

Comprehensive Cancer Center
Tübingen-Stuttgart

Post ASH 2024 San Diego

Hämostaseologie

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Comprehensive
Cancer Center
Tübingen - Stuttgart



Universitätsklinikum
Tübingen

Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK



Francis Couturaud. LBA-3 Extended Treatment of Venous Thromboembolism with Reduced- Vs Full-Dose Direct Oral Anticoagulants in Patients at High Risk of Recurrence.




Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK




American Society of Hematology
Helping hematologists conquer blood diseases worldwide


66th ASH Annual Meeting
San Diego,
LBA-3, December 10, 2024




EXTENDED TREATMENT OF VENOUS THROMBOEMBOLISM WITH REDUCED- VS FULL-DOSE DIRECT ORAL ANTICOAGULANTS IN PATIENTS AT HIGH RISK OF RECURRENCE. THE RENOVE TRIAL




INVESTIGATION NETWORK ON VENOUS THROMBOEMBOLISM




FRENCH CLINICAL RESEARCH INFRASTRUCTURE NETWORK




Institut national de la santé et de la recherche médicale



UMR 1304



CENTRE HOSPITALIER UNIVERSITAIRE



Université de Bretagne Occidentale

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CLINICALTRIALS.GOV #: NCT03285438
EudraCT #: 2017-002433-31



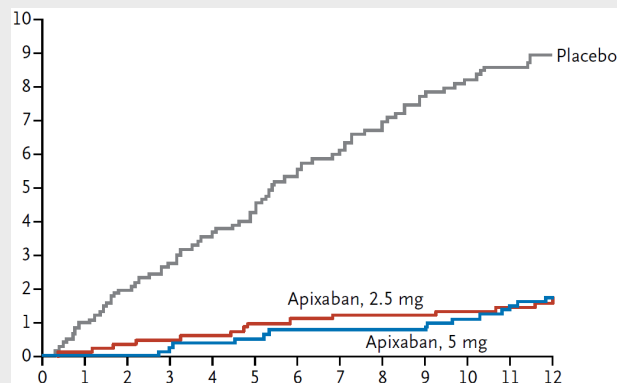
Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

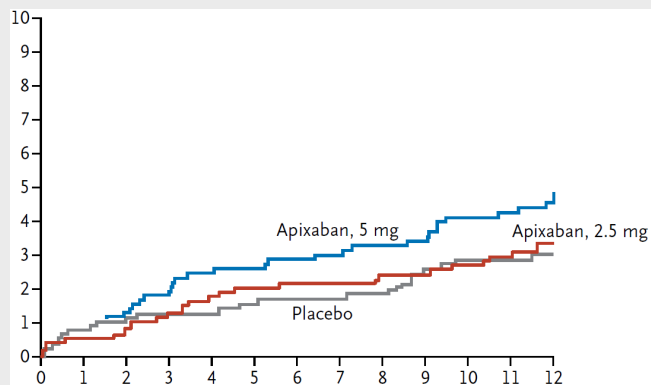
Rationale

Amplify-Ext

Symptomatic Recurrent VTE or VTE-Related Death

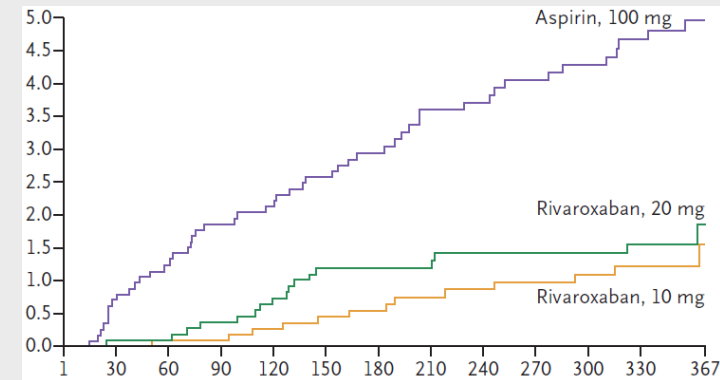


Major or Clinically Relevant Nonmajor Bleeding

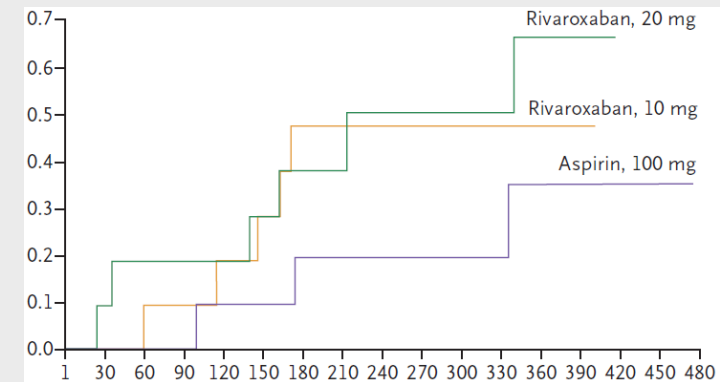


Einstein-Choice

Fatal or Nonfatal Venous Thromboembolism



Major Bleeding



Francis Couturaud. LBA-3 Extended Treatment of Venous Thromboembolism with Reduced- Vs Full-Dose Direct Oral Anticoagulants in Patients at High Risk of Recurrence.



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RENOVE-trial

Rationale

However, these two studies^{1,2}:

- were neither designed nor powered to demonstrate similar efficacy and improved safety with the reduced dose,
- with the inclusion of placebo¹ or aspirin² control groups, enrolled patients with uncertain need for extended anticoagulation.



Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

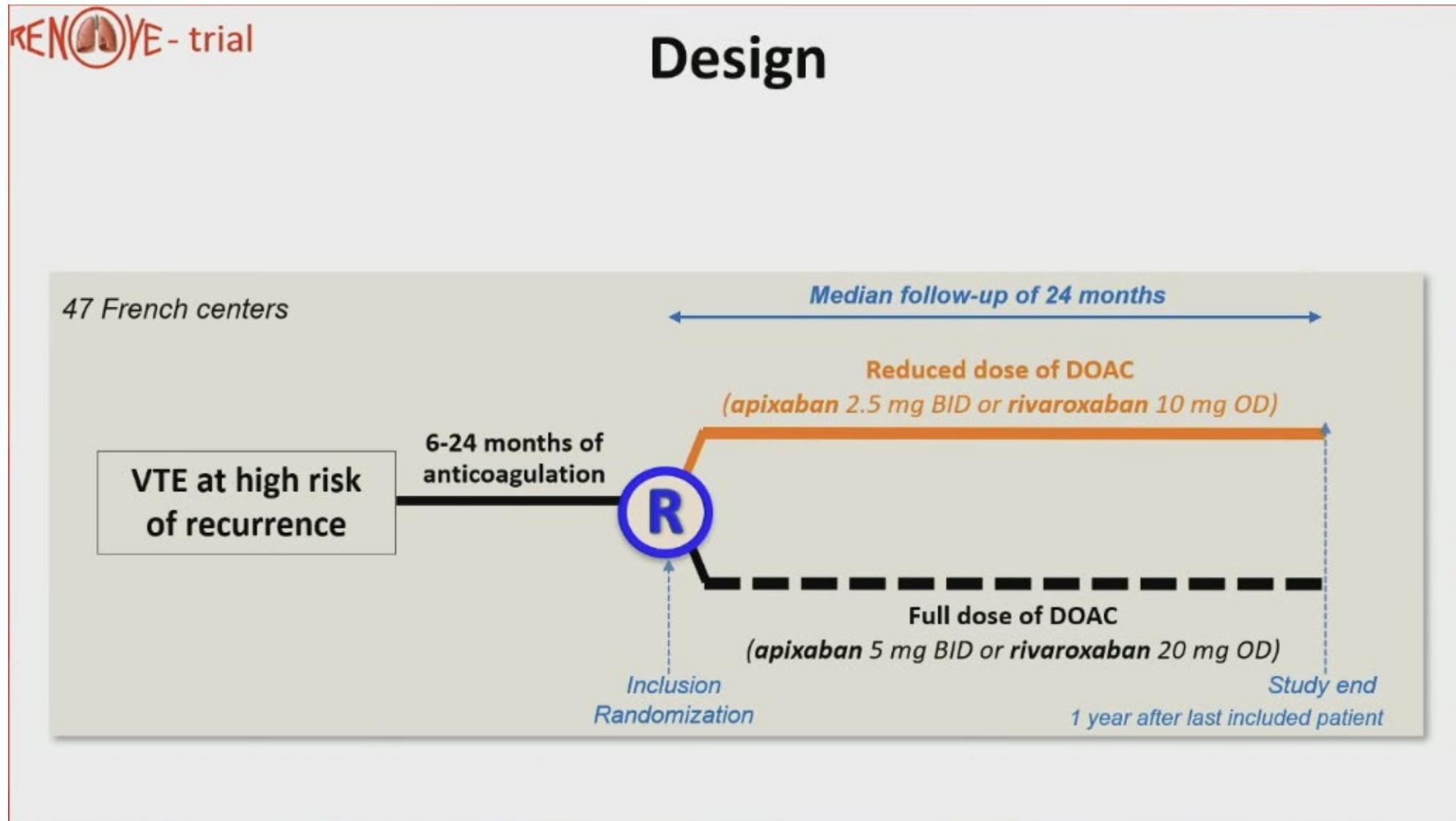
REN@VE - trial

Objectives

- **Primary objective:** to demonstrate **non-inferiority** of extended-phase anticoagulation using reduced-dose DOAC *versus* full-dose DOAC for the prevention of **recurrent VTE**.



Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK



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Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

Primary outcome

5-year cumulative incidence

	Reduced Dose (N=1383)	Full Dose (N=1385)	Adjusted HR (95% CI)	P-Value
Primary outcome				
Symptomatic recurrent VTE - no. (%)	19 (2.2)	15 (1.8)	1.32 (0.67 - 2.60)	0.23
Symptomatic recurrent PE	11	13		
Fatal PE	3	3		
Symptomatic isolated proximal DVT	9	2		

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Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

Primary outcome

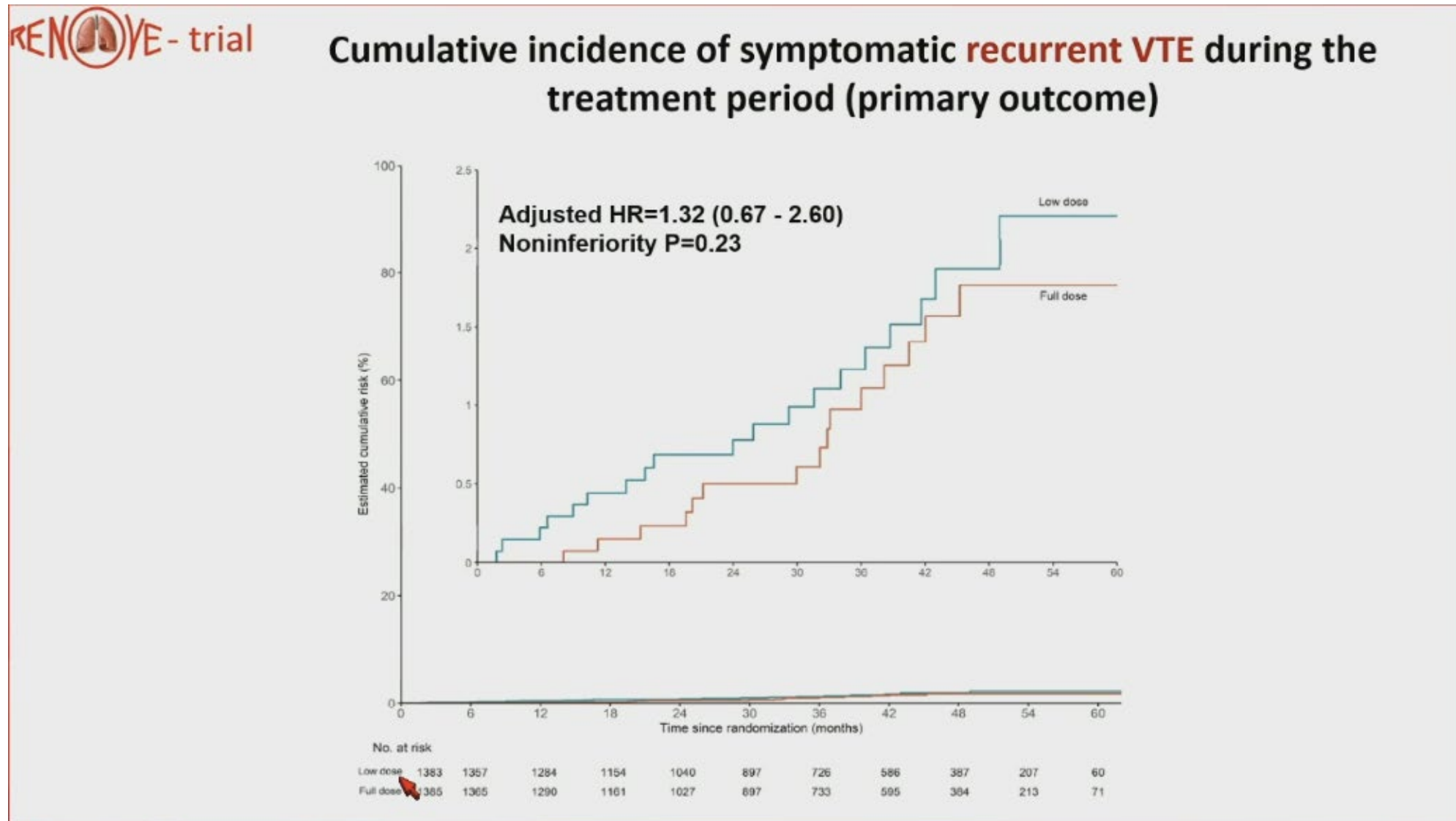
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Fatal PE	3	3		
Symptomatic isolated proximal DVT	9	2		
↓ ↓ ↓				
Annual incidence rates	0.50% (0.28-0.72)	0.40% (0.20-60)	Absolute difference 0.40% (-1.05; 1.85)	

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Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

Secondary outcomes

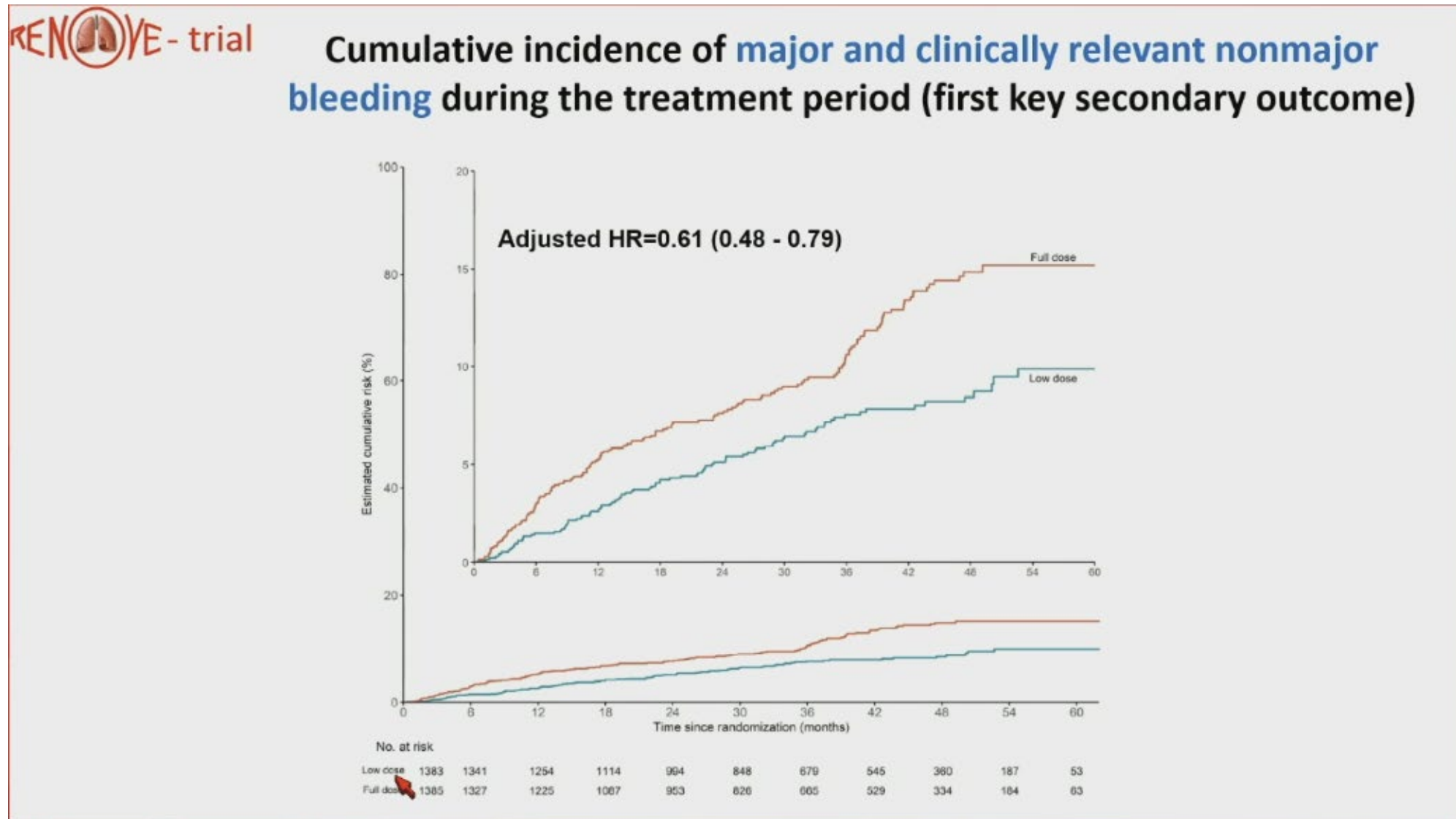
5-year cumulative incidence

	Reduced Dose (N=1383)	Full Dose (N=1385)	Adjusted HR (95% CI)	P-Value
<i>Key secondary outcomes</i>				
Clinically relevant bleeding - no. (%)	96 (9.9)	154 (15.2)	0.61 (0.48 - 0.79)	
Major bleeding	15 (2.1)	38 (4.0)	0.40 (0.22 - 0.72)	
Fatal	2	3		
Clinically relevant non major bleeding	84 (8.6)	118 (11.5)	0.70 (0.53 - 0.93)	
Composite (recurrent VTE, or clinically relevant bleeding) - no. (%)	113 (11.8)	166 (16.5)	0.67 (0.53 - 0.86)	

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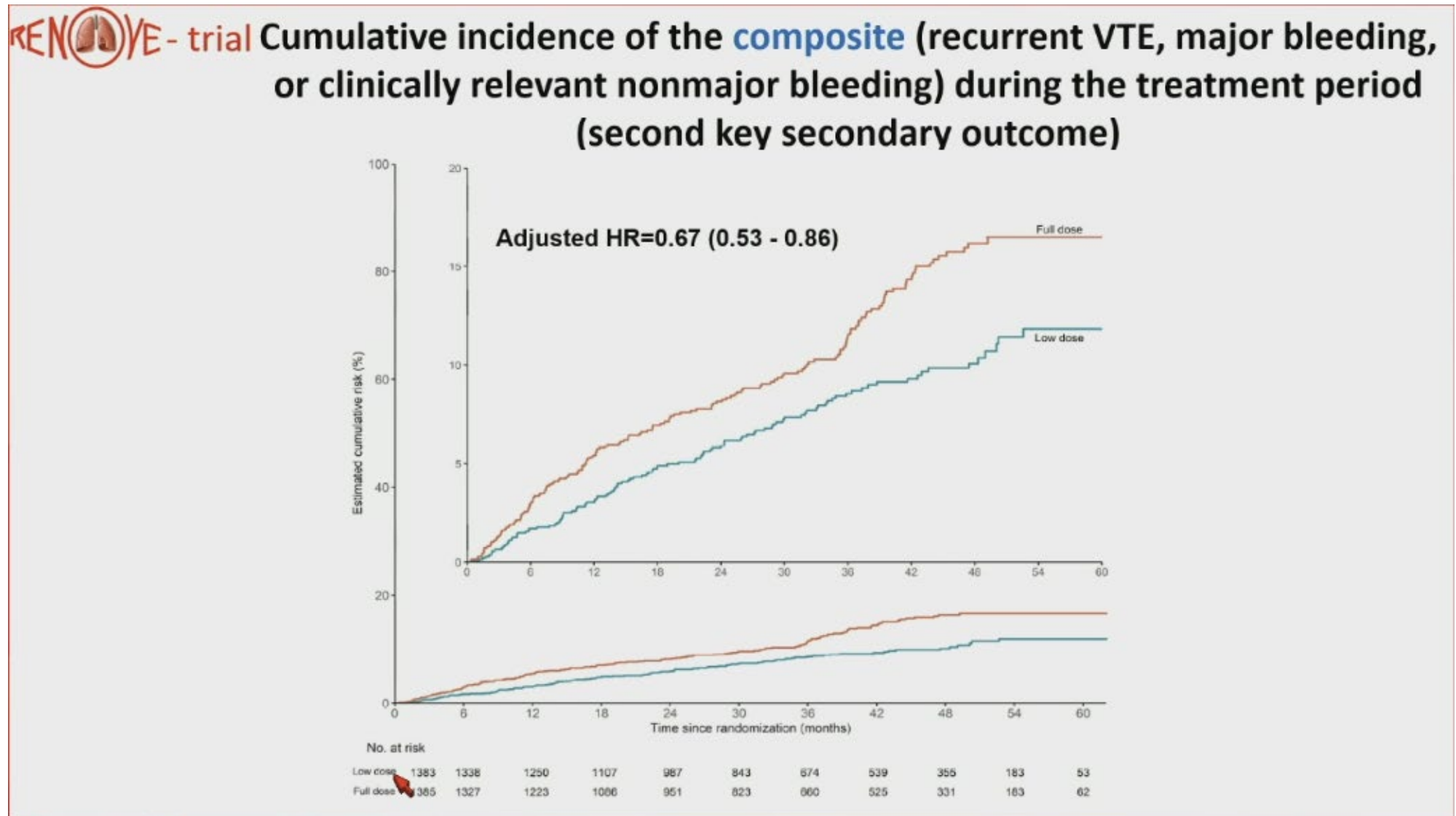
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Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK



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Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

Secondary outcomes

5-year cumulative incidence

	Reduced Dose (N=1383)	Full Dose (N=1385)	Adjusted HR (95% CI)	P-Value
Other secondary outcomes				
All-cause death	35 (4.3)	54 (6.1)	0.67 (0.44 - 1.03)	
Arterial cardiovascular events	78 (6.2)	69 (5.5)	1.17 (0.83 - 1.64)	



Extended Treatment of VTE with Reduced- Vs Full-Dose DOAK

RENOVE-trial

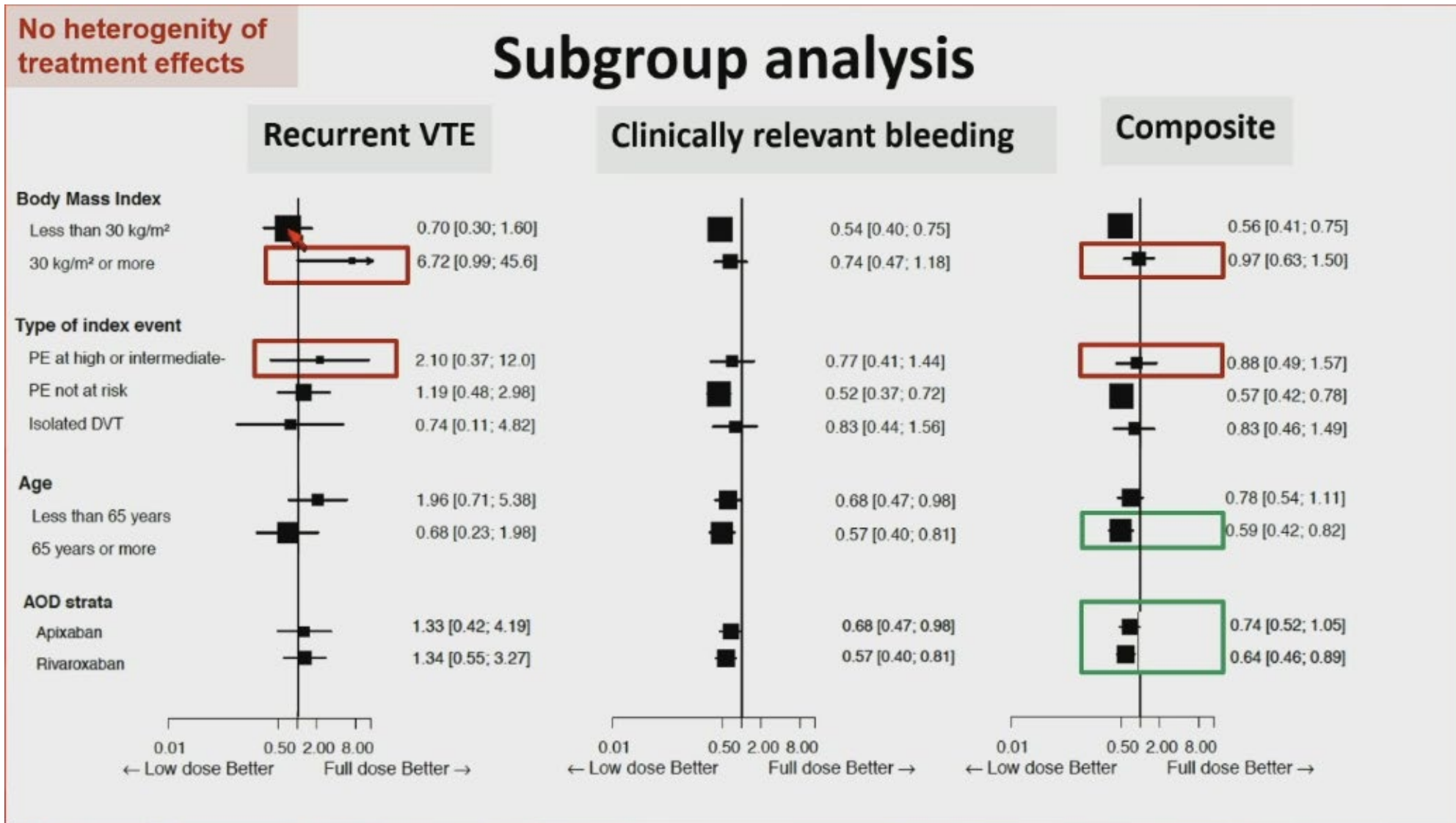
Conclusions

- DOAC dose reduction, in patients with VTE who need extended anticoagulation, **did not meet the study noninferiority** criteria.
- **Rates of recurrent VTE were low** in both the reduced- and full-dose groups.
- In the reduced-dose group, **clinically relevant bleeding** and **the composite** of recurrent VTE or clinically relevant bleeding **were lower** than in the full-dose group and did not appear to be offset by an increased risk of death or arterial thromboembolic events.
- These findings will be useful to **strengthen future guidelines and enrich shared-decision making process** for patients with VTE who need extended anticoagulation.

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Clinical and Economic Outcome Analysis in Acquired Hemophilia A



Ellen Cusano. 554 Clinical and Economic Outcome Analysis of First-Line Immunosuppression in Acquired Hemophilia A.



Clinical and Economic Outcome Analysis in Acquired Hemophilia A



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Clinical and Economic Outcome Analysis of First-Line Immunosuppression in Acquired Hemophilia A

Ellen Cusano, MD, FRCPC

Coagulation Medicine Fellow

UCSD Center for Bleeding and Clotting Disorders, San Diego, CA

Ellen Cusano. 554 Clinical and Economic Outcome Analysis of First-Line Immunosuppression in Acquired Hemophilia A.



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Acquired hemophilia A

- Rare bleeding disorder (1-2 per million per year) in which inhibitory antibodies neutralize factor VIII activity
- Pillars of treatment:
 - Hemostatic therapy to address active bleeding
 - Immunosuppressive treatment to eradicate inhibitors



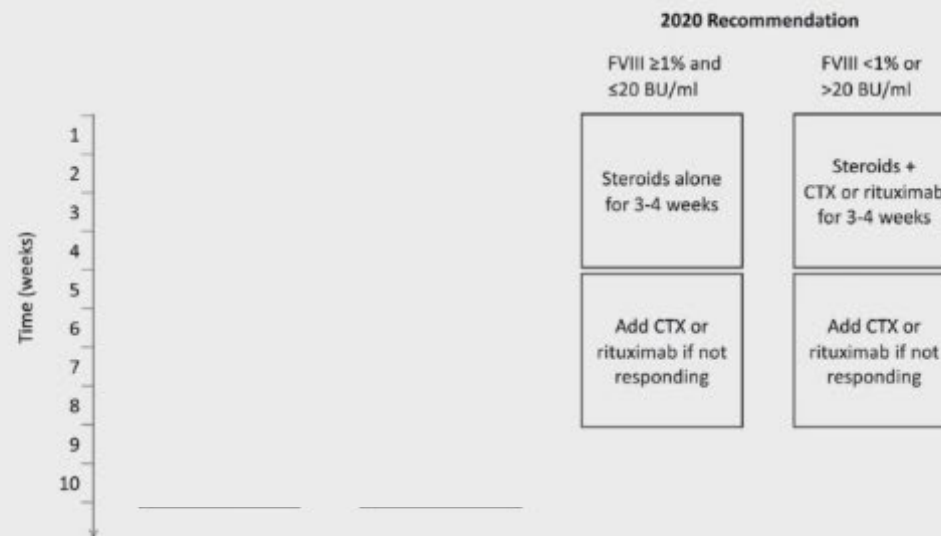
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Clinical and Economic Outcome Analysis in Acquired Hemophilia A

International recommendations on the diagnosis and treatment of acquired hemophilia A, Tiede et al (2020)



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Objectives

- **Primary**
 - Compare the **clinical efficacy** of first-line rituximab-based IST regimens with other IST regimens
 - Compare the **safety**
- **Secondary**
 - Compare the **economic burden**



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Study design

- National multicenter retrospective cohort



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Outcomes

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Outcomes

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	

Treatment response, n (%)						0.563
Complete remission	97 (77.0)	23 (69.7)	15 (78.9)	48 (76.2)	11 (100.0)	

Time to CR/PR, months						0.265
Median (IQR)	3.3 (2.5,4.9)	3.0 (2.3,4.8)	3.1 (2.6,3.7)	3.4 (2.4,5.5)	4.4 (3.3,4.8)	

Proportion of CR highest in combination IST group, lowest in prednisone monotherapy



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Outcomes

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	
Relapse, n (%)						0.032
Yes	22 (21.4)	11 (45.8)	1 (6.3)	8 (15.4)	2 (18.2)	

Vital status as of last follow-up, n (%)						p-value
Alive	96 (76.2)	23 (69.7)	14 (73.7)	50 (79.4)	9 (81.8)	0.090

Cause of death, n (%)						
Infection	7 (28.0)	0 (0.0)	3 (60.0)	4 (30.8)	0 (0.0)	
Bleeding	1 (4.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	
Unrelated to AHA	14 (56.0)	2 (33.3)	3 (60.0)	9 (69.2)	0 (0.0)	

*Lowest relapse proportion in rituximab group
Majority of deaths deemed unrelated to AHA*



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Bleeding events

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	
Major	122 (47.1)	31 (43.1)	16 (40.0)	64 (50.4)	11 (55.0)	

More major bleeds in cyclophosphamide and combination IST groups



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Bleeding events

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	

Mean dose of hemostatic or bypassing agent used per bleed (SD)						
rFVIIa (mg)	144.40 (190.51)	96.62 (77.43)	92.89 (151.09)	163.45 (164.06)	253.17 (423.88)	0.297
FEIBA (IU)	79113.15	71950.90	44532.14	93416.46	140403.33	0.153

More rFVIIa and FEIBA used per bleed in cyclophosphamide and combination groups



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Cost analysis

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	
Total average per patient (\$)	179,961.2	144,605.3	161,569.1	186,974.2	277,631.1	0.145
Mean cost of IST per patient (\$)						
Total	3,481.7	181.5	11,686.0	1,078.3	11,284.0	<0.001



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Cost analysis

	Entire cohort	Prednisone	Rituximab	Cyclophosphamide	Rituximab + Cyclophosphamide	p-value
Patients, n (%)	126 (100)	33 (26.2)	19 (15.1)	63 (50.0)	11 (8.7)	

Mean cost of hemostatic treatment per patient (\$)						
rFVIIa	176,170.5	117,876.4	113,324.3	199,411.4	308,863.3	0.297
FEIBA	158,226.3	143,901.8	8,9064.3	186,832.9	280,806.7	0.153

Greater mean cost of hemostatic treatment driven by rFVIIa and FEIBA per patient in those treated with cyclophosphamide or combination IST



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Limitations

- Sample size
- Retrospective nature of the study
- Missing information
 - Incomplete or inaccessible charting from up to >1 decade ago
- Change in costs over years not captured, not a one size fits all



Clinical and Economic Outcome Analysis in Acquired Hemophilia A

Conclusions

- In this Canadian cohort, the proportion of patients achieving CR was highest in the combination group, lowest in the prednisone group, and comparable between rituximab and cyclophosphamide groups
- Those treated with rituximab had lower frequency of relapse, incidence of infection and non-infection grade 3/4 AE compared to regimens containing cyclophosphamide
- Average total treatment costs per patient were lowest in the prednisone and rituximab groups
- Overall, most costs were from hemostatic treatments, not from IST, and differences between regimens may be due to the frequency and severity of bleeding events



Zwei randomisierte Studien - Cyclophosphamid vs Rituximab

Cyclophosphamide vs rituximab for eradicating inhibitors in acquired hemophilia A: A randomized trial in 108 patients

	Prednisone + Cyclophosphamide	Prednisone + Rituximab	<i>P</i>	Odds ratio [95 % CI] ⁺
Complete remission				
All patients — n (%)	N = 58	N = 50		
Month 3	41 (70.7)	34 (68.0)		[0.57;
Patients with poor prognosis i. e., titer > 20 BU/mL and FVIII < 1 IU/dL — n (%)	N = 28	N = 25		
Month 3	21 (75.0)	13 (52.0)	0.0204*	3.97
Time to 1st complete remission — days	N = 45	N = 41		
Median (Q1;	46 (43; 59)	48 (45; 52)		



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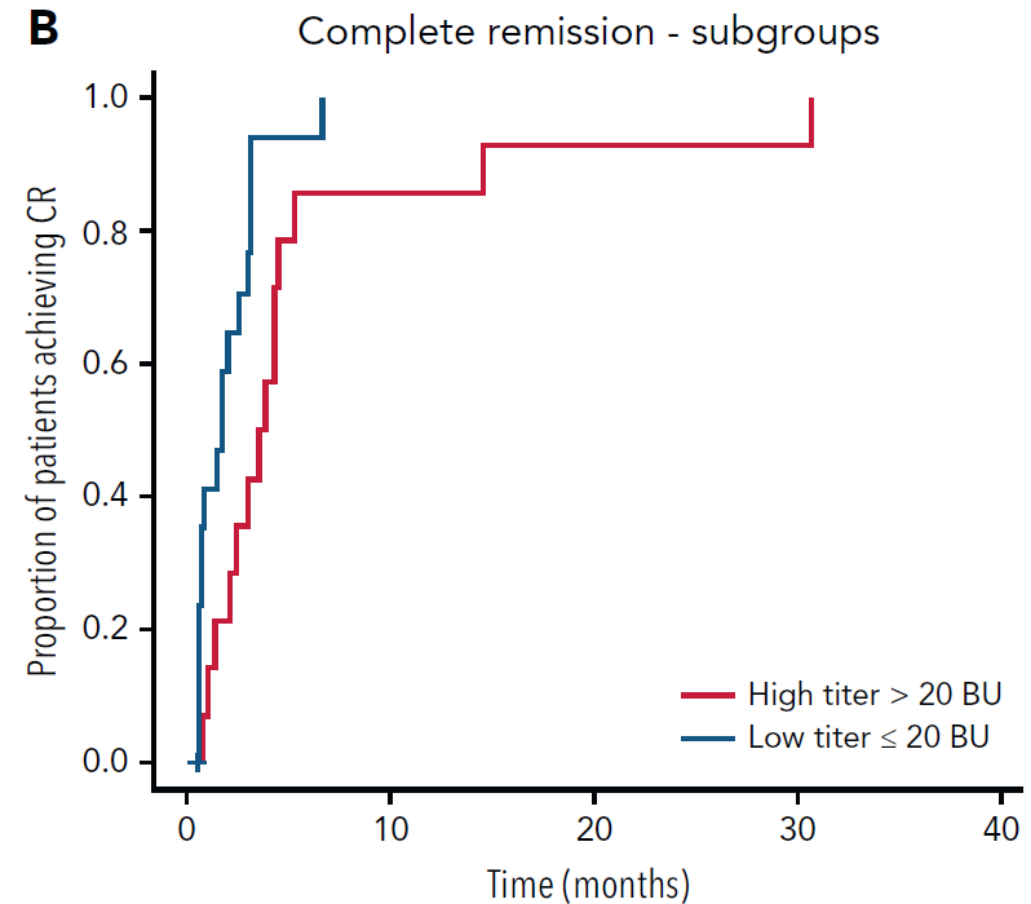
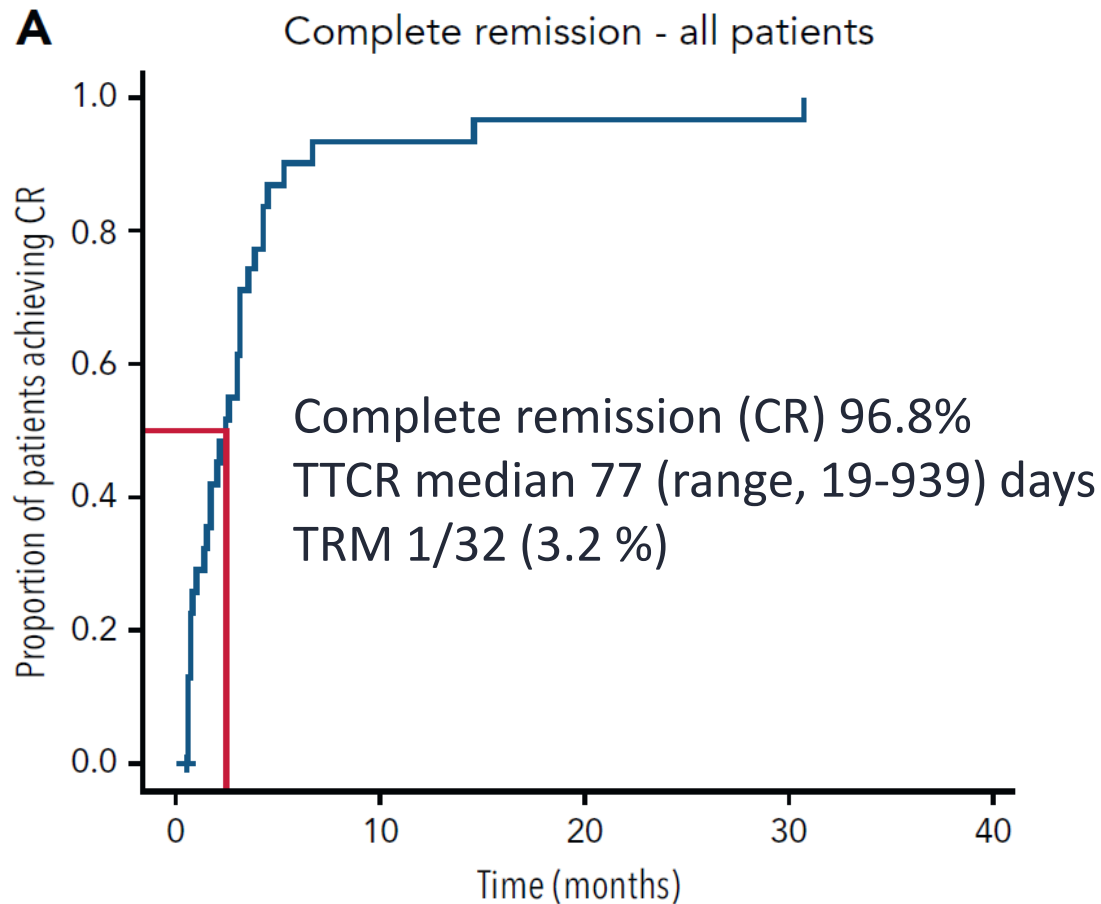
Single-dose rituximab plus glucocorticoid versus cyclophosphamide plus glucocorticoid in patients with newly diagnosed acquired hemophilia A: A multicenter, open-label, randomized noninferiority trial

	RTX + Glucocorticoid (n = 31)	CTX + Glucocorticoid (n = 32)	<i>p</i> value
<i>Primary endpoint</i>			
CR—no. (%)	24 (77.4)	22 (68.8)	.005
<i>Secondary endpoints</i>			
Median time to CR [IQR]—days	28.0 [20.8, 52.5]	36.0 [23.8, 50.3]	.41



Immunosuppressive Therapie - CyDRi

32 patients with AHA: cyclophosphamide 1000 mg on days 1 and 22
dexamethasone 40 mg on days 1, 8, 15, and 22
rituximab 100 mg on days 1, 8, 15, and 22



Sustained Improvement of Survival in Patients Receiving Emicizumab



Inga M. Schimansky. 555 Sustained Improvement of Survival in Patients Receiving Emicizumab Prophylaxis Instead of Immunosuppression during Early Management of Acquired Hemophilia a (AHA).



Sustained Improvement of Survival in Patients Receiving Emicizumab



GTH Acquired Hemophilia Working Group

Sustained Improvement of Survival in Patients Receiving Emicizumab Prophylaxis Instead of Immunosuppression During Early Management of Acquired Hemophilia A (AHA)

Inga Schimansky, Christiane Dobbstein, Robert Klamroth, Christina Hart, Ulrich J. Sachs, Richard Greil, Paul Knoebl, Johannes Oldenburg, Wolfgang Miesbach, Christian Pfrepper, Karolin Trautmann-Grill, Patrick Möhnle, Katharina Holstein, and Andreas Tiede

ABSTRACT #555



Sustained Improvement of Survival in Patients Receiving Emicizumab

Infection as a major risk for patients with AHA

	UK ¹	EU ²	FR ³	DE/AT ⁴	ES ⁵	NL ⁶
Year of publication	2007	2012	2013	2015	2021	2021
Fatal bleeding (%)	9.1	4.5	3.5	2.9	3.3	2.9
Fatal infection (%)	11	4.2	12	16	10	7.3

1. Collins PW, et al. Blood 2007; 109: 1870-7

2. Knöbl et al. J Thromb Haemost 2012; 10: 622-31

3. Borg et al. Haemophilia 2013; 19: 564-70

4. Tiede et al. Blood 2015; 125:1091-7

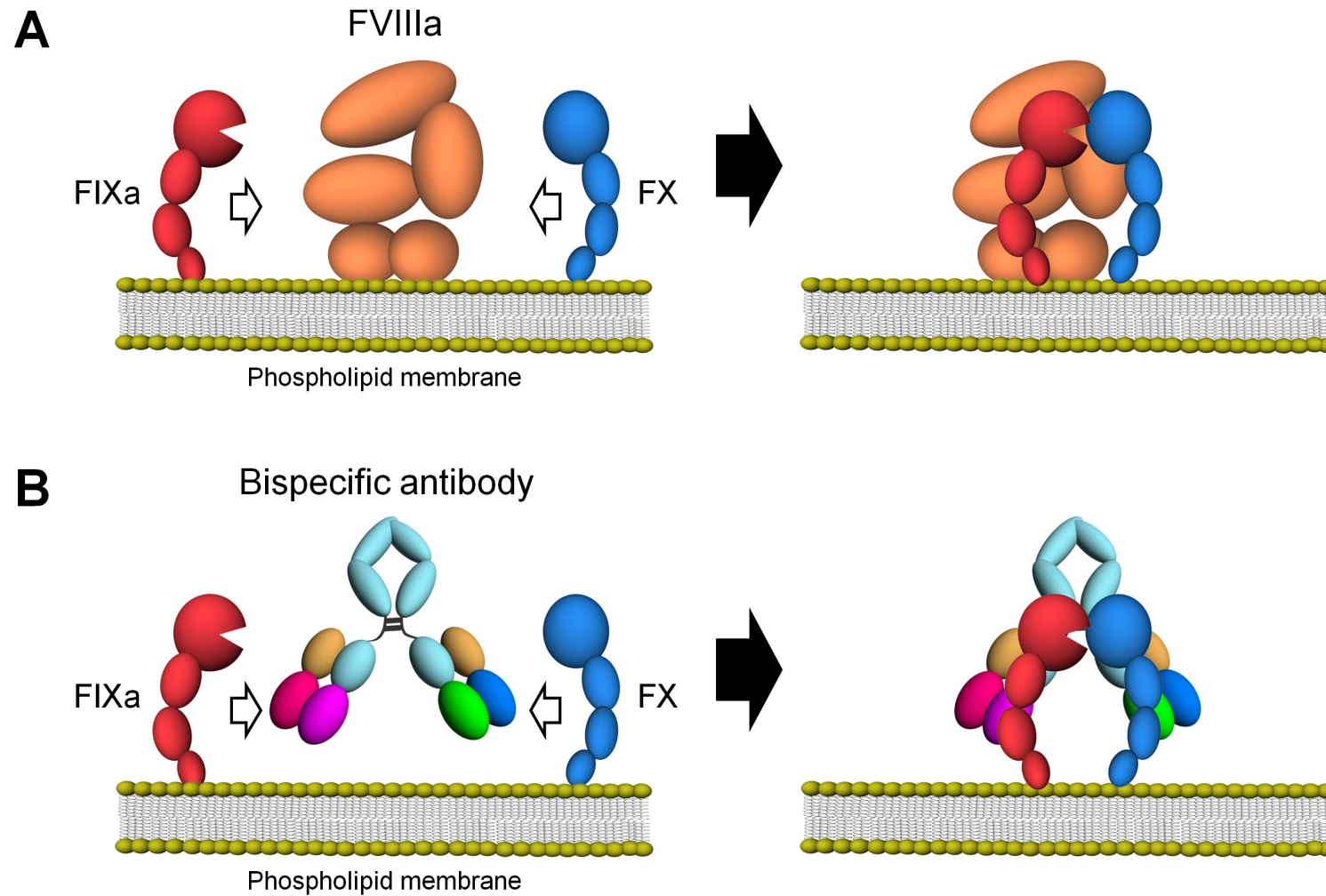
5. Minot-Castellano et al. Blood Adv 2021; 5: 3821-9

6. Schep et al. Am J Hematol 2021; 96: 51-9

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Emicizumab

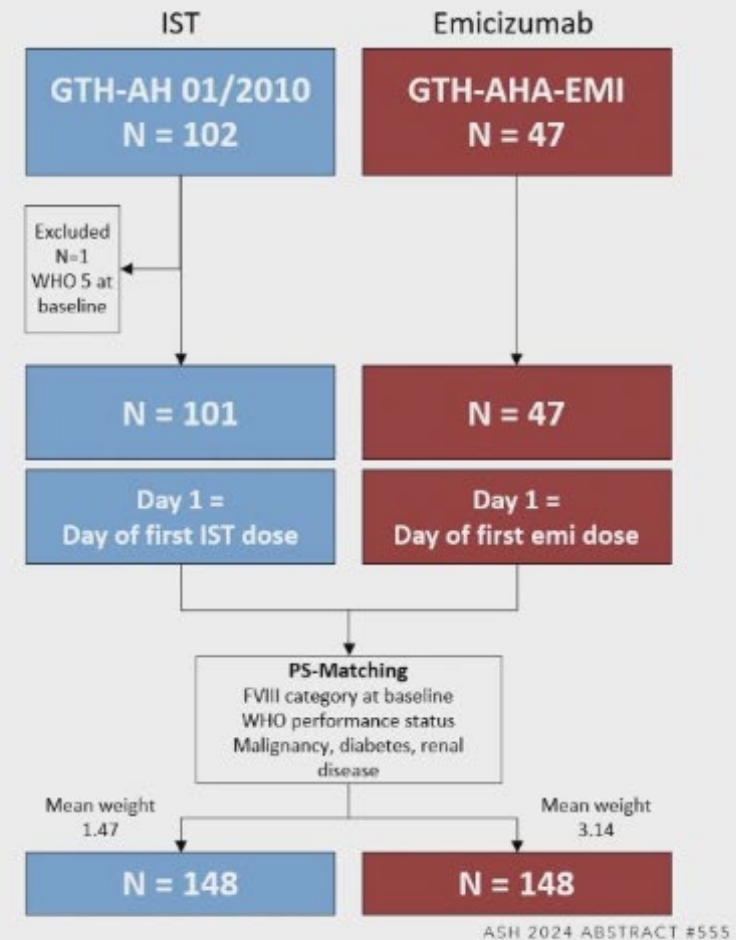


Sustained Improvement of Survival in Patients Receiving Emicizumab

Methods

- 2-year follow-up information was collected using an electronic case report form
- Sites reported data from last regular patient visit and additionally planned visits on site or over the telephone
- The matching strategy was predefined in the GTH-AHA-EMI study protocol and already reported for a short-term analysis¹

1. Hart, Klamroth, Sachs et al. J Thromb Haemost. 2024; 22 (10): 2692-2701



Sustained Improvement of Survival in Patients Receiving Emicizumab

Overall survival

1-year OS

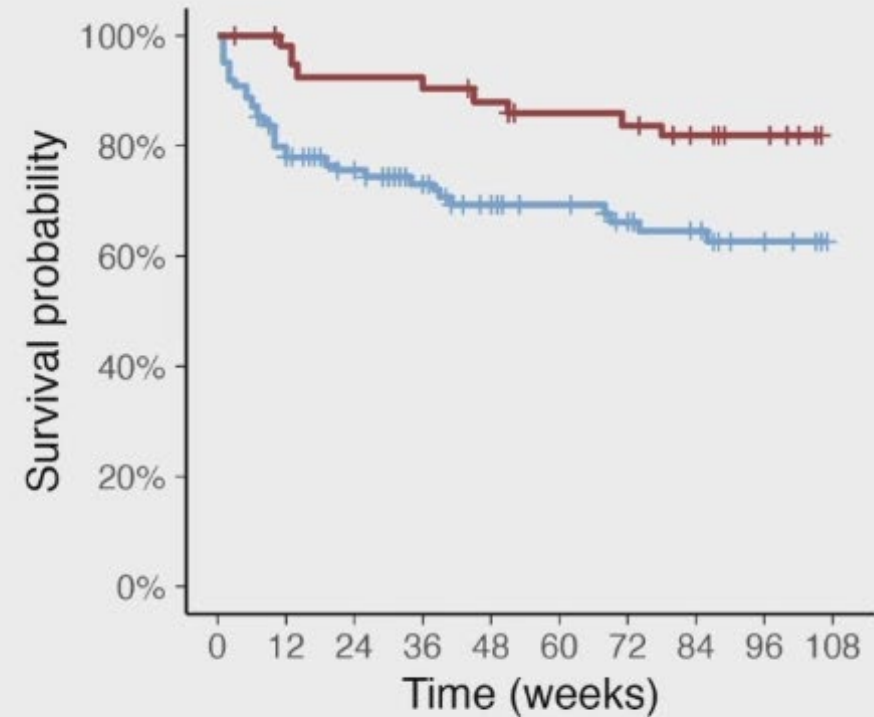
86% vs. 69% ($\Delta +17\%$)

2-year OS

82% vs. 63% ($\Delta +19\%$)

Relative risk of mortality reduced by 61%

HR 0.39 (95% CI 0.19-0.80, $p < 0.01$)



—+ GTH-AHA-EMI —+ GTH-AH 01/2010

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Sustained Improvement of Survival in Patients Receiving Emicizumab

IST in the **GTH-AHA-EMI** trial

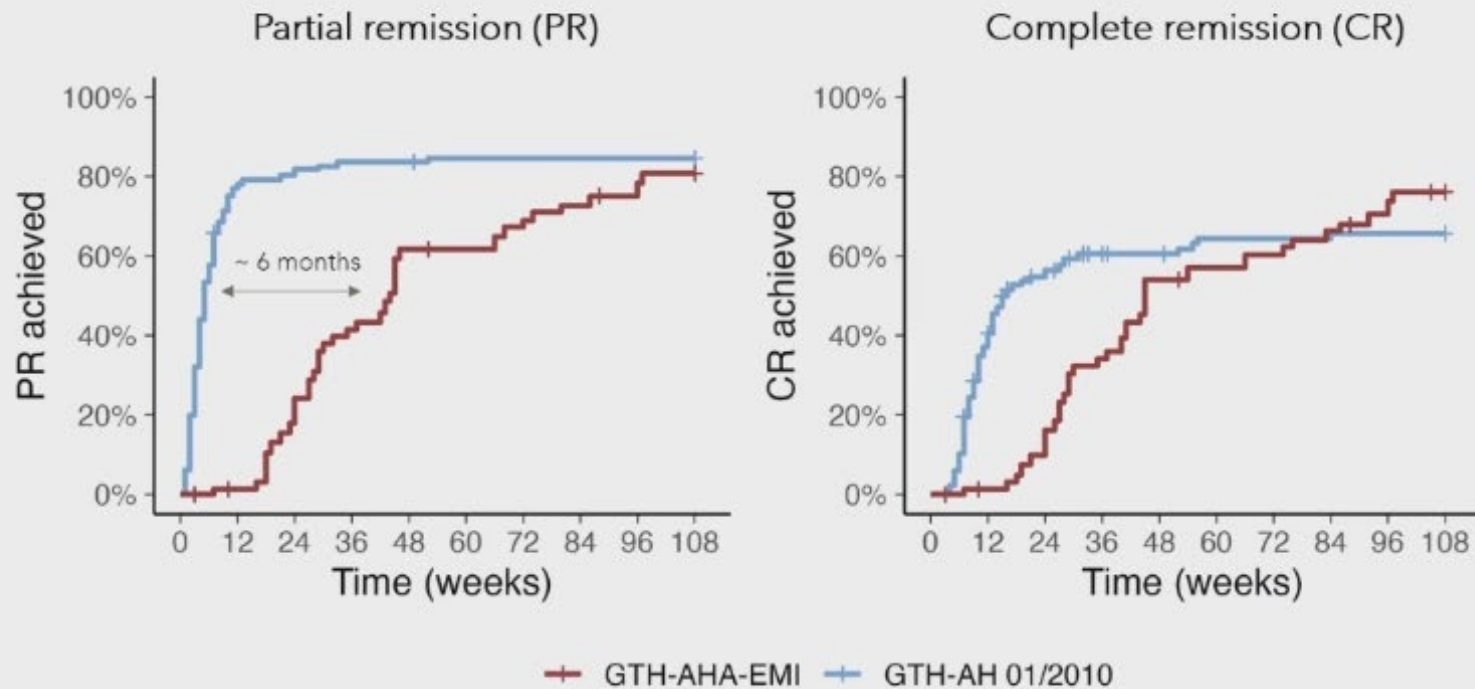
- IST was allowed after week 12
- 2 patients did not receive IST because there were too sick
- 6 patients did not receive IST and achieved spontaneous PR
- 35 patients received IST including:
 - Glucocorticoids (n=25)
 - Rituximab (n=24)
 - Cyclophosphamide (n=6)
 - Mycophenolate mofetil (n=8)

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Sustained Improvement of Survival in Patients Receiving Emicizumab

PS-matched time to remission **GTH-AHA-EMI** vs. **GTH-AH 01/2010**

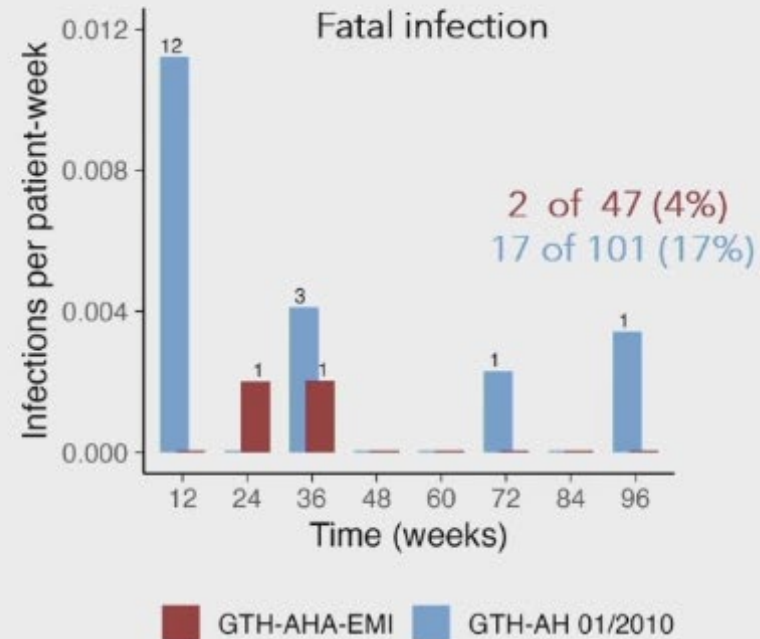
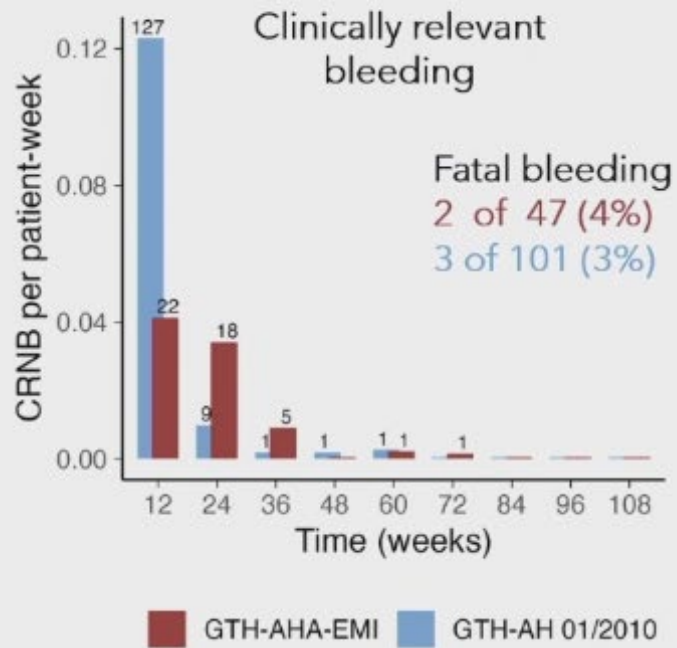


PR: FVIII >50% of normal, no bleeding, no hemostatic medication
CR: PR plus inhibitor negative, GC <15 mg prednisolone per day and other IST stopped



Sustained Improvement of Survival in Patients Receiving Emicizumab

PS-matched adverse event rates **GTH-AHA-EMI** vs. **GTH-AH 01/2010**



PR: FVIII >50% of normal, no bleeding, no hemostatic medication

CR: PR plus inhibitor negative, GC <15 mg prednisolone per day and other IST stopped



Sustained Improvement of Survival in Patients Receiving Emicizumab

Summary

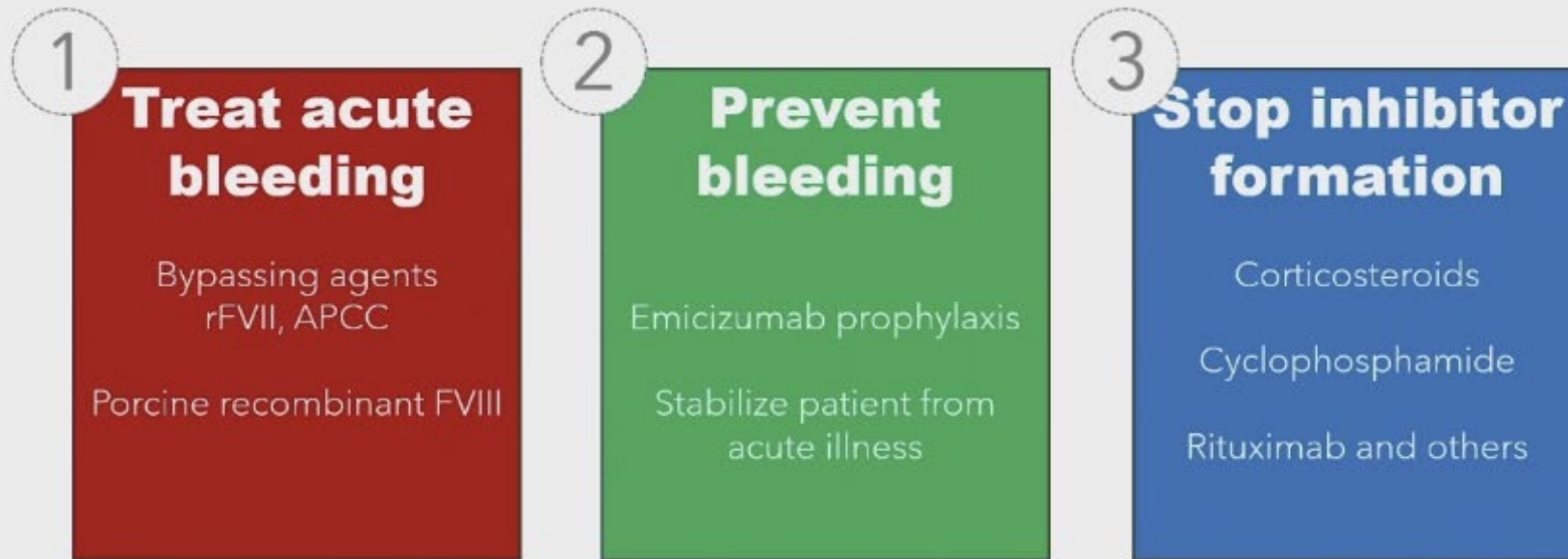
- PS-matched comparison of **GTH-AHA-EMI** (emicizumab, delayed IST) vs. **GTH-AH 01/2010** (immediate IST) indicated
 - Overall survival improved (+ 19% absolute)
 - Fatal infection reduced (4% vs. 17%)
 - Fatal bleeding similar (4% vs. 3%)
 - Bleeding reduced in weeks 1-12, but relatively increased in weeks 13-24
 - Remission achieved later but in similar proportions at final follow-up
- Spontaneous remission occurred in 6 out of 41 (15%) patients

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Sustained Improvement of Survival in Patients Receiving Emicizumab

The possible future treatment paradigm of AHA



rFVII, recombinant factor VIIa (eptacog alfa activated); APCC, activated prothrombin complex concentrate, hFVIII, human FVIII concentrates

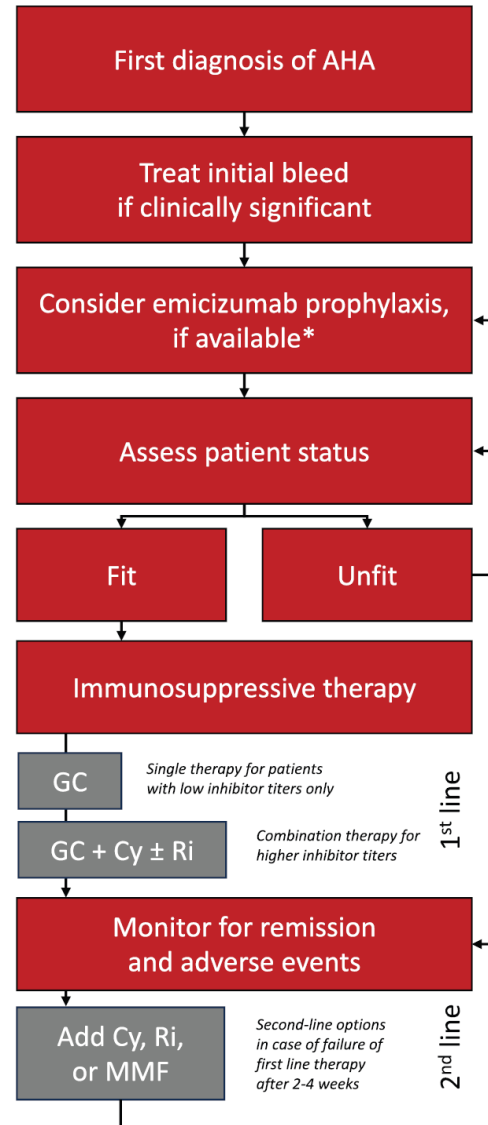
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und am Ende....

**Vielen Dank für
Ihre Aufmerksamkeit**

Erworbene Hämophile - Behandlungsalgorithmus



Hämostatische Therapie - Preise



rFVIIa
NovoSeven
Offizieller Preis
ZE
NUB

0,92 €/µg
0,87 €/µg

Erstdosis (75 kg)
Intervalle

6.204 €
2 - 3 h



APCC
FEIBA
1,77 €/I.E.
1,50 €/I.E.

6.646 € - 13.292 €
8 - 12 h



rpFVIII
Obizur
2,90 €/I.E.
3,41 €/I.E.

43.500 €
HWZ 10 h



Emicizumab
Hemlibra
64,20 €/mg
60,72 €/mg

43.333 €
7 Tage