Αναιμία και ΧΝΝ: τι νεότερο για τους σταθεροποιητές HIF

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Τμήμα Ιατρικής – Πανεπιστήμιο Θεσσαλίας

Πανεπιστημιακό Γενικό Νοσοκομείο Λάρισας

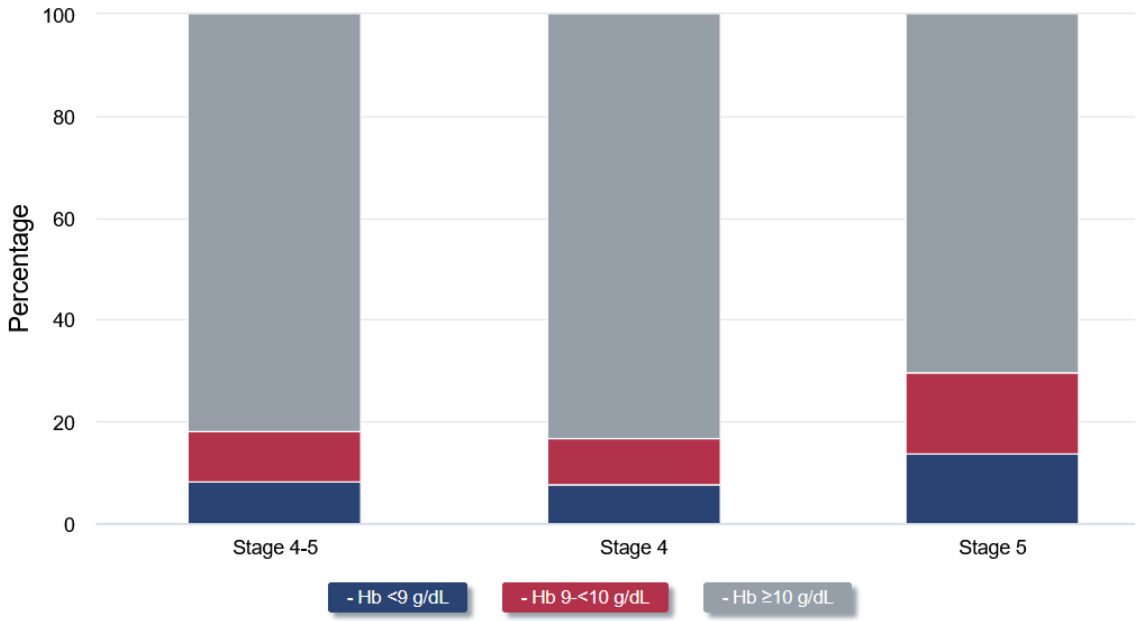
Αλεξανδρούπολη 21/05/2026

Anemia in CKD and Dialysis

Prevalence:

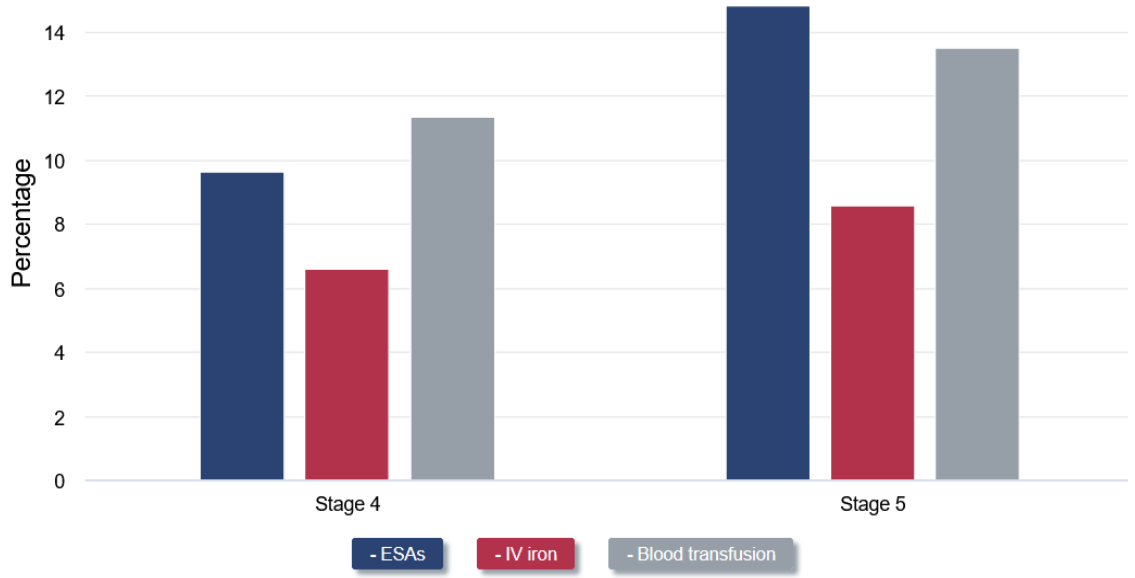
- ❖ Anemia is common in CKD, especially in advanced stages and dialysis patients
- ❖ Over 20% of dialysis patients have hemoglobin levels below 10 g/dl
- ❖ higher percentage received a blood transfusion than an ESA or intravenous iron (CKD 4)

Hemoglobin Category by CKD stage (overall and by stage)



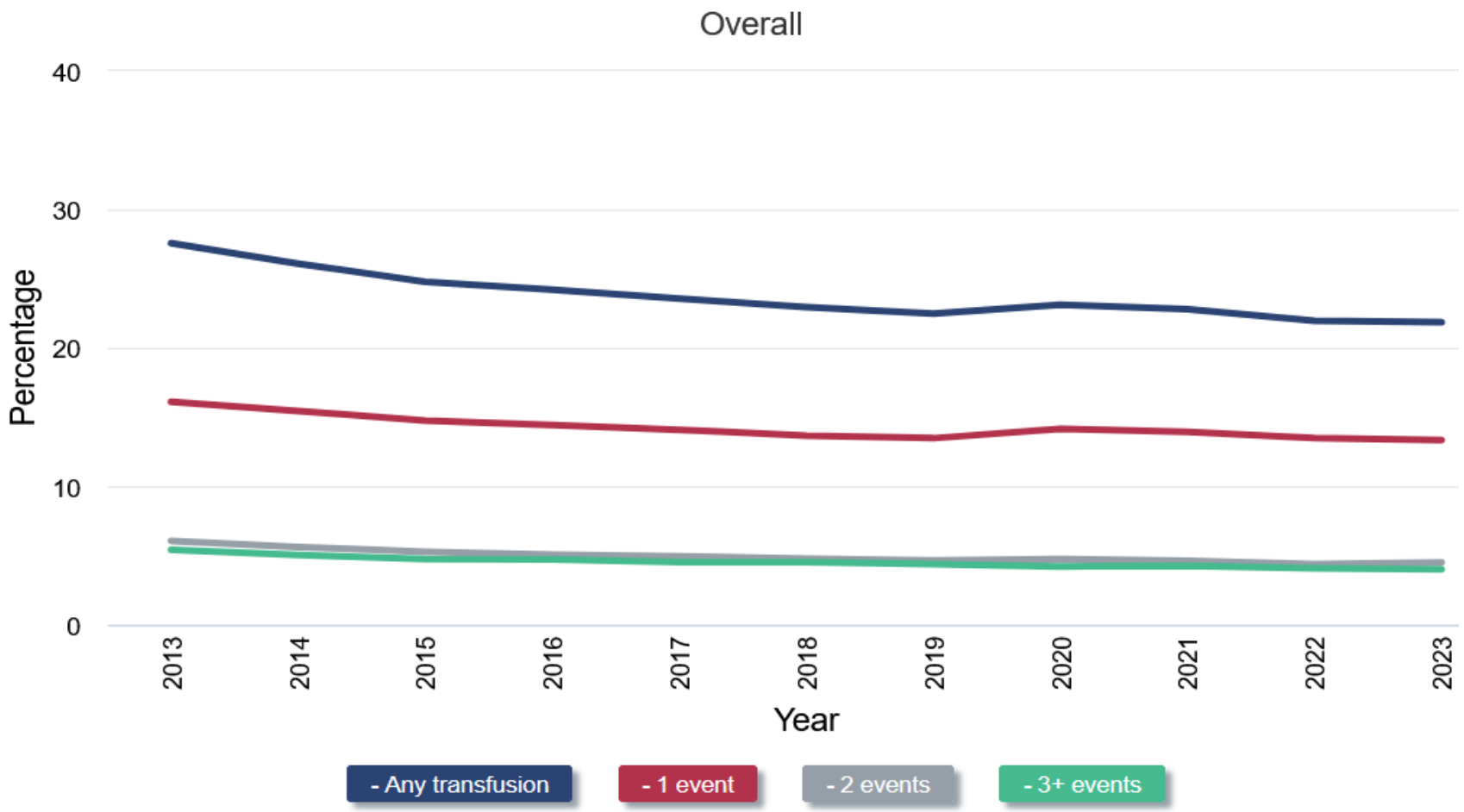
About 17% of M Health Fairview patients with stage 4 CKD, versus about 30% of patients with stage 5 CKD, had a hemoglobin level <10 g/dL.

CKD 4-5: use of ESAs, IV iron and Blood Transfusions



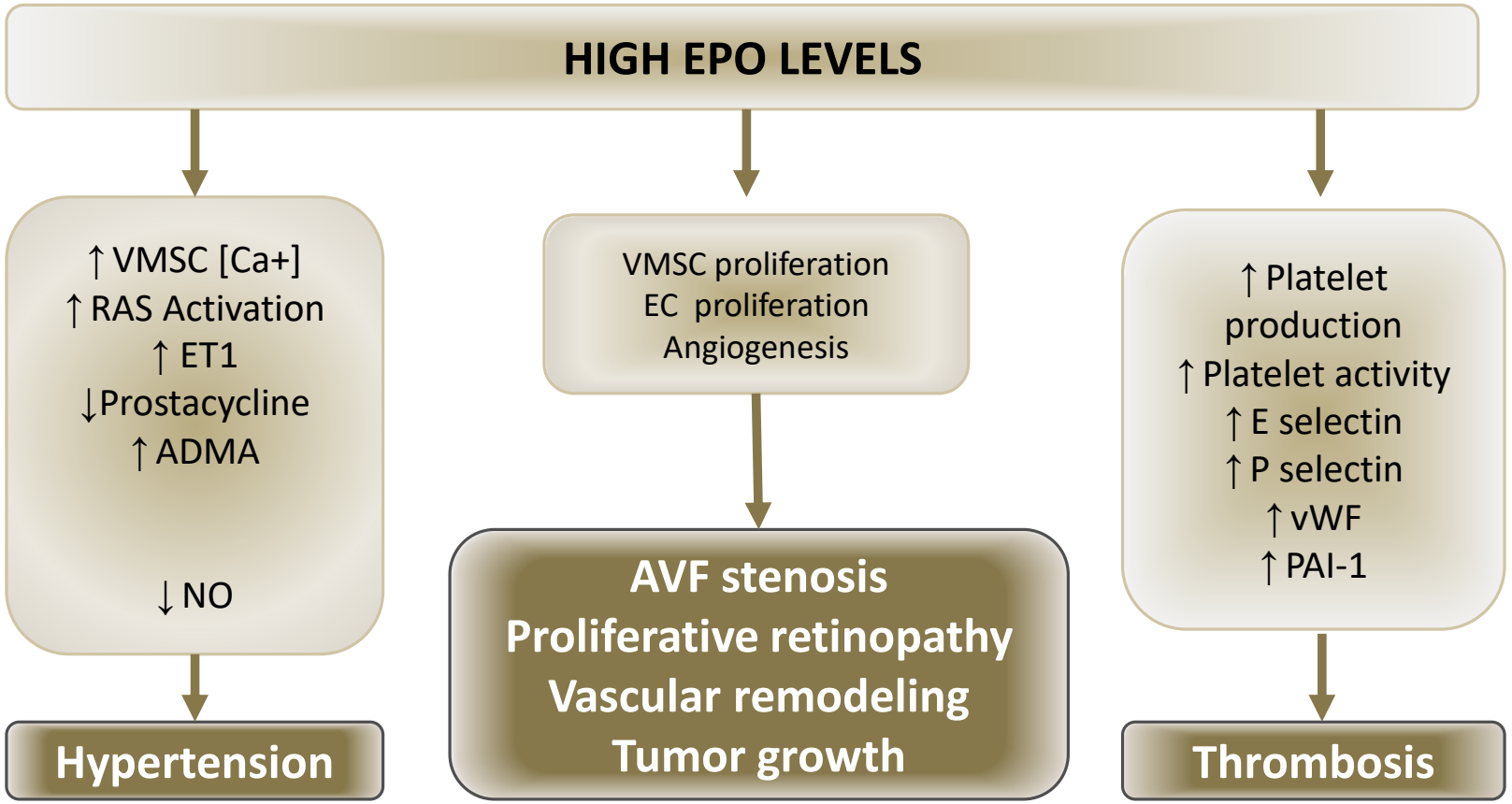
Among people insured by Medicare FFS with stage 4 CKD, a higher percentage received a blood transfusion than an ESA or intravenous iron in 2023. Among people with CKD 5, the percentage who received a blood transfusion was nearly as high as the percentage receiving an ESA.

RBC transfusions among patients with ESRD



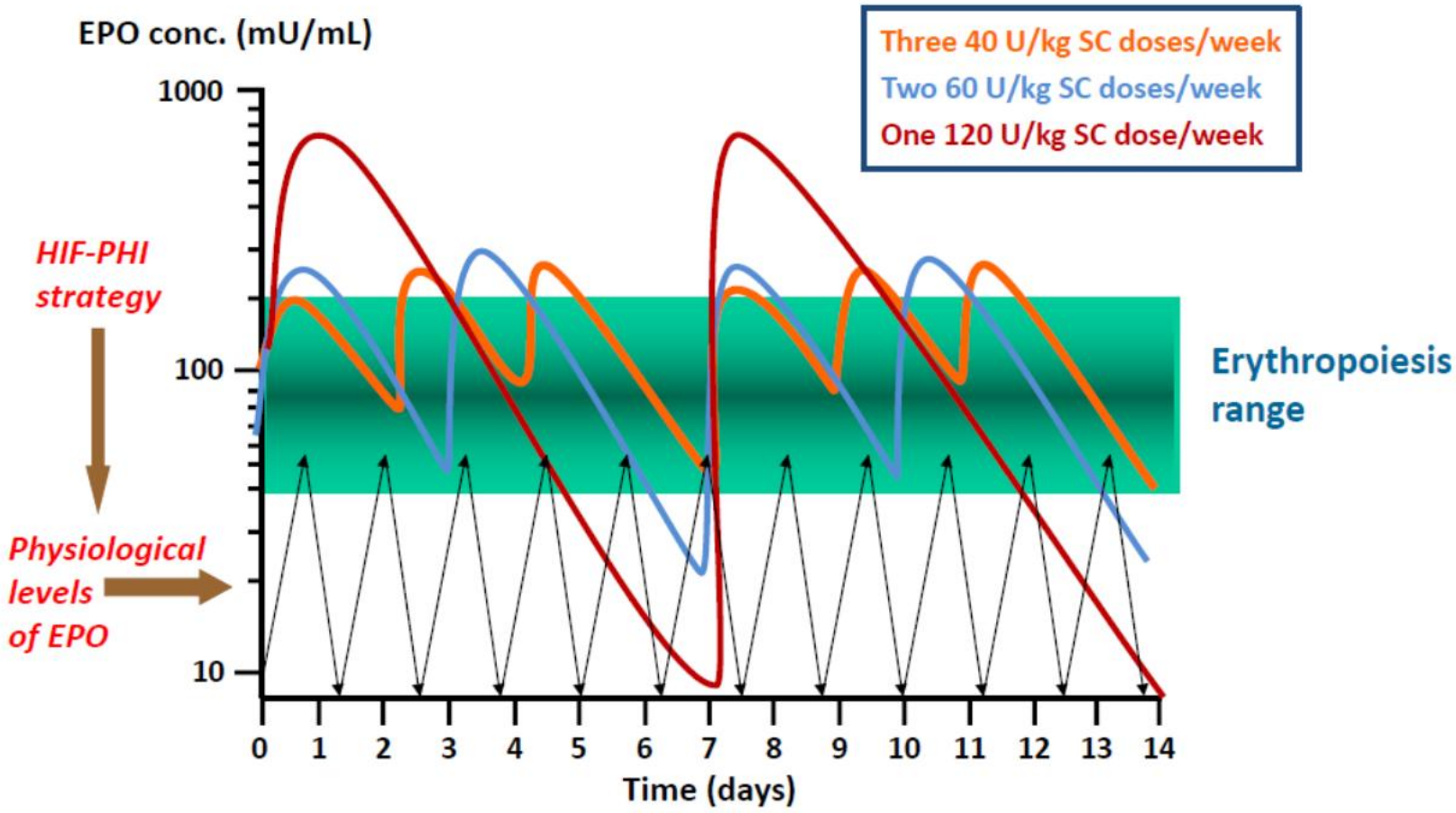
Use of blood transfusions in people insured by Medicare FFS receiving dialysis decreased from 2013 to 2023.

Non erythropoietic actions of EPO



Nosratola D Vaziri and Xin J Zhou, Nephrol Dial Transplant. 2009 Apr;24(4):1082-8

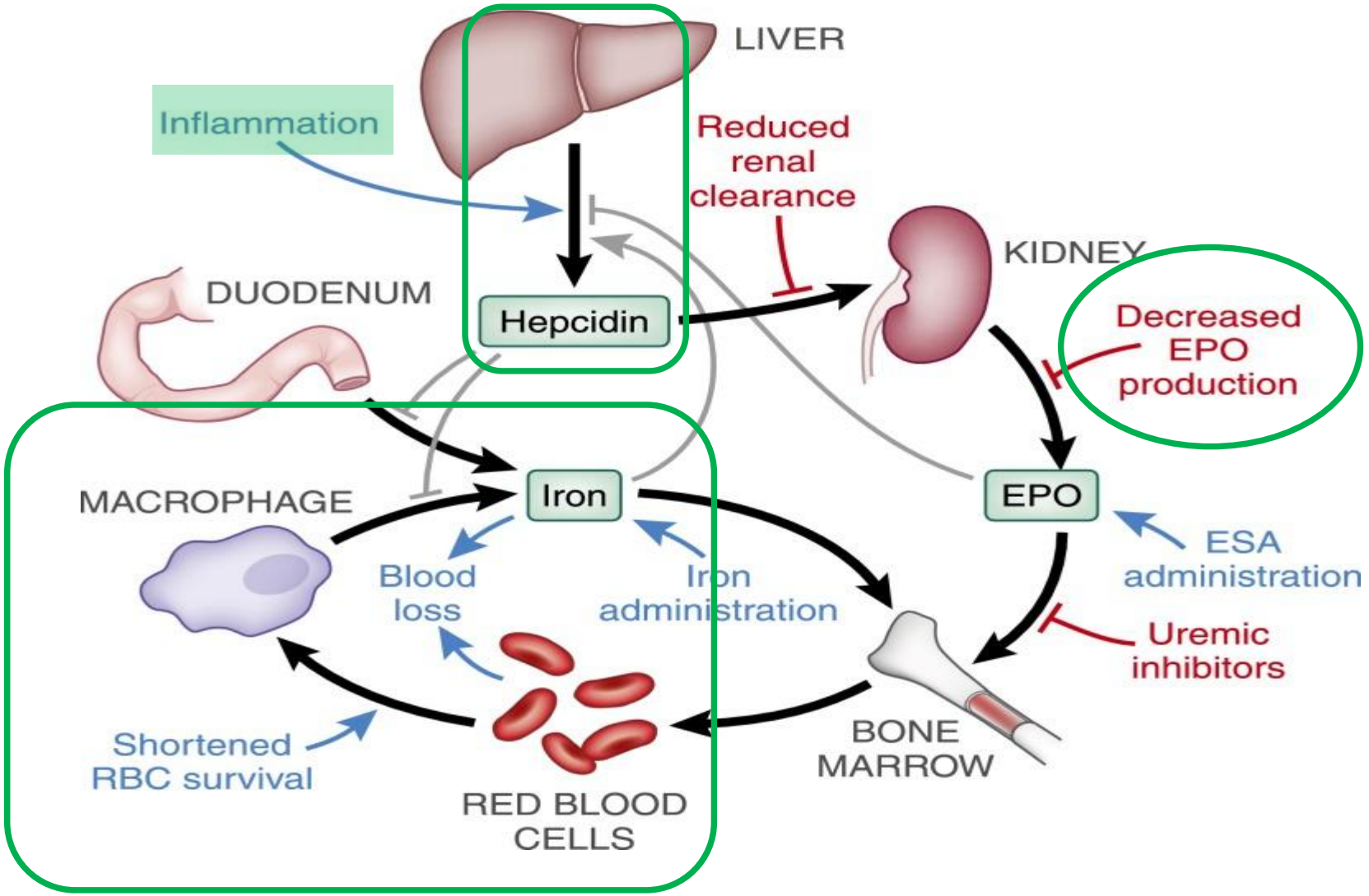
Epoetin concetration –time profiles



Anatole Besarab et al., J Am Soc Nephrol 1992, 2(9):1405-16

Pathophysiology of Anemia in CKD and action of HIF-PHIs

Mechanisms of Anemia in CKD

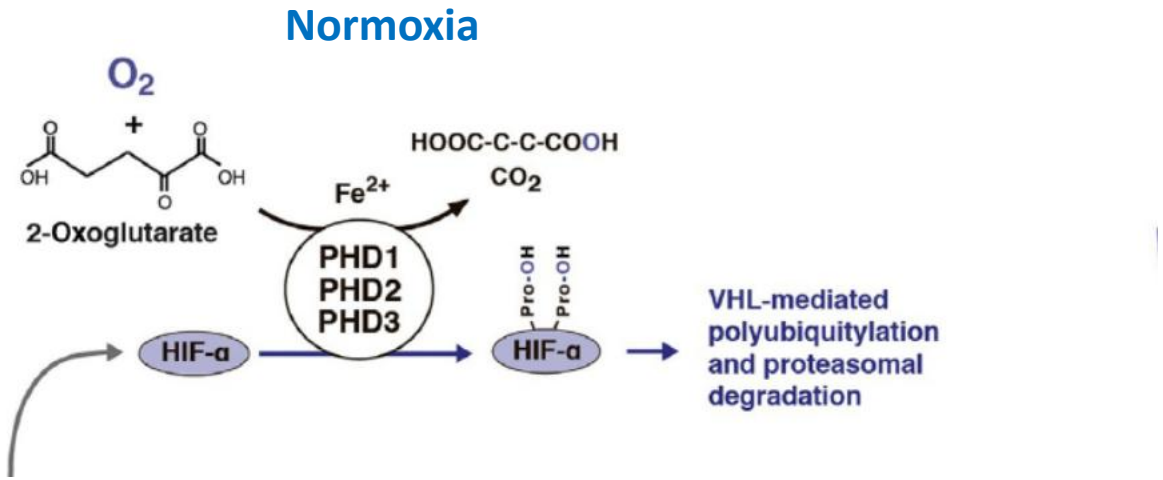


- **↓ EPO παραγωγή**
- **functional iron deficiency,**

  shortened RBC survival
- **↑ hepcidin → ↓ iron availibility**
- **chronic inflammation**

Jodie L. Babitt and Herbert Y. Lin. J Am Soc Nephrol 23: 1631–1634, 2012

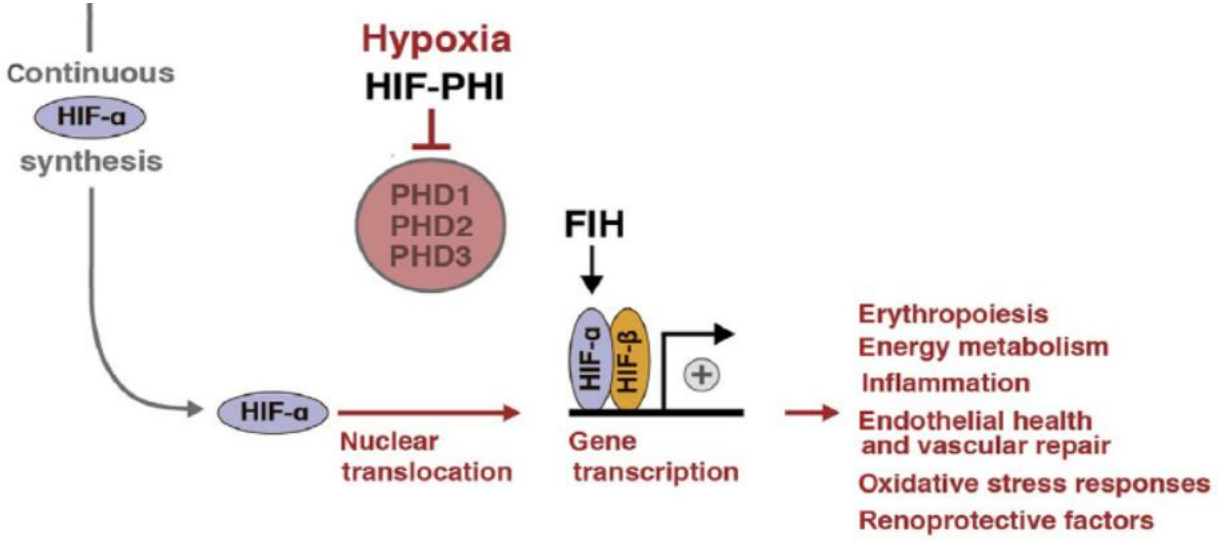
Schematic diagram of the hypoxia-inducible factor (HIF) pathway



- **HIF/PHD oxygen sencing pathway** plays a central role in cellular adaptation to hypoxia (βραβείο Nobel 2019)
- **HIF transcription factors**
  HIF-α and **HIF-β** are constitutively synthesized

Normoxia: HIF-α subunits hydroxylated by PHD enzymes

Erythropoietin production is triggered by Hypoxia, mediated by HIF

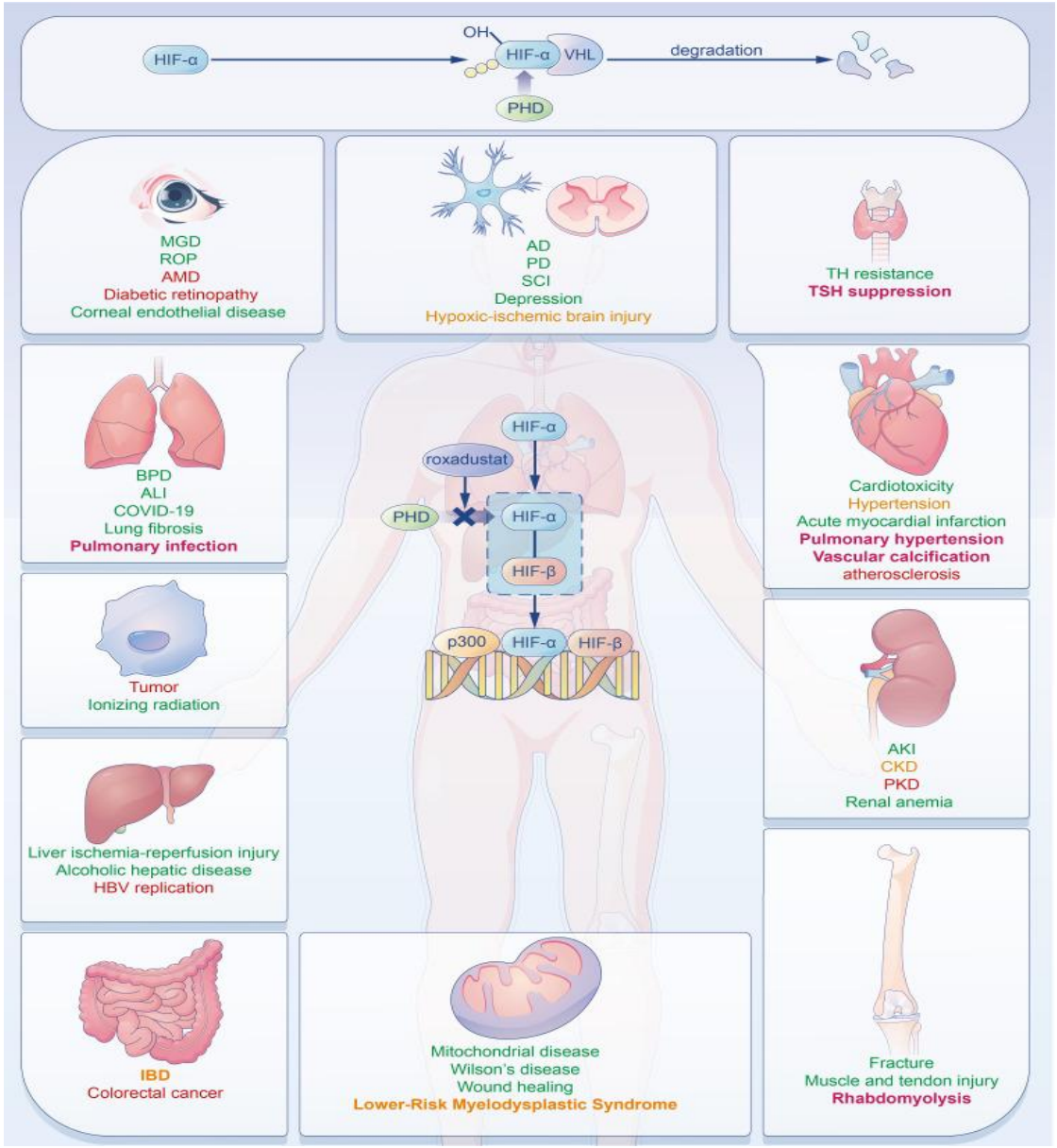


Hypoxia:

- Nuclear translocation and dimerization of HIF-α and HIF-β
- Binding to hypoxia response elements (HRE) of oxygen regulated genes
- Gene transcription
  ► erythropoesis

$$\text{Hypoxia} \rightarrow\uparrow HIF \rightarrow\uparrow EPO$$

Volker H. Haase. Kidney International Supplements (2021) 11, 8–25



Qiu-Yu Li et al., Biomolecules and Biomedicine, 2023, Vol. 23, No. 3, 354–363

HIF-PHIs TRIALS

Hypoxia Inducible Factor-Prolyl Hydrohylase Inhibitors (HIF-PHIs)

Jestuvroq

Oxemia

Evrenzo
(20, 50, 70, 100, 150 mg)

Vafseo
(150, 300, 450 mg)

Table 1. Overview of Approved Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors

HIF-PHI	Recommended Starting Dose	Maximum Dose	Dosing Frequency	Examples of Countries With Approval for Marketing
Daprodustat	• ND-CKD: 2～4 mg (ESA naive), 4 mg (switch from ESA) • DD-CKD: [Japan] 4 mg, [US] 1～4 mg (ESA naive), 4-12 mg (switch from ESA)	24 mg	QD	• Approved for DD-CKD and NDD-CKD: Japan • Withdrawn in US (FDA-approved for DD-CKD) and the EU (was recommended for EMA approval)
Desidustat	• ND-CKD: 100 mg (ESA naive), 100, 125, or 150 mg (switch from ESA) • DD-CKD: 100 mg	150 mg	TIW	India
Enarodustat	• ND-CKD and DD-CKD-PD: 2 mg • DD-CKD: 4 mg	8 mg	QD	China, Japan, South Korea
Molidustat	• ND-CKD: 25 mg (ESA naive), 25～50 mg (switch from ESA) • DD-CKD: 75 mg	200 mg	QD	Japan
Roxadustat	• [EU] 70 mg for BW < 100 kg, 100 mg for BW ≥ 100 kg • [Japan] 50 mg (ESA naive), 70～100 mg (switch from ESA)	3.0 mg/kg BW	TIW	China, Chile, Egypt, EU, Iceland, Japan, Kuwait, Lichtenstein, Mexico, Norway, Russia, Saudi Arabia, South Africa, South Korea, Turkey, United Arab Emirates, UK
Vadadustat	300 mg	600 mg	QD	• Approved for DD-CKD: US, Australia, EU, South Korea, Taiwan, Switzerland • Approved for both DD-CKD and NDD-CKD: Japan

ESA naive is defined as no previous use of ESA. Abbreviations: BW, body weight; CKD, chronic kidney disease; DD, dialysis-dependent (maintenance); EMA, European Medicines Agency; ESA, erythropoiesis-stimulating agent; EU, European Union; ND, non-dialysis-dependent; QD, once daily; TIW, 3 times weekly.

Portolés et al. Front. Med., 26 March 2021

Major Phase III studies

Non Dialysis Dependent CKD (NDD-CKD)

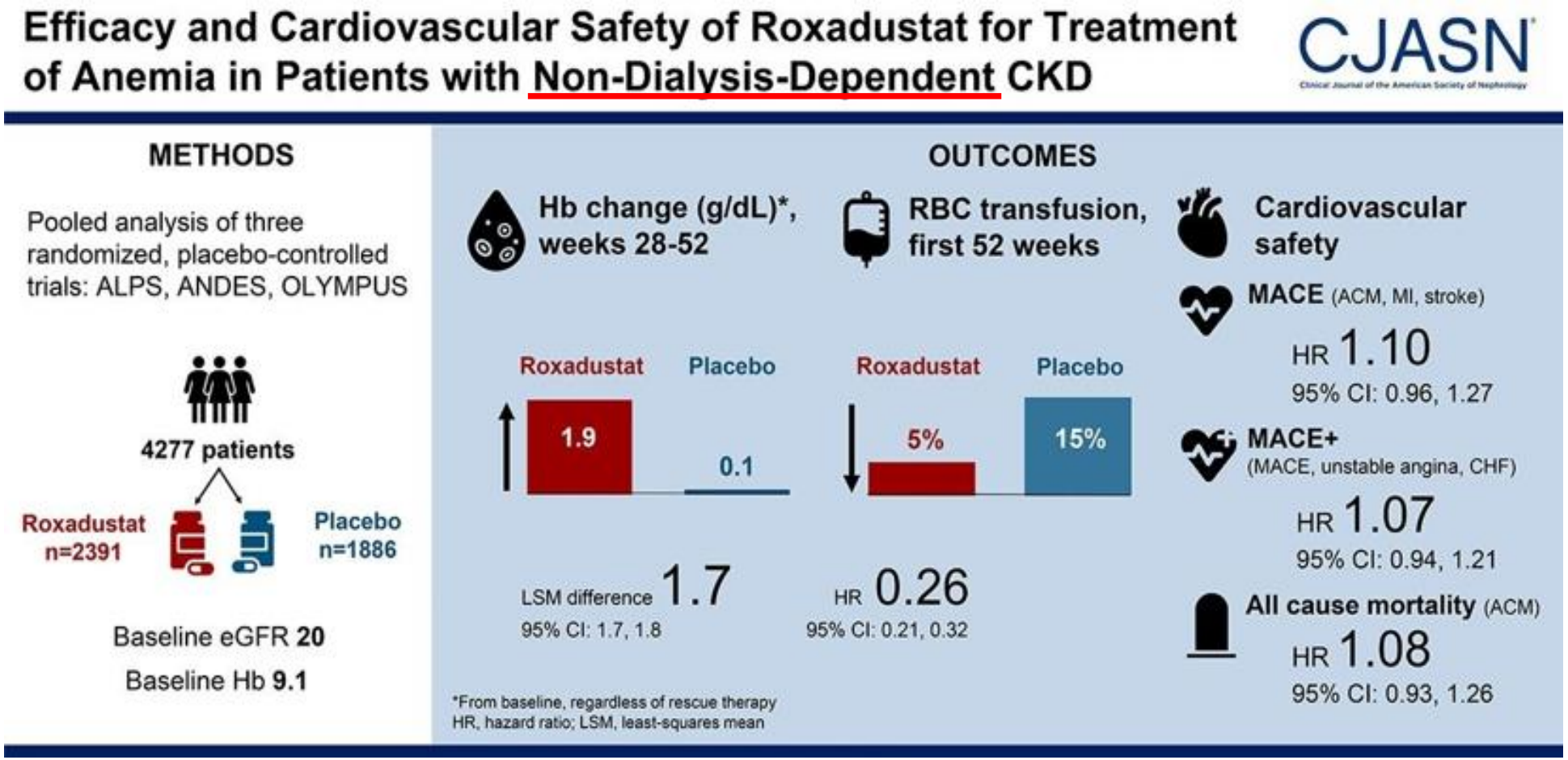
Study / drug	Participants	Comparator
Roxadustat		
OLYMPUS	2761	placebo
ANDES	922	placebo
ALPS	594	placebo
DOLOMITES	616	Darbepoetin
Vadadustat		
PRO$_2$TECT ESA -	1751	Darbepoetin
PRO$_2$TECT ESA +	1725	Darbepoetin
Daprodustat		
ASCEND-ND	3872	Darbepoetin
ASCEND-NHQ	614	placebo

Dialysis Dependent CKD (DD-CKD)

Study / drug	Participants	Comparator
Roxadustat		
PYRENEES	783	Darbepoetin/EPO
HIMALAYAS	958	EPO
SIERRAS	627	EPO
ROCKIES	1711	EPO
Vadadustat		
INNO$_2$VATE - Inc	369	Darbepoetin
INNO$_2$VATE - Prev	3554	Darbepoetin
Daprodustat		
ASCEND-D	2964	Darbepoetin
ASCEND-ID	312	Darbepoetin

Pooled analysis of Roxadustat Trials

NDD pool vs placebo
ALPS
ANDES
OLYMPUS



Provenzano Robert et al., Clin J Am Soc Nephrology. 2021, 16(8) 1190-1200

Adverse Event	Roxadustat (N = 101)	Placebo (N = 51)
	no. of patients (%)	
Any adverse event*	**37 (37)**	**25 (49)**
Anemia	0 (0)	3 (6)
Diarrhea	0 (0)	3 (6)
Peripheral edema	7 (7)	3 (6)
Pyrexia	2 (2)	3 (6)
Upper respiratory tract infection	5 (5)	4 (8)
Hyperkalemia	**16 (16)**	4 (8)
Metabolic acidosis	**12 (12)**	1 (2)
Gout	1 (1)	3 (6)
Back pain	0 (0)	3 (6)
Dizziness	1 (1)	4 (8)
Hypertension	6 (6)	2 (4)

* Patients may have had more than one adverse event.
Values are *n* (%).

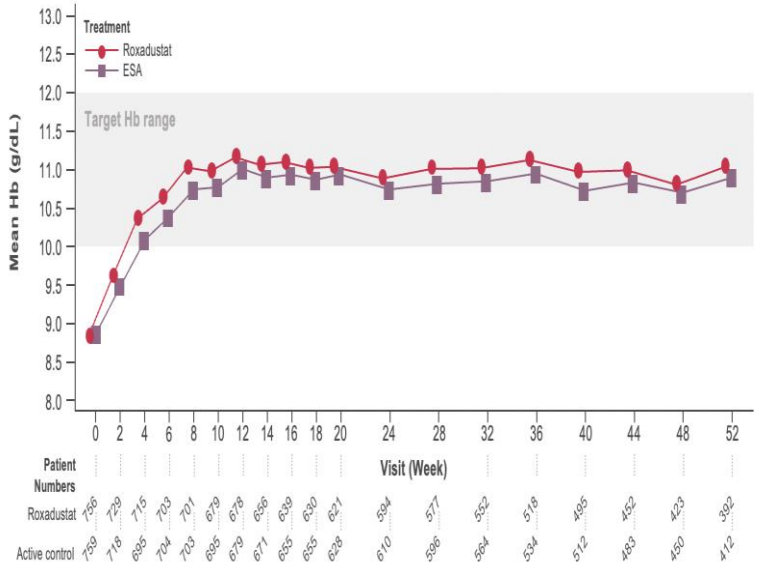
Adverse Event	Roxadustat (N = 101)	Placebo (N = 51)
	no. of patients (%)	
Any serious adverse event	**9 (9)**	**6 (12)**
Anemia	0 (0)	1 (2)
Coronary artery disease	0 (0)	1 (2)
Gastrointestinal hemorrhage	1 (1)	0 (0)
Acute cholecystitis	0 (0)	1 (2)
Cholelithiasis	0 (0)	1 (2)
Lung infection	1 (1)	1 (2)
Hyperkalemia	**2 (2)**	0 (0)
Hypokalemia	1 (1)	0 (0)
Metabolic acidosis	**1 (1)**	0 (0)
End-stage renal disease	1 (1)	0 (0)
Chronic glomerulonephritis	1 (1)	0 (0)
Azotemia	0 (0)	1 (2)
Renal impairment	0 (0)	1 (2)
Dysfunctional uterine bleeding	0 (0)	1 (2)
Acute respiratory failure	0 (0)	1 (2)
Rash	1 (1)	0 (0)
Hypertension	1 (1)	0 (0)

* Patients may have had more than one adverse event.
Values are *n* (%).

Efficacy and Cardiovascular Safety of Roxadustat in Dialysis-Dependent Chronic Kidney Disease: Pooled Analysis of Four Phase 3 Studies

IDD pool
HIMALAYAS
ROCKIES (subset)
SIERRAS (subset)

Mean Hb (g/dL) over 52 weeks (FAS)



Mean Hb was comparable over time with roxadustat vs ESA treatment in incident DD-CKD patients

Table 6 Cardiovascular safety endpoints in the incident dialysis and stable dialysis subgroups (SAF, OT-7)

Outcome/results	Incident dialysis[a]		Stable dialysis	
	Roxadustat (n = 760)	ESA (n = 766)	Roxadustat (n = 1594)	ESA (n = 1594)
MACE				
Events, n (%)	74 (9.7)	97 (12.7)	297 (18.6)	301 (18.9)
IR	6.7	8.2	10.4	9.2
HR (95% CI)	0.83 (0.61–1.13)		1.18 (1.00–1.38)	
MACE+				
Events, n (%)	88 (11.6)	121 (15.8)	357 (22.4)	403 (25.3)
IR	8.0	10.2	12.5	12.3
HR (95% CI)	0.76 (0.57–1.00)		1.03 (0.90–1.19)	
All-cause mortality				
Events, n (%)	52 (6.8)	70 (9.1)	212 (13.3)	207 (13.0)
IR	4.7	5.9	7.4	6.3
HR (95% CI)	0.83 (0.57–1.19)		1.23 (1.02–1.49)	

Treatment-emergent adverse events in the entire cohort (SAF, OT-7)

N (%) IR	Roxadustat (n = 2354)	ESA (n = 2360)
TEAE	2039 (86.6) 51.6	2030 (86.0) 45.5
Grade ≥ 3 TEAE[a]	1038 (44.1) 26.3	988 (41.9) 22.1
Serious TEAE	1288 (54.7) 32.6	1260 (53.4) 28.2
TEAE leading to discontinuation of study drug	253 (10.7) 6.4	175 (7.4) 3.9
TEAE leading to death	359 (15.3) 9.1	358 (15.2) 8.0

Vadatustat

Daprbustat

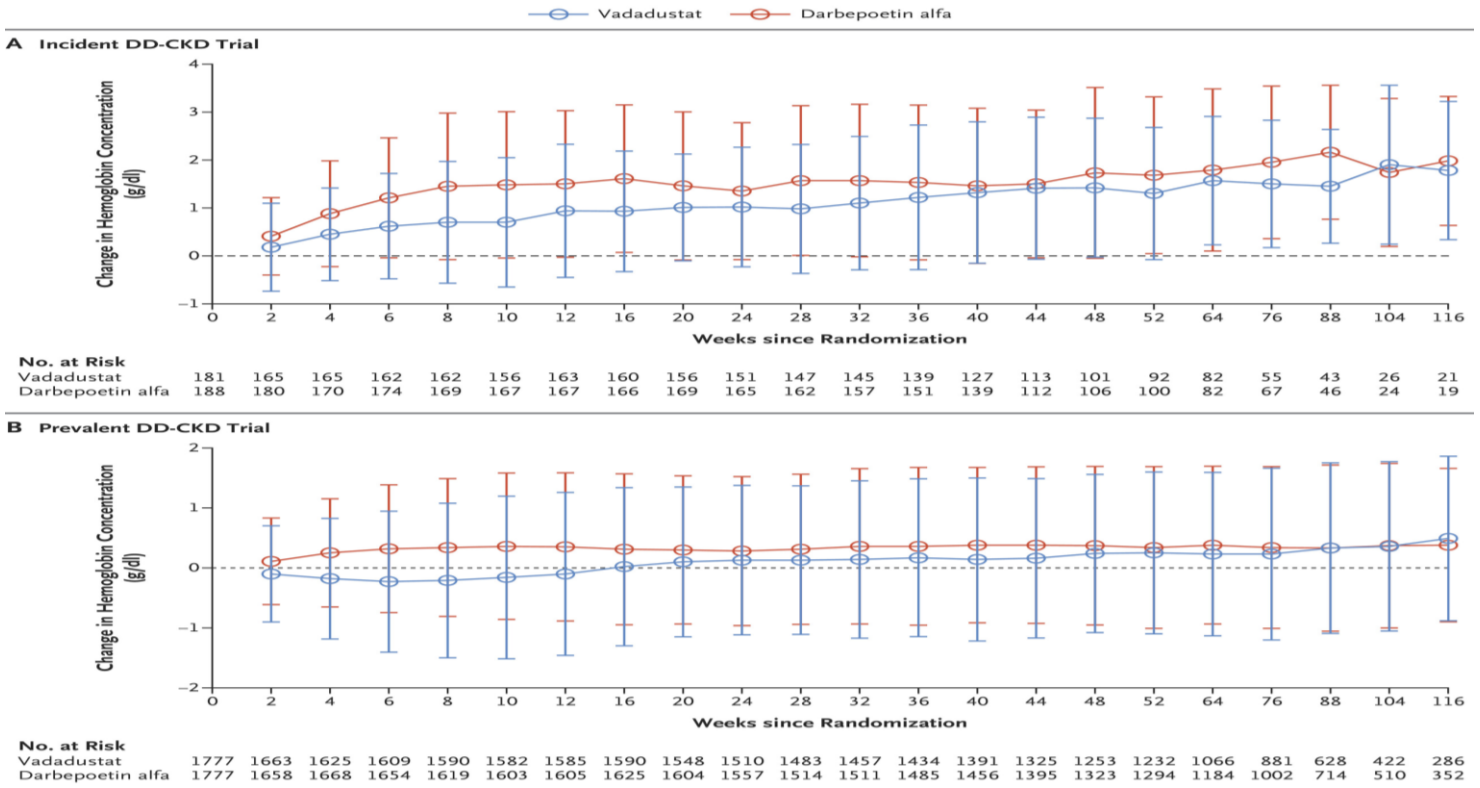
daily dosing

- μικρότερες διακυμάνσεις στα επίπεδα ερυθροποιητίνης (πιθανώς πιο σταθερή ενδογενής παραγωγή)

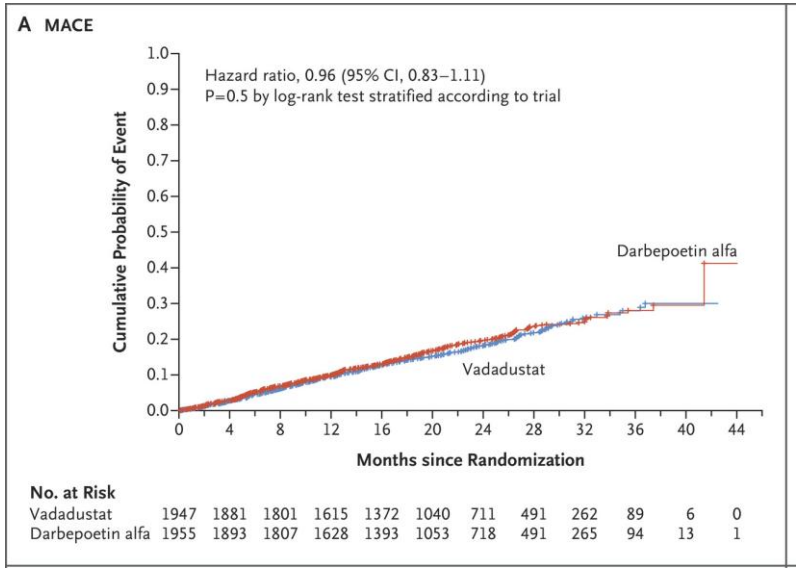
INNO2VATE trials:
DD-CKD (incident or prevelant)

3.923 patients - Vadadustat vs darbepoetin alfa

In both studies, Vafseo met the primary Hb endpoint according to predefined noninferiority margin (- 0.75 g/dL).



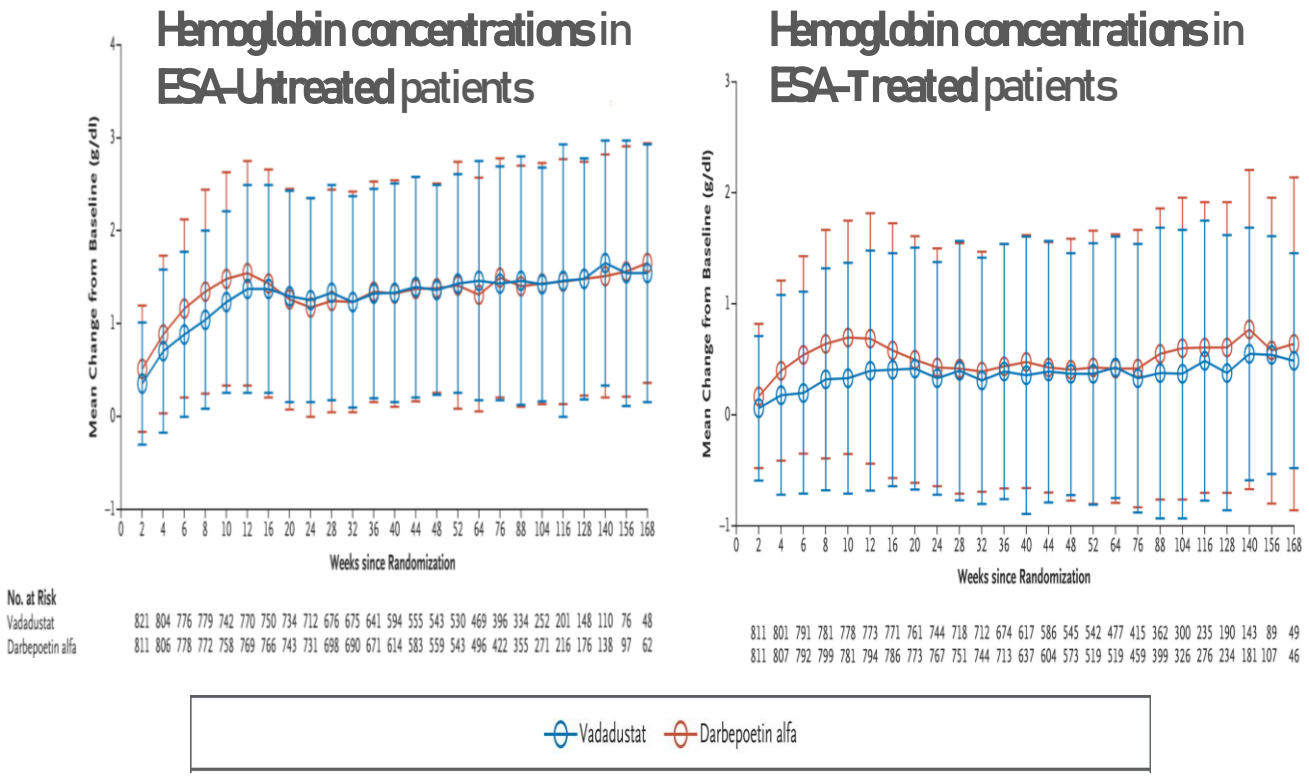
Composite end point of death from any cause, a nonfatal myocardial infarction, or a nonfatal stroke

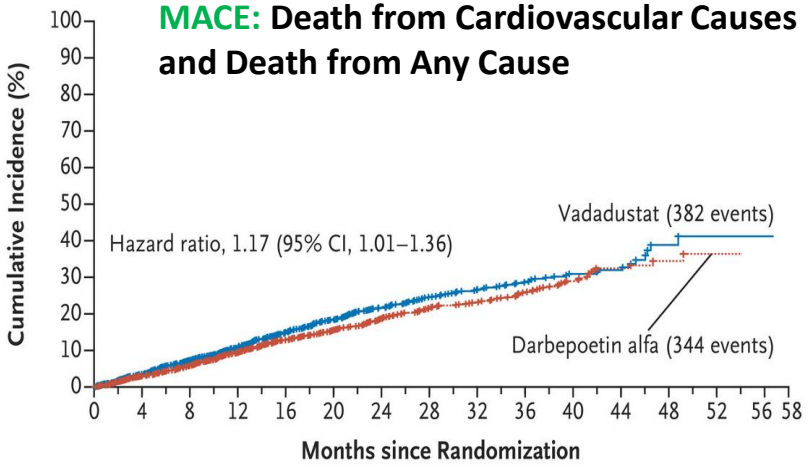


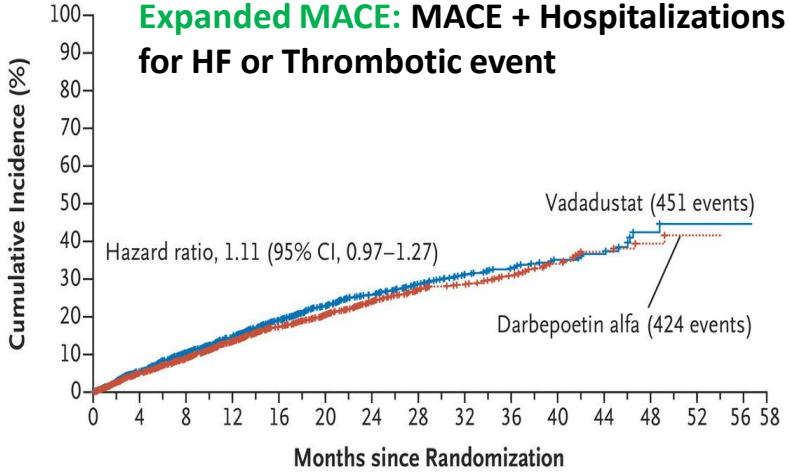
Kai-Uwe Eckardt et al., N Engl J Med 2021;384:1601-1612

PRO$_2$TECT Trials:
non-DD-CKD

Efficacy of Vadatustat on Hb levels in NDD-CKD







Glenn M. Chertow et al., N Engl J Med 2021;384:1589-1600

Thromboembolic events	**Vadadustat vs darbepoetin alfa**
Cerebrovascular accident events	0.8% vs 0.9% (0.5 vs 0.5 events/100 PY)
Deep vein thrombosis (DVT)	0.7% vs 0.5% (0.4 vs 0.3 events/100 PY)
Pulmonary embolism	0.3% vs 0.5% (0.2 vs 0.3 events/100 PY)
Transient ischaemic attack	0.8% vs 0.4% (0.5 vs 0.3 events/100 PY)
Acute myocardial infarction	4.3% vs 4.2% (3.1 vs 2.9 events/100 PY)
Arteriovenous graft thrombosis	1.1% vs 1.1% (0.9 vs 1.0 events/100 PY)
Arteriovenous fistula thrombosis	3.0% vs 2.3% (2.1 vs 1.6 events/100 PY)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VAFSEO safely and effectively. See full prescribing information for VAFSEO.

VAFSEO® (vadadustat) tablets, for oral use

Initial U.S. Approval: 2024

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

See full prescribing information for complete boxed warning.

- **VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). (5.1)**
- **Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels. (5.1)**
- **No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks. (2.4)**
- **Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions. (2.4)**

ORIGINAL ARTICLE

Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis

ASCEND-NND Clinical Trial

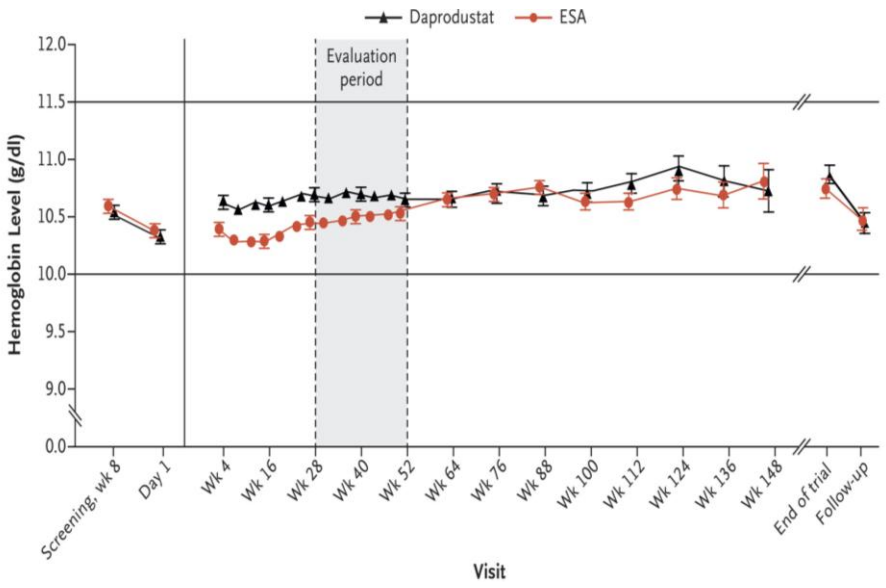


Table 3. Adverse Events and Laboratory Values (Safety Population).

Variable	Daprodustat (N=1482)		ESA (N=1474)		Relative Risk (95% CI)	P Value*
	Value	No. of Events	Value	No. of Events		
Adverse events — no. of patients (%)†						
Any adverse event	1307 (88.2)	10,501	1252 (84.9)	10,984	—	—
Any serious adverse event	773 (52.2)	2,021	748 (50.7)	2,218	—	—
Adverse events of special interest‡						
Thrombosis or tissue ischemia due to excessive erythropoiesis	20 (1.3)	30	11 (0.7)	12	1.81 (0.87–3.76)	0.11
Cardiomyopathy	15 (1.0)	16	16 (1.1)	17	0.93 (0.46–1.88)	0.85
Pulmonary-artery hypertension	9 (0.6)	9	12 (0.8)	13	0.75 (0.32–1.77)	0.50
Cancer-related death or tumor progression or recurrence	47 (3.2)	51	51 (3.5)	58	0.92 (0.62–1.35)	0.66
Esophageal or gastric erosions	60 (4.0)	75	81 (5.5)	100	0.74 (0.53–1.02)	0.06
Proliferative retinopathy, macular edema, or choroidal neovascularization	38 (2.6)	45	35 (2.4)	44	1.08 (0.69–1.70)	0.74
Exacerbation of rheumatoid arthritis	2 (0.1)	2	1 (0.1)	1	1.99 (0.18–21.91)	0.57
Worsening of hypertension	293 (19.8)	512	302 (20.5)	524	0.96 (0.84–1.11)	0.63

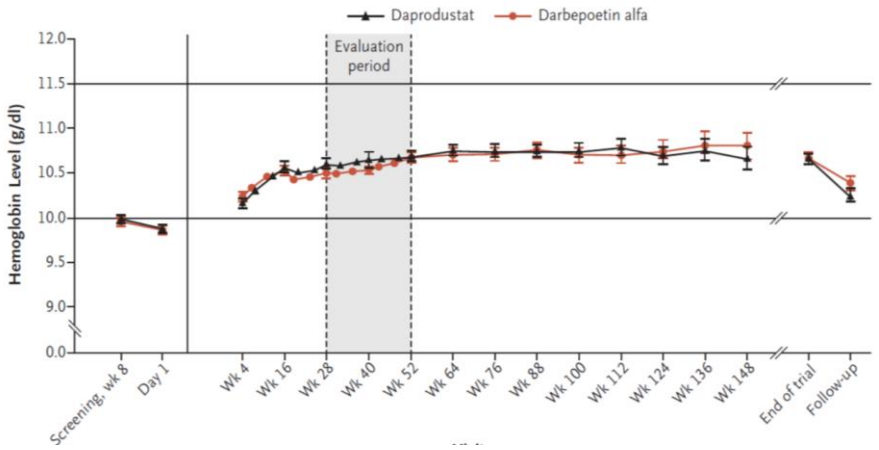
Ajay K. Singh et al., N Engl J Med 385;25 December 16, 2021

ASCEND-ND Clinical Trial

- 39 countries - 3872 patients
- daprodustat vs darbepoetin alfa

The NEW ENGLAND JOURNAL of MEDICINE

Daprodustat for the Treatment of Anemia in Patients Not Undergoing Dialysis



MACE or Thromboembolic Events

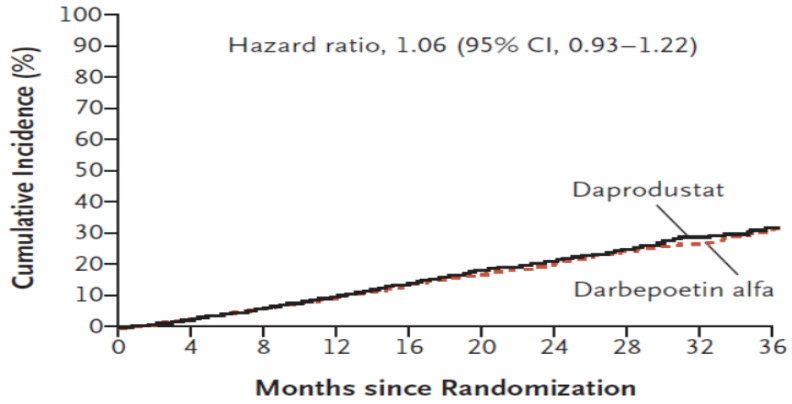


Table 3. Adverse Events and Laboratory Values (Safety Population).

Variable	Daprodustat (N=1937)		Darbepoetin Alfa (N=1933)		Relative Risk (95% CI)	P Value*
	Value	No. of Events	Value	No. of Events		
Adverse events — no. (%)†						
Any adverse event	1545 (79.8)	10,265	1487 (76.9)	9514	—	—
Any serious adverse event	850 (43.9)	1,960	703 (36.4)	1693	—	—
Adverse events of special interest‡						
Thrombosis or tissue ischemia due to excessive erythropoiesis	5 (0.3)	6	3 (0.2)	3	1.66 (0.40–6.95)	0.48
Cardiomyopathy	6 (0.3)	6	7 (0.4)	7	0.86 (0.29–2.54)	0.78
Pulmonary-artery hypertension	15 (0.8)	16	9 (0.5)	11	1.66 (0.73–3.79)	0.22
Cancer-related death or tumor progression or recurrence	72 (3.7)	82	49 (2.5)	67	1.47 (1.03–2.10)	0.04
Esophageal or gastric erosions	70 (3.6)	86	41 (2.1)	45	1.70 (1.16–2.49)	0.005
Proliferative retinopathy, macular edema, or choroidal neovascularization	54 (2.8)	70	44 (2.3)	55	1.22 (0.83–1.81)	0.31
Exacerbation of rheumatoid arthritis	2 (0.1)	2	4 (0.2)	4	0.50 (0.09–2.72)	0.41
Worsening of hypertension	344 (17.8)	489	363 (18.8)	519	0.95 (0.83–1.08)	0.41

01 February 2023

Issued: London, UK

For media and investors only

Jesduvroq (daprodustat) approved by US FDA for anaemia of chronic kidney disease in adults on dialysis

- ***Jesduvroq*** **is the only oral HIF-PHI approved in the US, offering adults on dialysis with anaemia of chronic kidney disease a new oral treatment option**

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Jesduvroq* (daprodustat), an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the once-a-day treatment of anaemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months. *Jesduvroq* is the first innovative medicine for anaemia treatment in over 30 years and the only HIF-PHI approved in the US, providing a new oral, convenient option for patients in the US with anaemia of CKD on dialysis.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use JESDUVROQ safely and effectively. See full prescribing information for JESDUVROQ.

JESDUVROQ (daprodustat) tablets, for oral use
Initial U.S. Approval: 2023

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

See full prescribing information for complete boxed warning.

- **JESDUVROQ increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). (5.1)**
- **Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels. (5.1)**
- **No trial has identified a hemoglobin target level, dose of JESDUVROQ, or dosing strategy that does not increase these risks. (2.4)**
- **Use the lowest dose of JESDUVROQ sufficient to reduce the need for red blood cell transfusions. (2.4)**

21 July 2023
EMA/329320/2023
EMEA/H/C/005746

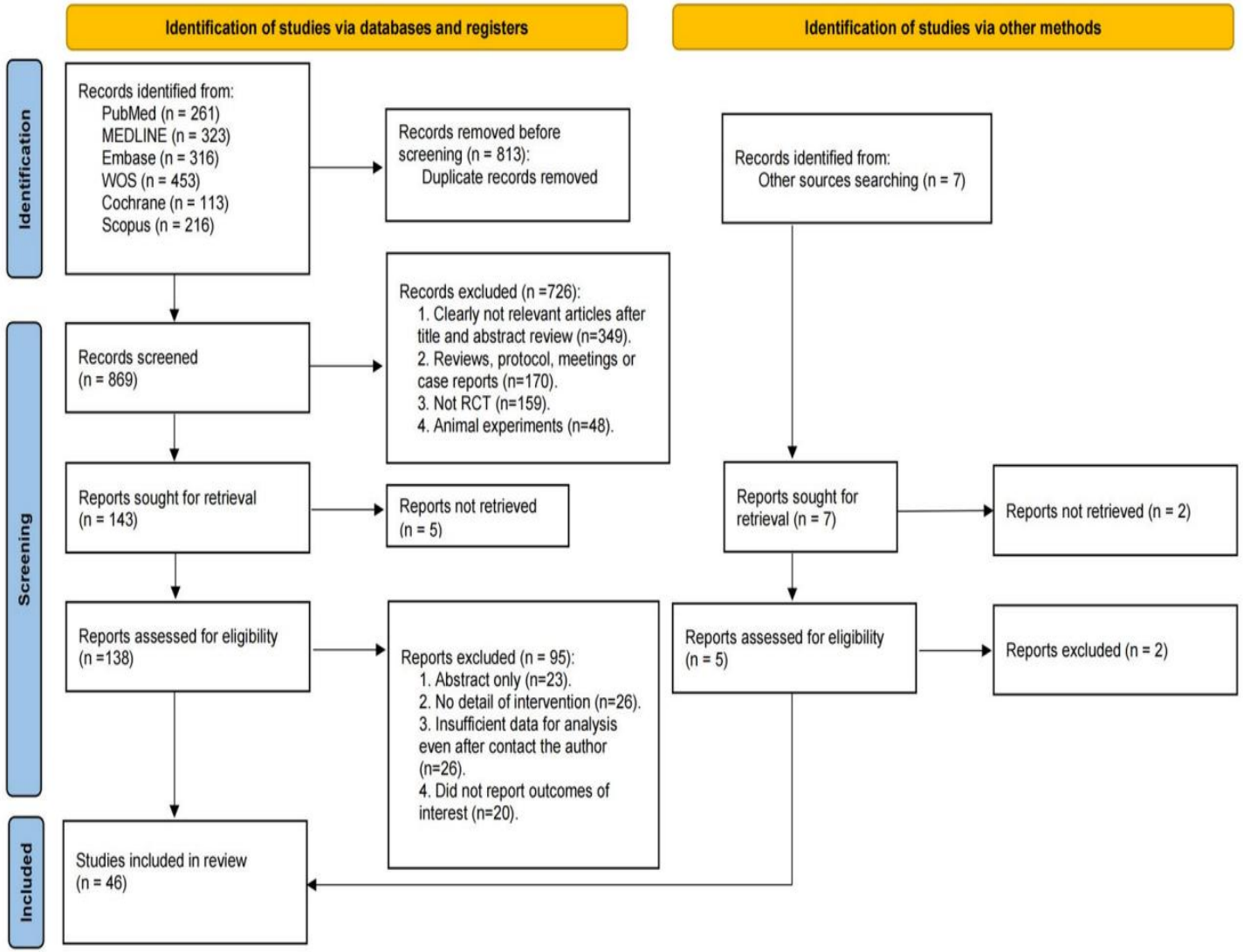
Withdrawal of application for the marketing authorisation of Jesduvroq (daprodustat)

SYSTEMATIC REVIEW

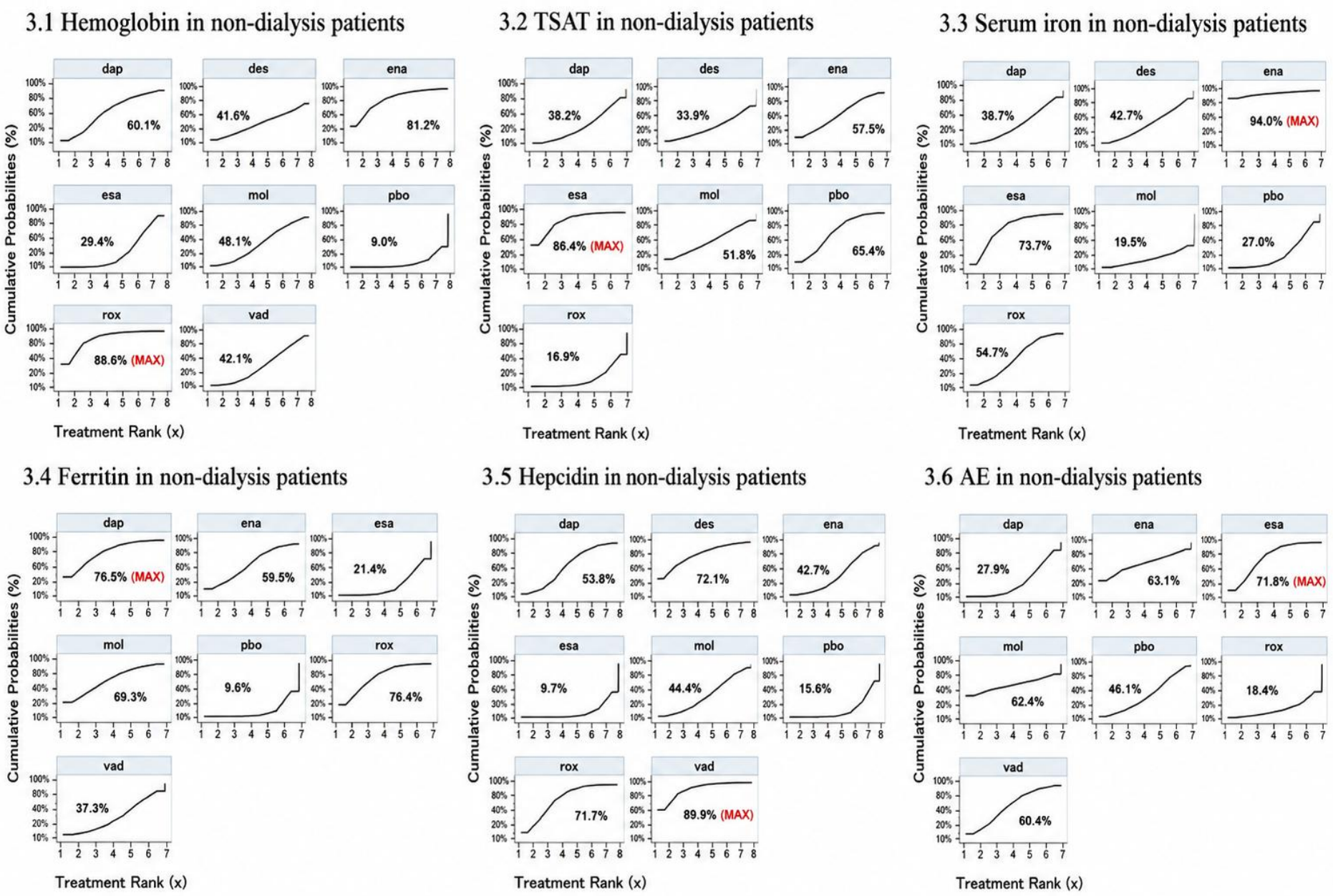
OPEN ACCESS Check for updates

Efficacy and safety of prolyl hydroxylase inhibitors for anemia in chronic kidney disease: a network meta-analysis

- network meta-analysis
- 46 RCTs
- **32.305 patients**



- **rox:** roxadustat
- **dap:** daprodustat
- **vad:** vadadustat
- **des:** desidustat
- **ena:** enarodustat
- **mol:** molidustat
- **pbo:** placebo



Yuanchen Niu et al., Renal Failure 2026, VOL. 48, NO. 1, 2616572

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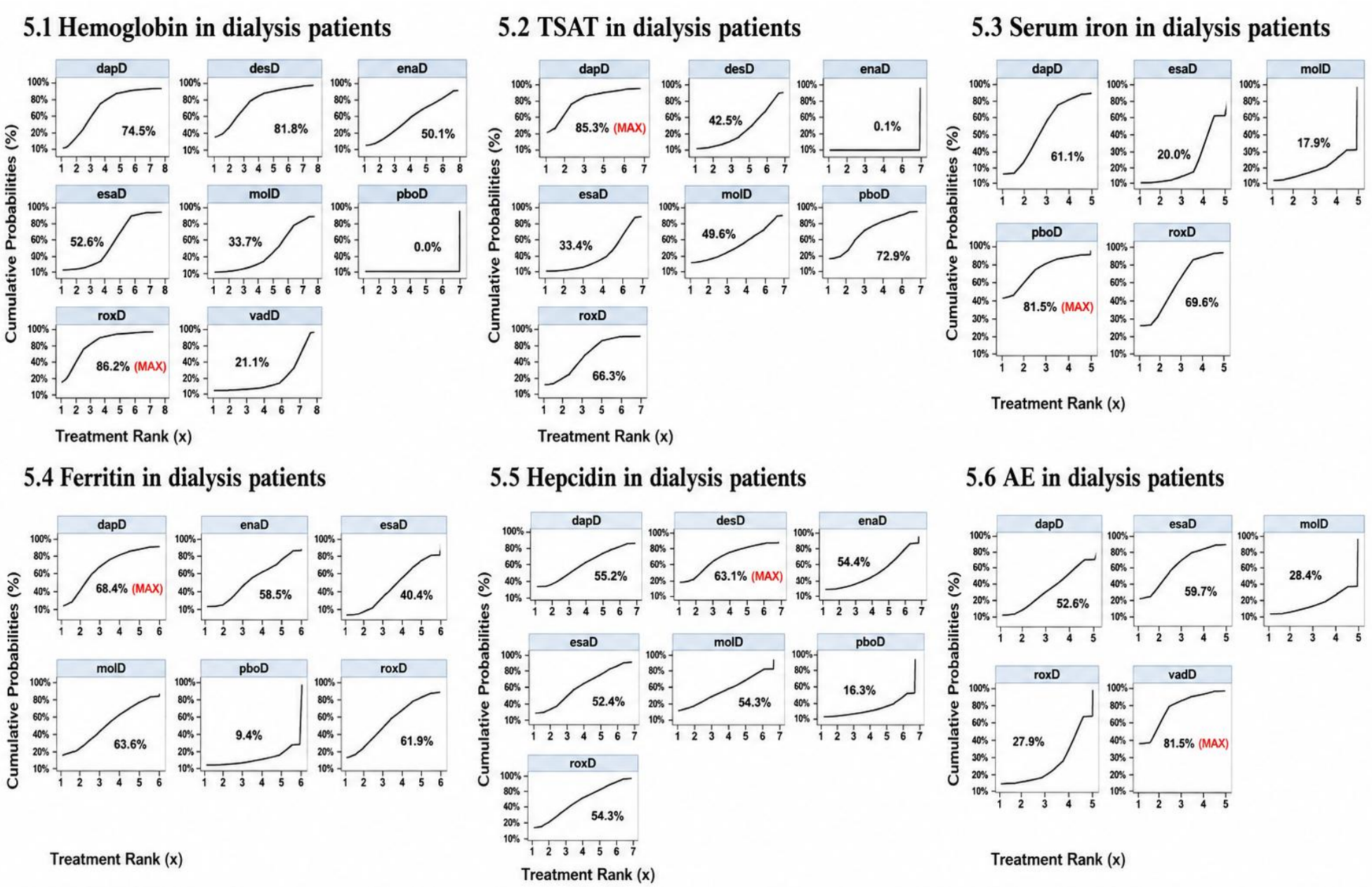


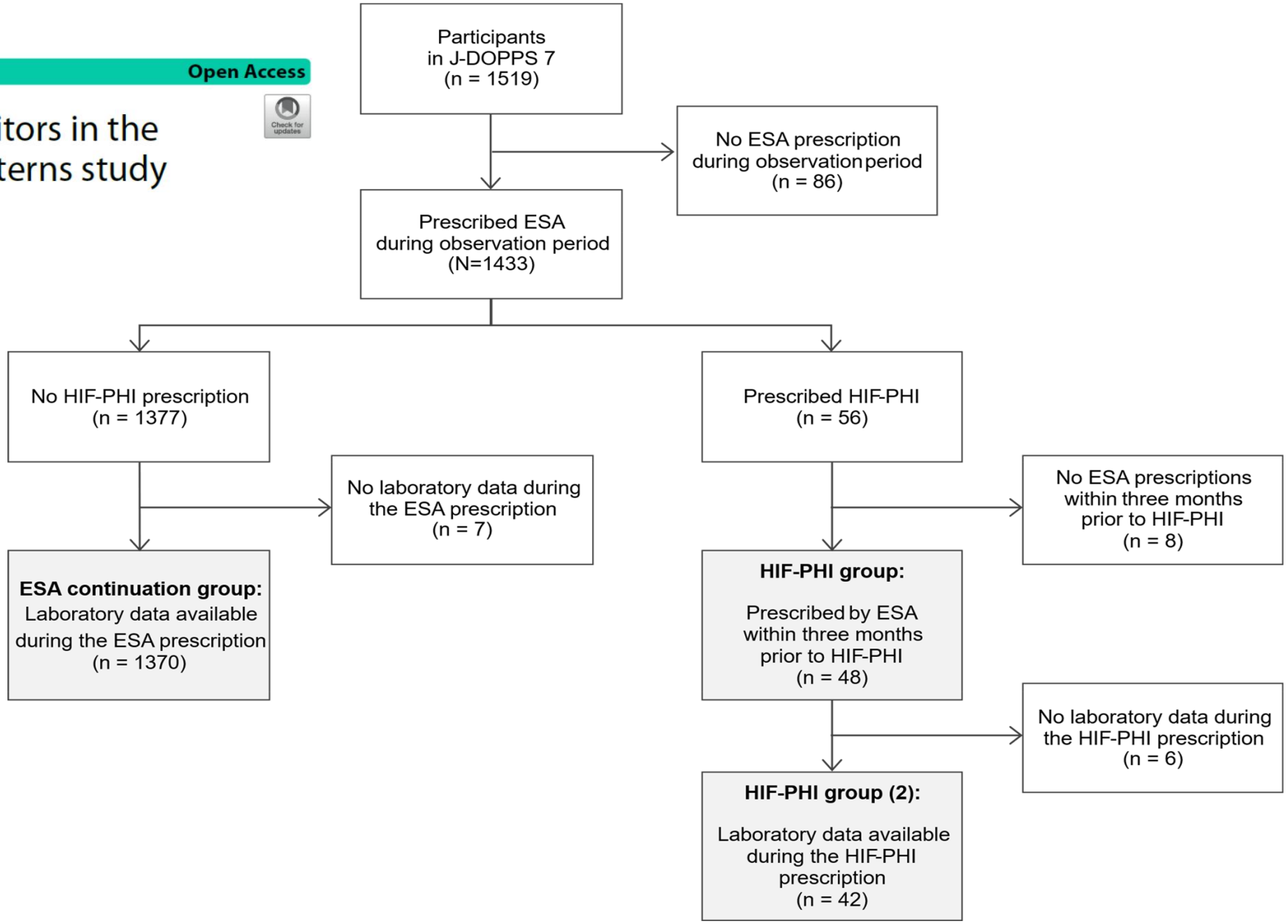
Yuanchen Niu et al., Renal Failure 2026, VOL. 48, NO. 1, 2616572

Real word data

Eriguchi et al. BMC Nephrology (2026) 27:250
https://doi.org/10.1186/s12882-026-04831-2

RESEARCH Open Access

Real-world use of HIF-PH inhibitors in the Japan dialysis and practice patterns study (J-DOPPS, 2019–2022)



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BMC Nephrology

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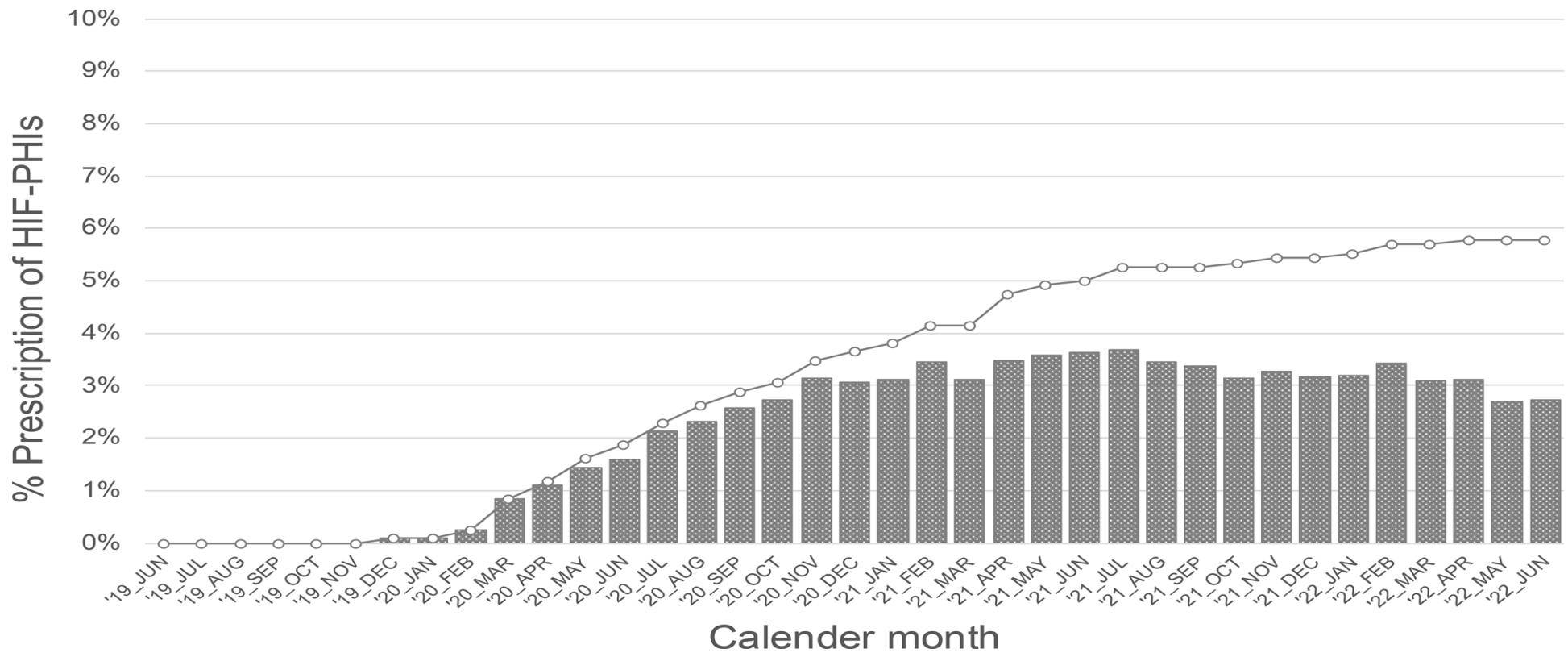
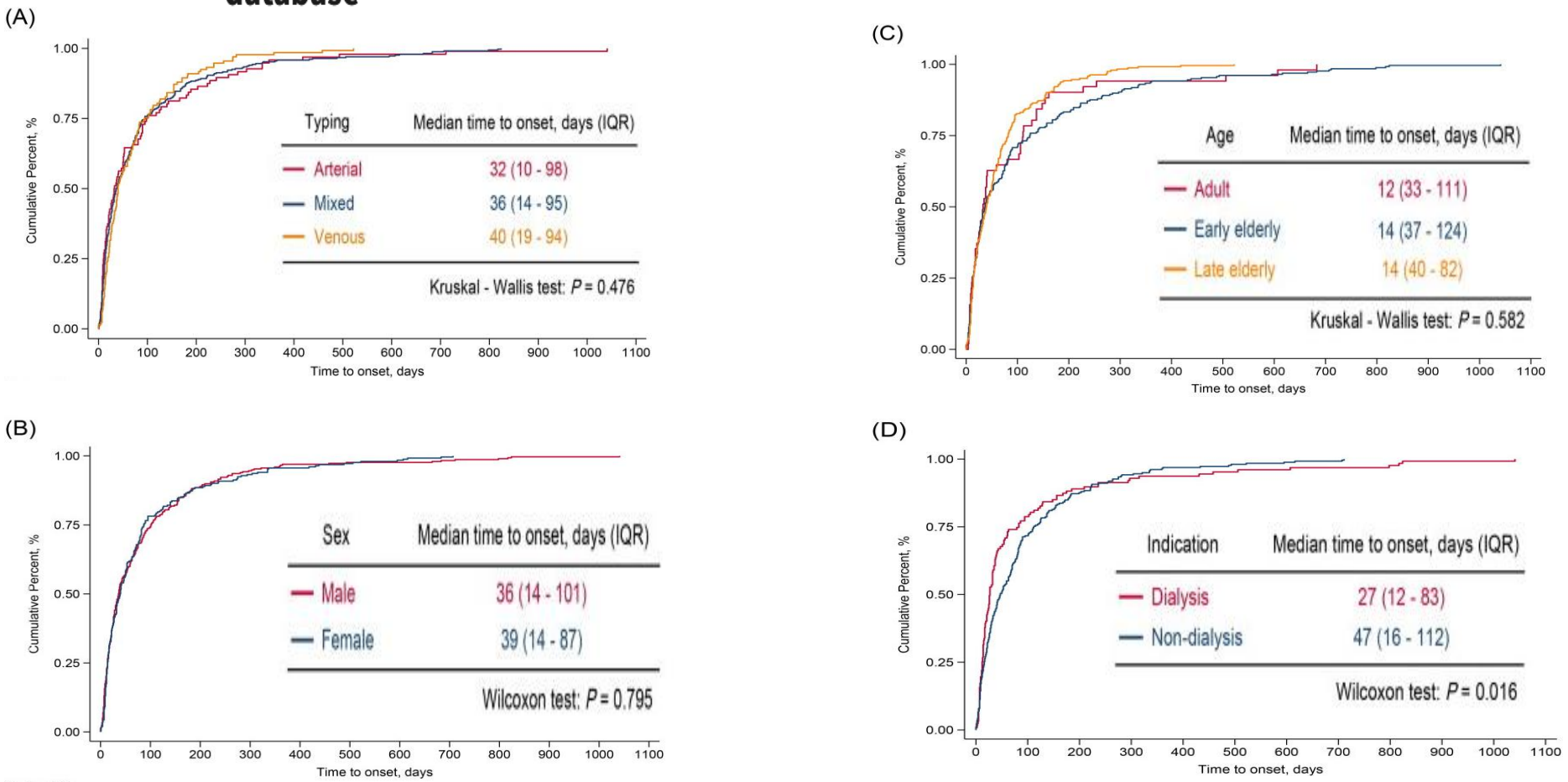


HIF-PHIs associated with embolic and thrombotic events: a real-world pharmacovigilance study based on the Japan Adverse Drug Event Report database



Τα θρομβωτικά επεισόδια εμφανίζονται ~ 1 μήνα → όχι σαφείς διαφορές μεταξύ υποομάδων → πιθανώς νωρίτερα στους Α/Κ ασθενείς

D. Wu et al.,Ren Fail. 2025 Apr 23;47(1):2491655

KDIGO 2026
Anemia management in CKD

KDIGO 2026 Clinical Practice Guideline for the Management of Anemia in Chronic Kidney Disease (CKD)

Recommendation 3.1.1: In people with anemia and CKD in whom correctable causes of anemia have been addressed, we suggest using an ESA rather than a HIF-PHI as first-line treatment of anemia (*2D*).

Practice Point 3.1.1: In people with anemia and CKD (whether receiving dialysis or not), the decision to use erythropoiesis-stimulating agents (ESAs) or hypoxia-inducible factor–prolyl hydroxylase inhibitors (HIF-PHIs) to raise Hb should be made through a shared decision-making process, considering each individual's symptoms, potential for harm from red blood cell (RBC) transfusions, and potential risk of adverse events (e.g., stroke, cardiovascular event, and cancer).

Practice Point 3.5.1: In people with anemia and CKD, including those with ESA hyporesponsiveness, do not use ESAs and HIF-PHIs in combination.

Table 6 | Considerations for people with anemia and CKD at risk for adverse events with HIF-PHIs

Theoretical risk or experimental evidence of disease development or progression	Concern about risk based on adverse event profiles in clinical trials	Insufficient data to assess risk; dedicated studies needed
• Active cancer or with a history of cancer not in complete remission for at least 2–5 yr (based on trial exclusion criteria)[231] • Polycystic kidney disease[232] • Proliferative retinal disease[233,234] • Pulmonary arterial hypertension[235–237] • Pregnancy[a]	• Prior cardiovascular events (i.e., stroke and myocardial infarction)[231] • Prior thromboembolic events (i.e., deep venous thrombosis and pulmonary embolism)[231] • Prior vascular access thrombosis[231] • Hepatic impairment[b] • Seizures, exfoliative dermatitis, hypothyroidism, and bacterial infections/sepsis (roxadustat)[238]	• Post–kidney transplant anemia[231] • Children[239]

Conclusions

“What happened?”

Οι Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitors:

- Ξεκίνησαν με μεγάλες προσδοκίες
- αλλά η πραγματική διείσδυση στην καθημερινή κλινική εφαρμογή παραμένει περιορισμένη

Τι υποσχέθηκαν οι HIF

- oral therapy
- physiologic EPO stimulation
- ↓ hepcidin
- ↓ IV iron
- efficacy despite inflammation
- πιθανώς καλύτερο CV profile

Τι έδειξαν οι μελέτες

- Hb correction:
  ✔ achieved
- Non-inferiority έναντι ESA:
  ✔ achieved
- MACE non-inferiority:
  ✔ achieved

ΑΛΛΑ:

- ✗ superiority
- ✗ practice-changing outcomes

Δεν υπάρχει “clear winner”

Η daprodustat φαίνεται να έχει πιο reassuring δεδομένα καρδιαγγειακής ασφάλειας

Απαιτούνται πιο ισχυρά head-to-head δεδομένα

Take-home messages

- Νέα θεραπευτική κατηγορία
- Δρουν μέσω HIF pathway
- Βελτιώνουν EPO + μεταβολισμό σιδήρου
- Αποτελεσματικότητα συγκρίσιμη με ESA
- Παραμένουν ερωτήματα για long-term δεδομένα ασφάλειας

ΕΛΛΗΝΙΚΗ ΝΕΦΡΟΛΟΓΙΚΗ ΕΤΑΙΡΕΙΑ
HELLENIC SOCIETY OF NEPHROLOGY

27ο Πανελλήνιο Συνέδριο Νεφρολογίας

Ευχαριστώ για την προσοχή σας !