New game changer in heart failure

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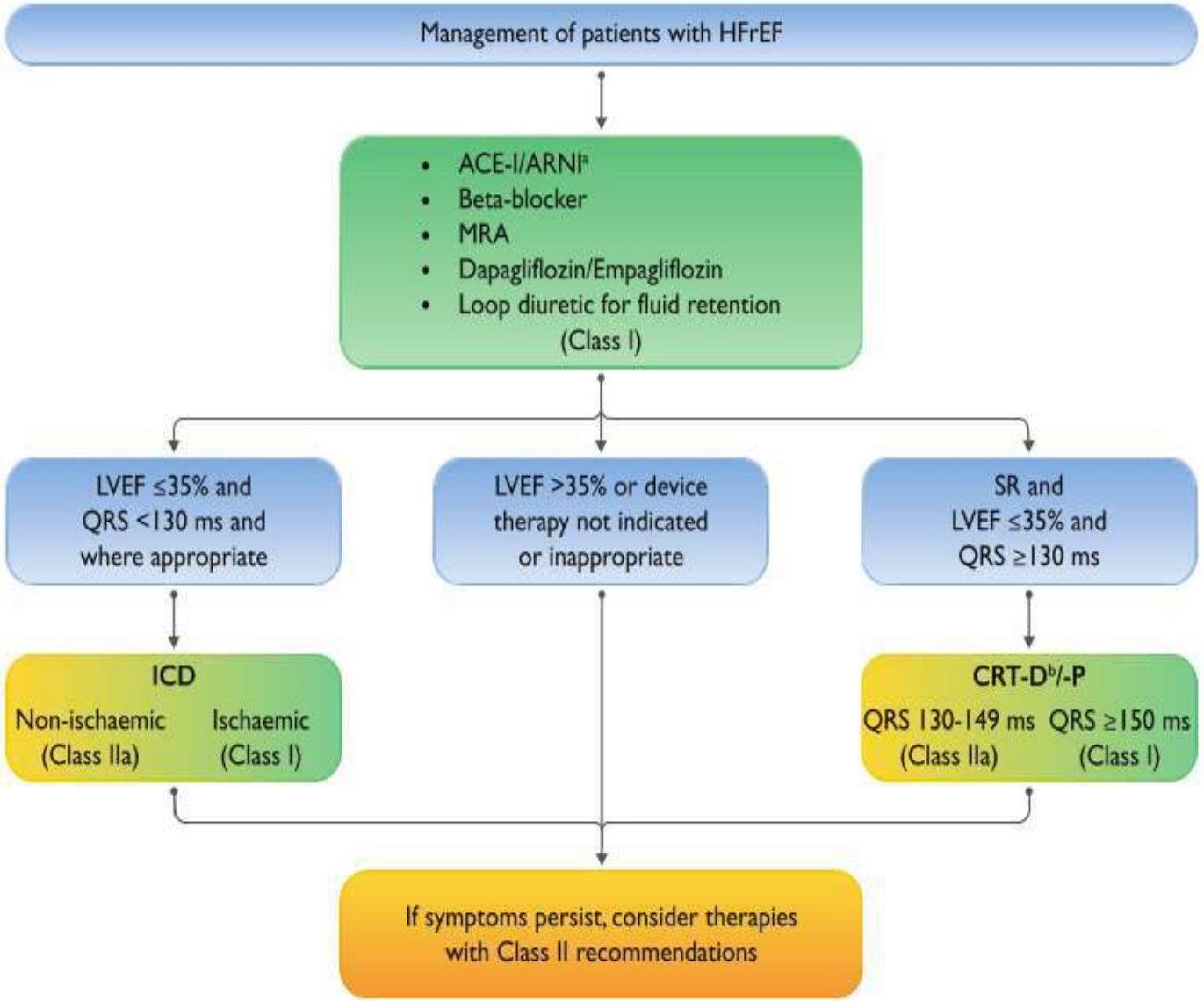
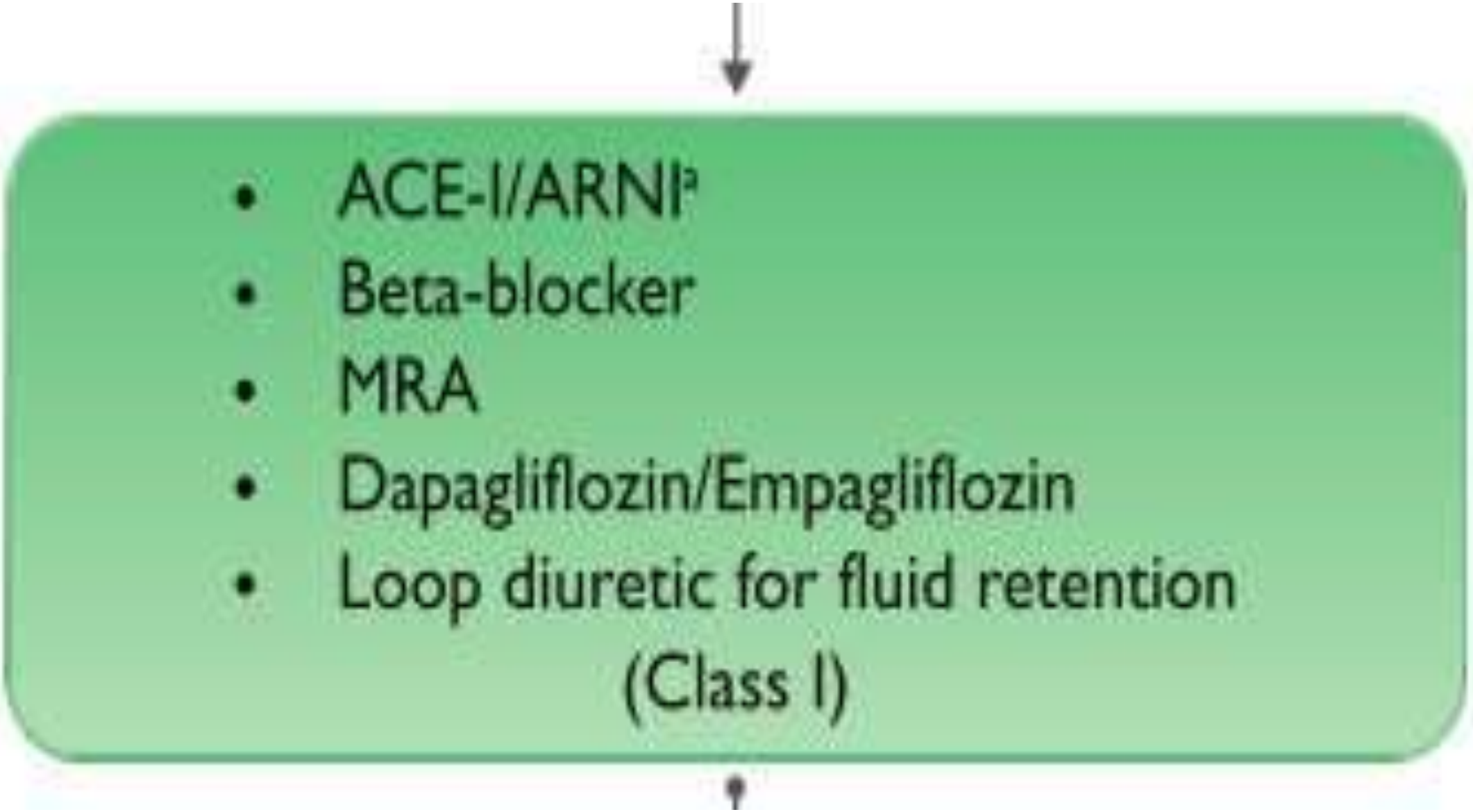
Universal Hospital

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

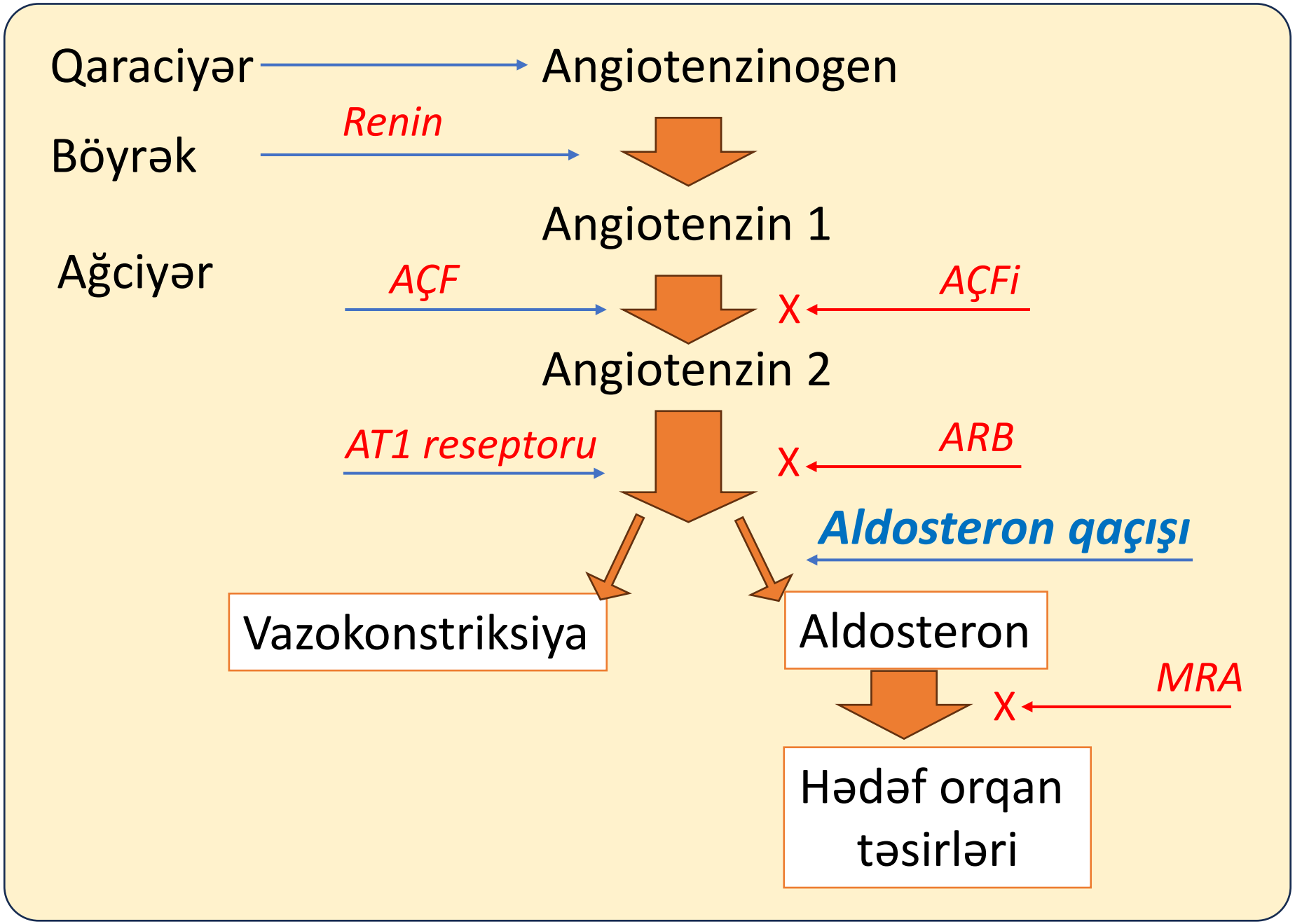


EHJ 2021;00:1-128; Circulation. 2022;145:00–00



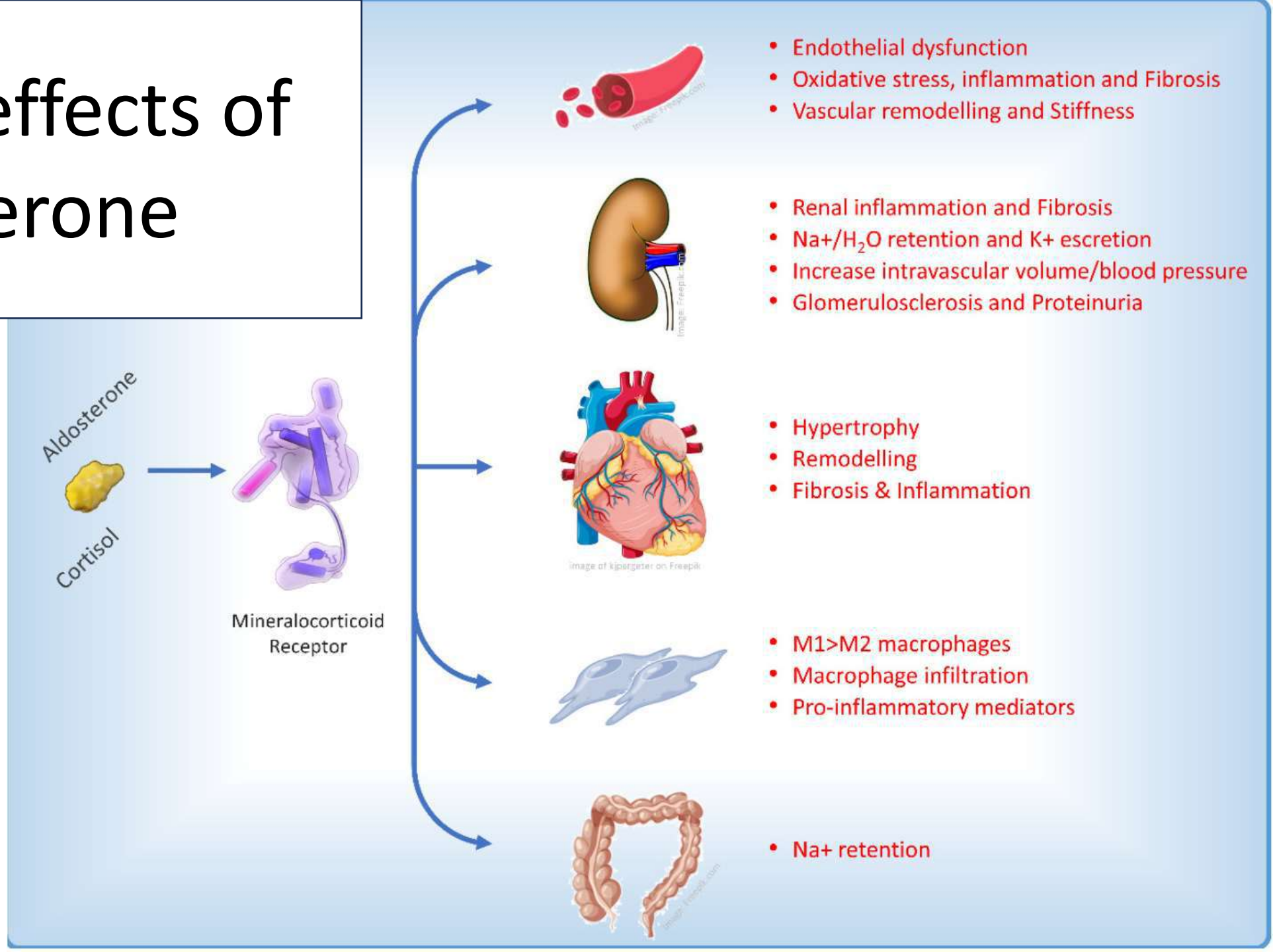
EHJ 2021;00:1-128; Circulation. 2022;145:00–00

Mineralokortikoid Reseptor Antagonistləri (MRA)

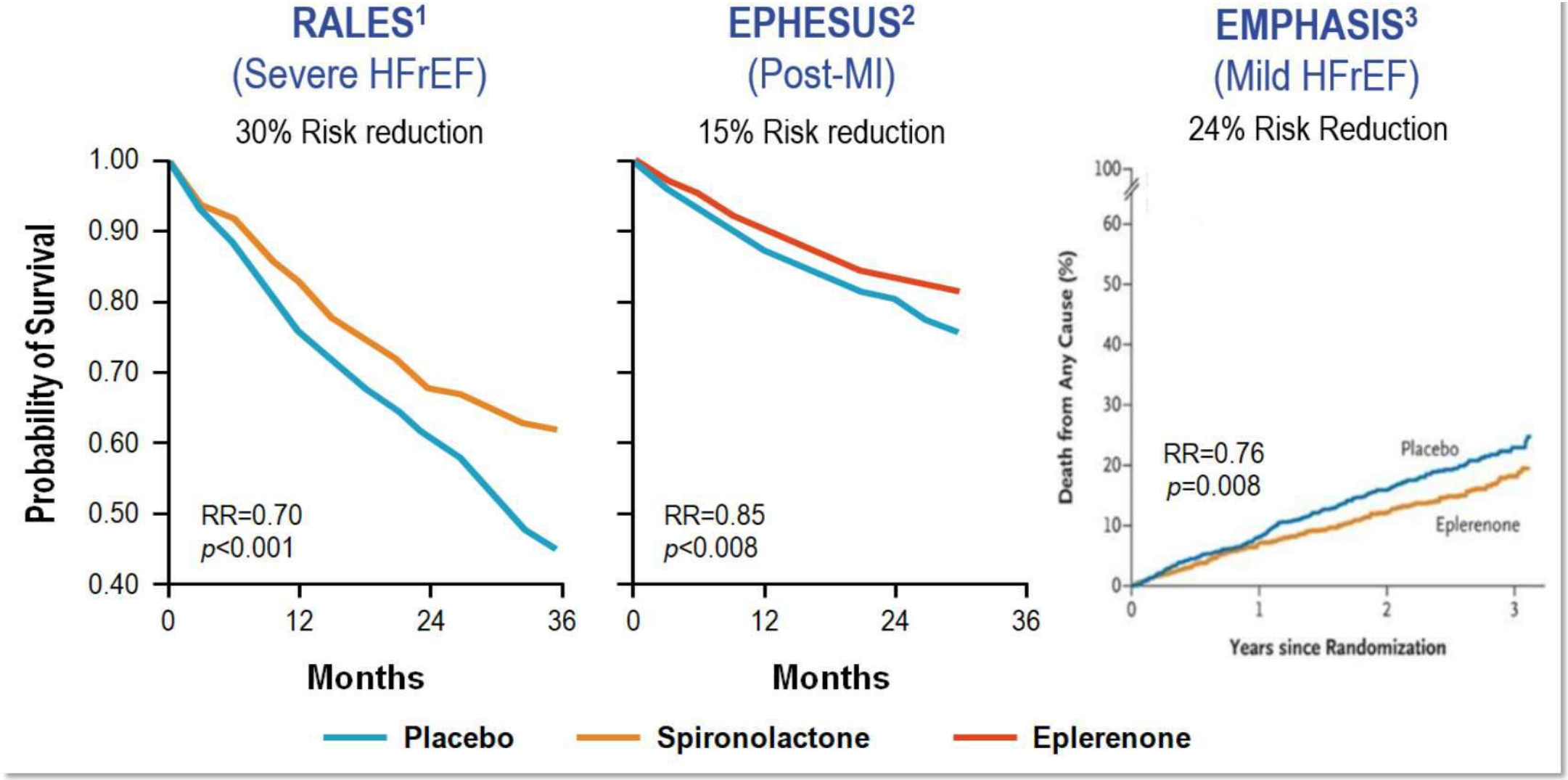


1. *Nappl JM. Sieg A. Vasc Health Risk Manag 2011;7:353-63*
2. *2012 ESC Kılavuzu, Türk Kardiyoloji Dern Arş Suppl 3, 2012;41-95*

Negative effects of Aldosterone



Impact of MRAs on Survival in HFrEF



1. Pitt B et al. *N Engl J Med*. 1999:341:709-717.

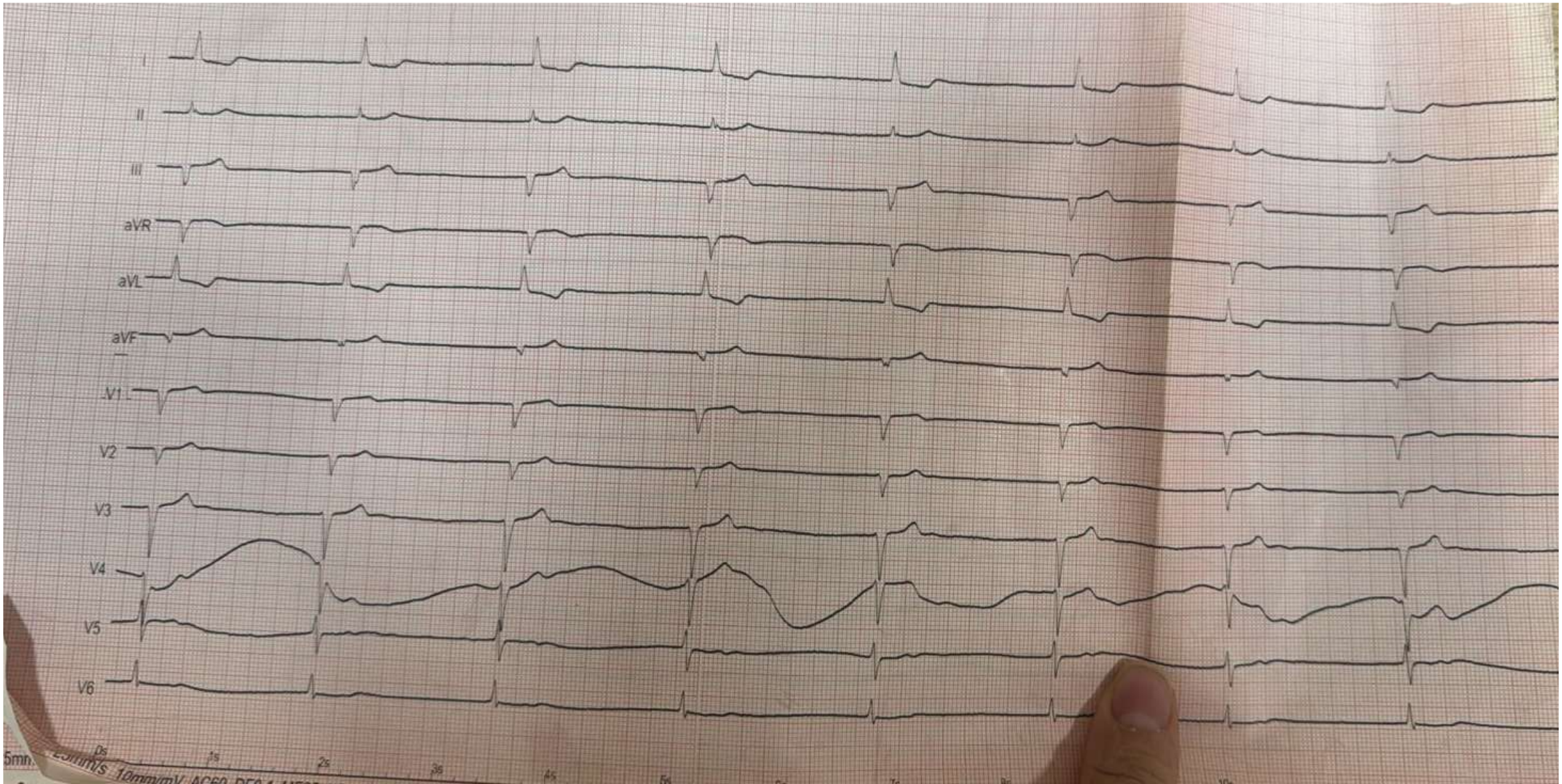
2. Pitt B et al. *N Engl J Med*. 2003;348:1309-1321.

3. Zannad F et al. *N Engl J Med*. 2011;364:11-21.

Case presentation

- Patient 63 yo male
- 2017 CABG, DM+, CKD+
- LVEF =35%
- Furosemid 40mq, Spironolactone 25mq, Empagliflozin 10mq, Bisoprolol 2.5mq, Rosuvastatin 40mq, ARNI 24/26mq.
- 2024 January - admitted to hospital via bradycardia.

Case presentation



Case presentation

Nov, 2023

Xəstənin

Həkim : 461

Şöbə : NEFROLOGİYA POLİKNİKASI

Əvvəlki nəticə tarixi

Təşkilat : 40

Yönləndirən həkim 0

Biokimya

Analiz adı	Natica	Yaziyyat	Normal dayarlar	əvvalki natica	Şərh
Kreatinin qanda	**1.81**	**H**	**0.70 - 1.20**	**1.82**	
C-reaktiv zülal (CRP)	0.4	N	0 - 0.5	0.5	
Zülal(Protein)/Kreatinin nisbəti	**1.72**	**H**	**0 - 0.3**	**2.4**	
Transferrin doyğunluğu	**19.3**	**L**	**20 - 50**		

Hormon

Analiz adı	Natica	Yaziyyat	Normal dayarlar	əvvalki natica	Şərh
PTH - parathormon	**91**	**H**	**15 - 65**	**64.7**	
Total PSA	1.2	N	0.0 - 4.1	1.29	

Case presentation

Jan, 2024

Cinsi : Kişi Yaşı : 63 Kart No :
Ata Adı : ORUC Diaqnozu : -

Biyokimya

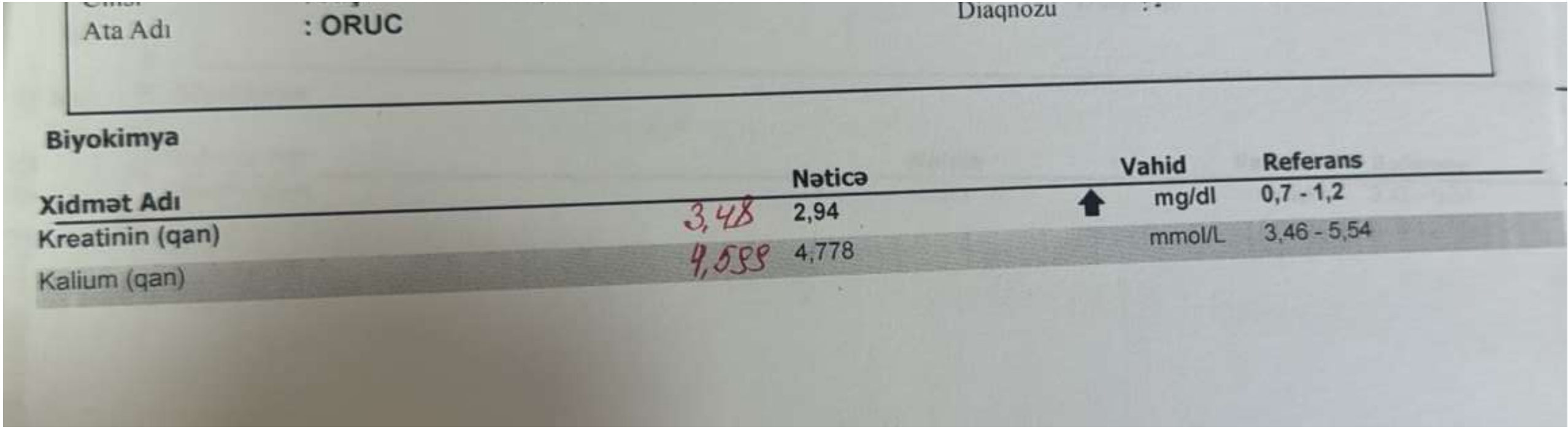
Xidmət Adı	Nəticə		Vahid	Referans
Kreatinin (qan)	3,03	↑	mg/dl	0,7 - 1,2
Kalium (qan)	6,804	↑	mmol/L	3,46 - 5,54
Kalsium (qan)	9,25		mg/dl	8,8 - 10,6

Case presentation

- İV Ca
- İnsuline + Glucosae
- MRA was stopped.

Case presentation

Jan, 2024 - discharge


Ata Adı : ORUC

Diaqnozu

Biyokimya

Xidmət Adı		Nəticə		Vahid	Referans
Kreatinin (qan)	3,48	2,94	⬆	mg/dl	0,7 - 1,2
Kalium (qan)	4,588	4,778		mmol/L	3,46 - 5,54

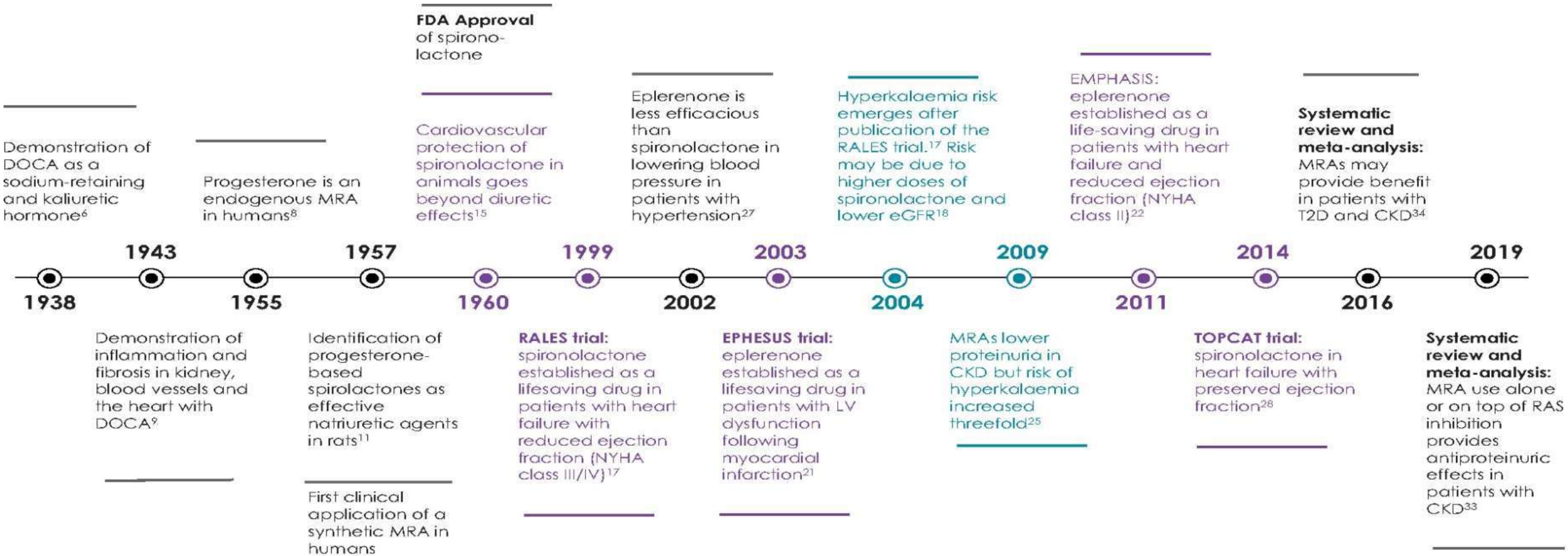
eGFR – 30ml/min

1 month later kreatin 1.6mg/dL, K - normal

Next step

1. I will not restart MRA
2. I will start the same MRA at half dose (12.5mg)
3. I will start MRA at full dose
4. Any other ideas?

Short history of MRA

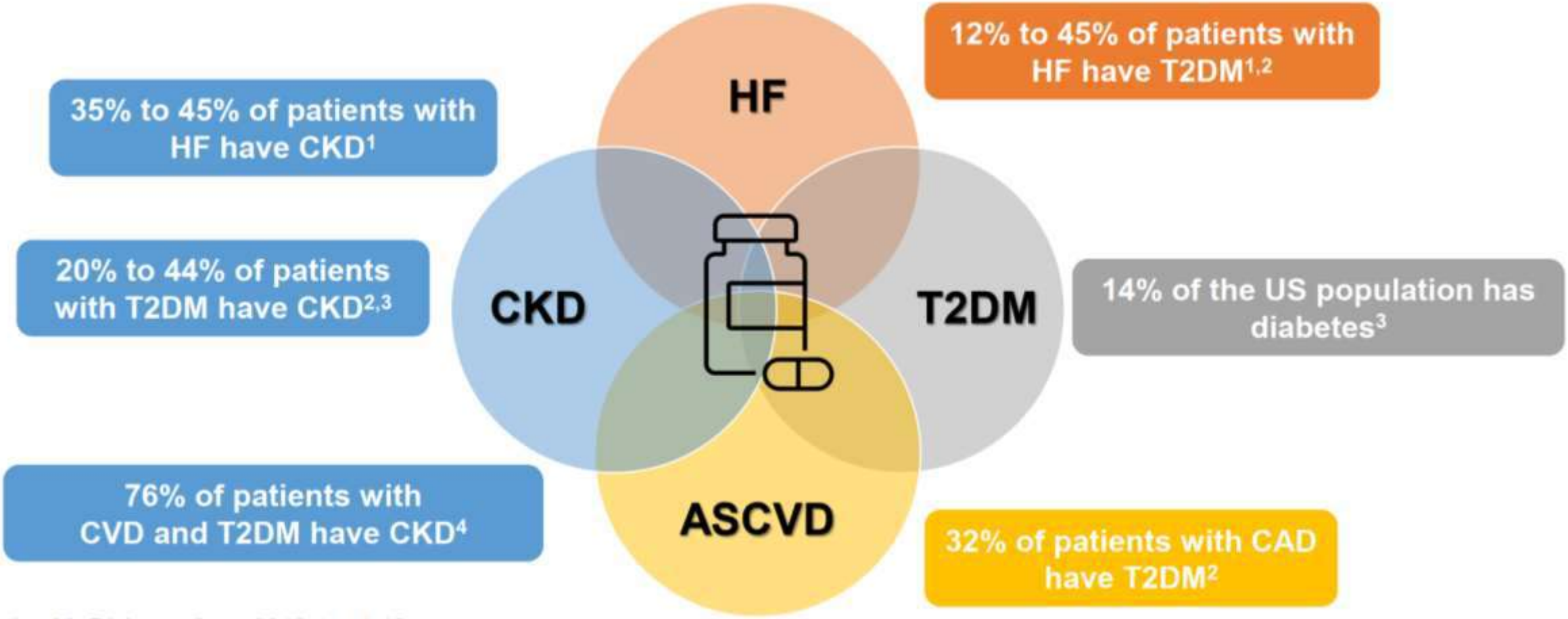


TEXT = Milestones

TEXT = Cardiac effects

TEXT = Risk of hyperkalaemia

Heart and kidney failure are associated



1. Packer M. *Diabetes Care*. 2018;41:11-13.
2. Wanner C. *Am J Cardiol*. 2017;120:S59-S67.
3. https://www.cdc.gov/nchs/data/databriefs/db319.pdf. Accessed November 7, 2019.
4. Wang T et al. *Diabetes Metab Syndr*. 2019;13:612-615.

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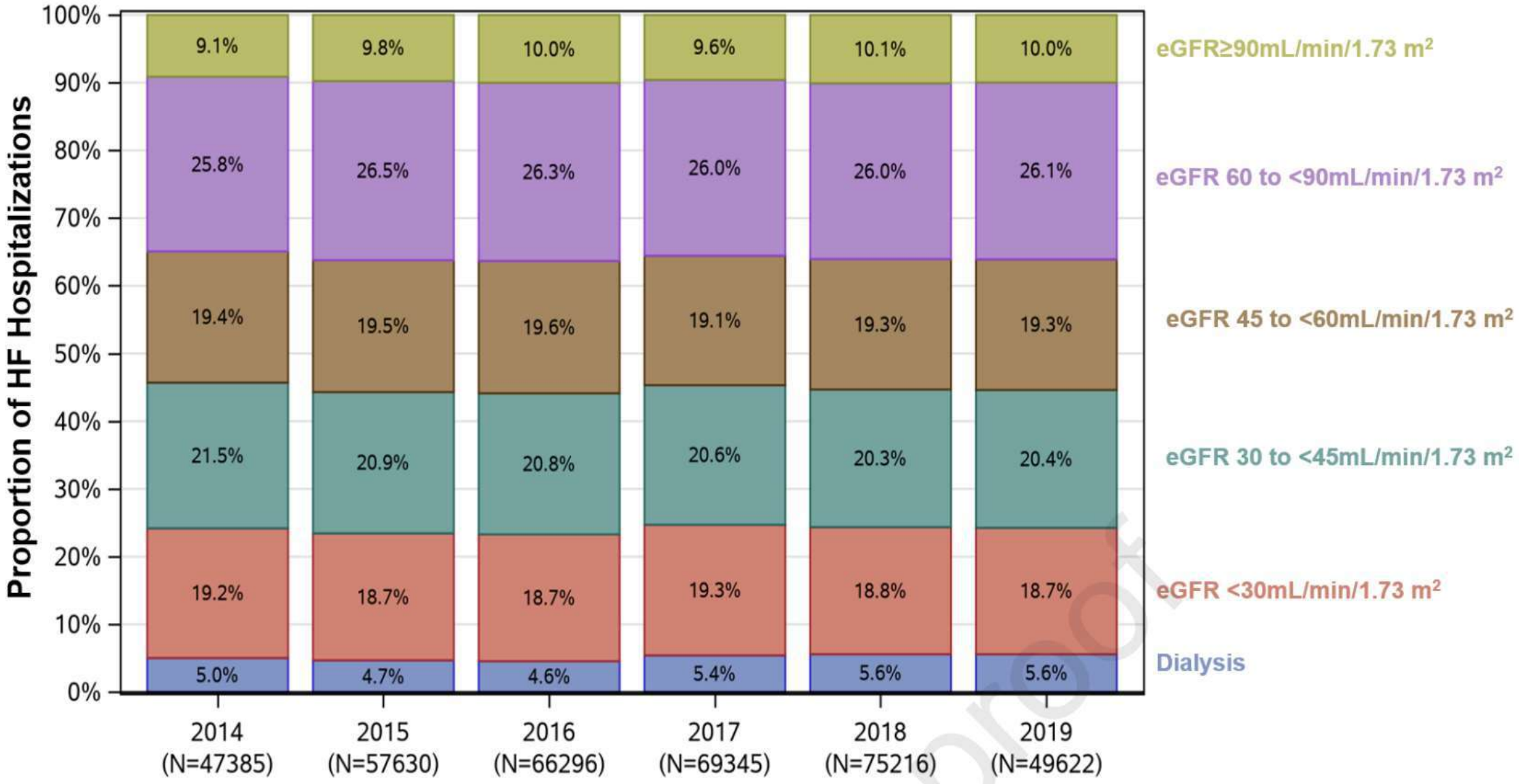

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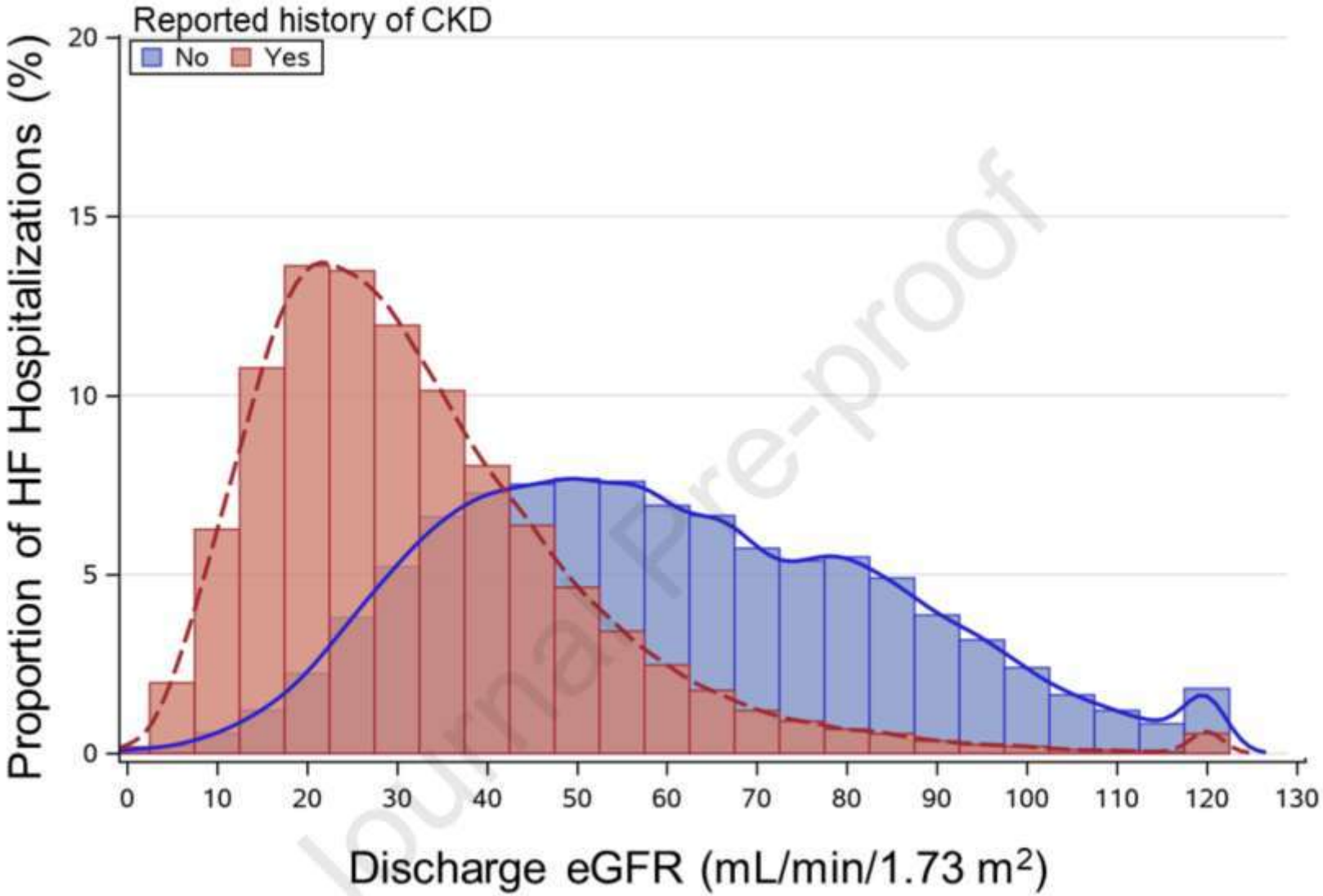
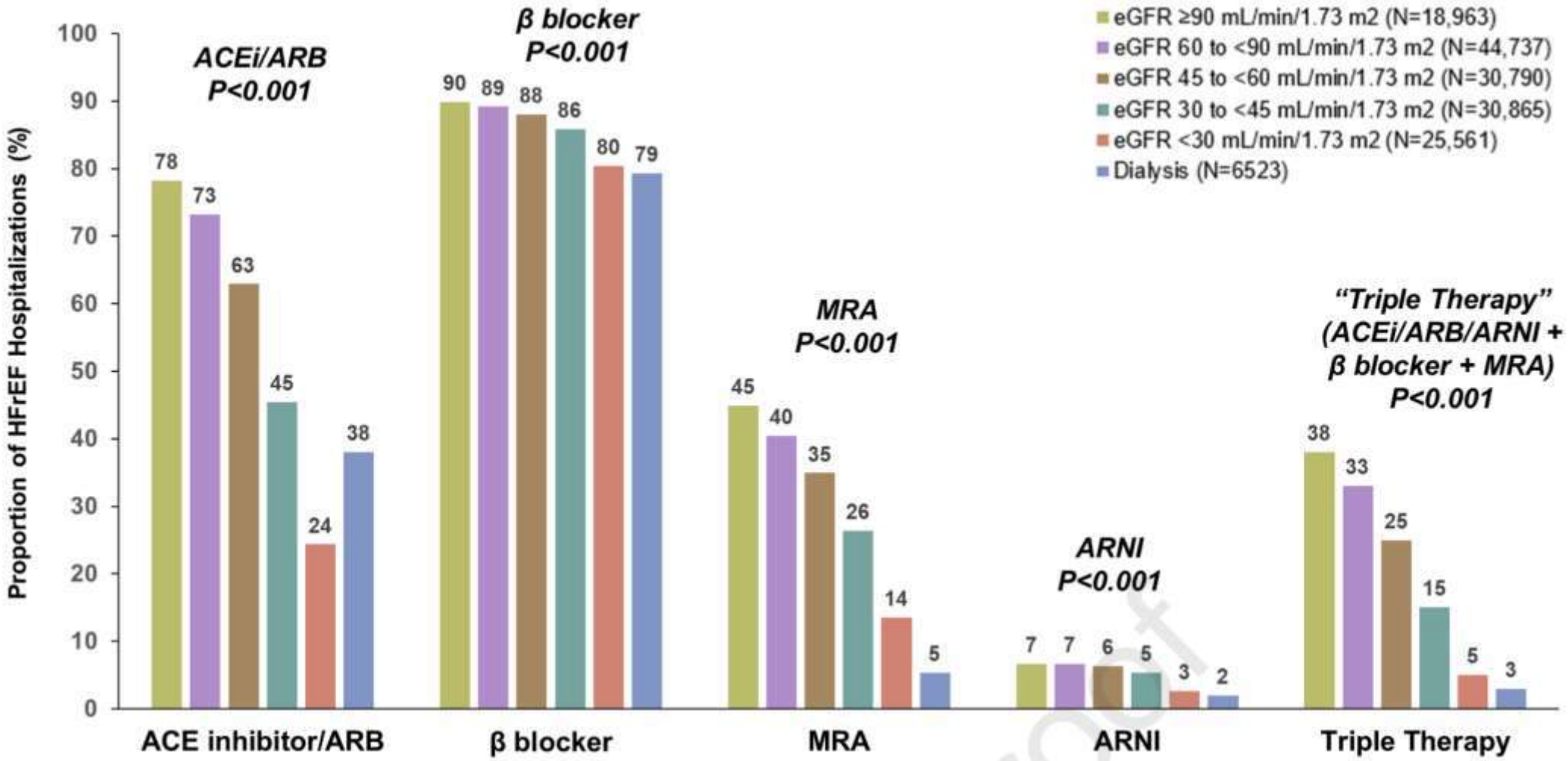
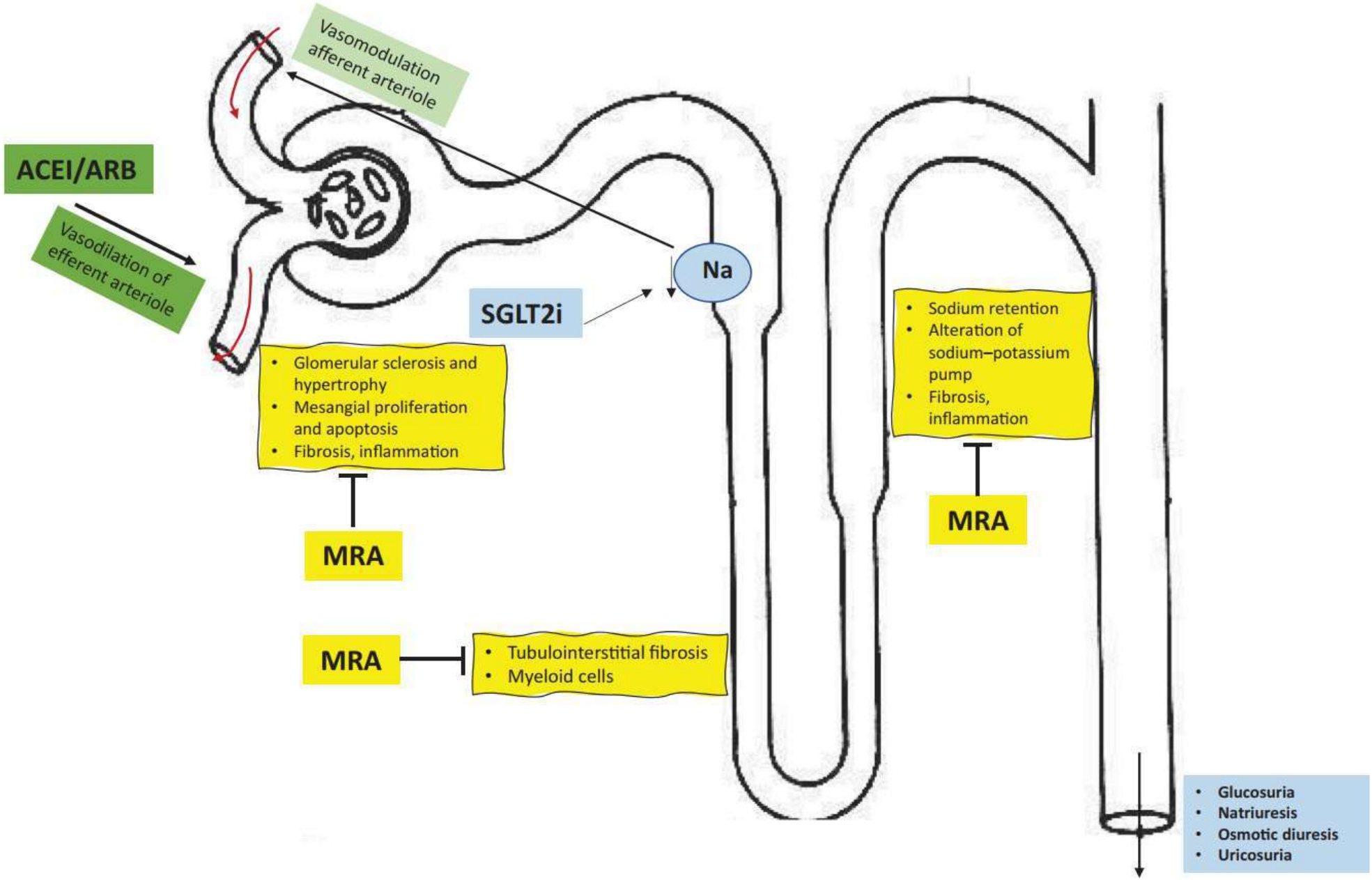


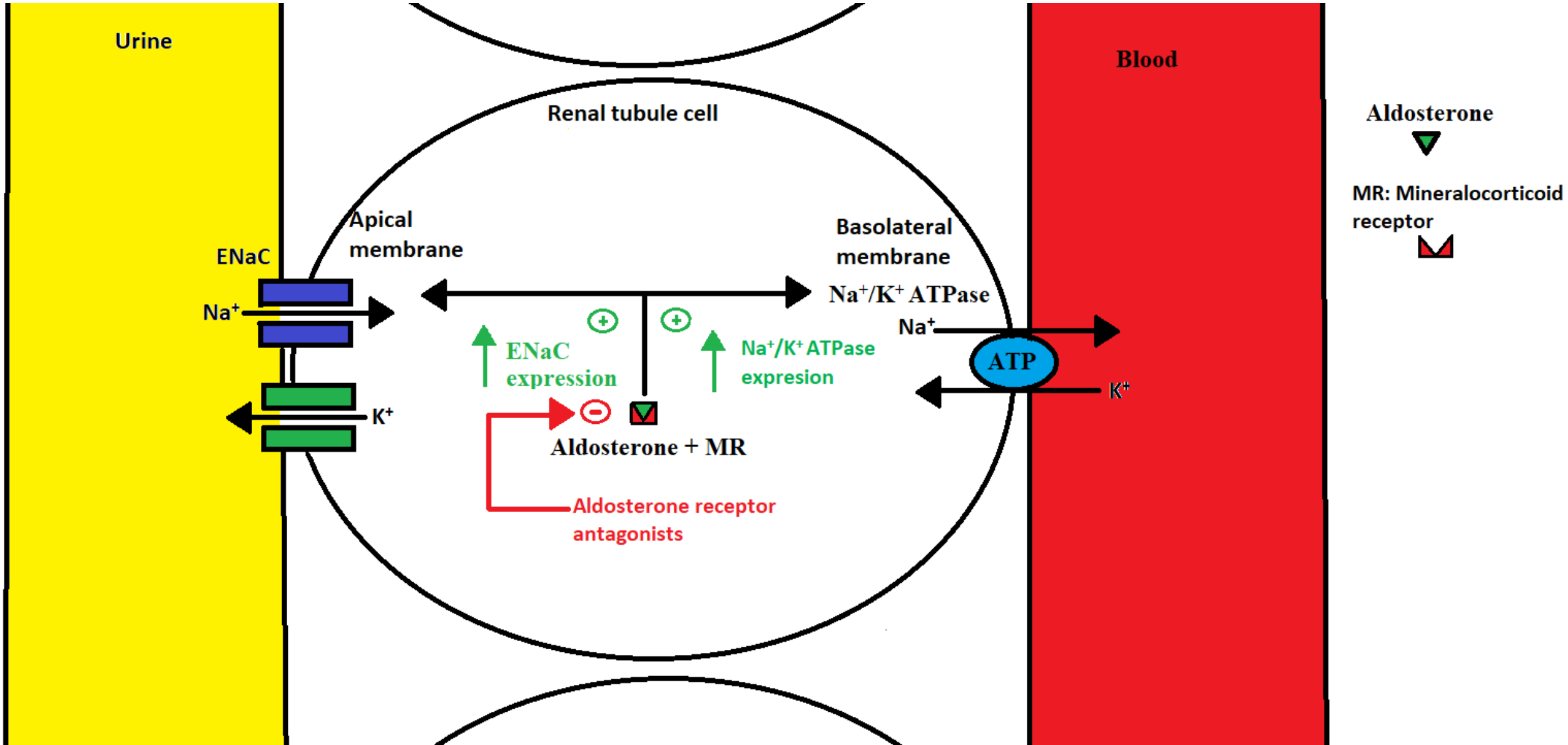
As eGFR falls, rejection of MRA use increases



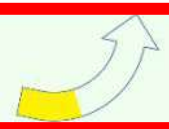
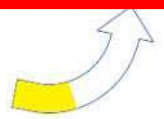
Why is Aldosterone harmful?



Aldosteron effect on K and Na



What do we have?

Characteristics	Spironolactone	Eplerenone	Finerenone
MR antagonist class	Steroidal		Non-steroidal
Structural prop.s	Flat	Flat	Bulky
Potency			
Selectivity			
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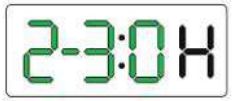
GR IC^{50} (nM)	2,410	≥ 21,980	≥ 10,000
AR rec. IC^{50} (nM)	77	≥ 21,240	≥ 10,000
PR EC^{50} (nM)	740	≥ 31,210	≥ 10,000
OR α & β IC^{50} (nM)	5,970 & 4,940	≥ 30,000 & ≥ 30,000	≥ 10,000 & ≥ 10,000
Metabolites	Multiple, active	No active	No active
Half-life			
Tissue distribution in rodents			
CNS penetration	+	+	–
Effect on BP	+++	++	+
Excretion (unchanged)	<1%	<3%	<1%

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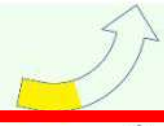
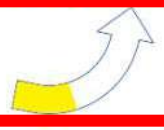
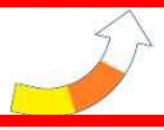
Potency			
Selectivity			
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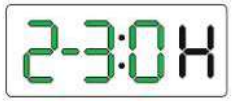
Half-life			
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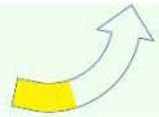
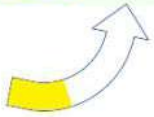
Potency			
Selectivity			
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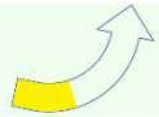
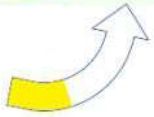
Potency			
Selectivity			
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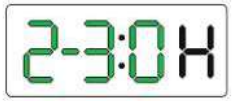
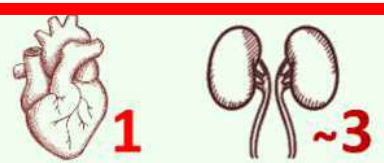
Half-life			
Tissue distribution in rodents			
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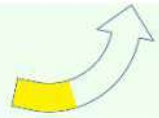
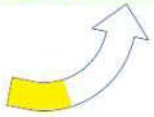
Potency			
Selectivity			
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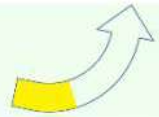
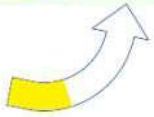
Potency			
Selectivity			
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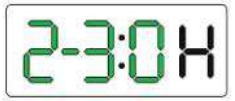
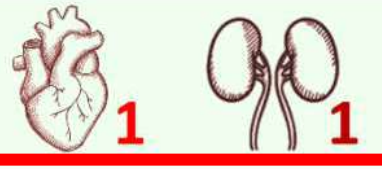
Half-life			
Tissue distribution in rodents			
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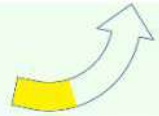
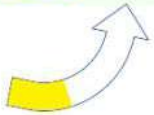
Potency			
Selectivity			
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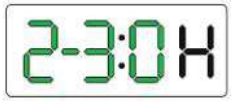
Half-life			
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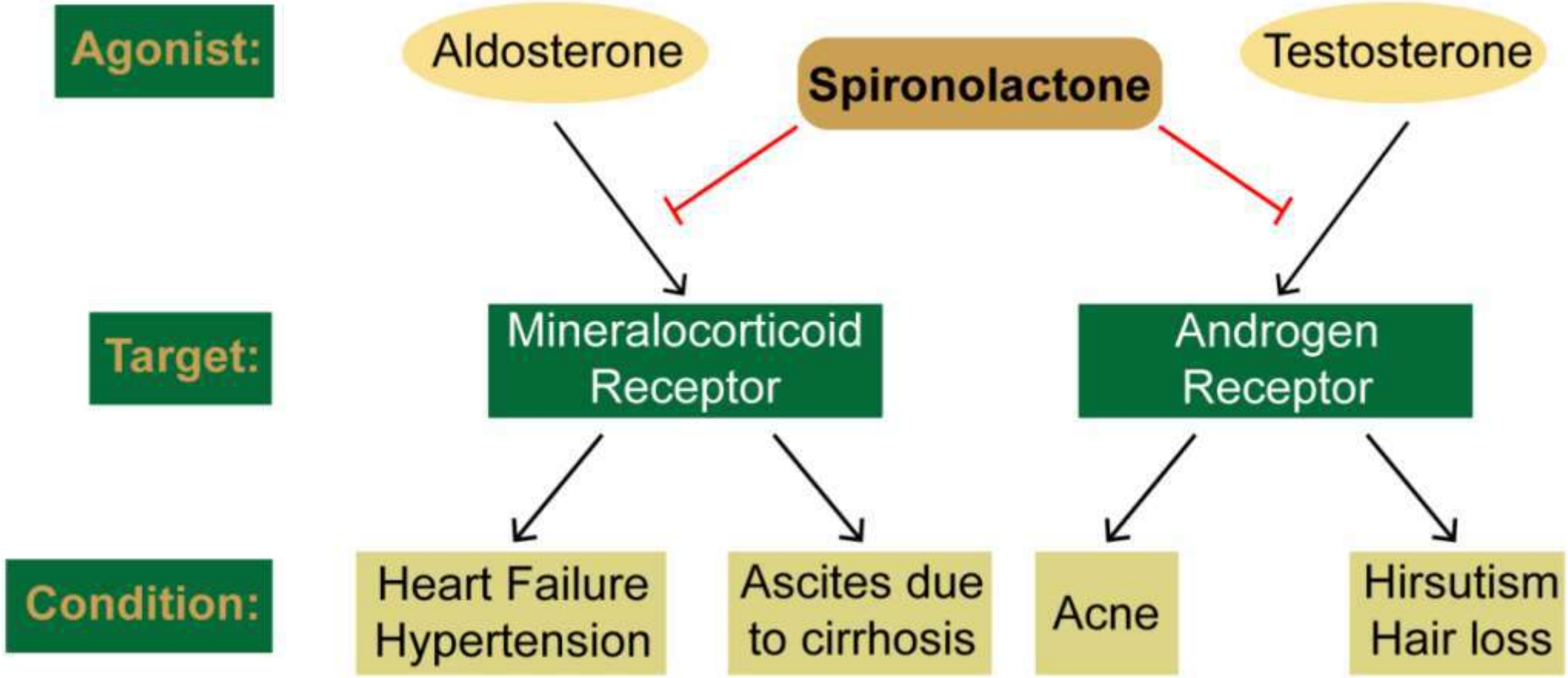
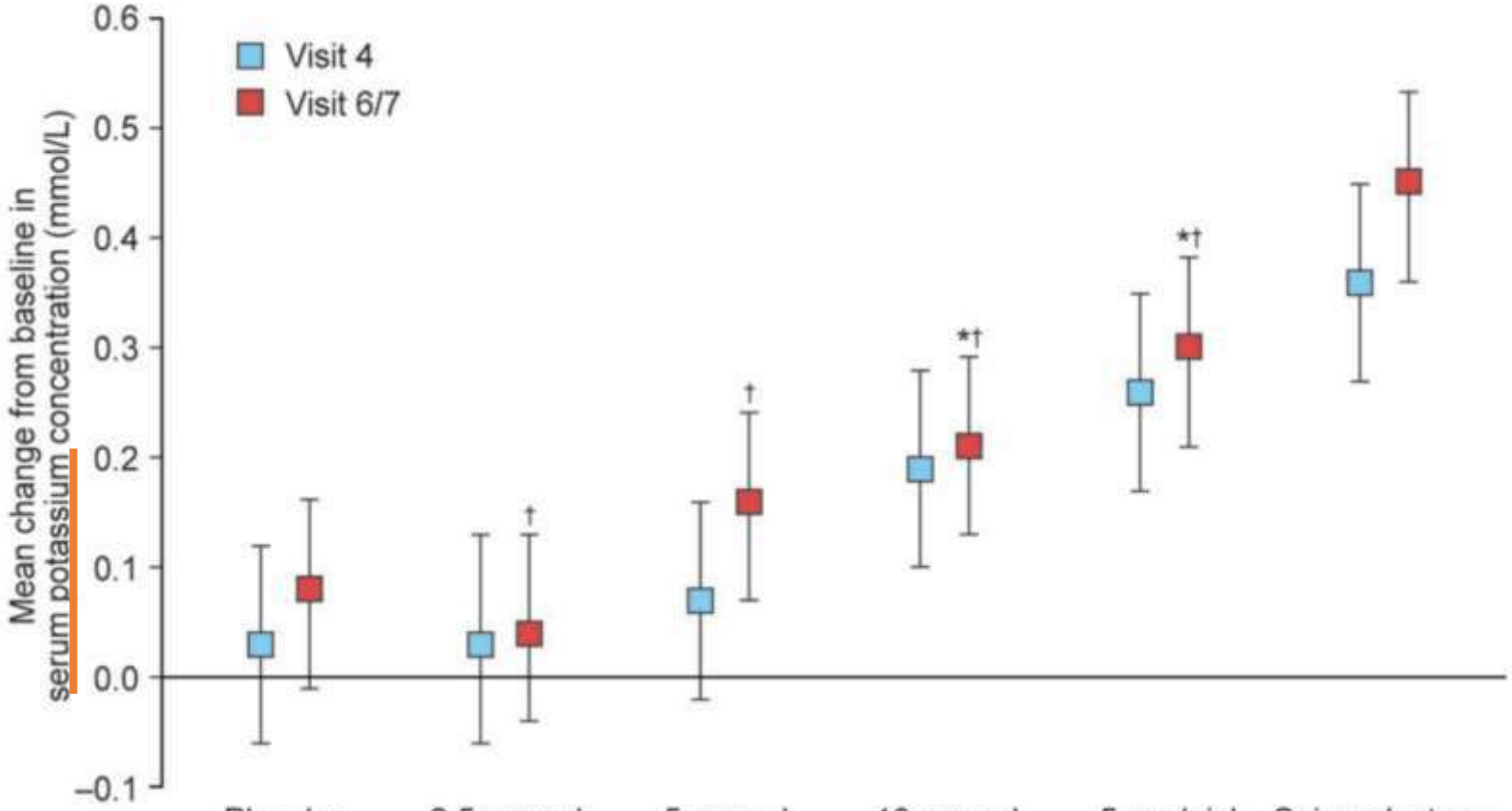
Spironolakton



Tamargo J et al. Semin Nephrol. 2014;34(3):285-306.


PRACTICAL
THEORETICAL

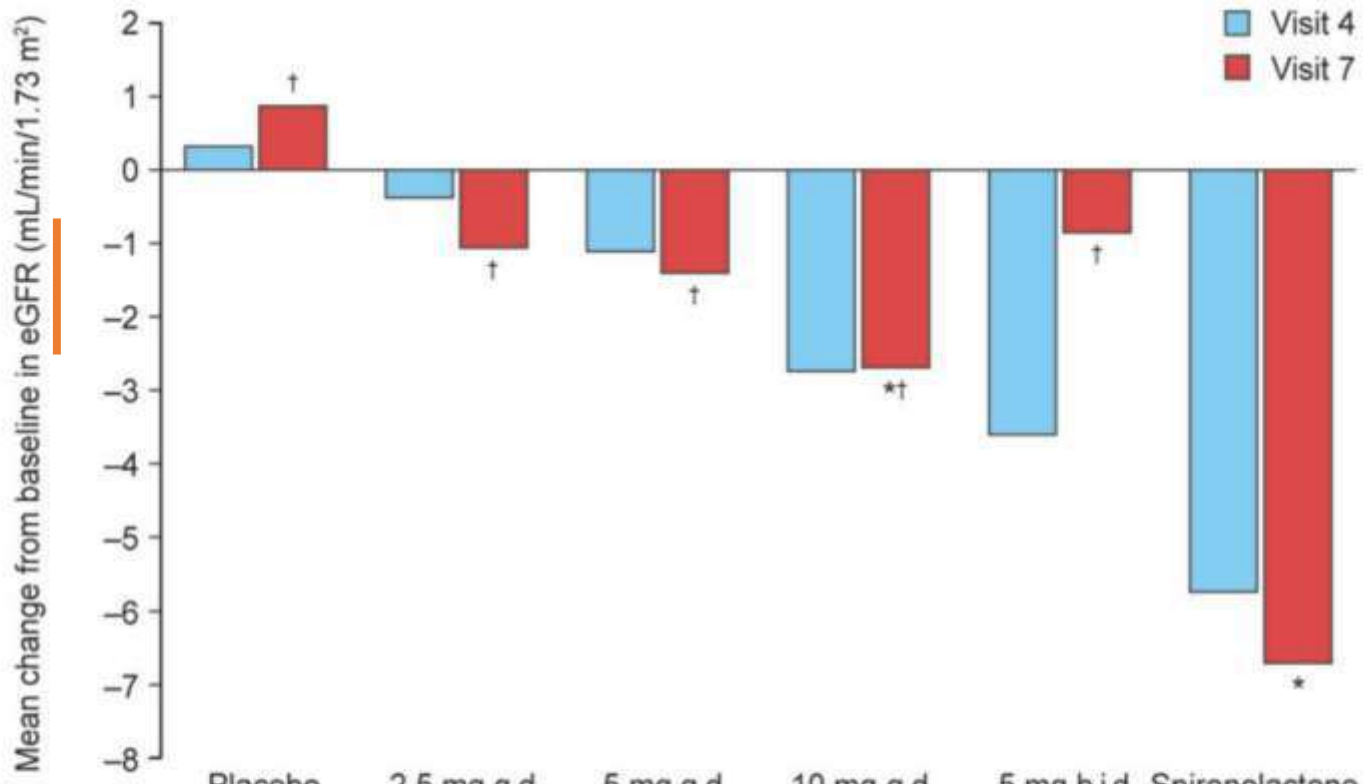
Finerenone was compared with spironolactone in the phase II ARTS study.



Visit 4, *n*	61	58	61	62	57	57
Visit 6, *n*	55	58	60	61	55	53
Visit 7, *n*	57	56	60	59	53	51

Pitt B, *et al*. *Eur Heart J* 2013;34:2453–2463

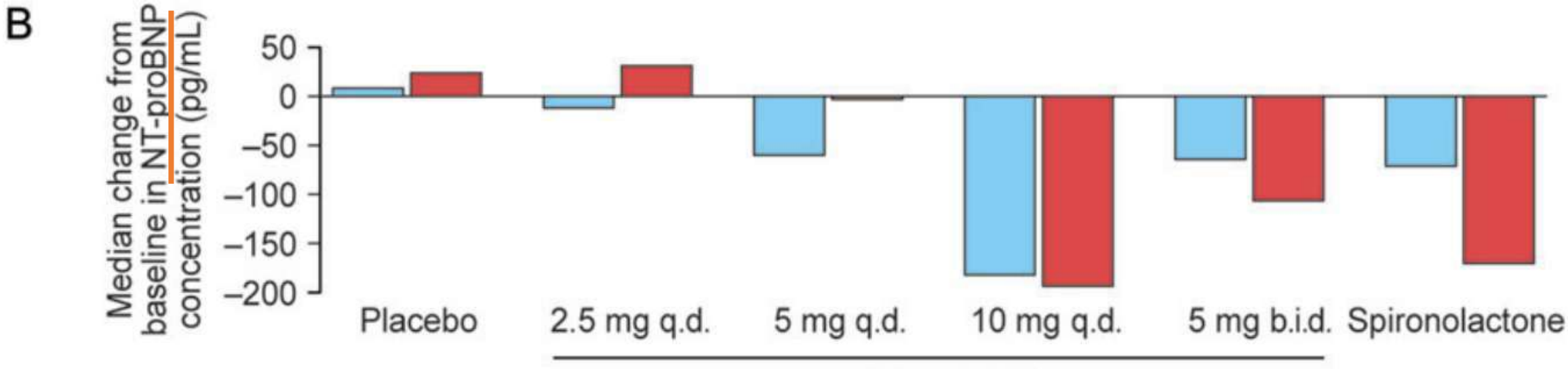
Finerenone was compared with spironolactone in the phase II ARTS study.



	Placebo	2.5 mg q.d.	5 mg q.d.	10 mg q.d.	5 mg b.i.d.	Spironolactone
		BAY 94-8862				
Visit 4, *n*	61	58	61	53	57	59
Mean	0.32	−0.38	−1.11	−2.74	−3.60	−5.73
SD	12.49	7.12	5.45	6.56	11.39	7.49
Visit 7, *n*	57	56	60	59	54	51
Mean	0.87	−1.06	−1.40	−2.69	−0.85	−6.70
SD	10.01	6.90	6.56	6.21	9.09	8.67

Pitt B, *et al*. *Eur Heart J* 2013;34:2453–2463

Finerenone was compared with spironolactone in the phase II ARTS study.



Pitt B, *et al*. *Eur Heart J* 2013;34:2453–2463

ARTS-HF Trial

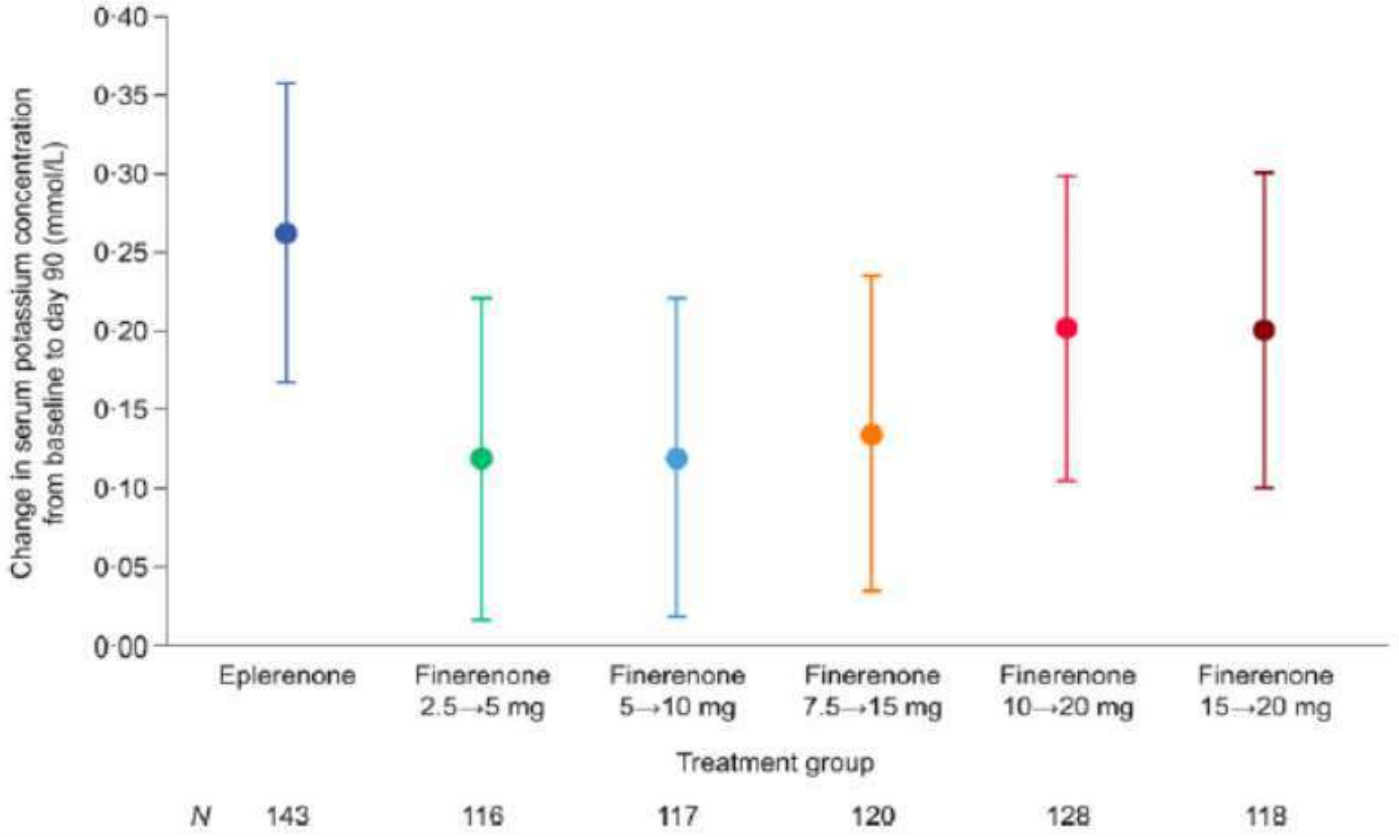


Figure 4 Mean change in serum potassium concentration from baseline to Day 90 in patients with worsening chronic heart failure with reduced ejection fraction receiving eplerenone or different doses of finerenone. Changes were assessed by analysis of covariance with the factors treatment group, comorbidities, mineralocorticoid receptor antagonist use at emergency presentation to hospital, region, and the baseline value as covariates.

European Heart Journal (2016) **37**, 2105–2114
doi:10.1093/eurheartj/ehw132

FASTTRACK CLINICAL RESEARCH
Heart failure/cardiomyopathy

A randomized controlled study of finerenone vs. eplerenone in patients with worsening chronic heart failure and diabetes mellitus and/or chronic kidney disease

ARTS-HF Trial

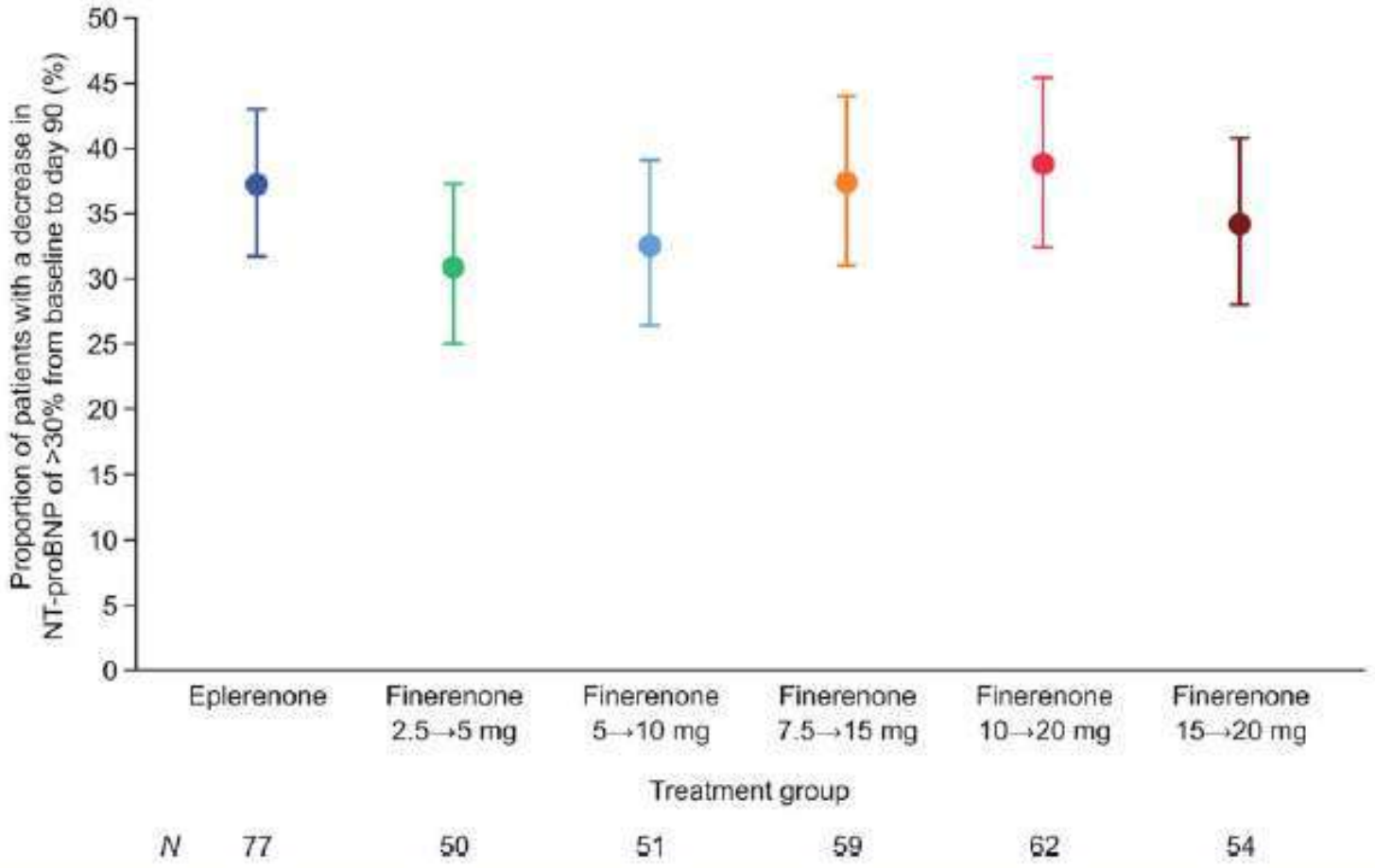


Figure 2 Proportion of patients with a decrease of >30% in plasma N-terminal pro-B-type natriuretic peptide concentration from baseline at Day 90 (full-analysis set). Patients who died prior to Day 90 or who experienced permanent (≥5 consecutive days) withdrawal of study drug after a cardiovascular hospitalization or emergency presentation for worsening chronic heart failure were counted as nonresponders for the primary efficacy analysis.

European Heart Journal (2016) **37**, 2105–2114
doi:10.1093/eurheartj/ehw132

FASTTRACK CLINICAL RESEARCH
Heart failure/cardiomyopathy

A randomized controlled study of finerenone vs. eplerenone in patients with worsening chronic heart failure and diabetes mellitus and/or chronic kidney disease

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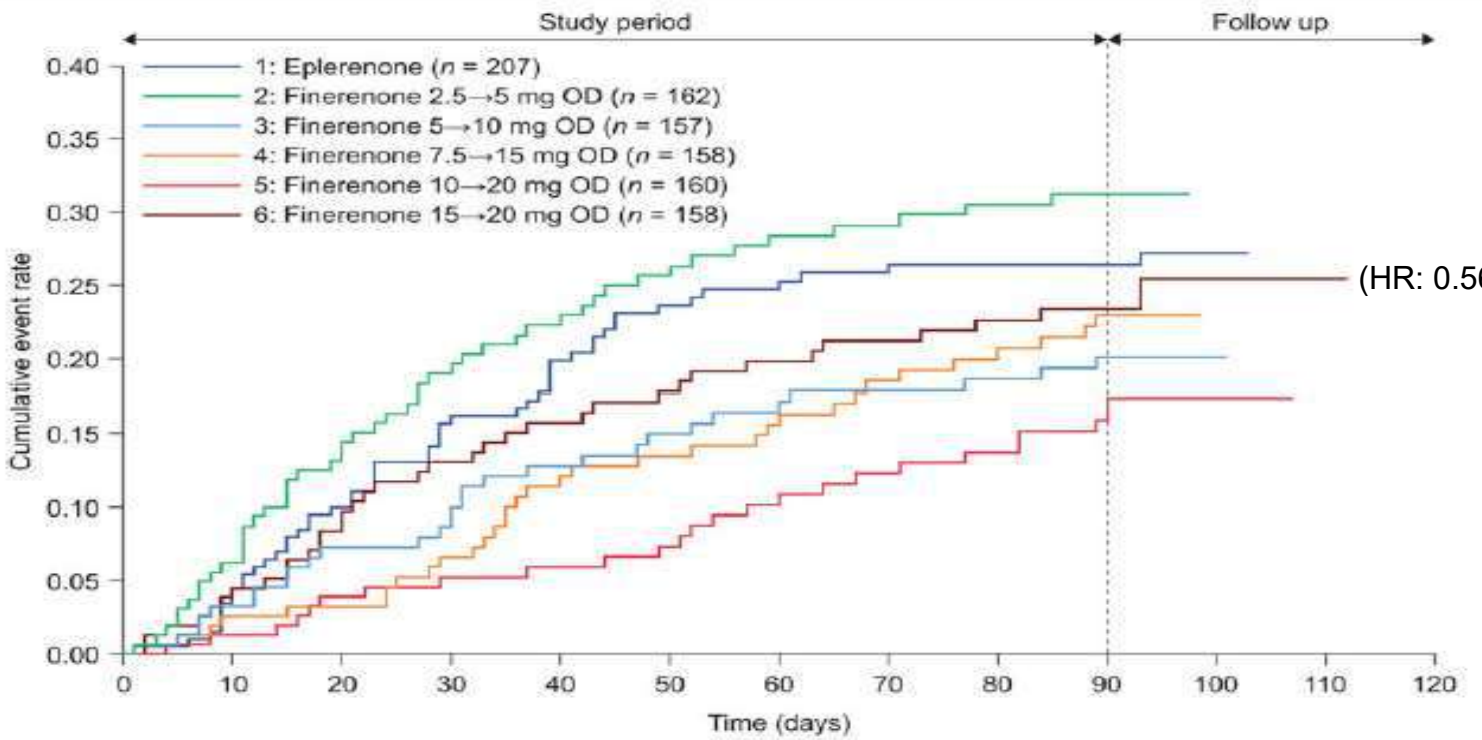
FASTTRACK CLINICAL RESEARCH
Heart failure/cardiomyopathy

A randomized controlled study of finerenone vs. eplerenone in patients with worsening chronic heart failure and diabetes mellitus and/or chronic kidney disease



(HR: 0.56; 95% CI: 0.35, 0.90).

Number of patients at risk

1	207	192	176	161	152	139	134	130	126	121	2	0	0
2	162	149	133	122	115	109	103	101	97	90	0	0	0
3	157	147	137	130	122	117	113	111	109	105	1	0	0
4	158	151	145	138	127	123	117	112	107	96	0	0	0
5	160	154	143	139	134	132	126	123	120	107	2	0	0
6	158	148	137	129	124	121	118	111	108	95	2	1	0

Figure 3 Mortality/morbidity outcomes in patients with worsening chronic heart failure with reduced ejection fraction receiving eplerenone or different doses of finerenone. Cumulative event rates of the composite endpoint of death from any cause, cardiovascular hospitalization, or emergency presentation for worsening chronic heart failure in the full-analysis set.

Next step

1. I will not restart MRA
2. I will start the same MRA at half dose (12.5mg)
3. I will start MRA at full dose
4. Any other ideas?

Case presentation

- Patient 63 yo male
- 2017 Bypass, ŞD+, XBÇ+
- LVEF =35%
- Furosemid 40mq, Spironolactone 25mq, Empagliflozin 10mq, Bisoprolol 2.5mq, Rosuvastatin 40mq, ARNI 24/26mq.
- 2024 January - admitted to hospital via bradycardia.

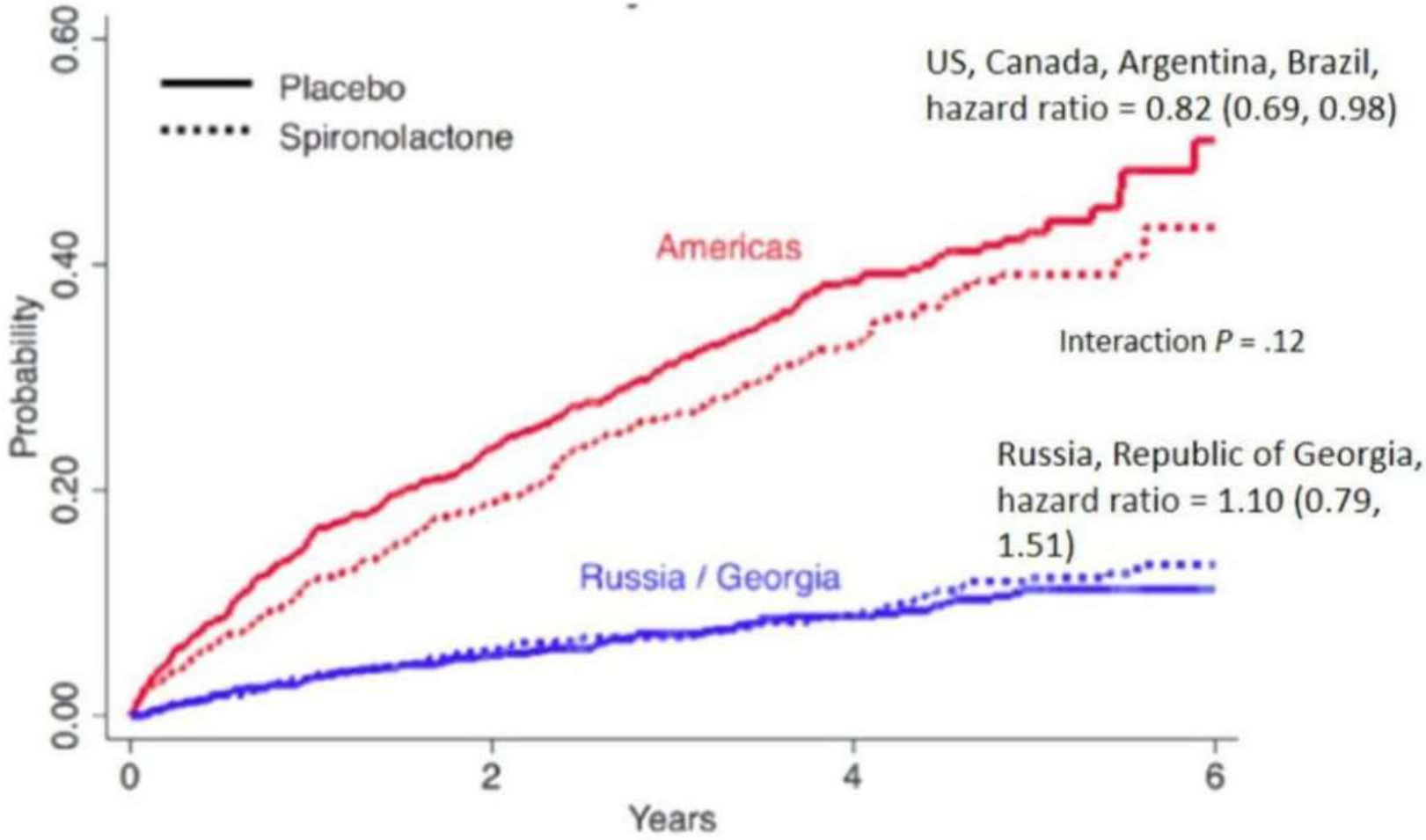
STOP SPİRONOLACTONE and START FINERENONE

Case presentation

IF

- Patient 63 yo male
- 2017 Bypass, ŞD+, XBÇ+
- LVEF =50% (HFpEF)
- Furosemid 40mq, Spironolactone 25mq, Empagliflozin 10mq, Bisoprolol 2.5mq, Rosuvastatin 40mq.
- 2024 January - admitted to hospital via bradycardia.

Impact of MRAs on Survival in HFpEF (TOPCAT)



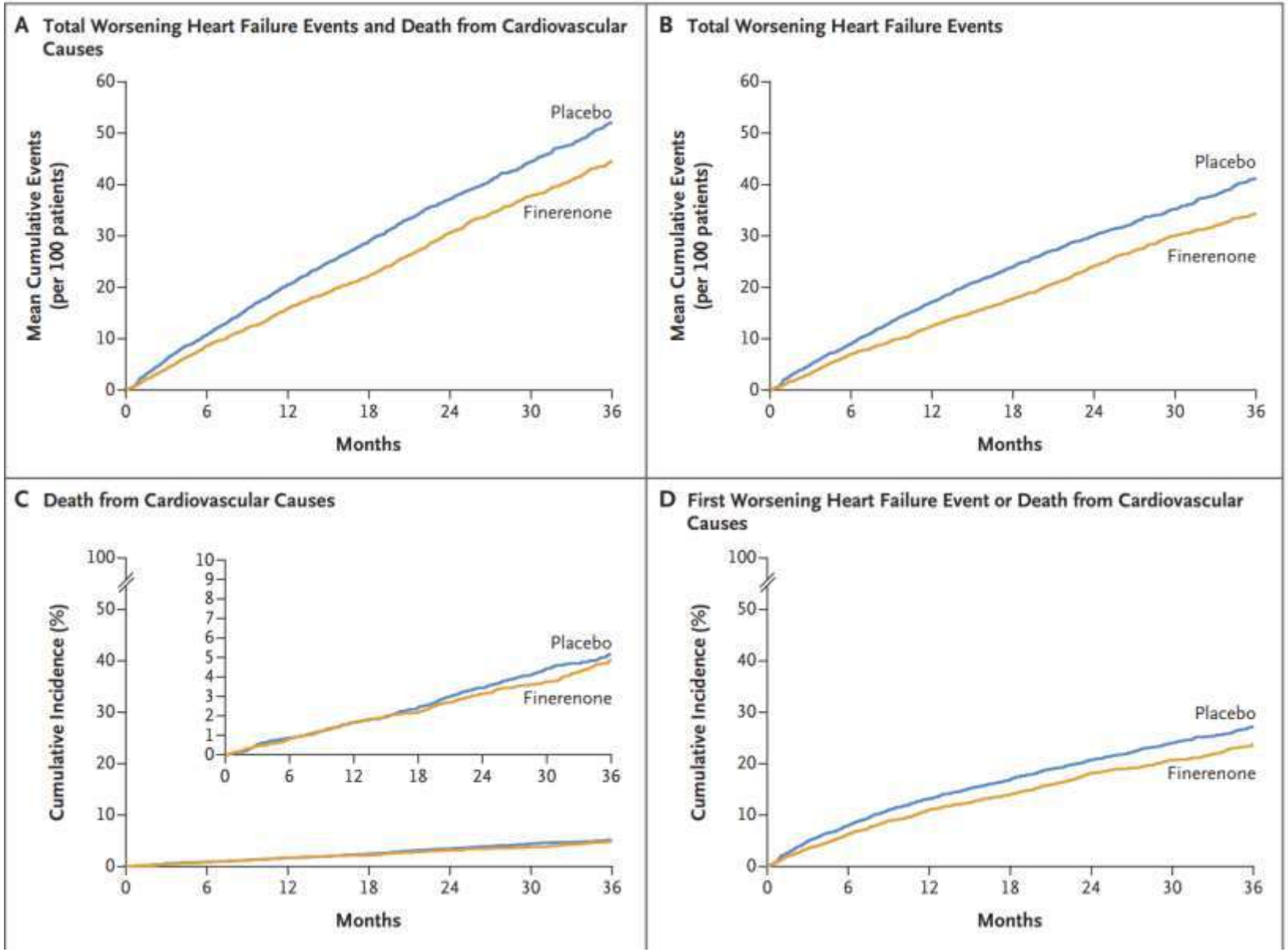
Pfeffer MA, et al. *Circulation*. 2015;131:34-42.

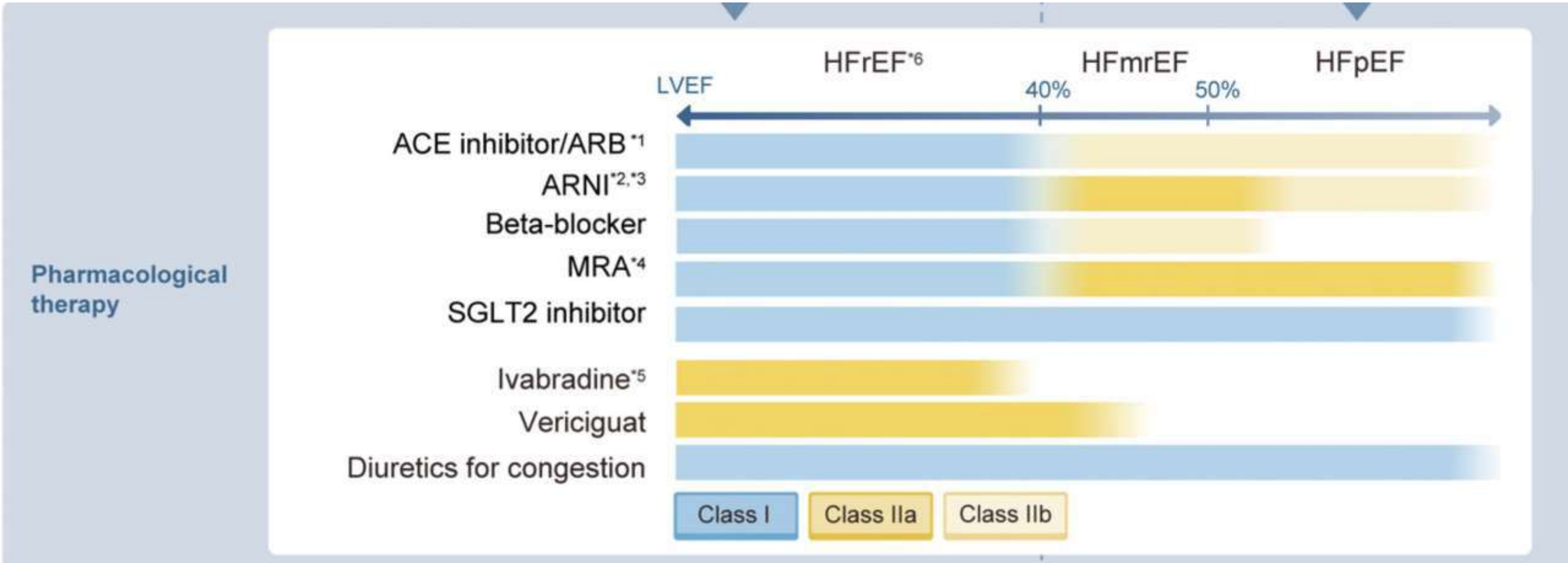
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 24, 2024 VOL. 391 NO. 16

Finerenone in Heart Failure with Mildly Reduced or Preserved Ejection Fraction

FINEARTS-HF Trial





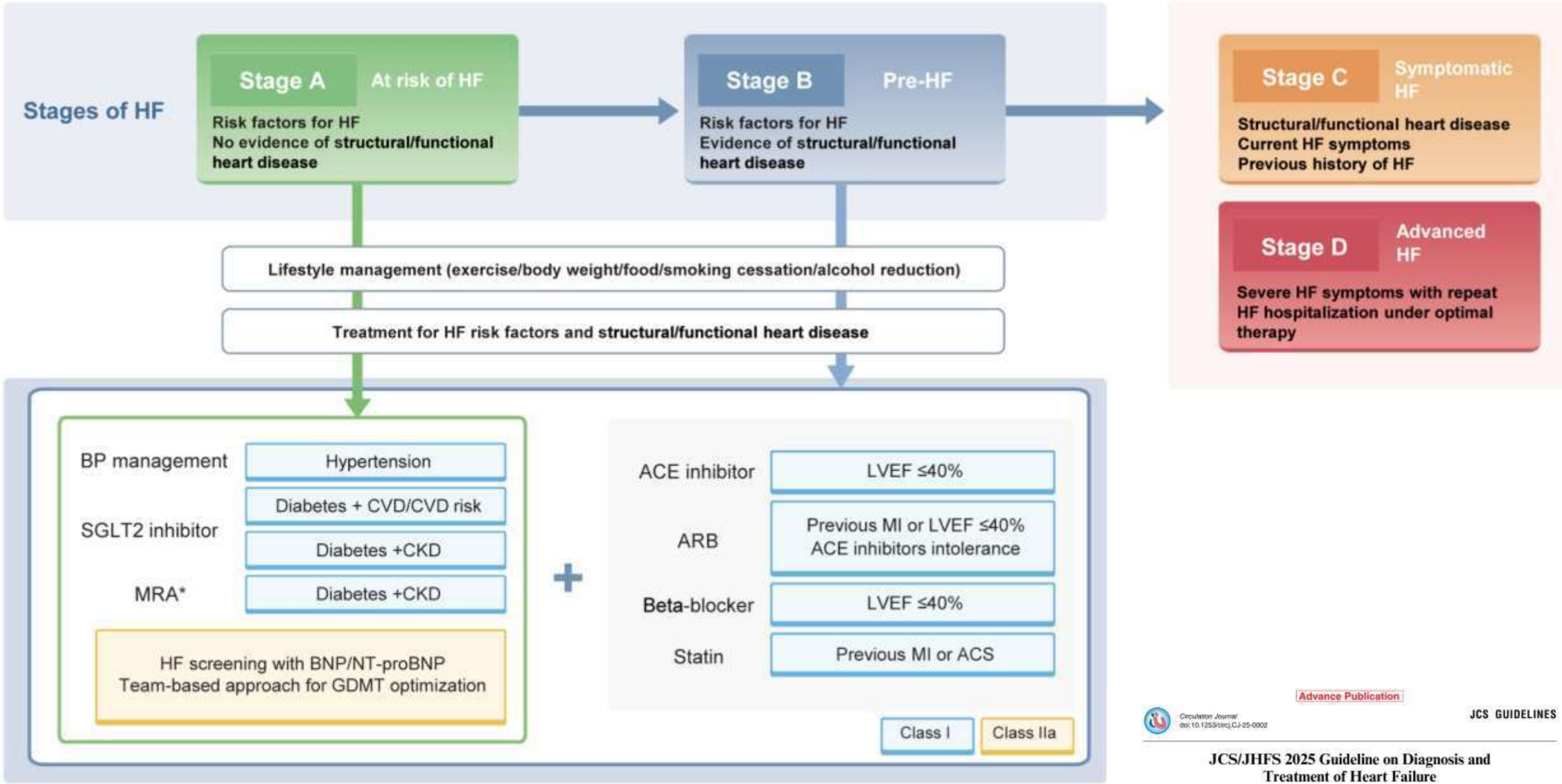
*4 In HFmrEF and HFpEF, finerenone is class Iia recommendation, and spironolactone and eplerenone are class IIb recommendation

Advance Publication
Circulation Journal
doi:10.1253/circj.CJ-25-0002
JCS GUIDELINES
JCS/JHFS 2025 Guideline on Diagnosis and Treatment of Heart Failure

Case presentation

IF

- Patient 63 yo male
- 2017 Bypass, ŞD+, XBÇ+
- LVEF =60% (No HF)
- Spironolactone 25mq, Empagliflozin 10mq, Bisoprolol 2.5mq, Rosuvastatin 40mq.
- 2024 January - admitted to hospital via bradycardia.



* Only indicated for finerenone

Advance Publication
Circulation Journal
doi:10.1253/circj.CJ-25-0002
JCS GUIDELINES

JCS/JHFS 2025 Guideline on Diagnosis and Treatment of Heart Failure


2015
2020
2025
2026
ARTS[2]
The MinerAlocorticoid Receptor antagonist Tolerability Study
FIDELIO-DKD[5]
Finerenone in reducing kiDnEy faiLure and disease prOgression in DKD
FINEARTS-HF[8]
FIND-CKD[10]
ARTS-DN[3]
MinerAlocorticoid Receptor AnTagonist Study In Diabetic Nephropathy
FIGARO-DKD[6]
Finerenone in reducinG cArdiovascular moRtality and mOrbidty in DKD
CONFIDENCE[9]
FIONA[11]
ARTS-HF[4]
MinerAlocorticoid Receptor AnTagonist Study In Heart Failure
FIDELITY[7]

2020

FIDELIO-DKD[5]

FInerenone in reducing ki**D**nEy fai**L**ure and d**I**sease pr**O**gression in DKD

FIGARO-DKD[6]

FInerenone in reducin**G** c**A**rdiovascular mo**R**tality and m**O**rbidity in DKD

FIDELITY[7]

inist

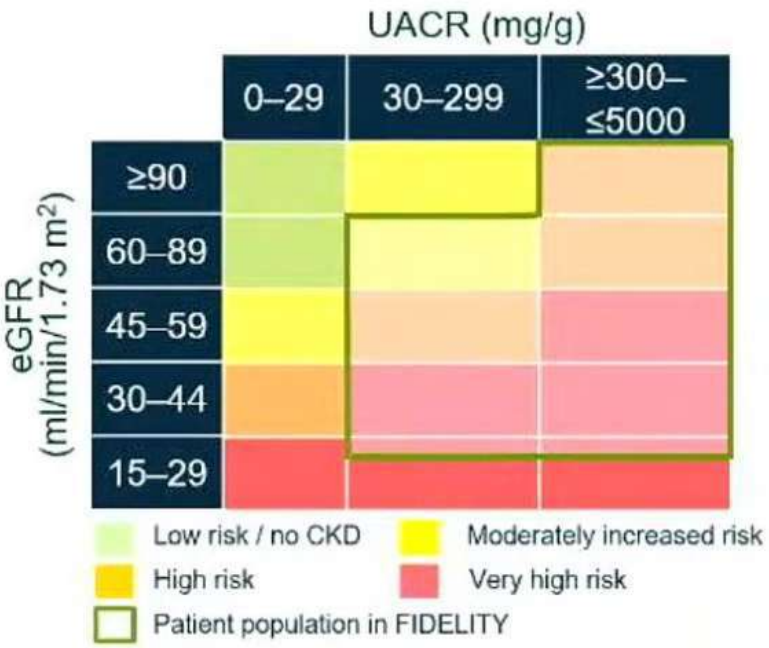
DM and CKD

FİDELİTY geniş, öncədən təyin olunmuş, FİDELİO-DBX və FİGARO-DBX tədqiqatlarını özündə birləşdirən təhlildir

13,171 randomizə olunmuş XBX/ŞD2T xəstəsi

Əsas kriteriyalar

- ✔ ŞD2T
- ✔ XBX
- ✔ Maksimal mono RAASi
- ✔ Serum [K+] ≤4.8 mmol/l
- ✘ Simptomatik AFaÜÇ



Broad disease spectrum
Robust data in both early disease and late disease

CV Composite
Time to CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF

57% eGFR kidney composite
Time to kidney failure, sustained ≥57% decrease in eGFR from baseline, or renal death

DM and CKD

FİNERON: KV hadisələr riskini azaltmasını sübut etdi

Standart müalicəyə əlavə olaraq

13% RRR
vs placebo

HR=0.87
(95% CI: 0.76-0.98)
P=0.026

2.1% ARR[16]
(95% CI: 0.4-3.8)

NNT: 47[16]
(95% CI: 26-266)

İlkin mürəkkəb son nöqtənin qarşısnı alınması

42 ay

FİGARO-DKD tədqiqatında erkən (1-2) mərhələli XBX xəstələrini yer aldı (eGFR ≥60 ml/dəq/1.73 m^2 + albuminuriya)

İlkin mürəkkəb son nöqtə: KV ölüm, qeyri-fatal Mİ, qeyri-fatal insult və ya ÜÇ hospitalizasiya

Müalicənin effekti əsasən ÜÇ-dən hospitalizasiya, həmçinin KV ölümə təsir ilə ölçüldü

Fineron qeyri-fatal insult riskinin azalması üçün nəzərdə tutulmamışdır

DM and CKD

FİNERON: XBX-nin proqressivləşməsinin azalmasını sübut etdi

FİDELİO-DKD tədqiqatında son (3-4) mərhələli XBX xəstələrini yer aldı (eGFR <60 ml/dəq/1.73 m^2 + albuminuriya)

İlkin mürəkkəb son nöqtə: böyrək çatışmazlığı, eGFR-in ≥40% davamlı azalması və ya böyrək ölümü

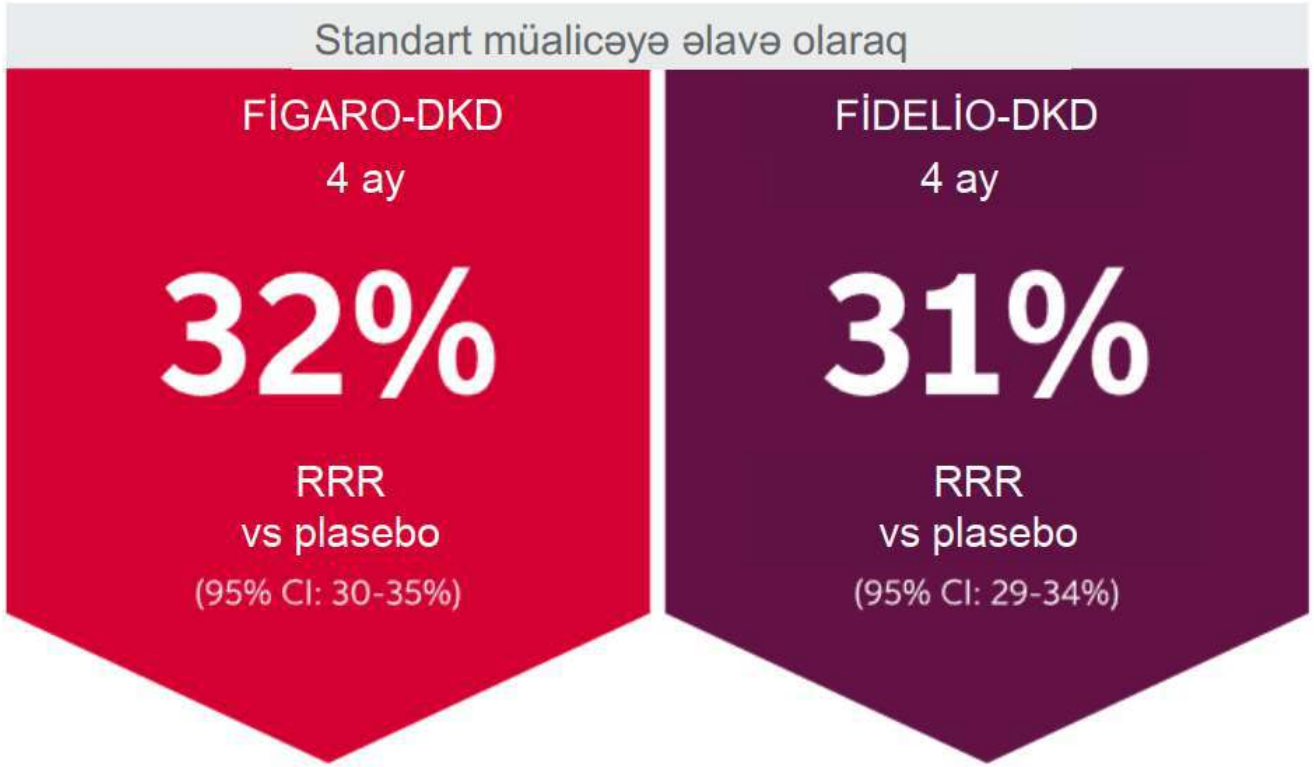
Tədqiqat zamanı çox az sayda böyrək ölümü rastlandı

FİGARO-DKD –dən RENAL NƏTİCƏLƏR

İkincili mürəkkəb son nöqtə olan böyrək çatışmazlığı, eGFR-in ≥40% davamlı azalması və ya böyrək ölümü
Fineron qəbul edən 350 xəstədə və 395 plasebo alan xəstədə əhəmiyyətli dərəcədə fərq olmamışdır

DM and CKD

FİNERON plasebo ilə müqayisədə XBX-nin geniş diapazonunda UACR-ni aşağı saldı



*Remained stable for the duration of the trials.[13]

Finerenone and new-onset diabetes in heart failure: a prespecified analysis of the FINEARTS-HF trial

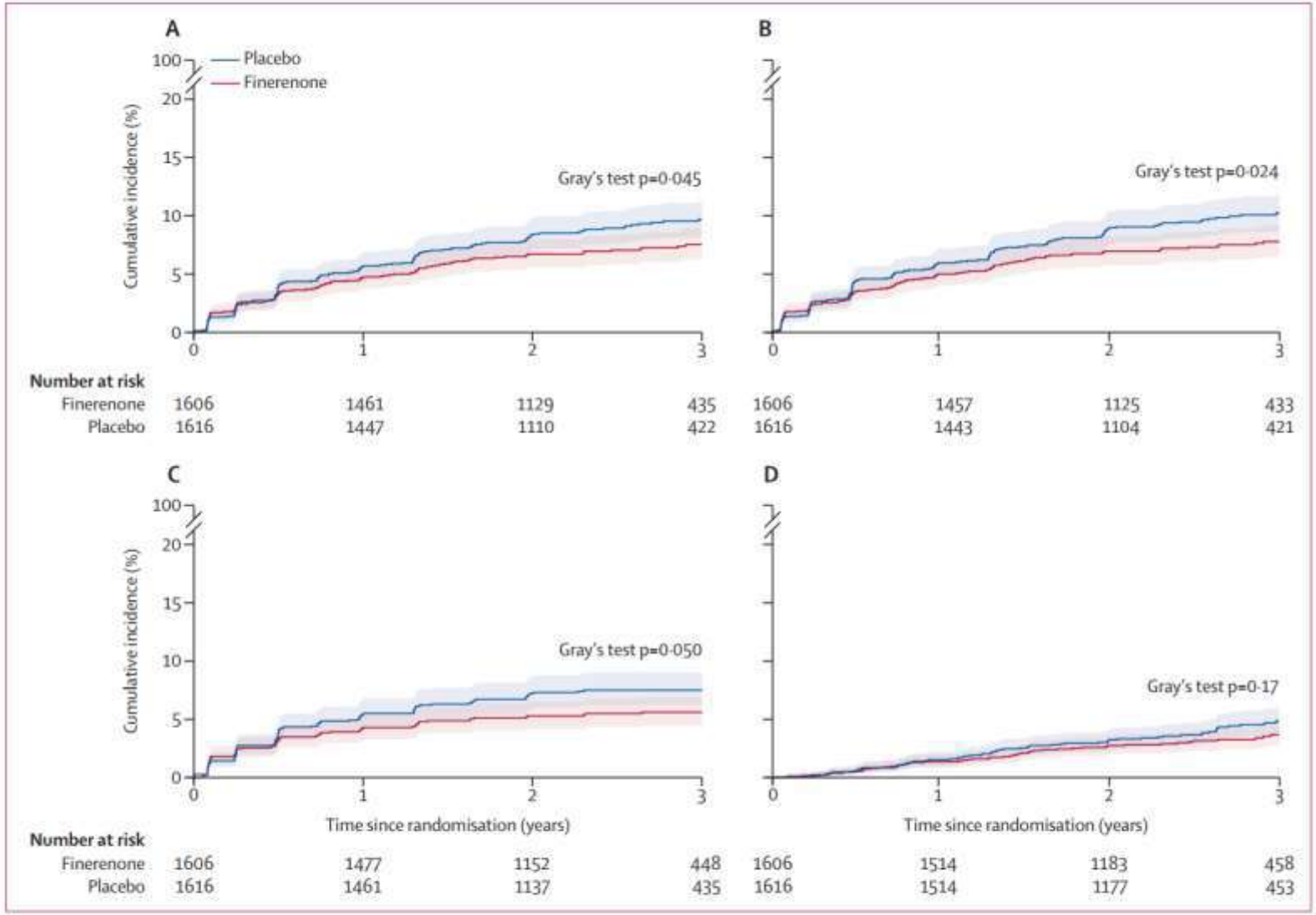
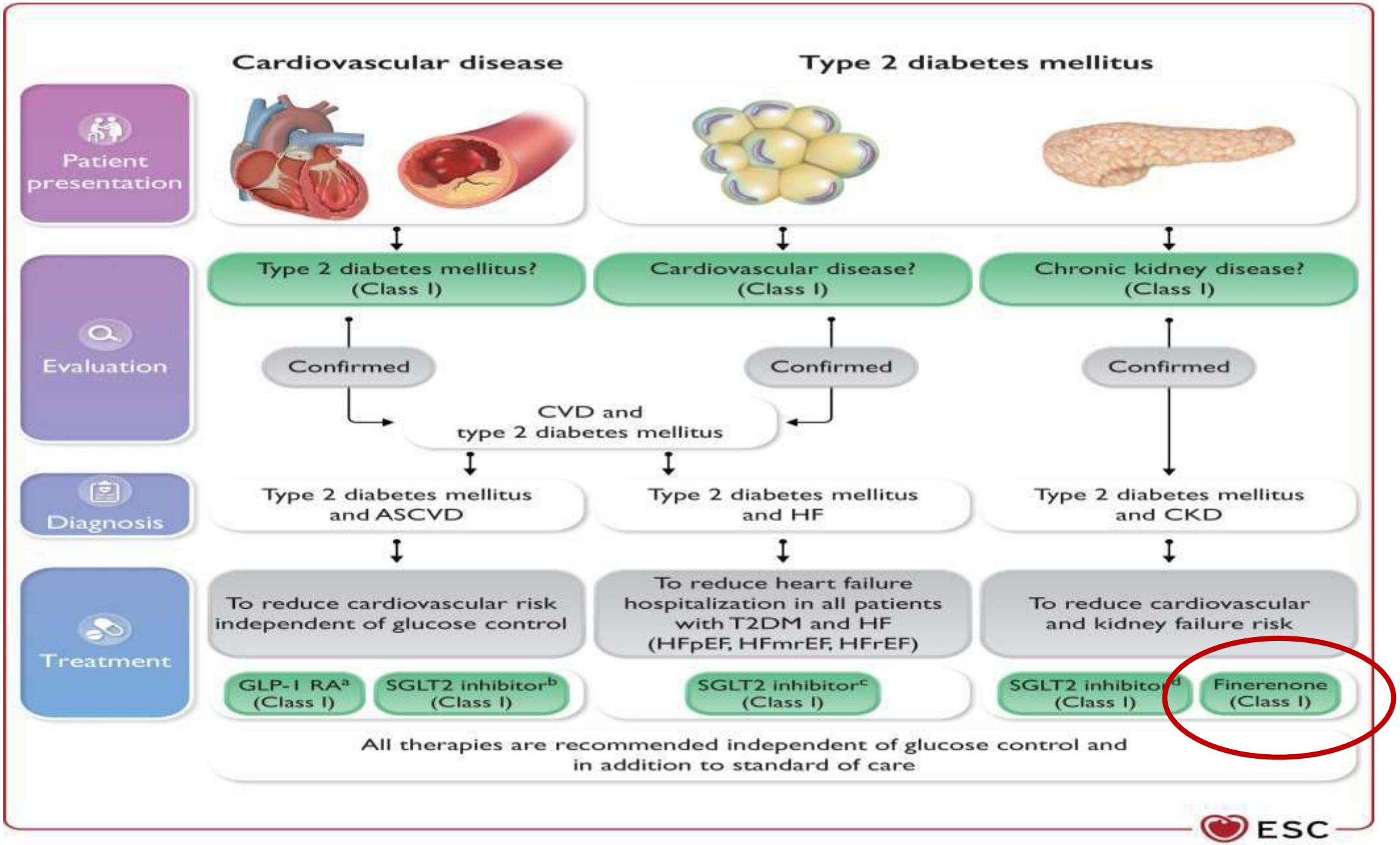
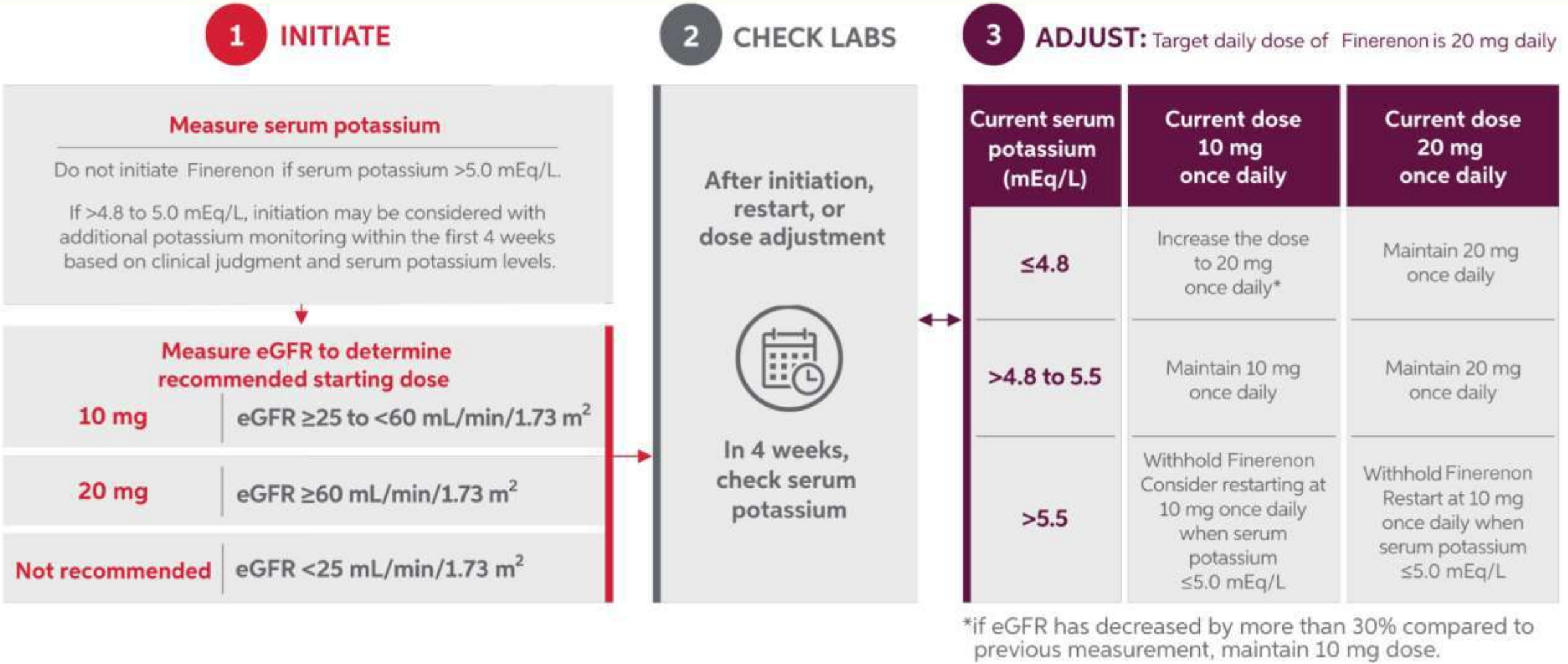


Figure 2: **Effect of finerenone compared with placebo on new-onset diabetes in participants without diabetes at baseline**
HbA_{1c} measurements or initiation of glucose-lowering drugs excluding (A) and including (B) SGLT2 inhibitors, HbA_{1c} measurements only (C), and initiation of glucose-lowering drugs excluding SGLT2 inhibitors (D). Shaded area represents 95% CI.


Cardiovascular disease
Type 2 diabetes mellitus
Patient presentation
Evaluation
Diagnosis
Treatment
Type 2 diabetes mellitus? (Class I)
Cardiovascular disease? (Class I)
Chronic kidney disease? (Class I)
Confirmed
Confirmed
Confirmed
CVD and type 2 diabetes mellitus
Type 2 diabetes mellitus and ASCVD
Type 2 diabetes mellitus and HF
Type 2 diabetes mellitus and CKD
To reduce cardiovascular risk independent of glucose control
To reduce heart failure hospitalization in all patients with T2DM and HF (HFpEF, HFmrEF, HFrEF)
To reduce cardiovascular and kidney failure risk
GLP-1 RA[a] (Class I)
SGLT2 inhibitor[b] (Class I)
SGLT2 inhibitor[c] (Class I)
SGLT2 inhibitor[d] (Class I)
Finerenone (Class I)
All therapies are recommended independent of glucose control and in addition to standard of care
ESC

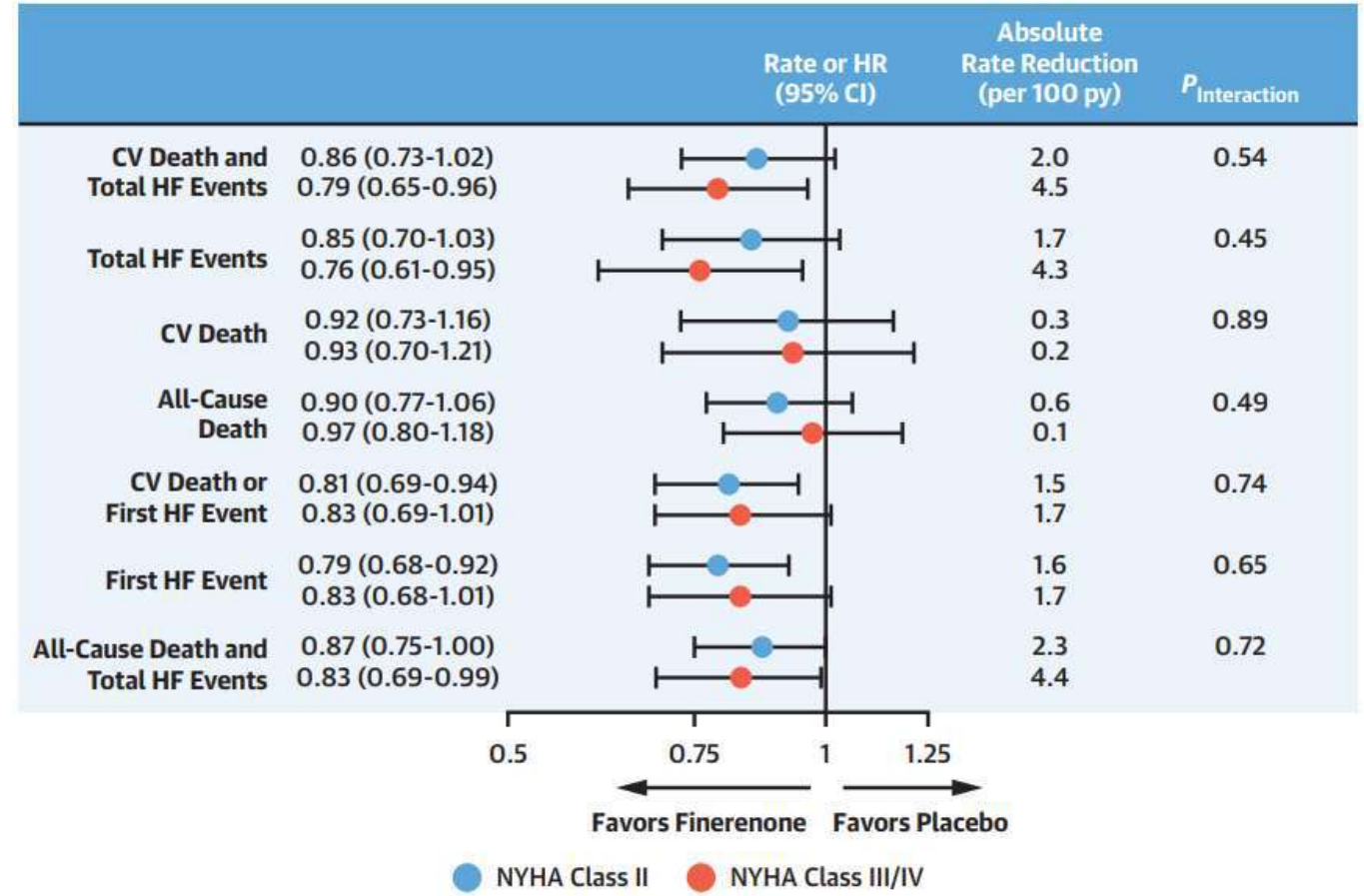
Finerenon dosing



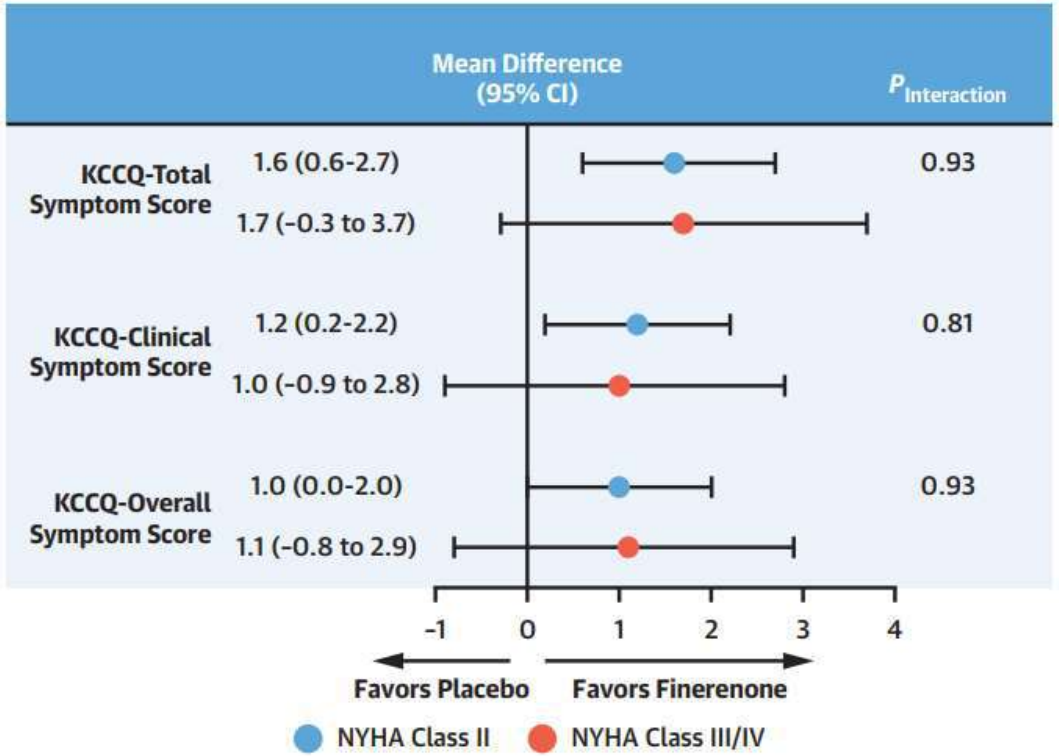
Finerenon and NYHA classes

Finerenone and NYHA Functional Class in Heart Failure: The FINEARTS-HF Trial

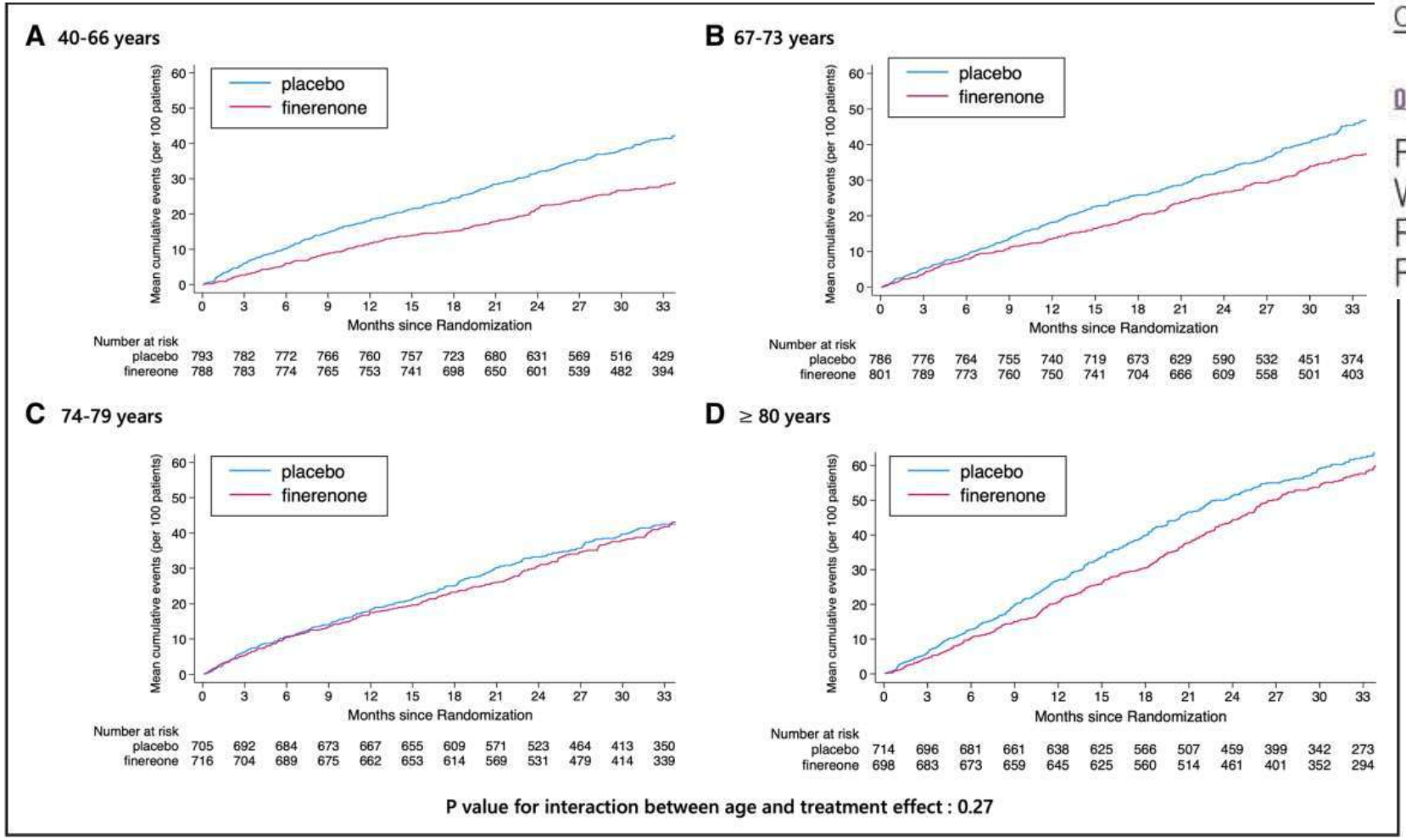
Finerenone Reduced Cardiovascular Death and Total HF Events Irrespective of NYHA Functional Class, With Greater Absolute Benefits in Participants with Worse NYHA Functional Class



Treatment Benefits of Finerenone on Patient-Reported HF-Related Health Status Were Consistent Irrespective of NYHA Functional Class



Finerenon outcomes by age



Circulation: Heart Failure

ORIGINAL ARTICLE

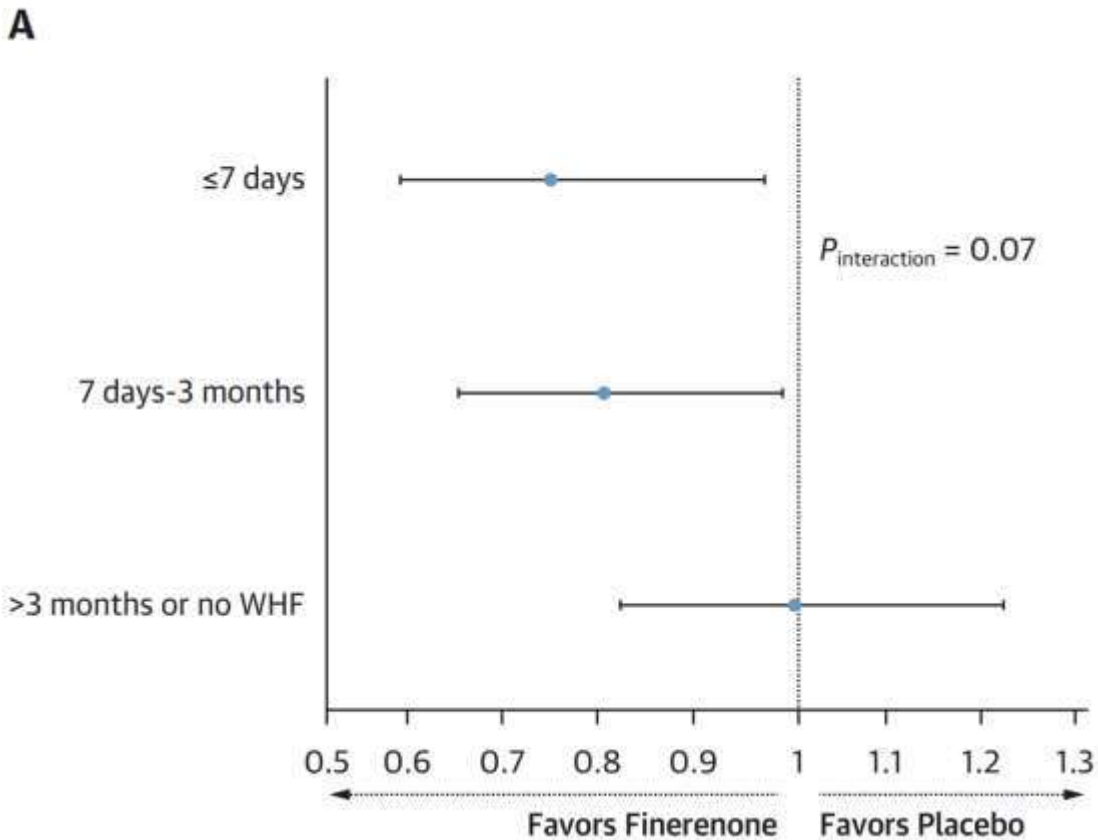
Finerenone Improves Outcomes in Patients With Heart Failure With Mildly Reduced or Preserved Ejection Fraction Irrespective of Age: A Prespecified Analysis of FINEARTS-HF

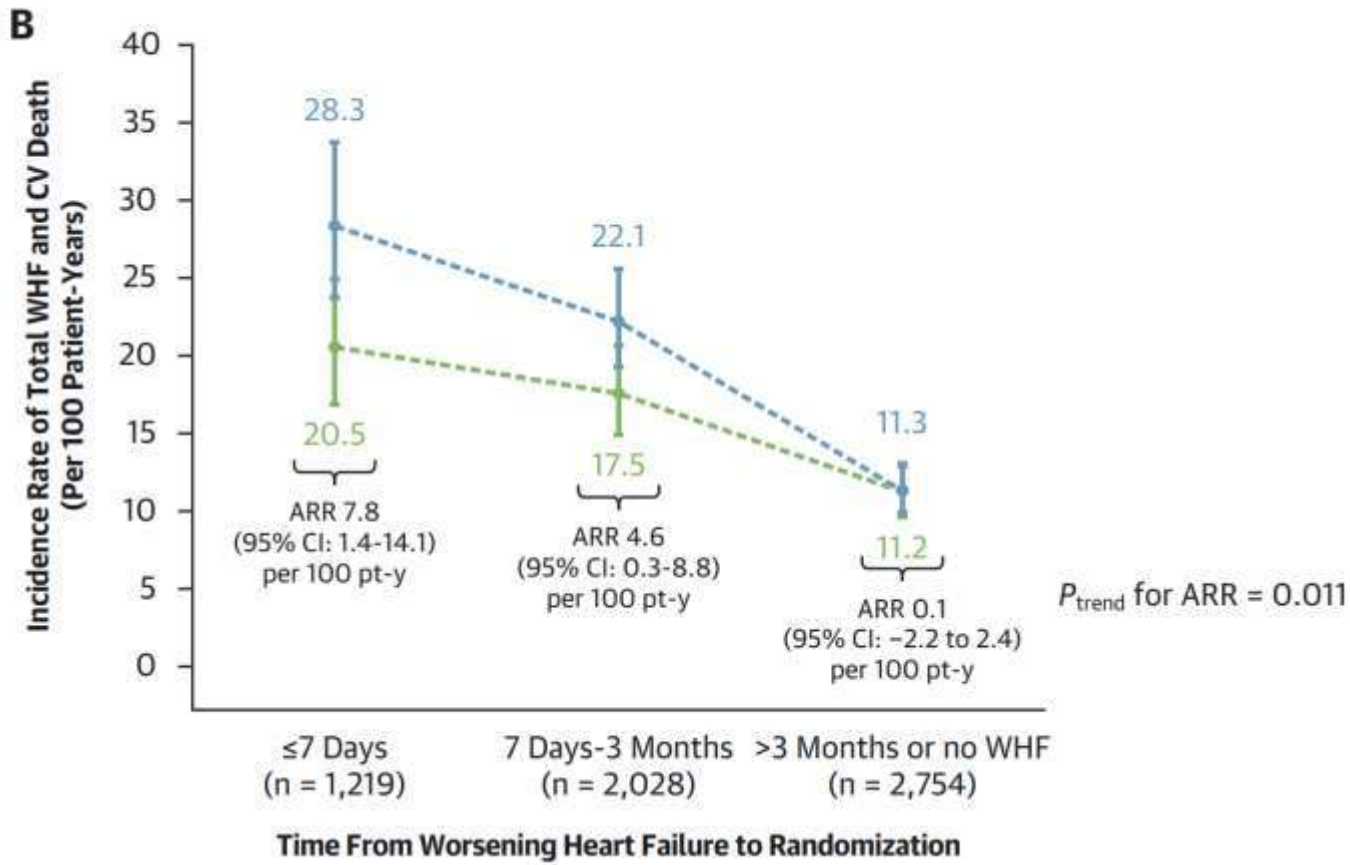
Figure 2. Effect of finerenone on the primary composite outcome according to age category (quartiles) in FINEARTS-HF (Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients With Heart Failure).
The figures show the Nelson-Aalen estimate of the cumulative hazard for the primary composite end point according to age categorized by quartile: 40 to 66 years (**A**), 67 to 73 years (**B**), 74 to 79 years (**C**), and ≥80 years (**D**). The blue solid lines indicate the placebo group, and the red solid lines indicate the finerenone group.

Finerenone in Patients With a Recent Worsening Heart Failure Event

The FINEARTS-HF Trial

Akshay S. Desai, MD, MPH,[a] Muthiah Vaduganathan, MD, MPH,[a] Brian L. Claggett, PhD,[a] Ian J. Kulac, MS,[a]





https://doi.org/10.1016/j.jacc.2024.09.004

Finerenone in Patients With a Recent Worsening Heart Failure Event

The FINEARTS-HF Trial

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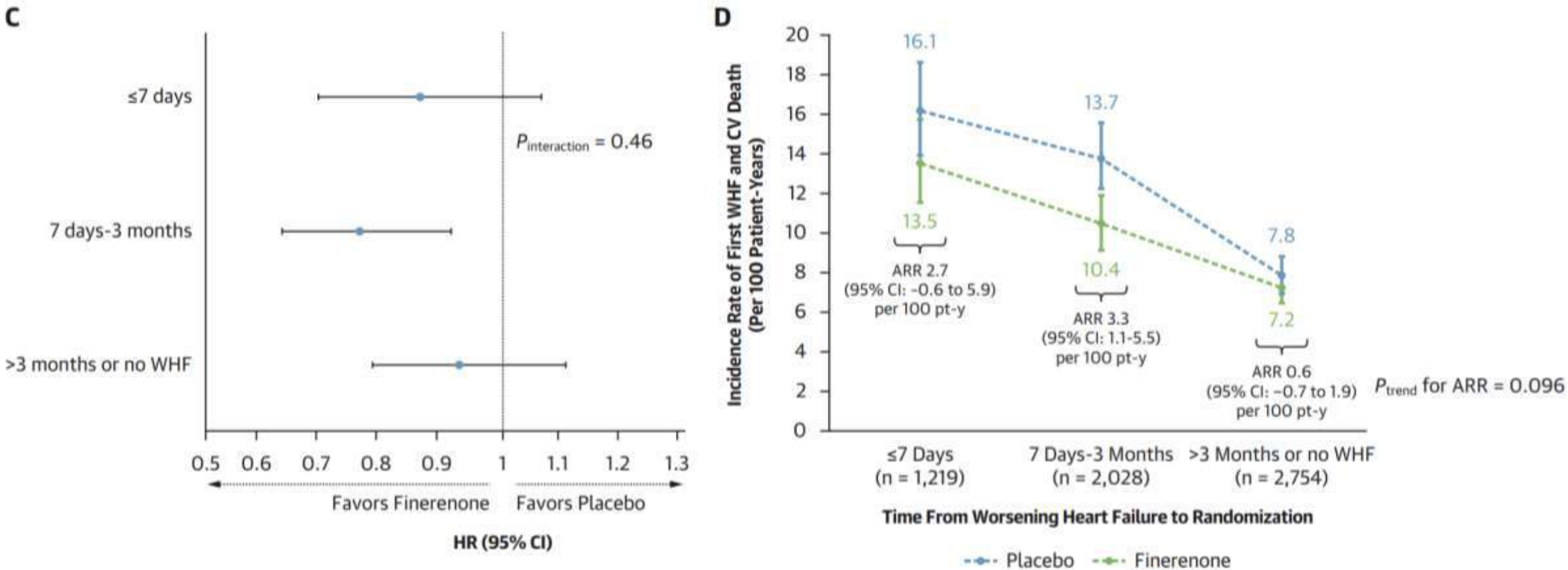


Desai AS, et al. JACC. 2025;85(2):106-116.

https://doi.org/10.1016/j.jacc.2024.09.004

Heart Failure 2025
World Congress on Acute Heart Failure

Blinded Withdrawal of Finerenone after Long-Term Treatment in FINEARTS-HF

Muthiah Vaduganathan, MD MPH
Brigham and Women's Hospital
Harvard Medical School
Boston, Massachusetts, USA

On Behalf of Co-Investigators: Brian L. Claggett; Jacob A. Udell; Akshay S. Desai; Pardeep S. Jhund; Alasdair D Henderson; James Lay-Flurrie; Flaviana Amarante; Andrea Glasauer; Carolyn SP Lam; Michele Senni; Sanjiv J Shah; Adriaan A. Voors; Faiez Zannad; Bertram Pitt; John JV McMurray; Scott D. Solomon

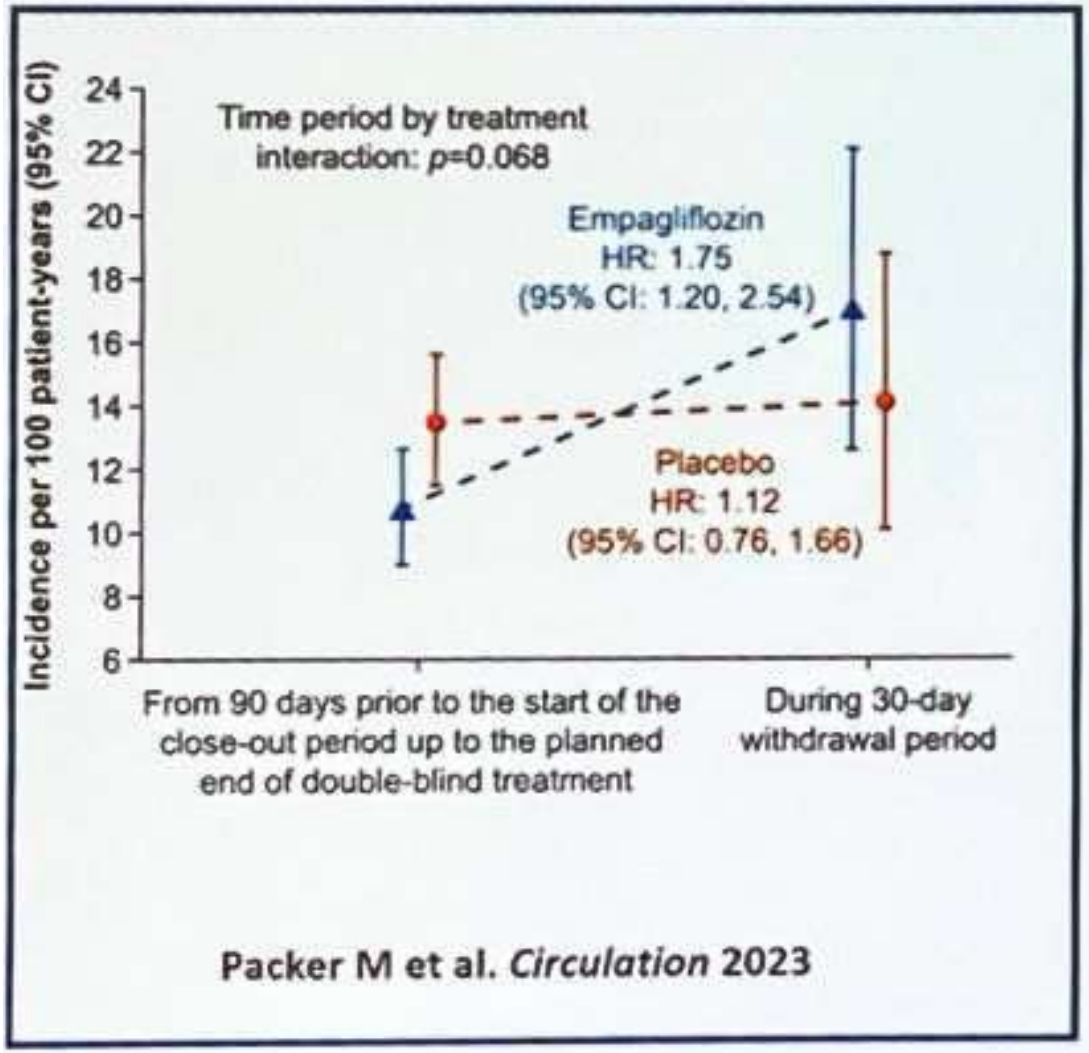
@mvaduganathan

FINEARTS-HF
FINerenone trial to investigate Efficacy and sAfety superioR to placebo in paTientS with Heart Failure

Disclosures: American Regent, Amgen, AstraZeneca, Bayer AG, Baxter Healthcare, BMS, Boehringer Ingelheim, Chiesi, Cytokinetics, Fresenius Medical Care, Galmed, Idorsia Pharmaceuticals, Impulse Dynamics, Lexicon Pharmaceuticals, Merck, Milestone Pharmaceuticals, Novartis, Novo Nordisk, Occlutech, Pharmacosmos, Relypsa, Roche Diagnostics, Sanofi, and Tricog Health

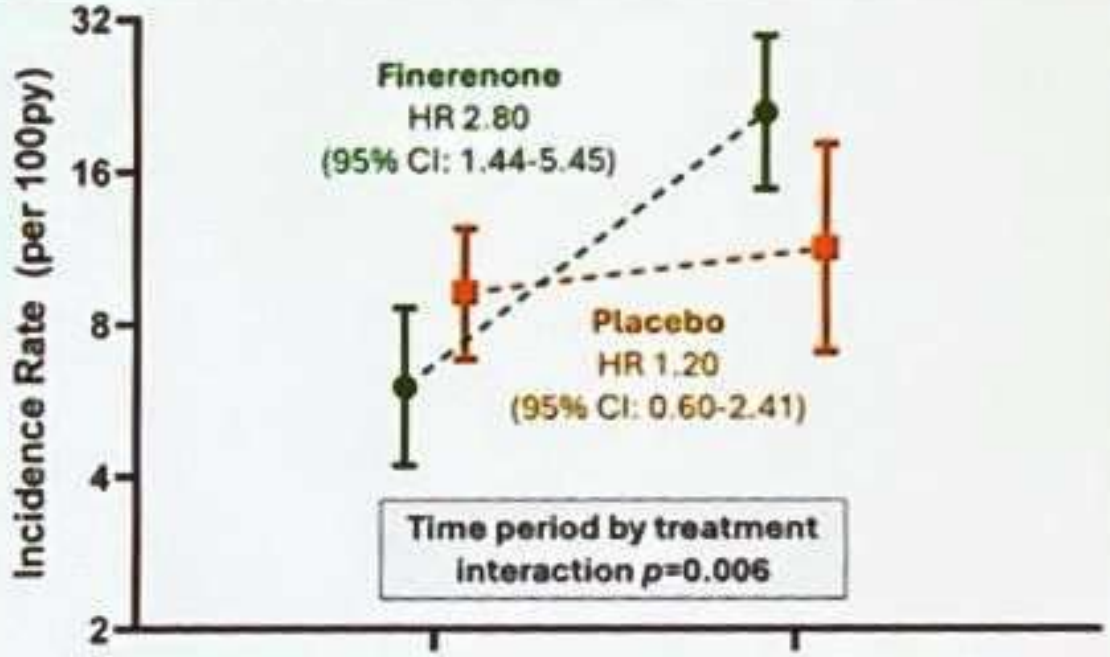
Muthiah Vaduganathan
USA

EMPEROR: Withdrawal of SGLT2i



Packer M et al. *Circulation* 2023

FINEARTS-HF: Withdrawal of nsMRA



Vaduganathan M et al. *JACC* 2025

Cost-effectiveness of finerenone in chronic kidney disease associated with type 2 diabetes in The Netherlands

Sara W. Quist[1,2*], Alexander V. van Schoonhoven[1,2], Stephan J. L. Bakker[3], Michał Pochopień[4], Maarten J. Postma[1,5], Jeanni M. T. van Loon[6] and Jeroen H. J. Paulissen[1,2]

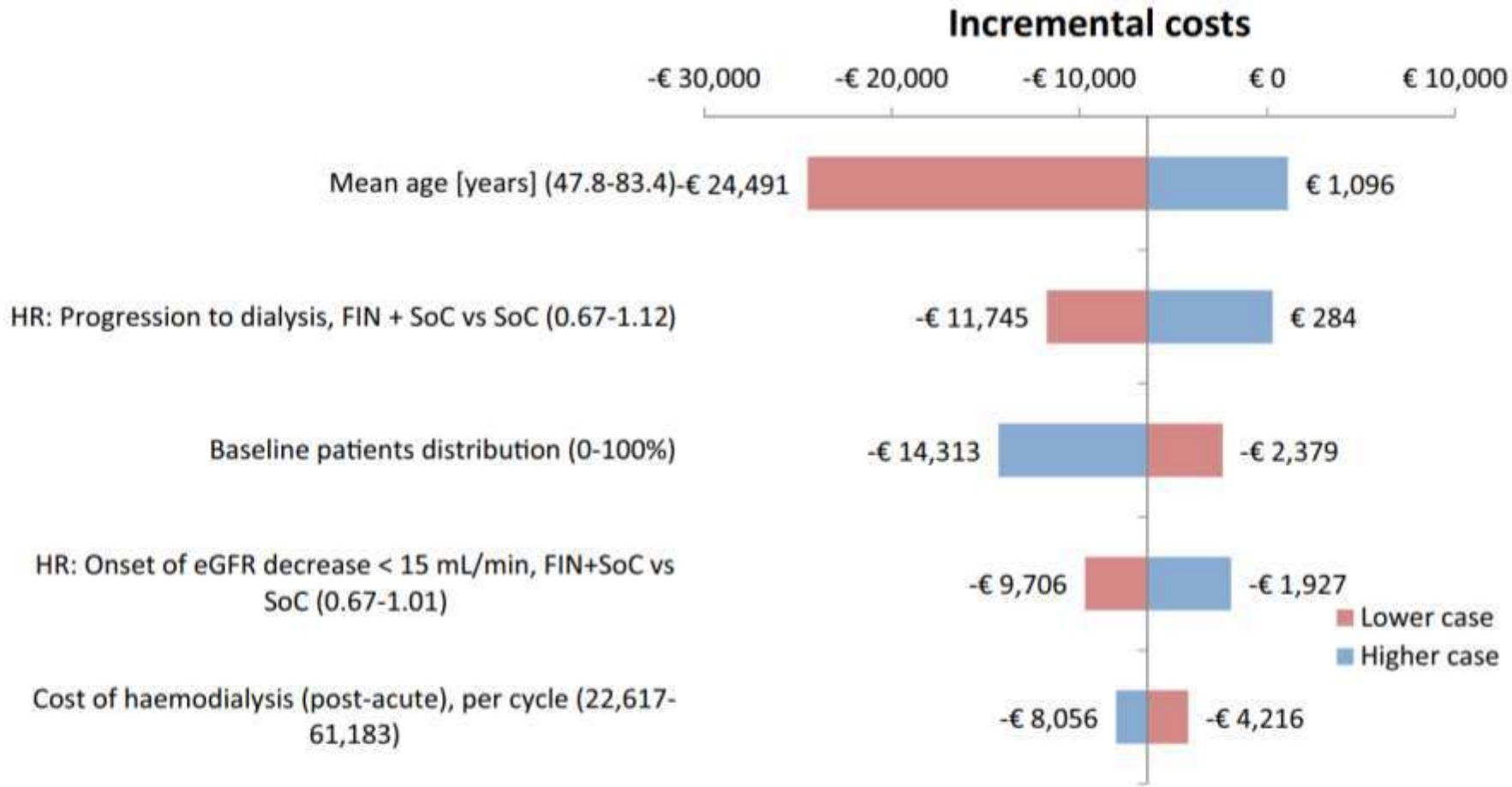


Fig. 3 Tornado diagram presenting parameters with most influence on incremental QALYs an costs Key: The lower case presents the outcome for the 2.5% CI of the distribution. The higher case presents the outcome of the 97.5% CI of the distribution. *CKD* chronic kidney diseas, *CV* cardiovascular event; *FIN* finerenone; *HR* hazard ratio, SoC standard of care

Dərmanın qiyməti deyil pasientin həyatı önəmlidir


תודה
Dankie
Gracias
Спасибо
شكراً
Merci
Takk
Köszönjük
Terima kasih
Grazie
Dziękujemy
Dėkojame
Ďakujeme
Vielen Dank
Paldies
Kiitos
Täname teid
谢谢
Təşəkkür edirəm
Tak
感謝您
Obrigado
Teşekkür Ederiz
감사합니다
Σας ευχαριστούμε
ขอบคุณ
Bedankt
Děkujeme vám
ありがとうございます
Tack