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Behandeling van niet-klassieke VTE - DOAC

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Disclosures

I have no conflicts of interest for this lecture

Affiliation/financial interest	**Company/party**
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Consultant:	–
Major stock/shareholder:	–
Advisory board:	–

Niet-klassieke VTE - DOAC

Behandeling van niet-klassieke VTE - DOAC

- ✓ Beperkt bewijs
- ✓ Off label
- ✓ We geven **<u>geen</u>** DOACs bij patiënten met:
  - ➢ Actieve bloeding/zeer hoog risico op bloeding
  - ➢ Diepe trombopenie (>$50*10^9$)
  - ➢ Ernstig nier/leverfalen
  - ➢ Onmogelijkheid om medicatie oraal in te nemen/malabsorptie

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Zeker ruimte voor DOACs bij CVT & SVT

2 RCTs bij CVT

JAMA Neurology | Original Investigation

Safety and Efficacy of Dabigatran Etexilate vs Dose-Adjusted Warfarin in Patients With Cerebral Venous Thrombosis
A Randomized Clinical Trial

José M. Ferro, MD, PhD; Jonathan M. Coutinho, MD, PhD; Francesco Dentali, MD; Adam Kobayashi, MD, PhD; Andrey Alasheev, MD, PhD; Patrícia Canhão, MD, PhD; Denis Karpov, MD, PhD; Simon Nagel, MD; Laura Posthuma, MD; José Mário Roriz, MD; Jorge Caria, MD; Mandy Frässdorf, PhD; Holger Huisman, MSc; Paul Reilly, PhD; Hans-Christoph Diener, MD, PhD; for the RE-SPECT CVT Study Group

REGULAR ARTICLE

blood advances

Safety and efficacy of rivaroxaban in pediatric cerebral venous thrombosis (EINSTEIN-Jr CVT)

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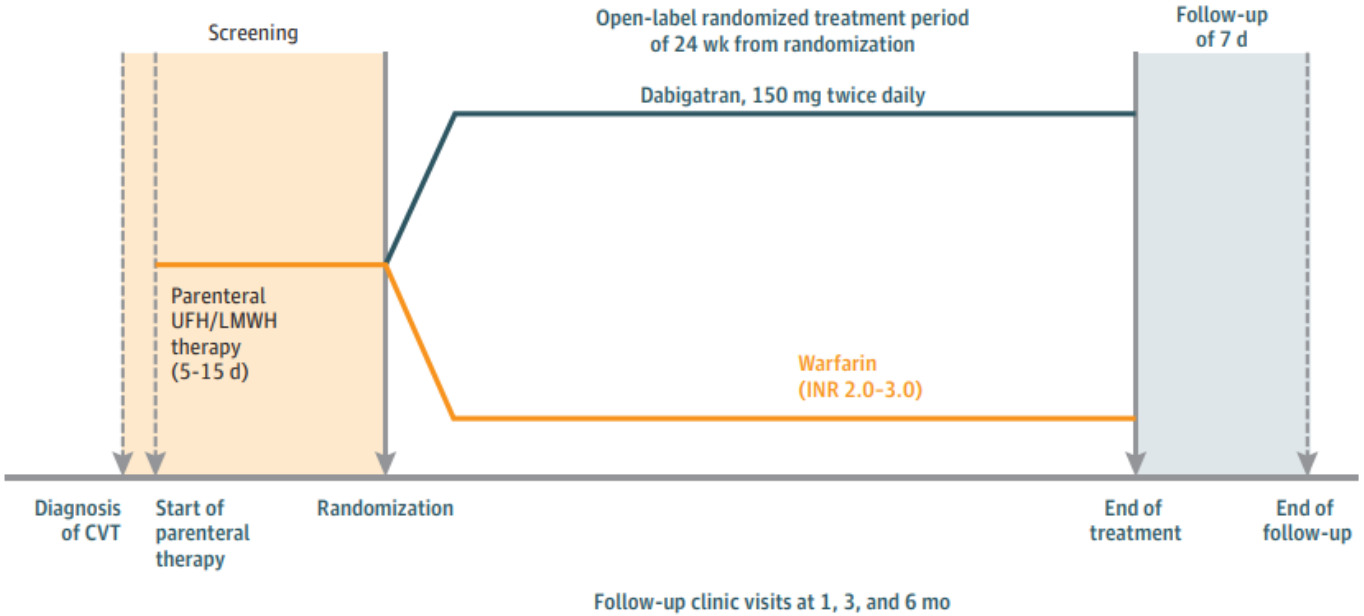
RE-SPECT CVT study



RE-SPECT CVT study

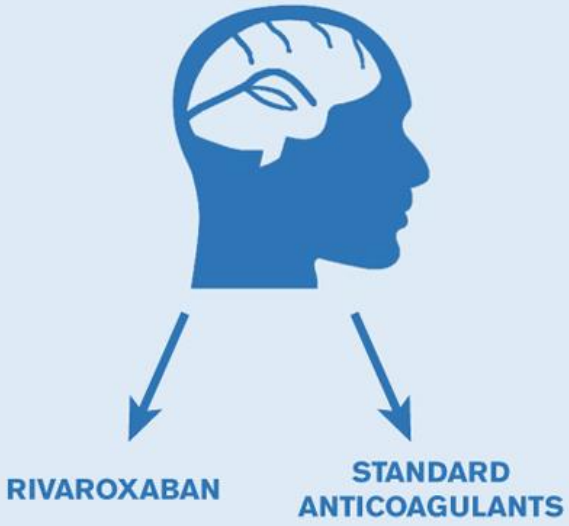
Outcomes	No. (%) [95% CI] Dabigatran Etexilate (n = 60)	Warfarin (n = 60)
Primary outcome		
Major bleeding or venous thrombotic event (recurrent CVT, DVT of any limb, pulmonary embolism, splanchnic vein thrombosis)	1 (1.7) [0.0-8.9]	2 (3.3) [0.4-11.5]
Secondary outcomes		
All venous thrombotic events	0 [0.0-6.0]	0 [0.0-6.0]
Recanalization: score of occluded veins/sinuses[a]		
Improved	33 (60.0) [45.9-73.0]	35 (67.0) [52.9-79.7]
No change	22 (40.0) [27.9-54.1]	17 (33.0) [20.3-47.1]
Secondary safety outcomes		
Major bleeding event	1 (1.7) [0.0-8.9]	2 (3.3) [0.4-11.5]
Clinically relevant non-major bleeding event	0 [0.0-0.6]	1 (1.7) [0.0-8.9]
Major bleeding or clinically relevant non-major bleeding event	1 (1.7) [0.0-8.9]	3 (5.0) [1.0-13.9]
Any bleeding	12 (20.0) [10.8-32.3]	12 (20.0) [10.8-32.3]
New intracranial hemorrhage or worsening of the hemorrhagic component of a baseline lesion[b]	1 (1.8) [0.0-9.6]	2 (3.8) [0.5-13.0]
New intracranial hemorrhage	0 [0.0-6.4]	2 (3.8) [0.5-13.0]
Worsening of the hemorrhagic component of a baseline lesion	1 (1.8) [0.0-9.6]	0 [0.0-6.7]

EINSTEIN-Jr. CVT

Safety and efficacy of rivaroxaban in pediatric cerebral venous thrombosis (EINSTEIN-Jr. CVT)

OBJECTIVE

To assess the safety and efficacy of rivaroxaban and standard anticoagulants for the treatment of pediatric cerebral venous thrombosis (CVT).



METHODS

Prespecified substudy of a randomized trial. Children (0-18 years) with CVT were randomized to rivaroxaban or standard anticoagulants.

RESULTS

Outcomes at 3 months	Rivaroxaban n= 73	Standard anticoagulants n= 41
Recurrent thrombosis	0	2.4%
Major bleeding	0	2.4%
Clinically relevant non-major bleeding	6.8%	0
More help with activities of daily living than before the CVT	5.5%	7.3%

CONCLUSION

Children with CVT treated with rivaroxaban or standard anticoagulants had a favorable clinical outcome, with a low risk of recurrent thrombosis or clinically relevant bleeding.

DOACs bij SVT

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LIVER FAILURE, CIRRHOSIS AND ITS COMPLICATIONS

WILEY Liver INTERNATIONAL

Antithrombotic treatment with direct-acting oral anticoagulants in patients with splanchnic vein thrombosis and cirrhosis

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Abstract

Background: Direct-acting oral anticoagulants (DOACs) are used in patients with splanchnic vein thrombosis (SVT) and cirrhosis, but evidence for safety and efficacy in this setting is limited. Our aim was to identify indications and reasons for starting or switching to DOACs and to report adverse effects, complications and short-term outcome.

Methods: Data collection including demographic information, laboratory values, treatment and complications through the Vascular Liver Disease Interest Group Consortium.

Results: Forty-five centres (90%) of the consortium completed the initial eCRF. We report here a series of 94 patients from 17 centres. Thirty-six patients (38%) had cirrhosis. Child-Pugh score was 6 (range 5-8), and MELD score 10.2 (range 6-19). Indications for anticoagulation were splanchnic vein thrombosis (75%), deep vein thrombosis (5%), atrial fibrillation (14%) and others (6%). DOACs used were rivaroxaban (83%), dabigatran (11%) and apixaban (6%). Patients were followed up for a median duration of 15 months (cirrhotic) and 26.5 months (non-cirrhotic). Adverse events occurred in 17% of patients and included one case of recurrent portal vein thrombosis and five cases of bleeding. Treatment with DOACs was stopped in three cases. The major reasons for choosing DOACs were no need for monitoring or inadequacy of INR to guide anticoagulation in cirrhotic patients. Renal and liver function did not change during treatment.

Conclusions: A consistent number of patients with SVT and/or cirrhosis are currently treated with DOACs, which seem to be effective and safe. These data provide a basis for performing randomized clinical trials of DOACs vs. low molecular weight heparin or vitamin K antagonists.

Abbreviations: DOACs, direct oral anticoagulants; LMWH, low molecular weight heparin; SVT, splanchnic vein thrombosis; VALDIG, Vascular Liver Disease Interest Group.

*Share first authorship
Vascular Liver Disease Interest Group (VALDIG) members are presented in appendix.

Registratie van 94 patiënten met SVT en/of cirrhose behandeld met een DOAC

- 75% SVT, ~40% ook cirrhose
- Vaakst rivaroxaban (83%), wisselende dosis
- 66% eerst LMWH (± VKA)

➢ DOAC gestopt vanwege een bloeding in 10%

DOACs bij SVT

REGULAR ARTICLE

blood advances

Check for updates

Rivaroxaban for the treatment of noncirrhotic splanchnic vein thrombosis: an interventional prospective cohort study

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Key Points

- SVT is a potentially life-threatening disease associated with a substantial risk of recurrence and bleeding.
- Rivaroxaban appears to be a reasonable alternative to standard anticoagulation for the treatment of SVT in patients without cirrhosis.

Heparins and vitamin K antagonists are the mainstay of treatment of splanchnic vein thrombosis (SVT). Rivaroxaban is a potential alternative, but data to support its use are limited. We aimed to evaluate the safety and efficacy of rivaroxaban for the treatment of acute SVT. In an international, single-arm clinical trial, adult patients with a first episode of noncirrhotic, symptomatic, objectively diagnosed SVT received rivaroxaban 15 mg twice daily for 3 weeks, followed by 20 mg daily for an intended duration of 3 months. Patients with Budd-Chiari syndrome and those receiving full-dose anticoagulation for >7 days prior to enrollment were excluded. Primary outcome was major bleeding; secondary outcomes included death, recurrent SVT, and complete vein recanalization within 3 months. Patients were followed for a total of 6 months. A total of 103 patients were enrolled; 100 were eligible for the analysis. Mean age was 54.4 years; 64% were men. SVT risk factors included abdominal inflammation/infection (28%), solid cancer (9%), myeloproliferative neoplasms (9%), and hormonal therapy (9%); 43% of cases were unprovoked. JAK2 V617F mutation was detected in 26% of 50 tested patients. At 3 months, 2 patients (2.1%; 95% confidence interval, 0.6-7.2) had major bleeding events (both gastrointestinal). One (1.0%) patient died due to a non–SVT-related cause, 2 had recurrent SVT (2.1%). Complete recanalization was documented in 47.3% of patients. One additional major bleeding event and 1 recurrent SVT occurred at 6 months. Rivaroxaban appears as a potential alternative to standard anticoagulation for the treatment of SVT in non-cirrhotic patients. This trial was registered at www.clinicaltrials.gov as #NCT02627053 and at eudract.ema.europa.eu as #2014-005162-29-36.

Submitted 22 February 2022; accepted 5 April 2022; prepublished online on *Blood Advances* First Edition 19 April 2022; final version published online 17 June 2022. DOI 10.1182/bloodadvances.2022007397.

Preliminary results of this study were part of an oral presentation at the 63rd annual American Society of Hematology meeting, Atlanta, GA, 13 December 2021.

The study protocol is available upon request to the corresponding author: walter.ageno@uninsubria.it.

The full-text version of this article contains a data supplement.

Interventiestudie in 100 patiënten met niet-cirrhotisch SVT, behandeld met rivaroxaban

- 43% 'spontane' SVT
- 80% eerst LMWH (5 dagen)

- ➢ 2%MB, 3% NMCRB na 3 maanden
- ➢ 2% recidief SVT na 3 maanden

DOACs bij SVT

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ORIGINAL ARTICLE

WILEY

Outcomes of long-term anticoagulant treatment for the secondary prophylaxis of splanchnic venous thrombosis

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Abstract

Background: Splanchnic vein thrombosis (SVT) is an uncommon but potentially life-threatening disease usually related to different underlying clinical conditions. The risk of SVT recurrences is high over time in patients with an underlying permanent prothrombotic condition. Vitamin K antagonists (VKA) represent the mainstay of treatment for SVT. Data about the efficacy and safety of direct oral anticoagulants (DOACs) are reported in the literature for the treatment of acute SVT, but less is known about their application for the secondary prophylaxis of venous thromboembolism (VTE). The aim of this study was to assess the efficacy and safety of long-term DOACs therapy in patients at high-risk of thrombosis, compared to VKA.

Methods: This is a retrospective single-centre study including 70 patients with SVT on long-term anticoagulant treatment with VKA followed-up at our Units between January 2017 and December 2019. All the patients were at high thrombotic risk defined as the presence of a permanent prothrombotic condition requiring long-term anticoagulation. During follow-up, 28 patients were shifted to DOACs and their clinical outcomes were compared to those of the patients who continued VKA therapy. All the arterial and venous thrombotic events of the splanchnic and extra-splanchnic districts as well as the haemorrhagic adverse events occurring during follow-up were recorded.

Results: Of the seventy patients enrolled in the study, 36 patients (51.4%) had a single-segment involvement thrombosis (28.5% of portal vein, 7.1% of superior mesenteric vein, 4.3% of splenic vein, 11.5% of hepatic veins) and 34 patients (48.6%) had multi-segment involvement at the time of diagnosis. 42 patients (60%) continued VKA therapy and 28 (40%) were switched to DOACs. Median follow-up was 6 years (range 2-8) during VKA and 1.9 years (range 1-5.2) during DOACs. The incidence of thrombotic events was similar between patients on VKA and those on DOACs. Patients on VKA developed deep vein thrombosis (DVT), and of the patients on DOACs 1 developed NSTEMI and 1 DVT. No major haemorrhagic events occurred. Minor bleedings occurred in 26% of patients on VKA and in none of the DOACs patients (*P*: 0.09).

Retrospectief statusonderzoek in 70 patienten met SVT, langdurige VKA behandeleling

- 40% MPN, 93% JAK 2 positief
- 10% genetische trombofilie
- 20% kanker, 12% cirrhose (CP A/B)

- ➢ 28 geswitched naar DOAC
- ➢ Na 2 jaar 0 majeure bloedingen en 2x VTE

DOACs bij SVT

blood advances

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Anticoagulant therapy for splanchnic vein thrombosis: an individual patient data meta-analysis

Tracking no: ADV-2022-007961R1

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Abstract:
Robust evidence on the optimal management of splanchnic vein thrombosis (SVT) is lacking. We conducted an individual patient meta-analysis to evaluate the effectiveness and safety of anticoagulation for splanchnic vein thrombosis (SVT). MEDLINE, EMBASE, and clincaltrials.gov., were searched up to June 2021 for prospective cohorts or randomized clinical trials including patients with SVT. Data from individual datasets were merged, and any discrepancy with published data was resolved by contacting study authors. Three studies for a total of 1635 patients were included. Eighty-five percent of patients received anticoagulation for a median duration of 316 days (range 1 to 730 days). Overall, incidence rates for recurrent VTE, major bleeding, and mortality were 5.3/100 patients-years (p-y) (95% CI, 5.1 to 5.5), 4.4/100 p-y (95% CI, 4.2 to 4.6), and 13.0/100 p-y (95% CI, 12.4 to 13.6), respectively. The incidence rates of all outcomes were lower during anticoagulation and higher after treatment discontinuation or when anticoagulation was not administered. In multivariable analysis, anticoagulant treatment appeared to be associated with a lower risk of recurrent VTE (Hazard Ratio [HR] 0.42; 95% CI, 0.27 to 0.64), major bleeding (HR 0.47; 95% CI, 0.30 to 0.74), and mortality (HR 0.23; 95% CI, 0.17 to 0.31). Results were consistent in patients with cirrhosis, solid cancer, myeloproliferative neoplasms, unprovoked SVT, and SVT associated with transient or persistent non-malignant risk factors. In patients with SVT the risk of recurrent VTE and major bleeding is substantial. Anticoagulant treatment is associated with reduced risk of both outcomes.

Conflict of interest: COI declared - see note

COI notes: E.V. , M.C., N.R., M.L.P., A.D.G., R.L.R, M.S., V.R., and M.M. have nothing to disclose. M.D.N. received honoraria for participation at advisory boards from Bayer, Daiichi Sankyo, Pfizer, Leo Pharma, Sanofi, and Viatris, outside the submitted work. W.A. has received a research grant from Bayer to support a clinical study in patients with splanchnic vein thrombosis, received honoraria for participation at advisory boards from Bayer, BMS/Pfizer, Sanofi, Leo Pharma, and Portola, and reports grants and personal fees from Bayer, and personal fees from BMS/Pfizer, Daiichi Sankyo, Sanofi, Aspen, Janssen, and Portola, Werfen, outside the submitted work. M.B.M. is a recipient of a Río Hortega grant from Instituto de Salud Carlos III, Spain. J.C.G.P. is a consulting for Cook Medical, Shionogi, WL Gore y Asociados, Vifor Pharma, and Boehringer Ingelheim and has received a research frant from Mallinckrodt and Noorik. J.B.W. received honoraria and institutional research support from Bayer AG, Boehringer Ingelheim, Bristol-Myers Squibb/Pfizer, Daiichi Sankyo, DOASENSE, Norgine, Sanofi and Alexion. S.S. has received research funding from Boehringer Ingelheim and Octapharma and honoraria from Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, Pfizer, Sanofi. J.J.L.N. has received honoraria for lectures from Bayer, Pfizer and Rovi; educational events from Leo Pharma and Pfizer; support for attending meetings and travel from Bayer, BMS, Pfizer, Leo Pharma, Rovi, and Sanofi; and Advisory Board participation from Pfizer.

IPDMA van 1635 SVT patiënten die behandeld zijn met antistolling

- 33% v. porta trombose, 33% multivessel
- 28% unprovoked, 32% kanker, 18% cirrhose

- ➢ 1.7% alleen met DOAC behandeld, 4% naar DOAC gewisseld
- ➢ 0 recidief VTE, MB 3%/jaar

ISTH SSC aanbeveling 2020

5. In non-cirrhotic patients with symptomatic acute splanchnic vein thrombosis who have no signs of active bleeding, we suggest full therapeutic dose of DOACs, and consider LMWH and VKAs with INR range of 2.0-3.0 in patients who cannot tolerate or have contraindications for DOACs. This panel acknowledges the fact that none of the anticoagulants are specifically approved for the treatment of splanchnic vein thrombosis.
6. In patients with cancer-associated symptomatic acute splanchnic vein thrombosis, we recommend LMWH or DOACs. We suggest LMWH in patients with luminal gastrointestinal cancer, active gastrointestinal mucosal abnormalities, genitourinary cancer at high risk of bleeding, or receiving current systemic therapy with potentially relevant drug-drug interactions with DOACs.
7. In cirrhotic patients with symptomatic acute splanchnic vein thrombosis, we suggest therapeutic dose LMWH, and a switch to VKAs or DOACs if not contraindicated by severity of liver dysfunction.

Behandeling van niet-klassieke VTE - DOAC

Bewijs met name voor CVT solide

CVT

- ✓ Start met LMWH
- ✓ RCT bewijs voor DOAC onderhouds-behandeling
- ✓ DOAC goede optie voor langetermijn profylaxe (>6 mnd)

SVT

- ✓ Start met LMWH
- ✓ Observationeel (beperkt) bewijs dat DOAC onderhoudsbehandeling veilig is voor geselecteerde patiënten
- ✓ Oppassen bij cirrhose