
Mean/median post-procedural time to be discharged (hh:mm)—IQR	5:48 (± 1:03)/5:51 (3:38–7:57)
Major vascular complications needing surgical intervention, n (%)	0 (0)
Major vascular complications needing further medical evaluation/investigation, n (%)	0 (0)
Hematoma > 6 cm, n (%)	3 (6.25)
Asymptomatic superficial bruising ≤ 6 cm, n (%)	15 (31.25)
Necessity of pain medication, n (%)	3 (6.25)
Paracetamol, n (%)	2 (4.16)
Single administration, n (%)	1 (2.08)
Repeated administration, n (%)	1 (2.08)
Salicylic acid, n (%)	1 (2.08)

BMI = body-mass index; DM = diabetes mellitus.  
Fabbricatore D, et al. *Europace*. 2023;25(4):1361-1368.

# STYLE AF-Study: Methods



# STYLE AF Results: Baseline Pt Characteristics

Variable	VCS Group N=63	F8 Group N=62	<i>p</i>
Female gender, n (%)	25 (39.7%)	20 (32.3%)	0.457
Age, years	64.0 (56.0, 74.0)	68.5 (60.8, 75.3)	0.146
Body mass index, kg/m <sup>2</sup>	29.4 ± 5.6	27.5 ± 4.7	0.042
Arterial hypertension, n (%)	40 (63.5%)	36 (58.1%)	0.585
Coronary artery disease, n (%)	15 (23.8%)	15 (24.2%)	1
Cardiomyopathy, n (%)	7 (11.1%)	8 (12.9%)	0.789
LVEF, n (%)	55 (54.5, 60.0)	55.0 (52.0, 60.0)	0.829
Oral anticoagulation, n (%)	60 (95.2%)	56 (90.3%)	0.323
Direct oral anticoagulation, n (%)	59 (93.7%)	52 (83.9%)	0.096
Antiplatelet therapy, n (%)	4 (6.3%)	3 (4.8%)	1
CHA <sub>2</sub> DS <sub>2</sub> -VASc ≥3	25 (39.7%)	27 (43.5%)	0.718
HAS-BLED ≥3	14 (22.2%)	7 (11.3%)	0.150

LVEF = left ventricular ejection fraction; CHA<sub>2</sub>DS<sub>2</sub>-VASc = congestive heart failure, hypertension, age ≥75 (doubled), diabetes, stroke (doubled), vascular disease, age 65-74, and sex category (female)

Tilz RR, et al. *Europace*. 2024;26(5):euae105

# STYLE AF Results: Procedural Characteristics

Variable		VCS Group N=63	F8 Group N=62	p
Energy source	Cryoballoon, n (%)	51 (81.0%)	49 (79.0%)	0.826
	PFA, n (%)	11 (17.5%)	9 (14.5%)	0.808
	Laser, n (%)	1 (1.6%)	1(1.6%)	1
	RF, n (%)	0 (0.0%)	3 (4.8%)	0.119
Number of punctures	1, n (%)	9 (14.3%)	8 (12.9%)	1
	2, n (%)	54 (85.7%)	52 (83.9%)	0.808
	3, n (%)	0 (0.0%)	2 (3.2%)	0.243
Procedure duration, min		48.0 (40.0, 59.0)	48.0 (36.5, 59.3)	0.481
Amount of heparin, UI		12500 ± 3349.3	12532.3 ± 2785.9	0.953
Protamine use, n (%)		3 (4.8%)	6 (9.7%)	0.323
Amount of protamine, UI		7000 (5000, -)	7000 (6500, 7750)	0.440
VCS failure, n (%)		2 (3.2%)		

VCS = vasculitis; PFA = pulsed field ablation.  
Tilz RR, et al. *Europace*. 2024;26(5):euae105.

# STYLE AF Results: Primary Endpoints (EP)



	VCS Group n=63	F8 Group n=62	<i>p</i>
Primary efficacy EP Time to ambulation	109.0 (82.0, 160.0)	269.0 (243.8, 340.5)	<0.001
Primary safety EP Major periprocedural AE until discharge	0 (0%)	0 (0%)	0.999

AE = adverse event.

Tilz RR, et al. *Europace*. 2024;26(5):euae105.

# STYLE AF Results: Secondary Endpoints



	VCS Group n=63	F8 Group n=62	<i>p</i>
Time to haemostasis, min	1 (1, 2)	5 (2, 10)	<0.001
Time to discharge eligibility, min	270 (270, 270)	340 (300, 458)	<0.001
Major VA related complications, n (%)	0 (0%)	0 (0%)	

# STYLE AF Results: Minor Complications and Comfort Questionnaires

Complications present on the day of procedure and the day after that (total)			
Variable	VCS Group	F8 Group	<i>p</i>
Patients with complications, n (%)	13 (20.6%)	22 (35.5%)	0.075
Groin haematoma >6 cm, n (%)	2 (3.2%)	1 (1.6%)	1
Groin haematoma <6 cm, n (%)	6 (9.5%)	15 (24.2%)	<b>0.033</b>
Bleeding, n (%)	6 (9.5%)	8 (12.9%)	0.584
Haemoglobin drop, n (%)	0 (0.0%)	1 (1.6%)	0.496
Groin pain, n (%)	16 (25.4%)	21 (33.9%)	0.332
Comfort questionnaire - all patients			
Question	VCS Group	F8 Group	<i>p</i>
How <b>satisfied</b> are you with the lying time you had to spend on your back?	9.0 (6.0, 10.0)	7.0 (5.0, 8.0)	<b>0.016</b>
How <b>comfortable</b> was it for you to have to lie on your back?	8.0 (4.0, 9.8)	6.5 (5.0, 8.0)	0.312
How severe was the <b>pain</b> when you had to lie on your back?	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	0.588

# STYLE AF Conclusions

- Following AF ablation, the use of a VCS results in a significantly shorter time to ambulation, time to haemostasis, and time to discharge eligibility
- No major vascular access related complications were identified
- The use of MC and a figure-of-eight suture showed a trend towards a higher incidence of minor vascular access related complications

# A Venous Vascular Closure System Device Was Evaluated in 5 EP Clinical Trials: VASCADE MVP

## AMBULATE Pivotal Trial

Pivotal for FDA approval  
JACC EP: Natale et al. Oct 2019

## AMBULATE CAP Continued Access Protocol

JCE: Al-Ahmad et al. Jan 2021

## AMBULATE Same Day Discharge Clinical Studies

Retrospective SDD  
Prospective SDD 1  
Prospective SDD 2  
JCE: Eldadah et al. Nov 2022

Access Sites **3,788**

Patients **1,223**

**0%**

Major Complications<sup>a</sup>

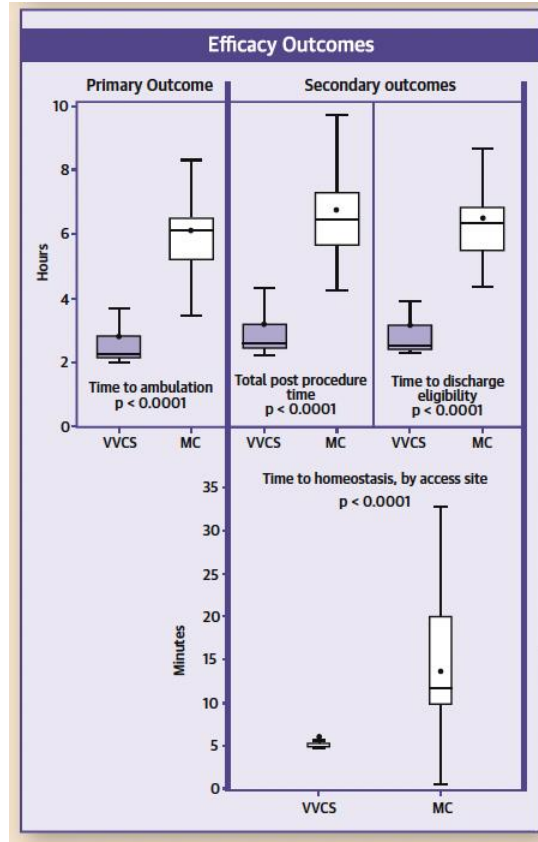
<sup>a</sup>Major and minor complications definitions may vary for each study, refer to the publication for specific definitions.  
Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199.  
Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34(2):348-355. National Institute of Health. Accessed August 25, 2025.  
<https://clinicaltrials.gov/study/NCT04538781?tab=table>.



# AMBULATE Trial: Findings

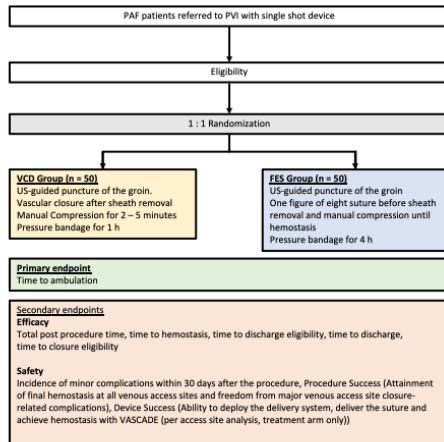
Safety and Pain Medication Usage Outcomes			
	VVCS Device	Manual Compression (MC)	p-value
<b>Primary Safety Outcomes, per limb</b>			
Major access site closure-related complication	0(0.00%)	0(0.00%)	-
<b>Secondary Safety Outcomes, per limb</b>			
Minor access site closure-related complication	2(1.00%)	5(2.40%)	0.45
<b>Pain Medication Usage During Bedrest</b>			
Any pain medication	24(24%)	51(49%)	0.0003
Opioid narcotic	15(15%)	37(36%)	0.001
No pain medication	76(76%)	53(51%)	-

*Data are presented as n (%)*  
*p-values from one-sided t-test for means, and one-sided Wilcoxon rank sum test for medians, unadjusted for stratification factor*



# Future: Vascular Closure Devices

- Device with 58% more collagen and 9% increase in disc size, 15F outer diameter
- VASC-AF study: For single-shot EP procedures (ongoing)
- Device for large access sites



# Workflow Changes: VCDs

- Before introduction of VCS

- Figure of 8 + 8h pressure bandage
- Removal of stitches on the next day
- Painful for patients and staff



- Afterwards

- Device + 2h pressure bandage
- No removal of stitches
- Happy patients, nurses, and physicians
- Same day discharge ready!



# Future Outlook and Impact of Vascular Closure Devices Conclusion

- Most complications during EP procedures are related to vascular access
- Immediate haemostasis with closure devices
- US-guided puncture in combination with venous closure systems: Shorter time to ambulation and time to discharge eligibility
- Ready for same day discharge!

# Thank You Very Much!

Prof. Dr. Christian-H. Heeger

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[@ChristianHeeger](#)





CardioVascular  
Learning Network

CME

# Regulatory Updates and System-Level Changes: Review of Recent Regulatory and Reimbursement Changes Relevant to SDD in EP Labs

Roland R. Tilz

Klinik für Rhythmologie, UHZ Lübeck

Ärzteschaft

## Vorgaben zur Kalkulation der Hybrid-DRG 2026 beschlossen

🕒 Donnerstag, 10. Juli 2025



/alfa27, stock.adobe.com

# Development of Hospital Reimbursement in Germany

- Until 2003
  - General hospital services reimbursed via hospital-specific daily rates
  - Payment per hospital day, independent of actual treatment effort
- 2003 – introduction of DRGs
  - Payment based on case groups, reflecting diagnosis and treatment effort
  - Incentive to increase efficiency and reduce length of stay
  - Established as the standard reimbursement system in hospitals



# Development of Hospital Reimbursement in Germany

- 2024 – Introduction of Hybrid DRGs
  - With the April 2025 decision, the Hybrid DRG Catalog 2026 is shaping
  - Immediate implementation: Hospitals must already begin reassessing their service structures to reduce costs for short stay patients
  - Covers at least one million cases annually from 2026
    - In 2030, 2 million cases planned
  - Applies to services with short length of stay ( $\leq 2$  days)
  - Recognized as “outpatient-equivalent inpatient” and reimbursed accordingly – what matters is not the location of care, but its efficiency, quality, and economic viability
  - Reimbursement: Mandatory same lump-sum payment (=DRG!) for hospitals and contract physicians, but with a big deduction (average so far 30% -40%) compared to in-patient reimbursement!

# Hybrid DRGs

- Hybrid DRGs are not a new concept – the term has shaped discussions on cross-sector care and outpatient treatment in hospitals for years
- New development (April 30, 2025 decision): The “Beschluss des Bewertungsausschusses” fundamentally changes the system
  - For the first time: A mandatory catalog is introduced, covering at least one million cases annually – billable as outpatient or inpatient with short length of stay
  - This turns a structural policy signal into a direct mandate for hospitals
  - Underlying logic: Services with short length of stay (generally up to two days) are now considered “outpatient-equivalent inpatient” – and reimbursed accordingly
  - This challenges traditional DRG processes, requires new calculation models, and forces hospitals to reassess their service spectrum

# What Does “Outpatient-Equivalent Inpatient” (Ambulant Äquivalent Stationär) Mean?

- Services listed in the hybrid DRG catalog with a length of stay of usually up to two days will be considered billable as outpatient – even if performed in an inpatient setting
- The decisive factor is not the place of service, but the combination of catalog assignment and short length of stay
- This represents a fundamental change in the traditional DRG system

# What Exactly Is Included in the Hybrid DRG Catalog 2026?

- The new catalog covers at least one million cases per year – treated outpatient or short-stay inpatient
  - Concept: Those who deliver services quickly, efficiently, and without unnecessary bed occupancy will be reimbursed equally
  - One million cases. Outpatient or short-stay. Starting in 2026
  - It is no longer just about “outpatient before inpatient” – but increasingly about “outpatient-equivalent inpatient.”
  - What matters is not the location of care, but its efficiency, quality, and economic viability
  - With the April 2025 decision, the hybrid DRG Catalog 2026 is finalized
  - Immediate implementation: Hospitals must already begin reassessing their service structures

# Impact on Costs

$$\text{Hybrid}_{\text{DRG}} = \left( \frac{\text{Fallzahl}_{\text{Praxis}} + \text{Fallzahl}_{115b}}{\text{Fallzahl}_{\text{gesamt}}} \right) * \text{Fallwert}_{\text{Praxis}} + \left( \frac{\text{Fallzahl}_{\text{stationär}}}{\text{Fallzahl}_{\text{gesamt}}} \right) * \text{Fallkosten}_{\text{stationär}}$$

+ Sach- und Laborkosten ausschließlich Implantat-/Transplantatkosten<sub>stationär</sub>

+ Implantat-/Transplantatkosten<sub>stationär</sub>

- Material costs and costs for implants are excluded from the existing DRG before the adjustment for new hybrid DRG are applied
- 2024 DRG costs are adjusted to year 2026 (inflation)
- Adjusted 2024 costs are placed back into the new hybrid DRGs
- We start with same m DRGs

$$\text{Hybrid}_{\text{DRG}} = \left( \frac{\text{Fallzahl}_{\text{ambulant}}}{\text{Fallzahl}_{\text{gesamt}}} \right) * \text{Fallwert}_{\text{ambulant}} + \left( \frac{\text{Fallzahl}_{\text{KH}}}{\text{Fallzahl}_{\text{gesamt}}} \right) * \text{Fallkosten}_{\text{KH}}$$

+ Sach- und Laborkosten ausschließlich Implantat-/Transplantatkosten<sub>KH</sub>

+ Implantat-/Transplantatkosten<sub>KH</sub>

# Hybrid DRGs 2026: Ablation Procedures

<b>F50M</b>	<b>F50A</b>	Ablations for arrhythmias with highly complex ablation in the left atrium, ventricle, or pulmonary veins
<b>F50N</b>	<b>F50B</b>	Ablations for arrhythmias with complex ablation
<b>F50O</b>	<b>F50C</b>	Ablations for arrhythmias (general)

- The current 15% revenue reduction for 1-day cases (one overnight stay) in DRGs F50A, F50B, F50C will be reversed
- Revenues for these DRGs will increase again for 1-day cases
- However, only ~5% of current 1-day cases are expected to benefit
- Estimated DRG-decline is much smaller, because of the exclusion of the material/implants costs from out-patient deduction & and zero out-patient-cases

# Top 10 Hybrid-DRGs, Based on Simulated Cases

Hybrid-DRG	Bezeichnung der Hybrid-DRG	Bezeichnung der "Mutter"-DRG	Fallzahl in §-21-Daten 2024
G24Q	Hybrid-DRG 2 der DRG G24D	Eingriffe bei Hernien ohne plastische Rekonstruktion der Bauchwand, ohne beidseitigen Eingriff, ohne komplexen Eingriff, Alter > 17 Jahre	105.601
F50M	Hybrid-DRG der DRG F50A	Ablative Maßnahmen bei Herzrhythmusstörungen mit hochkomplexer Ablation im linken Vorhof, Ventrikel oder Pulmonalvenen [...]	70.749
F49R	Hybrid-DRG 2 der DRG F49F	Invasive kardiolog. Diagnostik außer bei akutem Myokardinfarkt, o. äußerst schwere CC, ohne IntK > 196 / 184 / 368 P., Alter > 17 J., o. kard. Mapping, o. best. and. kard. Diagnostik, [...]	66.891
H08M	Hybrid-DRG der DRG H08C	Laparoskopische Cholezystektomie oder bestimmte Eingriffe an Leber und Bauchwand, [...]	66.283
L20N	Hybrid-DRG der DRG L20C	Transurethrale Eingriffe außer Prostataresektion und komplexe Ureterorenoskopien oder bestimmte Eingriffe an den Harnorganen, ohne äußerst schwere CC oder [...]	58.744
F58N	Hybrid-DRG 2 der DRG F58B	Perkutane Koronarangioplastie oder bestimmte kardiologische Diagnostik mit Gefäßeingriff, ohne äußerst schwere CC	57.048
L20M	Hybrid-DRG der DRG L20B	Transurethrale Eingriffe außer Prostataresektion und komplexe Ureterorenoskopien oder bestimmte Eingriffe an den Harnorganen, ohne äußerst schwere CC oder [...]	57.031
I21M	Hybrid-DRG der DRG I21Z	Lokale Exzision [...] oder komplexe Eingriffe an Ellenbogengelenk und Unterarm oder bestimmte Eingriffe an der Klavikula	52.628
G26N	Hybrid-DRG der DRG G26B	Andere Eingriffe am Anus oder Anoproktoplastik und Rekonstruktion von Anus und Sphinkter bei Analfissuren und Hämorrhoiden, Alter > 17 Jahre, [...]	36.680
N25M	Hybrid-DRG der DRG N25Z	Andere Eingriffe an Uterus und Adnexen oder bestimmten Hernien außer bei bösartiger Neubildung, ohne komplexe Diagnose oder [...]	32.995

EP

Coro

PCI

(green = new)



# EP Exclusion Criteria

- Cases in F50A with implantation of an event recorder were excluded from Hybrid-DRG F50A
- Reason: Cases with the combination “ablation plus event recorder” in this DRG generally show corresponding NUB payments
- This exclusion was not implemented via context factors, because the procedure implantation of an event recorder is not a NUB service outside this DRG

# Hybrid DRGs 2026: Ablation Procedures

- All ablation procedures, regardless of type or location, could fall under a Hybrid DRG
- Initially excluded (eg, PFA procedures) now appear to be included
- Cases with 1- or 2-day stays can be grouped into hybrid DRGs
- From 2026 onwards, ~70% of ablation cases are expected to be billed under hybrid DRGs
- Exact reimbursement levels are still uncertain

# Hybrid DRGs 2026: Open Points

- Finalized Hybrid DRG catalog and detailed OPS code list
- Specific procedure grouping rules per hybrid DRG
- Definition of context factors (criteria excluding cases from hybrid DRGs)
- Final revenue levels/reimbursement rates for each hybrid DRG

# Conclusions: Hybrid DRGs: Outlook 2026 (Cardiology)

- Hybrid DRGs will come on January 2026
- Further details are expected to be published after September 26, 2025
- Material and implant costs are excluded from outpatient deductions
- The deduction per hybrid DRG is minimal (simulation: ~3–6%)
- The political savings target of €0.5 billion is unlikely to be achieved
- Further adjustments (and delays) are expected!

# Thank You.

