Digitales Forum Herz und Niere

Herz - Retter & Nieren - Freund
zwei Fachkreise im Dialog mit Ihnen

01.02.2023

Online-Fortbildung

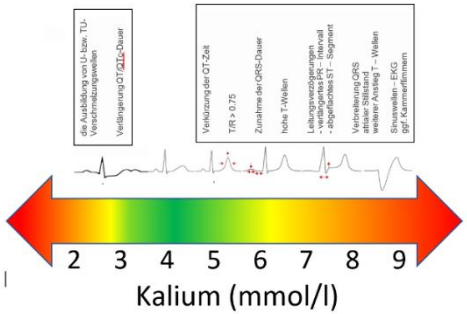
FRESENIUS MEDICAL CARE
NEPHROLOGICA DEUTSCHLAND GMBH

VIFOR PHARMA DEUTSCHLAND GMBH

Der kardio-renale Patient im Praxisalltag:

Aktuelles zur Hyperkaliämie und zum Eisenmanagement

Dr. med. Carsten Hafer



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Offenlegung von Interessenkonflikten

Carsten Hafer

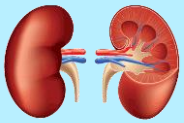
Meine Interessenkonflikte innerhalb der letzten 12 Monate:

- **Vifor Pharma**
- **Fresenius Medical Care**

✓ Honorare für Vortrags- und/ oder Beratertätigkeiten

Bei Wunsch nach dem Vortrag und / oder Literatur bitte eine E- Mail an:

Post@CarstenHafer.de



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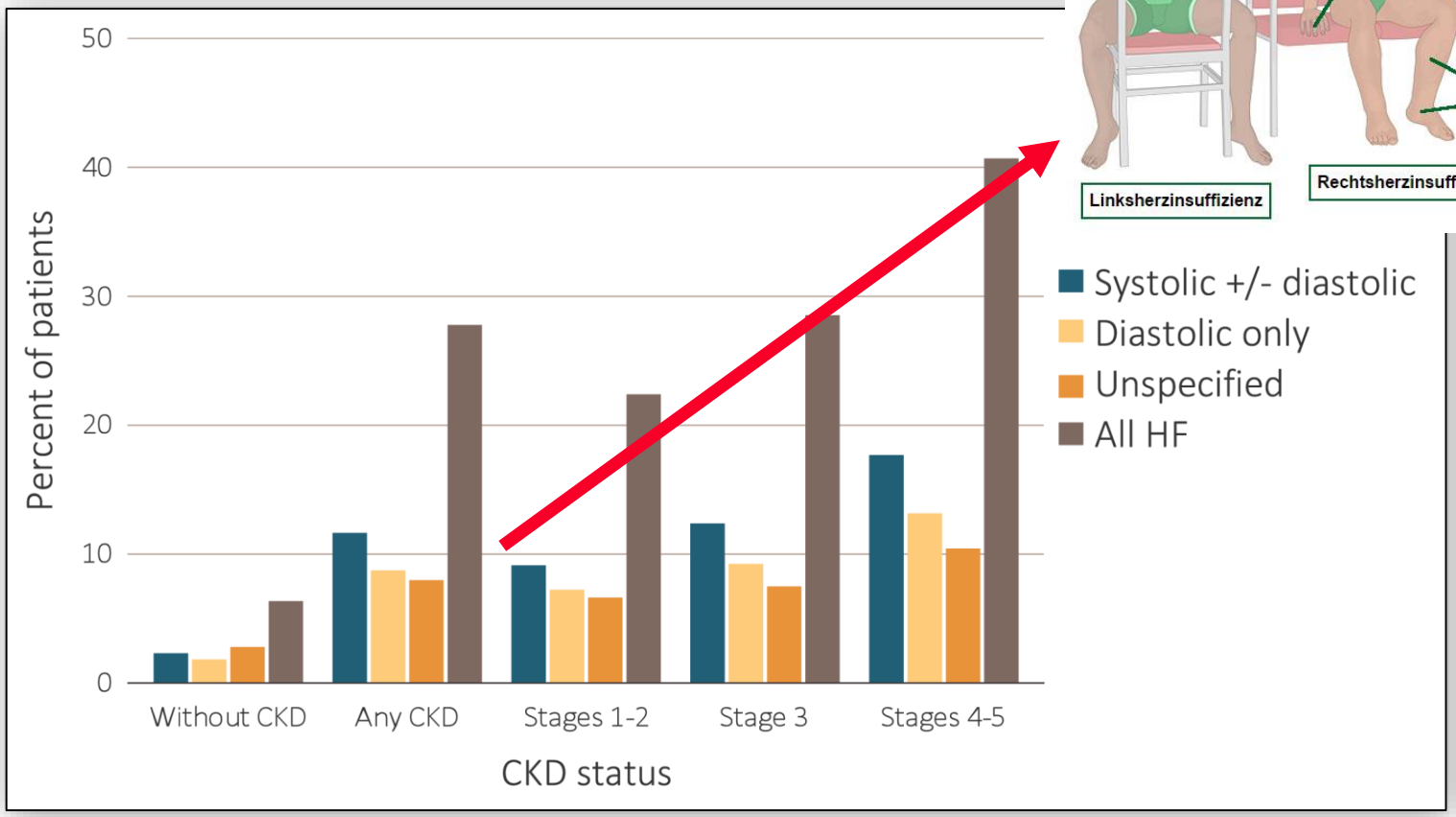
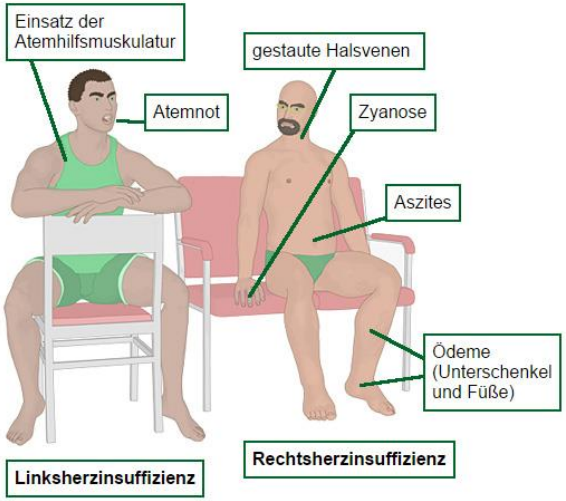
Herzinsuffizienz + / - CKD





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Renale und kardiovaskuläre Erkrankungen

Verlauf in mehreren Stadien

Dialyse

GFR ⇓

Albuminurie

Proteinurie

Alte, DM, RR ↑

Schwere Herzinsuffizienz

Infarkt,

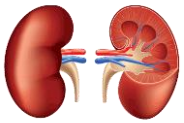
AVK, …

KHK, LVH

Alte, DM, RR ↑

Renale Erkrankungen

Kardiovaskuläre Erkrankung



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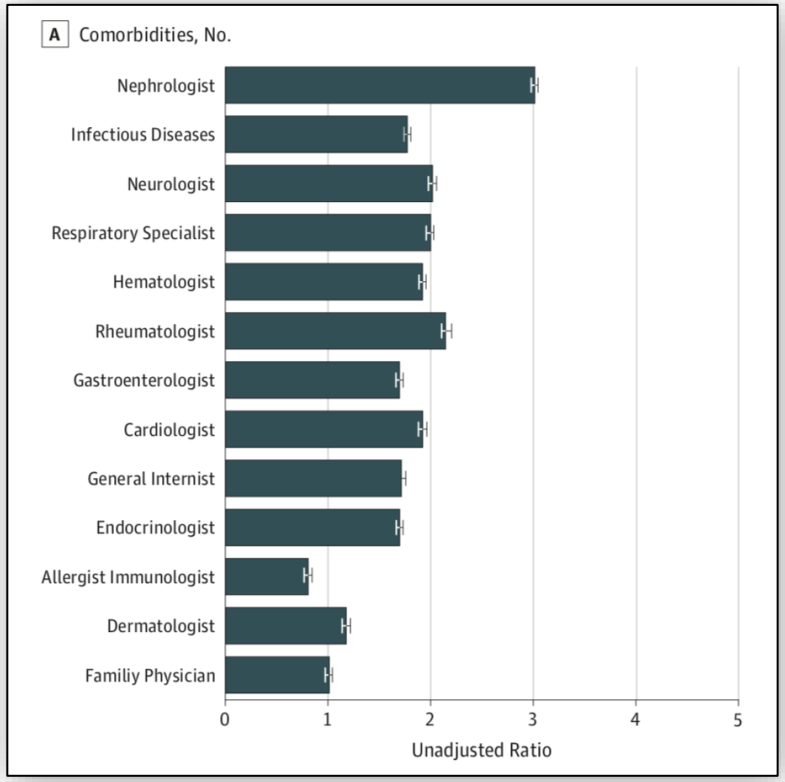
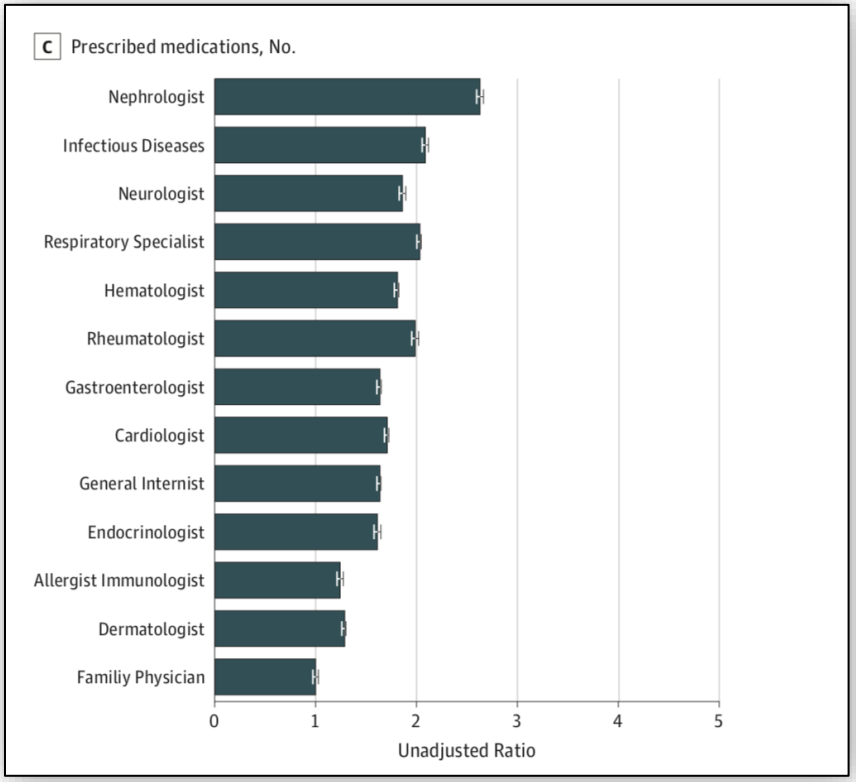
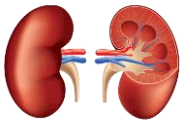
Komplexität der Versorgung







TONELLI et al. JAMA Network Open. 2018;1(7):e184852.

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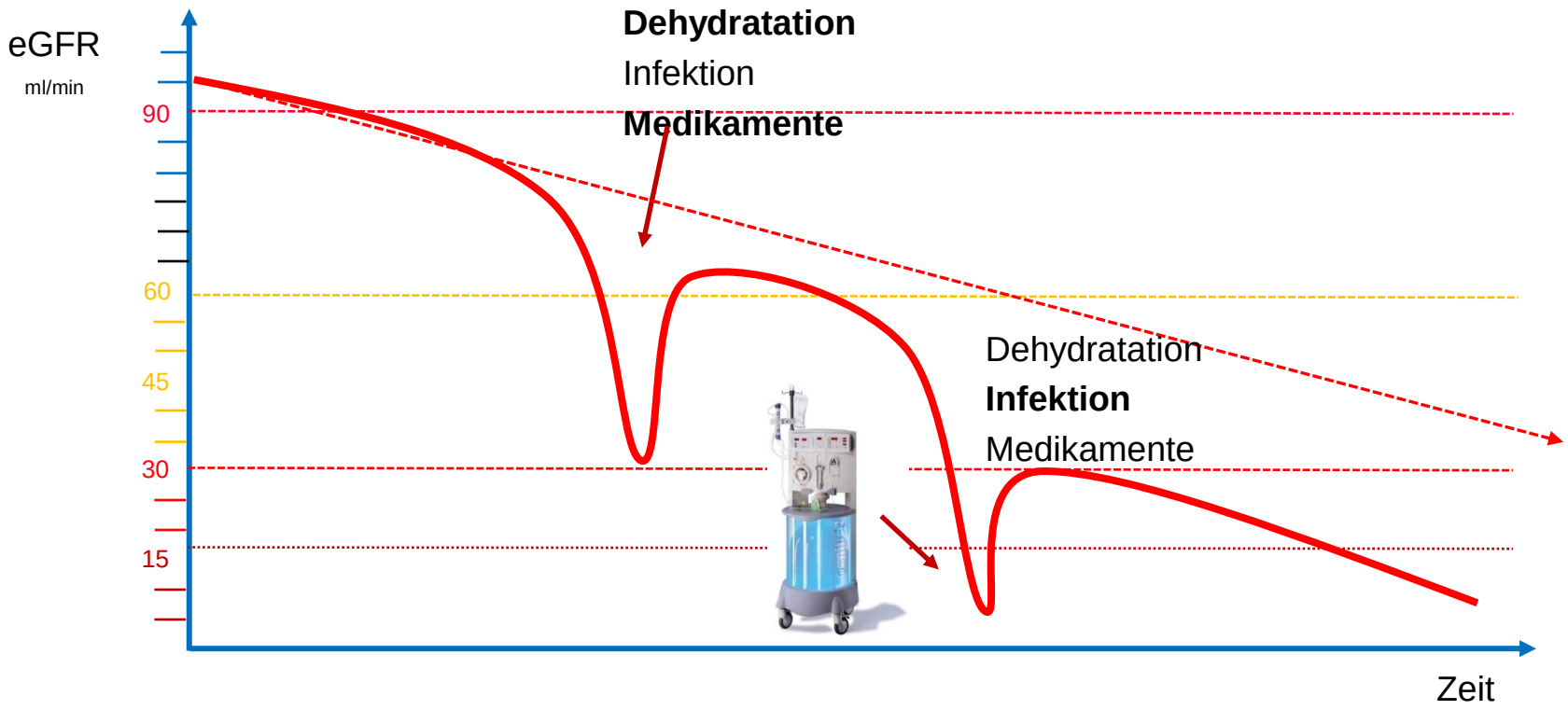
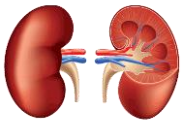
Funktionsverlust und Einflußfaktoren





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Diagnostik:
eGFR und Albuminurie

Prognosis of CKD by GFR and Albuminuria Categories: KDIGO 2012				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
GFR categories (ml/min/ 1.73m²) Description and range	G1	Normal or high	≥90			
	G2	Mildly decreased	60-89			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	<15			

Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney International Supplements* 3, 15–18, 2013

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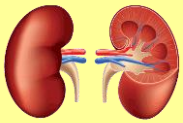
Erstbesuch einer 61-jährigen Patientin in der Praxis

- Diabetes mellitus Typ IIB
- art. Hypertonie
- chron. Niereninsuffizienz
- KHK nach vorausgegangenem Herzinfarkt (mit 56 Jahren) mit 2 Stents
- metabolisches Syndrom,

Ich bin sonst jeden Tag mit meinem Hund spazieren gegangen, das schaff ich jetzt kaum noch. Auch die Treppe zum Schlafzimmer schaff ich kaum noch rauf. Nachts kann ich nicht mehr durchschlafen und muss auf die Toilette gehen

Was ist nur los mit mir? Ich bin außerdem immer so müde.

- **Apixaban 2,5 mg 1 – 0 – 1**
- **ASS 100 0 – 1 – 0**
- **Valsartan 40 mg 1 – 0 - 1**
- **Torasemid 10 mg 1 – 0 – 0**
- **Spironolacton 25 mg 1 – 0 - 0**



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Anamnese der Symptome

Symptome:

Verschlechterung des Allgemeinzustandes

Starke Belastungsdyspnoe

Schwindel und ausgeprägte Schwäche

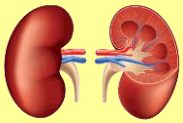
Klinik:

1,65 m, Körpergewicht: 81 kg, BMI: 30, 130/70 mm Hg

Herzfrequenz: 88 bpm

Beinödeme.

Gewichtszunahme



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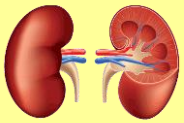
61-jährige Patientin

Diabetes mellitus Typ IIB
art. Hypertonie
chron. Niereninsuffizienz
KHK nach Herzinfarkt → 2 Stents

Apixaban 2,5 mg	**1 – 0 – 1**
ASS 100	**0 – 1 – 0**
Valsartan 40 mg	**1 – 0 - 1**
Torasemid 10 mg	**1 – 0 – 0**
Spironolacton 25 mg	**1 – 0 - 0**

Erythrozyten: 4,2
Hb: 12,5 g/dL
Na: 134 mmol/L
Ca: 2,2 mmol/L
K: 4,9 mmol/L
Serum-Fe: 96 mg/dL
Ferritin: 56 mg/dL
Hba1c: 7,5 %
CRP: 4 mg/L

TSH: 1,8 µU/mL
Lipide: im Normbereich
BNP: 300 ng/L
eGFR: 32 ml/min/1,73m^2
Kreatinin: 1,9 mg/dL
Harnsäure: 6,8



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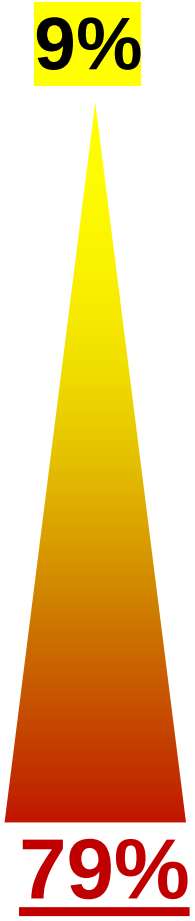
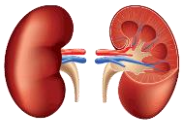
Inzidenz Anämie bei Herzinsuffizienz



NYHA and other classifications of cardiovascular disability

Class	NYHA functional classification [1]	Canadian Cardiovascular Society functional classification [2]	Specific activity scale [3]
I 1	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous or rapid prolonged exertion at work or recreation.	Patients can perform to completion any activity requiring ≥7 metabolic equivalents (ie, can carry 24 lb up 8 steps; do outdoor work [shovel snow, spade soil]; do recreational activities [skiing, basketball, squash, handball, jog/walk 5 mph]).
II 2	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair-climbing after meals, in cold, in wind, or when under emotional stress, or only during the few hours after awakening. Walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal conditions.	Patients can perform to completion any activity requiring ≥5 metabolic equivalents (eg, have sexual intercourse without stopping, garden, rake, weed, roller skate, dance foxtrot, walk at 4 mph on level ground) but cannot and do not perform to completion activities requiring ≥7 metabolic equivalents.
III 3	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less-than-ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking 1 to 2 blocks on the level and climbing 1 flight in normal conditions.	Patients can perform to completion any activity requiring ≥2 metabolic equivalents (eg, shower without stopping, strip and make bed, clean windows, walk 2.5 mph, bowl, play golf, dress without stopping) but cannot and do not perform to completion any activities requiring >5 metabolic equivalents.
IV 4	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.	Patients cannot or do not perform to completion activities requiring >2 metabolic equivalents. Cannot carry out activities listed above (specific activity scale III).

Ferritin: 56 mg/dL



Silverberg DS, et al.: The use of subcutaneous erythropoietin and intravenous iron for the treatment of the anemia of severe, resistant congestive heart failure improves cardiac and renal function and functional cardiac class, and markedly reduces hospitalizations. J Am Coll Cardiol. 2000;35(7):1737.

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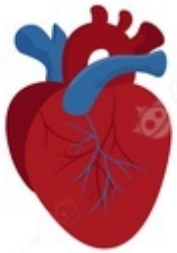
Voll CRAS!

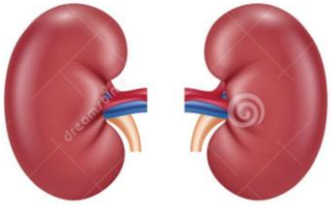
Cardio

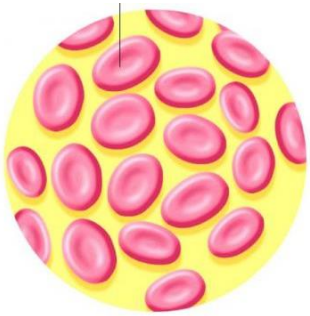
Renales

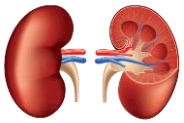
Anämie

Syndrom









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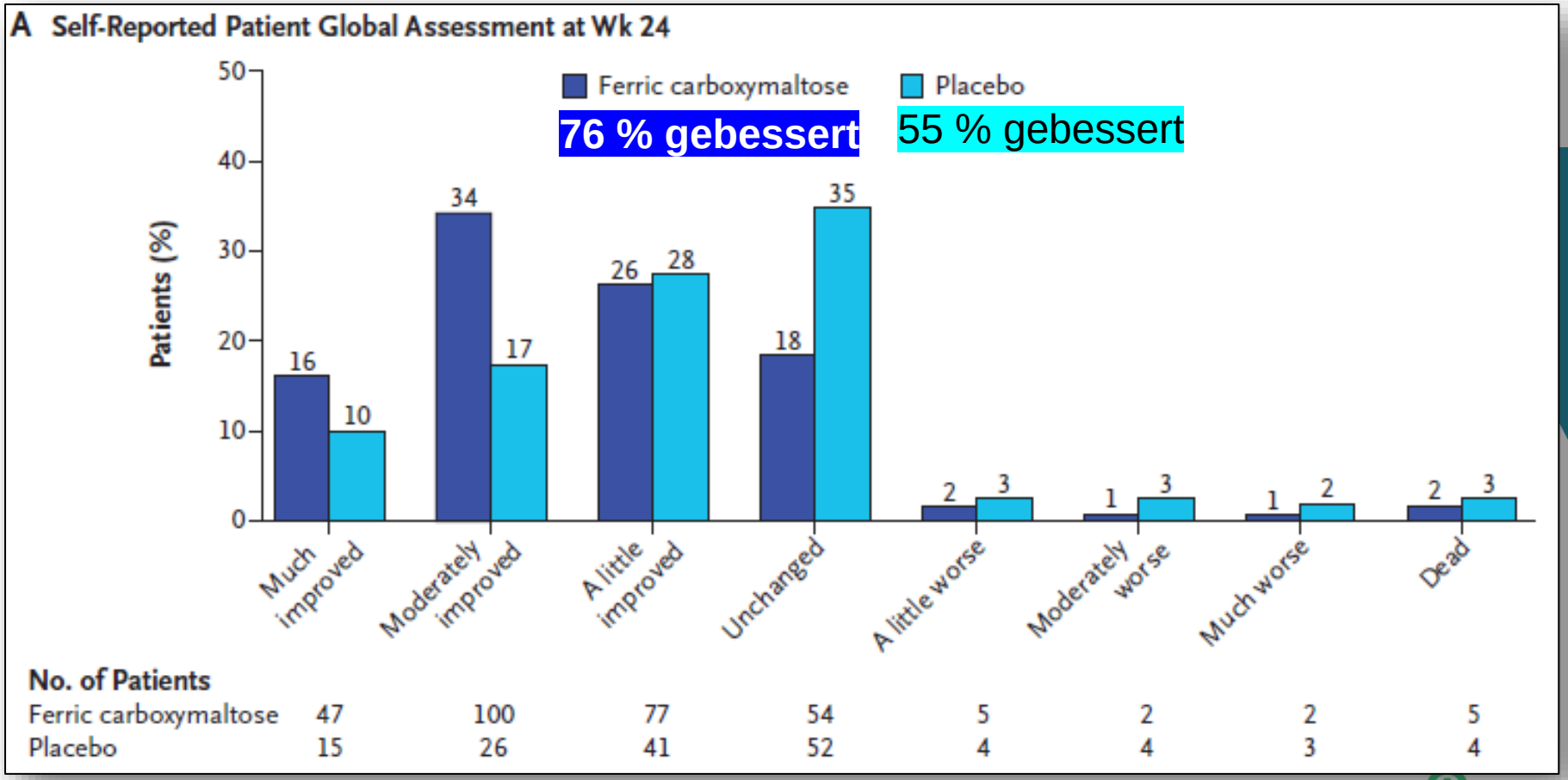
FAIR-HF
Eisen bei Herzinsuffizienz



ANKER et al. : **Carboxymaltose in patients with heart failure and iron deficiency.**
N Engl J Med 361:2436-48, 2009

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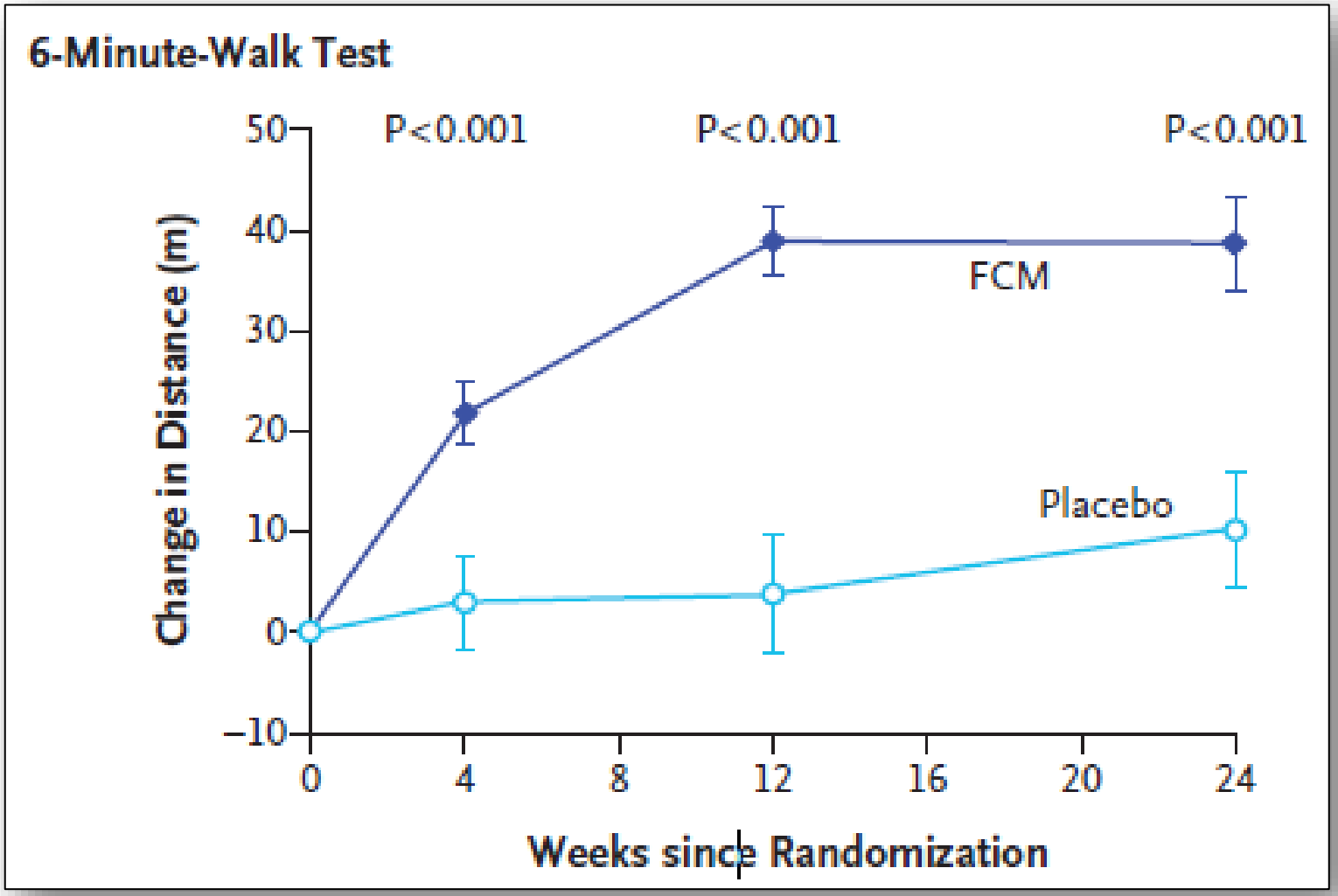
FAIR-HF
Verbesserte 6 – Minuten Gehstrecke



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N Engl J Med 361:2436-48, 2009

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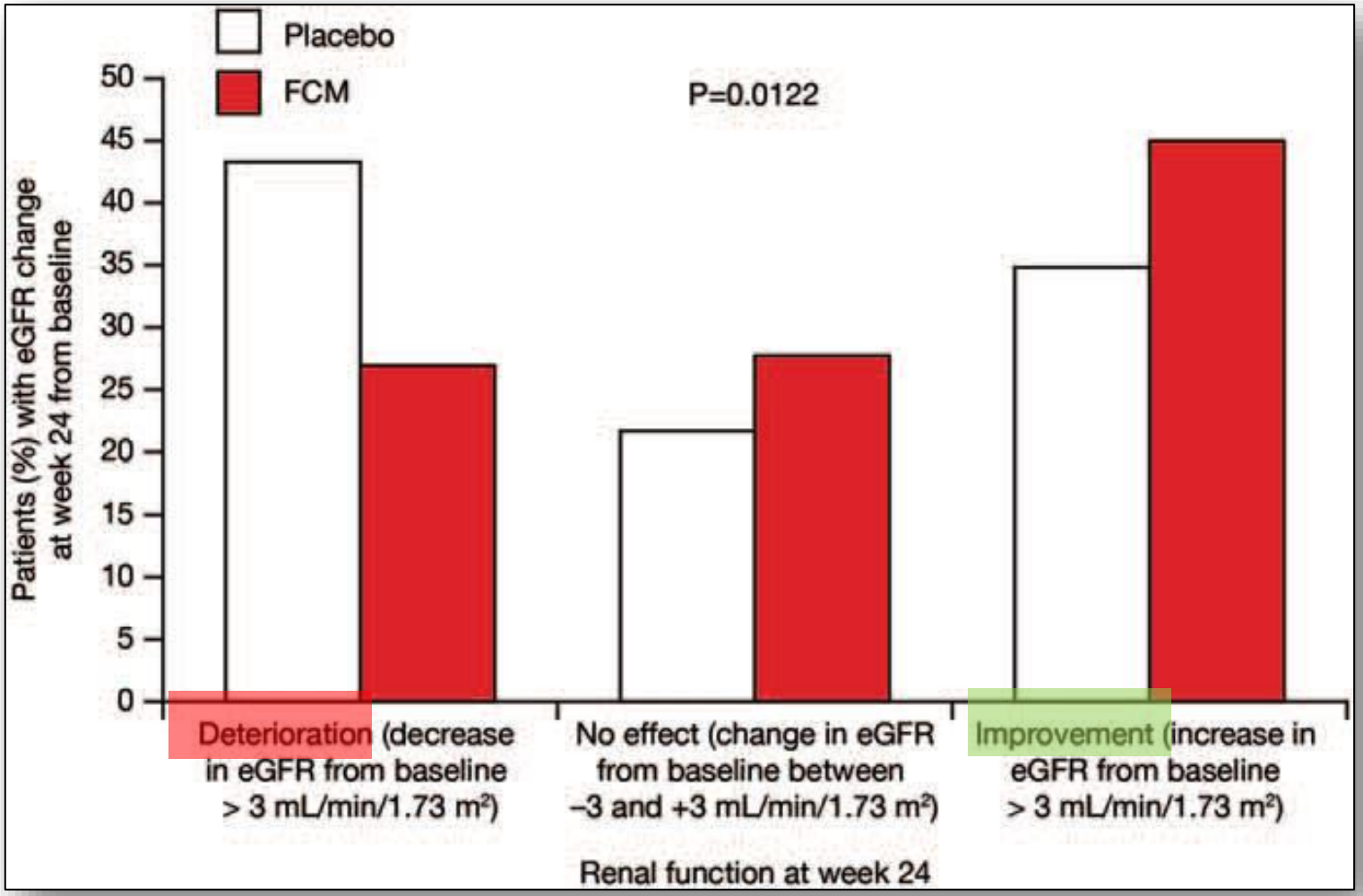
CONFIRM- HF
Nierenfunktion unter Eisencarboxymaltose 2



PONIKOWSKI et al. : **The impact of intravenous ferric carboxymaltose on renal function: an analysis of the FAIR-HF study**. European Journal of Heart Failure, 2015

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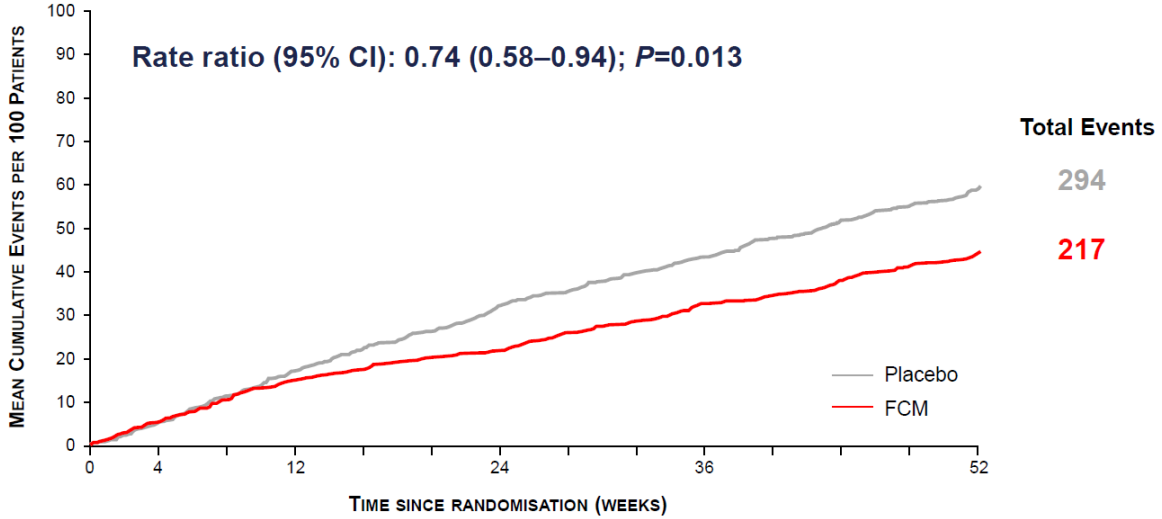
AFFIRM-HF
Eisen bei dekompensierter Herzinsuffizienz

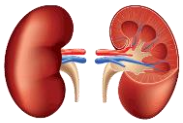
Eisenmangel mit akuter HF-Episode:

Behandlung mit FCM

► Reduktion Hospitalisierungen und kardiovaskulärem Tod um 21 % (p=0,059)

► **26-%ige Reduktion der HF-Rehospitalisierung (p=0,013)**





Ponikowski P, et al. The Lancet. 2020

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Eisen: oral oder i.v.

Advantages and disadvantages of oral versus IV iron

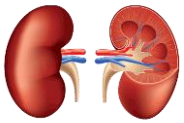
Bei kardiorenalem Syndrom ist die orale Eisensubstitution <u>nicht</u> empfehlenswert

- oft chronische Inflammation
  → erhöhte Hepcidinspiegel

		for several months ▪ Total costs may be higher
IV iron	▪ Effective for most patients ▪ More rapid correction of	▪ Requires monitored intravenous infusion

Eisensubstitution mit Eisencarboxymaltose verbessert Leistungsfähigkeit und Lebensqualität

for further details. Advantages, disadvantages, costs, and burdens for any individual patient may depend on a number of factors.



SCHWENGER V et al. : **Niereninsuffizienz im Kontext der kardiopulmorenalen Pathophysiologie** Der Internist 2021 (63): 1153 -1165

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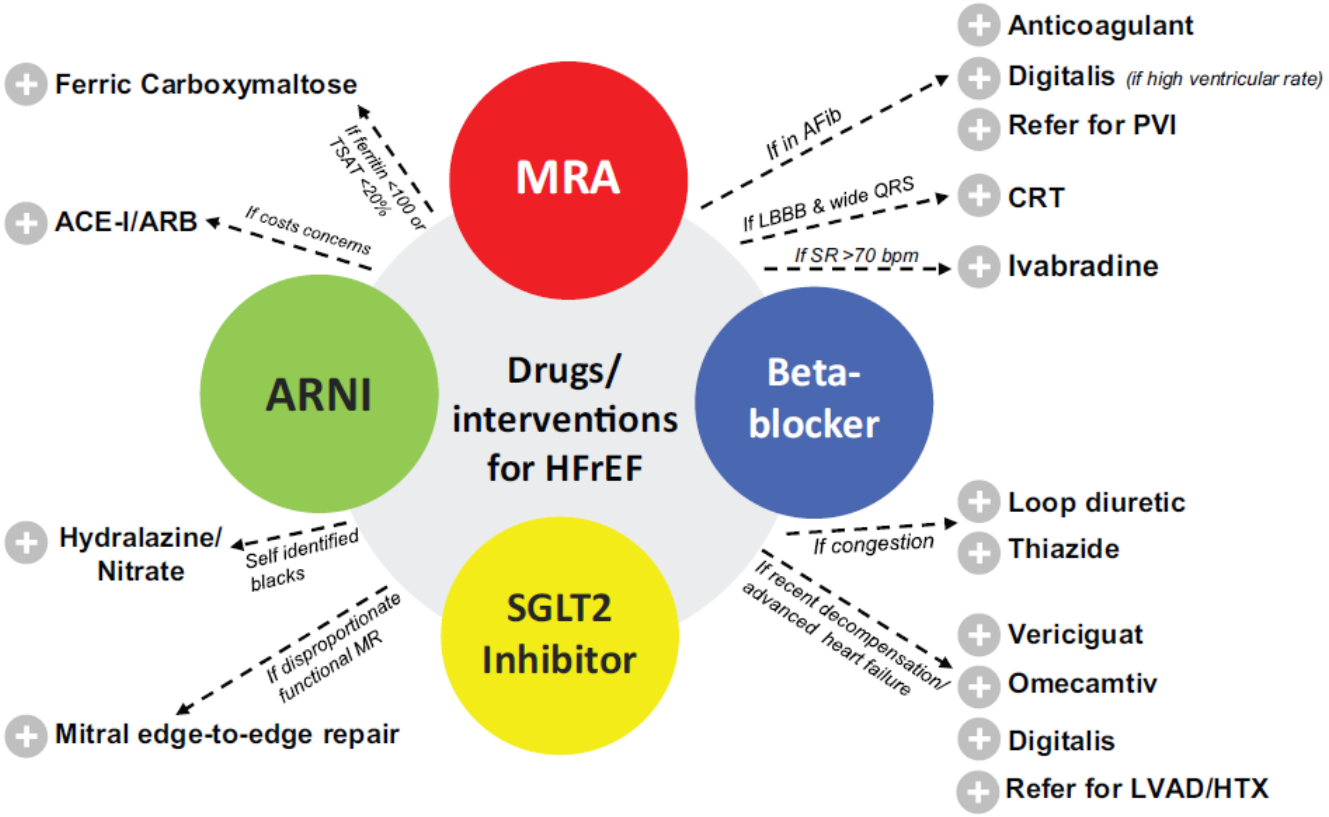
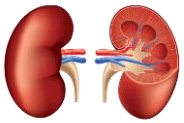
ESC European Society of Cardiology
European Heart Journal (2021) **42**, 681–683
doi:10.1093/eurheartj/ehaa1012

EDITORIAL

Heart failure drug treatment: the fantastic four

Johann Bauersachs *





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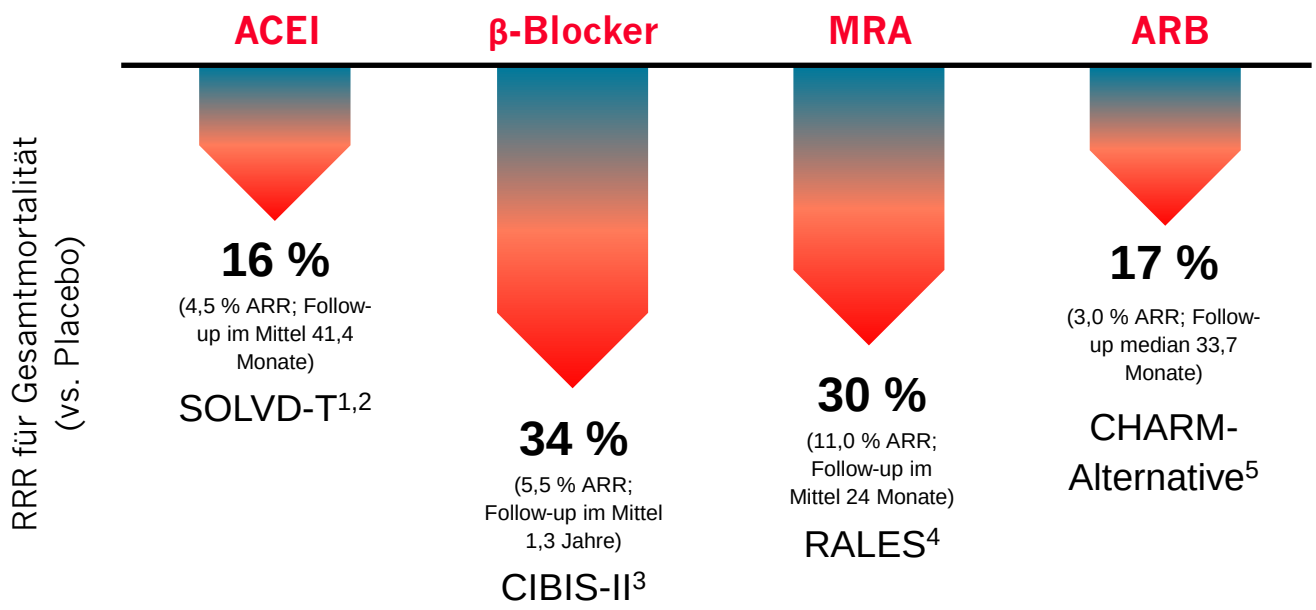
Hohe Mortalität bei HFrEF



Dennoch ist die Mortalität weiterhin erheblich:
~ 50 % der Patienten versterben innerhalb von 5 Jahren nach Diagnosestellung[6–10]

1. McMurray et al. Eur Heart J 2012;33:1787–847; 2. SOLVD Investigators. N Engl J Med 1991;325:293–302; 3. CIBIS-II Investigators. Lancet 1999;353:9–13; 4. Pitt et al. N Engl J Med 1999;341:709-17; 5. Granger et al. Lancet 2003;362:772-6; 6. Levy D et al. N Engl J Med 2002;347(18):1397-402; 7. Roger VL et al. JAMA 2004;292:344–50; 8. Engelfriet PM et al. Eur J Heart Fail 2011;13(4):377-83; 9. Zarrinkoub R et al. Eur J Heart Fail 2013;15 (9):995-1002;10. Gerber Y et al. JAMA Intern Med 2015;175(6):996-1004

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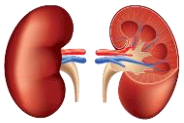
Merke

Bei Patienten mit Herzinsuffizienz ist der wichtigste therapeutische Zielparameter nicht der Blutdruck, sondern die erreichte Medikamentendosis mit Betablockern und Inhibitoren des Renin-Angiotensin-Aldosteron-Systems.

Merke

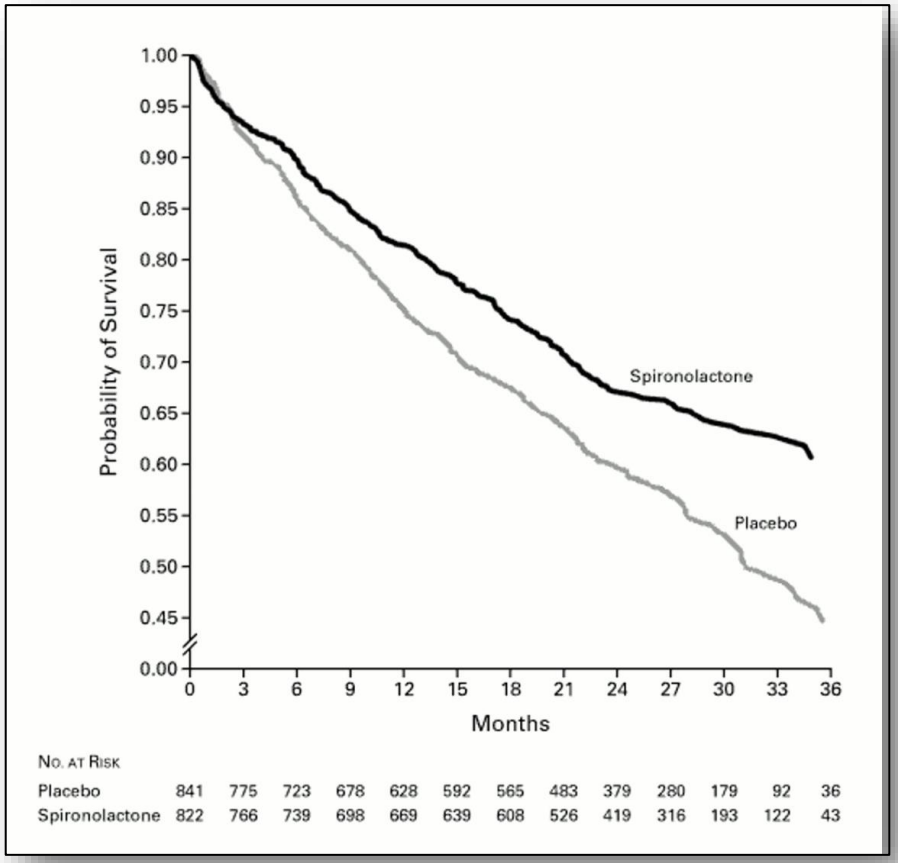
Die eGFR ist ein Schätzwert für die Nierenfunktion, und die Interpretation eines Abfalls sollte immer im Zusammenhang mit der klinischen Situation, insbesondere Medikamentenumstellungen, beurteilt werden.

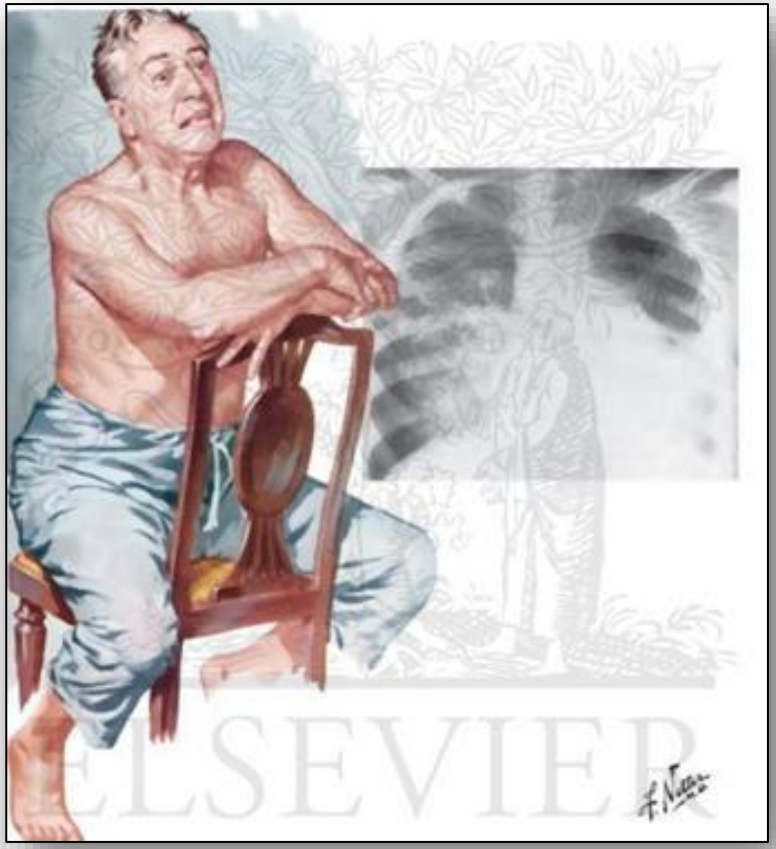


Brandenburg, V., et al. (2021). "[Symptom control in heart failure patients - how to handle GFR decrease and hyperkalaemia]." Dtsch Med Wochenschr.

Spironolacton

The effect of spironolactone on morbidity and mortality in patients with severe heart failure. RALES study.





PITT et al.

NEJM 341(10):709-17, 1999

Klinikum Braunschweig

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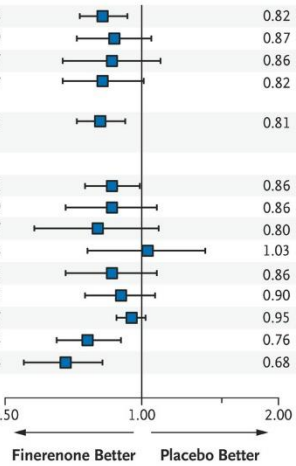
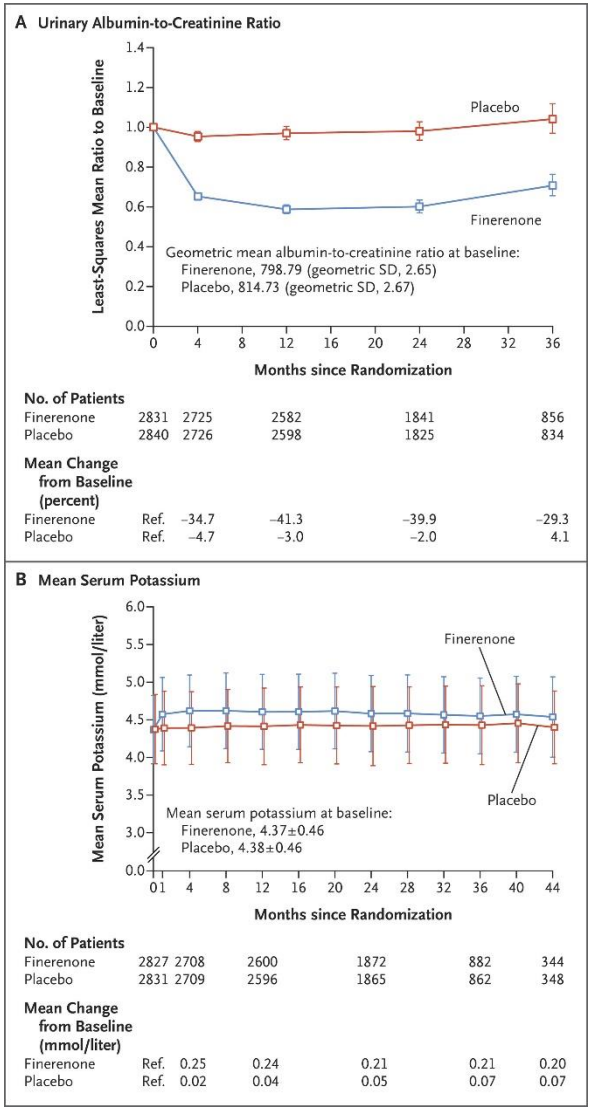
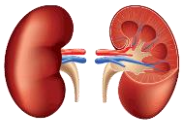
FIDELIO – Studie (Finerenon bei DM und CKD)

Outcome	Finerenone (N=2833)	Placebo (N=2841)	Finerenone (N=2833)	Placebo (N=2841)	Hazard Ratio (95% CI)	P Value
	no. of patients with event (%)		*no. of patients with event per 100 patient-yr*			
Primary composite outcome	504 (17.8)	600 (21.1)	7.59	9.08	0.82 (0.73–0.93)	0.001
Kidney failure	208 (7.3)	235 (8.3)	2.99	3.39	0.87 (0.72–1.05)	—
End-stage kidney disease	119 (4.2)	139 (4.9)	1.60	1.87	0.86 (0.67–1.10)	—
Sustained decrease in eGFR to <15 ml/min/1.73 m²	167 (5.9)	199 (7.0)	2.40	2.87	0.82 (0.67–1.01)	—
Sustained decrease of ≥40% in eGFR from baseline	479 (16.9)	577 (20.3)	7.21	8.73	0.81 (0.72–0.92)	—
Death from renal causes	2 (<0.1)	2 (<0.1)	—	—	—	—
Key secondary composite outcome	367 (13.0)	420 (14.8)	5.11	5.92	0.86 (0.75–0.99)	0.03
Death from cardiovascular causes	128 (4.5)	150 (5.3)	1.69	1.99	0.86 (0.68–1.08)	—
Nonfatal myocardial infarction	70 (2.5)	87 (3.1)	0.94	1.17	0.80 (0.58–1.09)	—
Nonfatal stroke	90 (3.2)	87 (3.1)	1.21	1.18	1.03 (0.76–1.38)	—
Hospitalization for heart failure	139 (4.9)	162 (5.7)	1.89	2.21	0.86 (0.68–1.08)	—
Death from any cause	219 (7.7)	244 (8.6)	2.90	3.23	0.90 (0.75–1.07)	—
Hospitalization for any cause	1263 (44.6)	1321 (46.5)	22.56	23.87	0.95 (0.88–1.02)	—
Secondary composite kidney outcome	252 (8.9)	326 (11.5)	3.64	4.74	0.76 (0.65–0.90)	—
Sustained decrease of ≥57% in eGFR from baseline	167 (5.9)	245 (8.6)	2.41	3.54	0.68 (0.55–0.82)	—





Adverse events affecting ≥5%		
Hyperkalemia	446 (15.8)	221 (7.8)



Bakris, G. L., et al. (2020). **"Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes**."
New England Journal of Medicine 383(23): 2219-2229.

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Unsere Patientin

Abixapan 2,5 mg	1 – 0 – 1
ASS 100	0 – 1 – 0
Valsartan 40 mg	1 – 0 - 1
Torasemid 10 mg	1 – 0 – 0
Spironolacton 25 mg	1 – 0 - 0

+ Bisoprolol 2,5 mg 1-0-1

+ Plus SGLT2 –Hemmer 10 mg 1-0-0

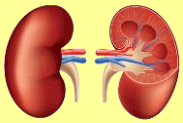
+ Plus Atorvastatin 40 mg tgl. 0-0-1

+ Eisen (Carboxymaltose)

+ Plus Koronarangiographie oder Kardio MRT

→ **Kreatinin 1,9 mg%**

→ **Kalium 5,9 mmol/l**



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Das Dilemma bei der Behandlung von Patienten mit kardiorenalen Erkrankungen

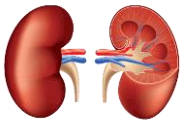
RAAS-Inhibitoren können bei Patienten mit chronischer Niereninsuffizienz, Z.n. AMI und Herzinsuffizienz **nephro-protektiv** wirken.[1]

ACE-Hemmer oder die Kombination von Sartan und MRA können die **wirksamste Behandlung** einer resistenten Hypertonie darstellen.[2]

RAAS-Inhibitoren werden in großem Umfang eingesetzt, können aber eine **Hyperkaliämie** verursachen oder verschlimmern.[2]

AMI = akuter Myokardinfarkt; MRA = Aldosteronantagonist; RAAS = Renin-Angiotensin-Aldosteron-System

1. Iino Y, et al. Hypertens Res. 2004;27:21–30; 2. Williams B, et al. Lancet. 2015;386:2059–68



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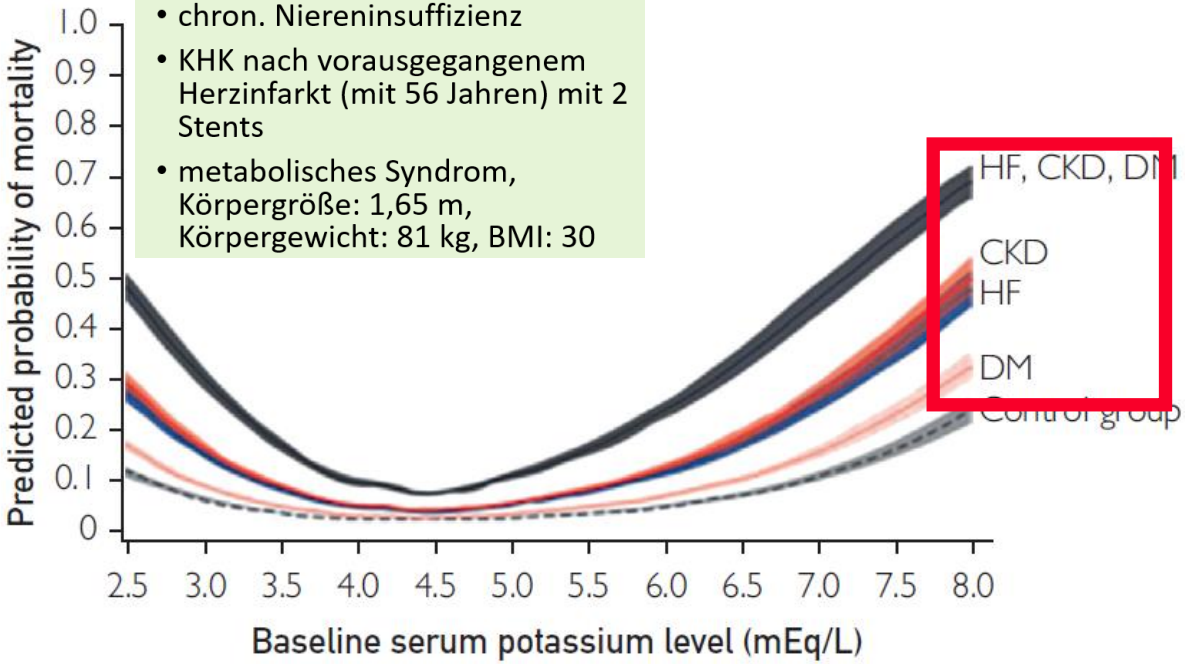
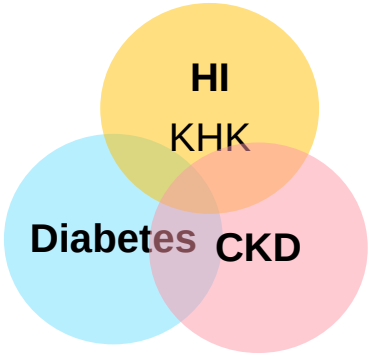
Assoziation Kalium und Mortalität

- Diabetes mellitus Typ IIB
- art. Hypertonie
- chron. Niereninsuffizienz
- KHK nach vorausgegangenem Herzinfarkt (mit 56 Jahren) mit 2 Stents
- metabolisches Syndrom, Körpergröße: 1,65 m, Körpergewicht: 81 kg, BMI: 30





Collins AJ et al et al. **Association of serum potassium with all-cause mortality in patients with and without heart failure, chronic kidney disease, and/or diabetes.** Am J Nephrol. 2017;46(3):213-221

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Praxisalltag … ein anderes Beispiel

Mai 2020

Knochenschmerz

→ **Ibuprofen**

V.a. Harnwegsinfekt

→ **Sulfamethoxazol/ Trimethoprim**

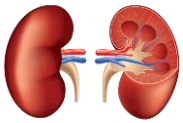
Zucker entgleist

Durchfall

Durch Kaliumaustritt aus den Zellen
▪ Betablocker ▪ Digitalisintoxikation ▪ i.v. Gabe von kationischen Aminosäuren (z. B. in parenteraler Ernährungslösung) ▪ Mannitol ▪ Suxamethonium (depolarisierendes Muskelrelaxans)
Hemmung der Aldosteronsekretion
▪ ACE-Hemmer ▪ AT1-Antagonisten ▪ Renininhibitoren ▪ NSAR und COX-2-Inhibitoren ▪ Calcineurininhibitoren (CAVE: Nieren- und Herztransplantation) ▪ Heparin
Wirkungsverminderung des Aldosteron
▪ Aldosteronantagonisten ▪ kaliumsparende Diuretika ▪ Trimethoprim, Pentamidin
Kaliumhaltige Medikamente
▪ Kochsalzersatz ▪ Penicillin G ▪ Blutkonserven

S. ZIESCHANG

https://www.akdae.de/Arzneimitteltherapie/AVP/vorab/Hyperkaliaemie.pdf



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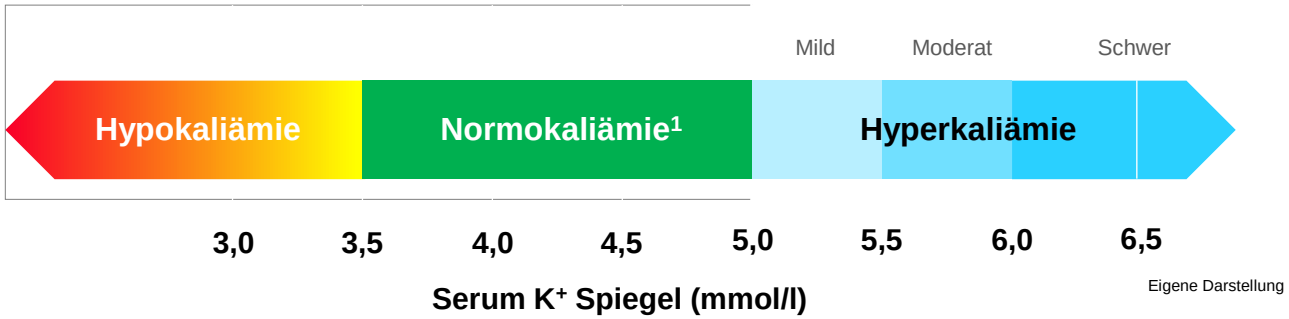
Definition Hypo - / Hyperkaliämie

Hyperkaliämie:

- ist definiert als Serum K^+-Spiegel >5,0 mmol/l[1–3]
- wird unterteilt in: **milde, moderate** oder **schwere** Hyperkaliämie[2]
- tritt bei Hochrisikopatienten **häufig wiederholt** auf[2]
- kann lebensbedrohlich sein[4]



Eigene Darstellung

Rastegar A, et al. *Postgrad Med J*. 2001;77:759–64;
Einhorn LM, et al. *Arch Intern Med*. 2009;169:1156–62
Kovesdy CP. *Am J Med*. 2015;128:1281–7
Hollander-Rodriguez JC, et al. *Am Fam Phys*. 2006;73:283–90.

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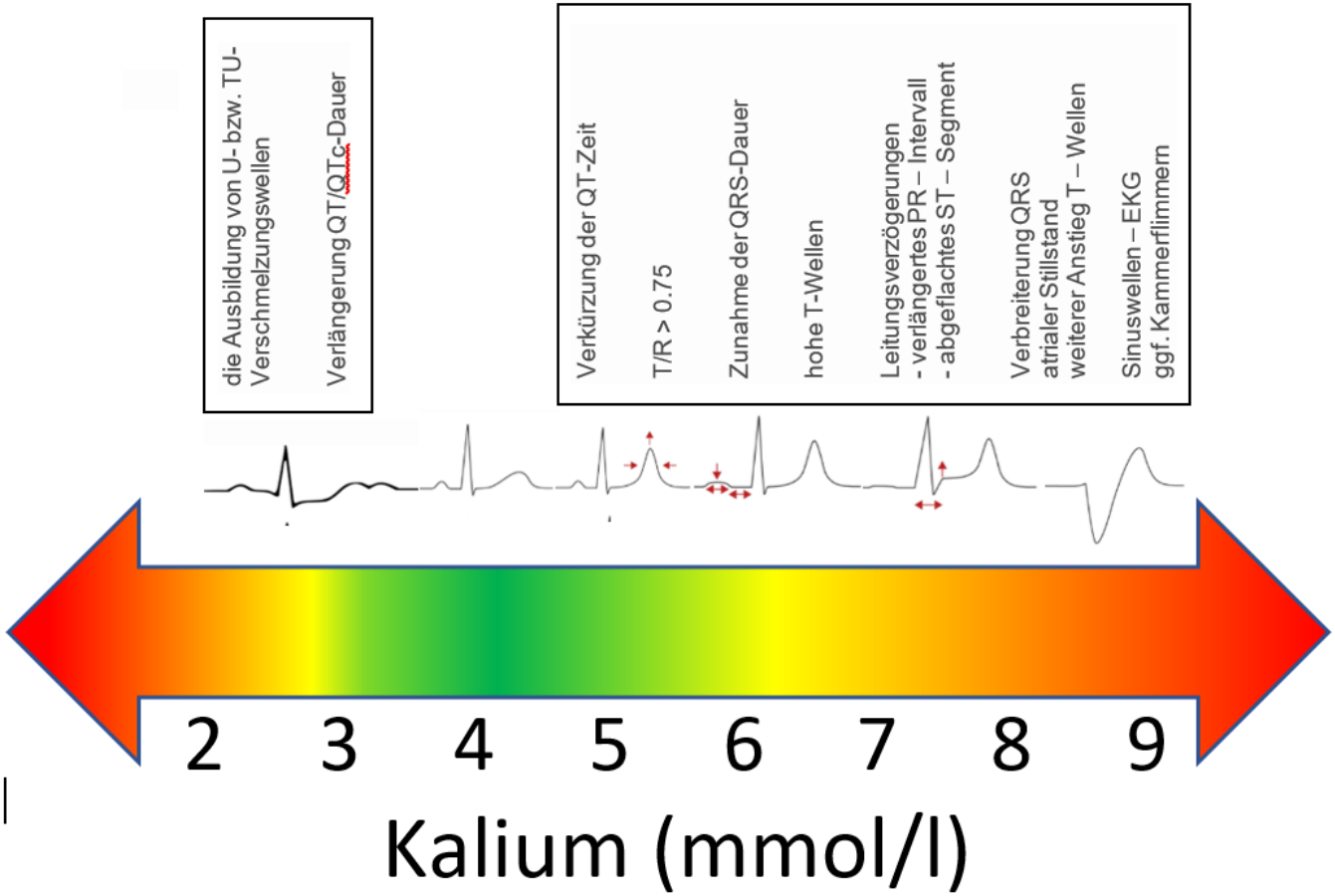
EKG - Veränderungen



Hafer, C. (2021). **„Kalium – was Intensivmediziner wissen müssen."**
Intensivmedizin up2date 2021

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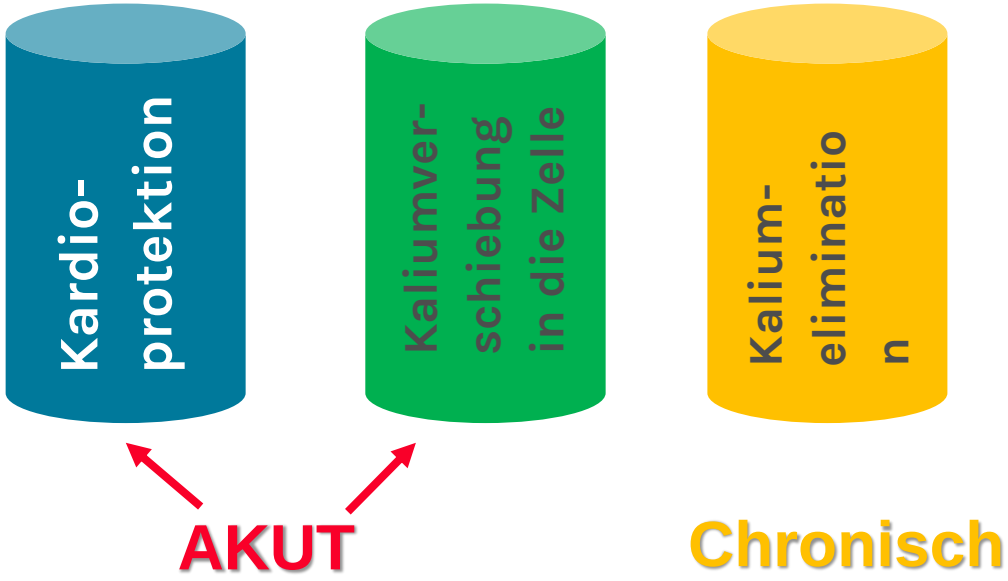
Therapie:
3 Säulen bei Hyperkaliämie

Drei Säulen



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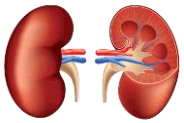
Pseudohyperkaliämie

32–75 % der Messfehler entstehen durch Fehler während der Blutabnahme, der Zentrifugation oder beim Transport.

- **lange Stauzeit**
- **Hämolyse** der Probe vor Verarbeitung
- **Muskuläre Aktion! „Faust machen“** ~ 1 mmol/l
- **Hohe Zellzahlen**
  - Leukämie und Thrombozytose > 500 Tsd/µl

- **Blutzucker und Blutgasanalyse**

Schwierig in der nicht-nephrologischen ambulanten realen Welt



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Adäquate RAAS - Inhibition

Mortalitätsrisiko verbessert sich unter adäquater Guideline gerechter RAASi Dosierung

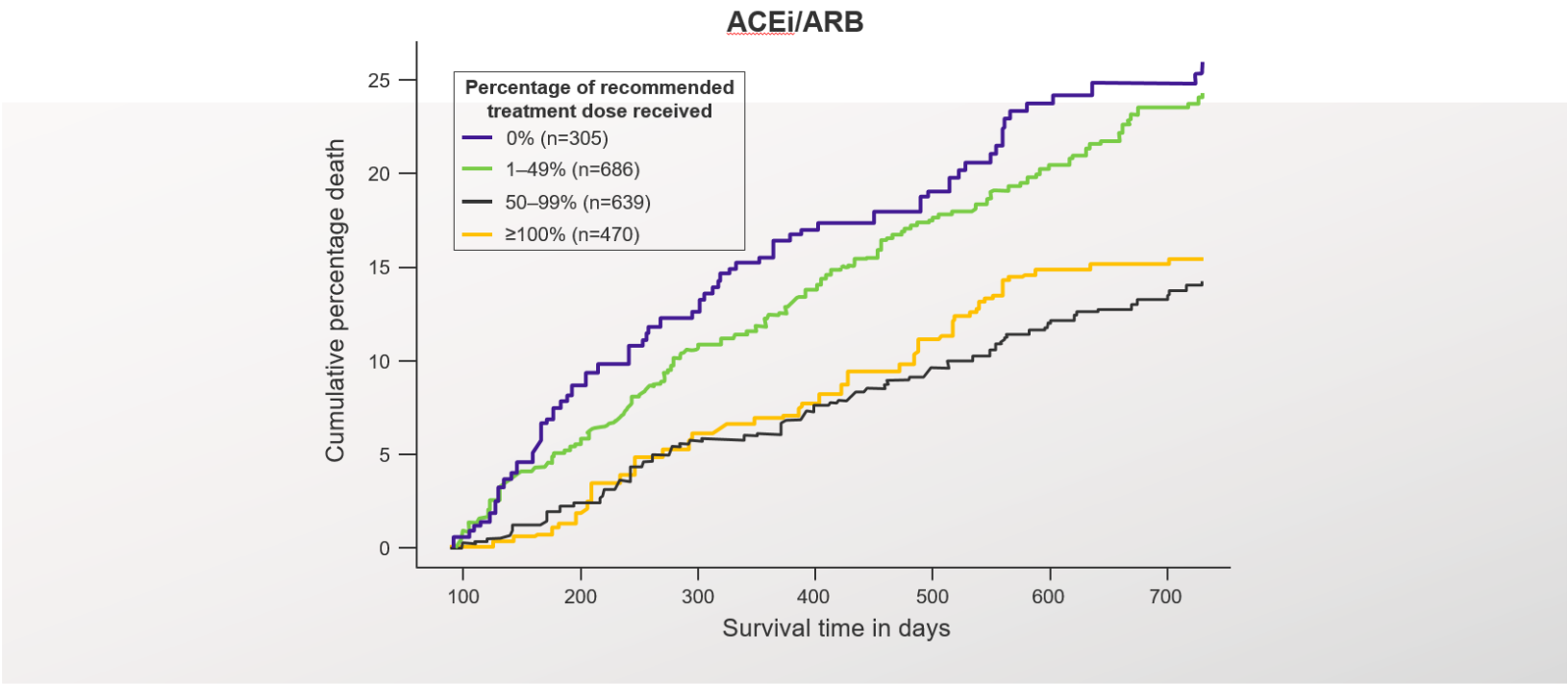
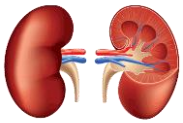


Figure shows adjusted mortality rate for patients receiving 0, 1–49, 50–99% or ≥100% of the recommended ACEi/ARB dose together with the risk set sizes at each time point.
ACEi, angiotensin-converting-enzyme inhibitor; ARB, angiotensin receptor blocker; RAASi, renin-angiotensin-aldosterone system inhibitor

Modifiziert nach Ouwerkerk W, et al. *Eur Heart J.* 2017;0:1–10.



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Does hyperkalemia limit the beneficial effects of ACE inhibitor therapy?

CJASN
Clinical Journal of the American Society of Nephrology

ADVANCE Trial subgroup analysis

≥55 yrs
T2DM & high risk for cardiovascular events

n= 9,694
with normokalemia at start of run-in

ACE inhibitor- based therapy (perindopril-indapamide) initiated for run-in period

Then randomized to ACE or placebo

Serum K (mEq/L) 3 wk after initiating ACE		Overall	< 3.5	3.5-<5.0	≥ 5.0
Composite of major vascular events	HR ACE v Placebo (95% CI)	0.91 (0.83-1.00)	1.38 (0.53-3.59)	0.92 (0.83-1.02)	0.99 (0.69-1.44)
			P heterogeneity = 0.66		
All-Cause Mortality	HR ACE v Placebo (95% CI)	0.86 (0.75-0.98)	0.40 (0.04-3.82)	0.86 (0.74-1.00)	0.82 (0.47-1.45)
			P heterogeneity = 0.80		

Conclusion Continuation of ACE inhibitor-based therapy consistently decreased the risk of cardiovascular and kidney outcomes and death, regardless of short-term changes in serum potassium.

Toshiaki Ohkuma, Katie Harris, Mark Cooper, et al. ***Short-Term Changes in Serum Potassium and the Risk of Subsequent Vascular Events and Mortality***. CJASN doi: 10.2215/CJN.00180122. **Visual Abstract by Anna Gaddy, MD**

Ohkuma T et al. : **Short-Term Changes in Serum Potassium and the Risk of Subsequent Vascular Events and Mortality: Results from a Randomized Controlled Trial of ACE Inhibitors.**
Clin J Am Soc Nephrol. 2022;17(8):1139-49.

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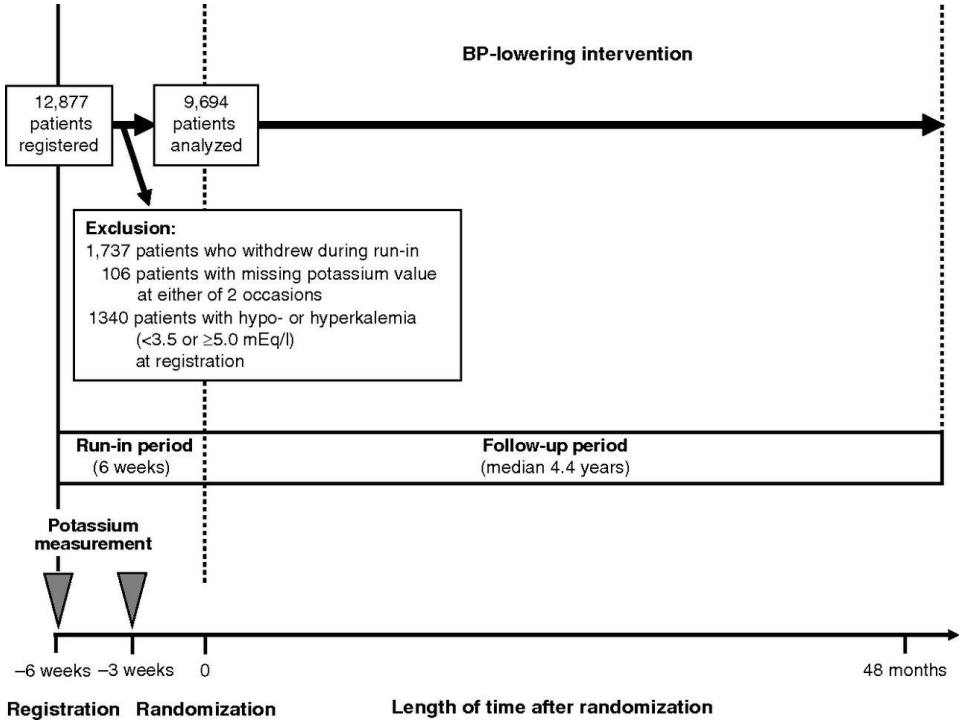
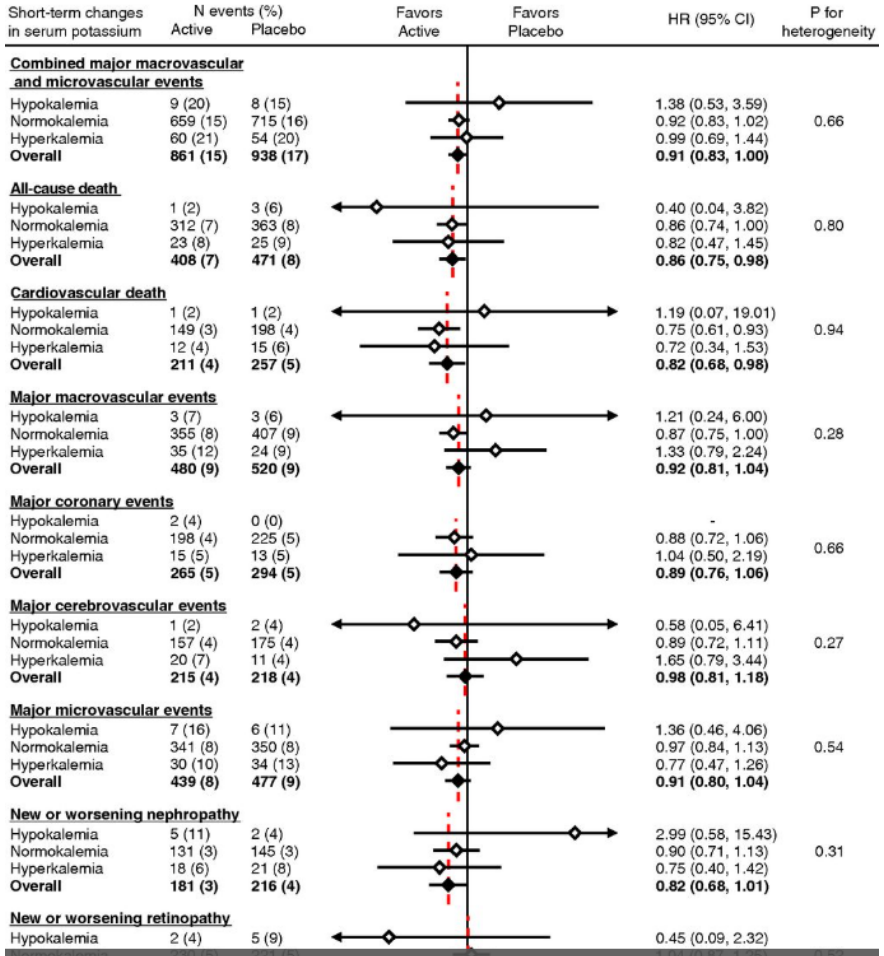
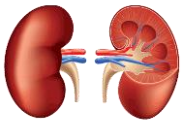
Hyperkaliämie bei Start RAAS – Blockade → NICHT absetzen





Modification of randomized treatment effects of ACE inhibitor–based therapy on the risk of major clinical outcomes according to short-term changes in serum potassium after treatment initiation. Short-term changes in serum potassium were defined on the basis of the measurement made 3 weeks after initiating ACE inhibitor–based therapy. White diamonds indicate the HRs for subgroups defined by short-term change in serum potassium. Black diamonds indicate the HRs of overall randomized participants of the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation trial (n=11,140). Active indicates perindopril-indapamide.



Ohkuma T et al. : **Short-Term Changes in Serum Potassium and the Risk of Subsequent Vascular Events and Mortality: Results from a Randomized Controlled Trial of ACE Inhibitors.**
Clin J Am Soc Nephrol. 2022;17(8):1139-49.

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STOP RAAS-I bei CKD?

Stopping renin-angiotensin system inhibitors in patients with advanced CKD and risk of adverse outcomes: a nationwide cohort study

JASN
JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY

METHODS

10.254 patients with eGFR<30 ml/min/1.73 m^2

Stopping within 6 months vs. continuing RASi

5 year follow-up

Analytical approach:
Target trial emulation based on cloning, censoring and weighting

OUTCOME

5-year risk	Continuing	Stopping	Difference
Mortality	40.9% (38.9, 42.8)	54.5% (48.5, 61.2)	**13.6%** (7.0, 20.3)
MACE	47.6% (45.9, 49.4)	59.5% (53.8, 66.1)	**11.9%** (5.7, 18.6)
KRT	36.1% (34.7, 37.7)	27.9% (23.5, 32.5)	**-8.3%** (-12.8, -3.6)

Conclusion
In this nationwide study of people with advanced CKD, stopping RASi was associated with a higher absolute risk of mortality and MACE, but a lower absolute risk of KRT.

doi: 10.1681/ASN.2020050682

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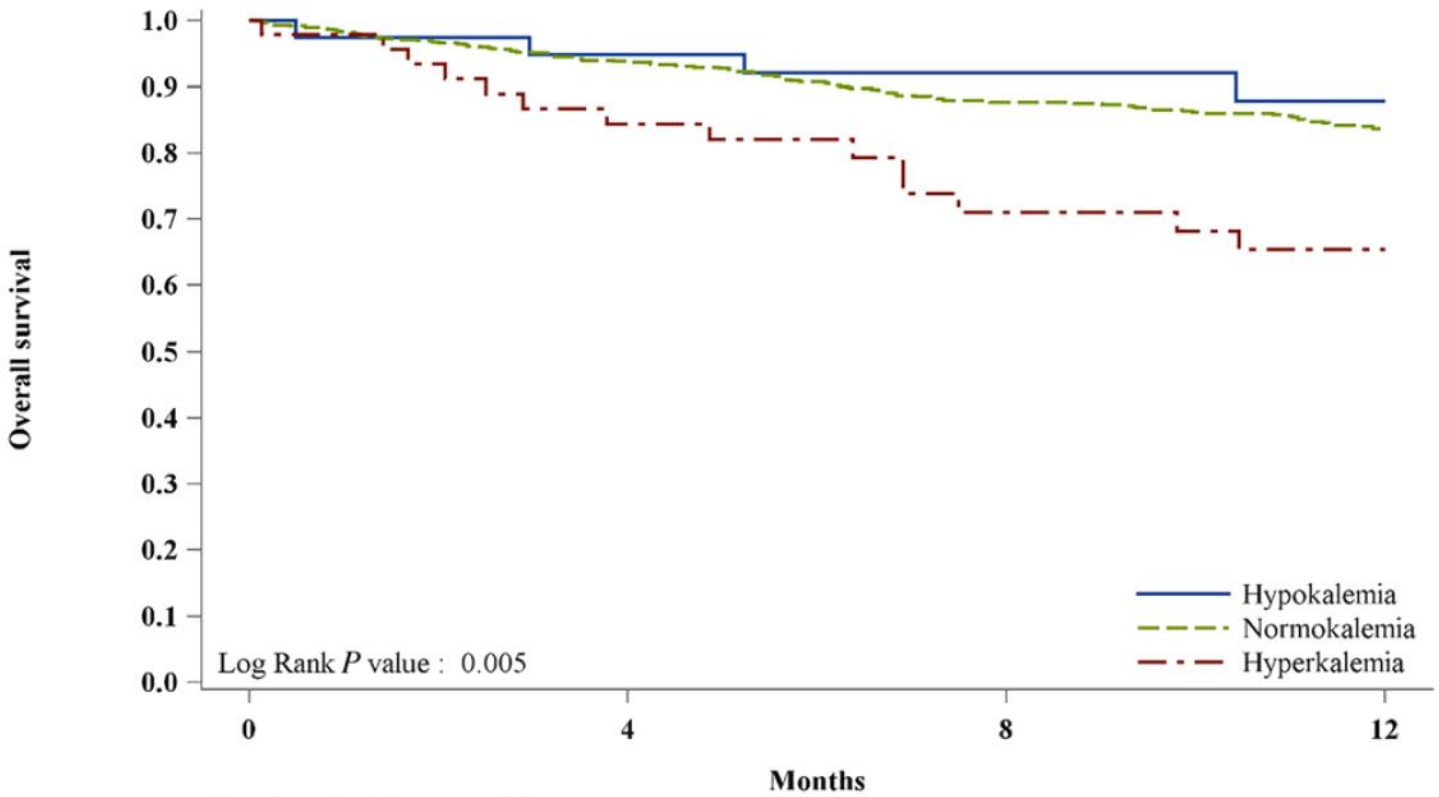
Erhöhte Mortalität bei ADHF und Hyperkaliämie



Number of subjects at risk				
Hypokalemia	40	36	28	20
Normokalemia	840	724	565	452
Hyperkalemia	46	36	25	23

C. M. Lombardi et al.: **Prognostic significance of serum potassium in patients hospitalized for acute heart failure.** ESC Heart Failure 2022

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Rezidiv - Risiko Hyperkaliämie unter RAASi

What is the risk of recurrence of RAASi-related hyperkalemia with ambulatory treatment options?

CJASN
Clinical Journal of the American Society of Nephrology

Population-based, retrospective cohort study

Study Population

n = 49571
RAASi associated hyperkalemia (K > 5.3 mEq/L)

Mean age 79yrs

Mean eGFR 56ml/min/1.73m²

Most prescribed Intervention - RAASi discontinuation 74%

Intervention → 1 year → Risk of

	Recurrent Hyperkalemia [Adjusted HR (95%CI)]	Cardiovascular events [Adjusted HR (95%CI)]	All-cause mortality [Adjusted HR (95%CI)]
No intervention	Ref	Ref	Ref
RAASi discontinuation	0.82 (0.78-0.85)	0.96 (0.91-1.02)	1.05 (0.96-1.15)
RAASi dose decrease	0.94 (0.86-1.02)	1.35 (1.23-1.48)	1.15 (1.00-1.33)
New Diuretic	0.95 (0.78-1.17)	1.00 (0.74-1.34)	1.23 (0.80-1.89)
Diuretic Dose increase	0.99 (0.87-1.12)	1.70 (1.51-1.91)	1.36 (1.14-1.62)
Sodium Polysterene Sulfonate	1.30 (1.04-1.63)	1.29 (0.98-1.69)	0.97 (0.62-1.53)

Conclusions: Among adults of advanced age with RAASi-related hyperkalemia, RAASi discontinuation is the most common pharmacologic intervention and is associated with the lowest risk of recurrent hyperkalemia with no apparent increase in short-term risks for cardiovascular events or all-cause mortality.

Gregory L. Hundemer, Robert Talarico, Navdeep Tangri, et al. ***Ambulatory Treatments for RAAS Inhibitor-Related Hyperkalemia and the 1-Year Risk of Recurrence***. CJASN doi: 10.2215/CJN.12990820. **Visual Abstract by Aakash Shingada, MD**

Hundemer, G. L., et al. (2021). **"Ambulatory Treatments for RAAS Inhibitor–Related Hyperkalemia and the 1-Year Risk of Recurrence."** Clinical Journal of the American Society of Nephrology: CJN.12990820.

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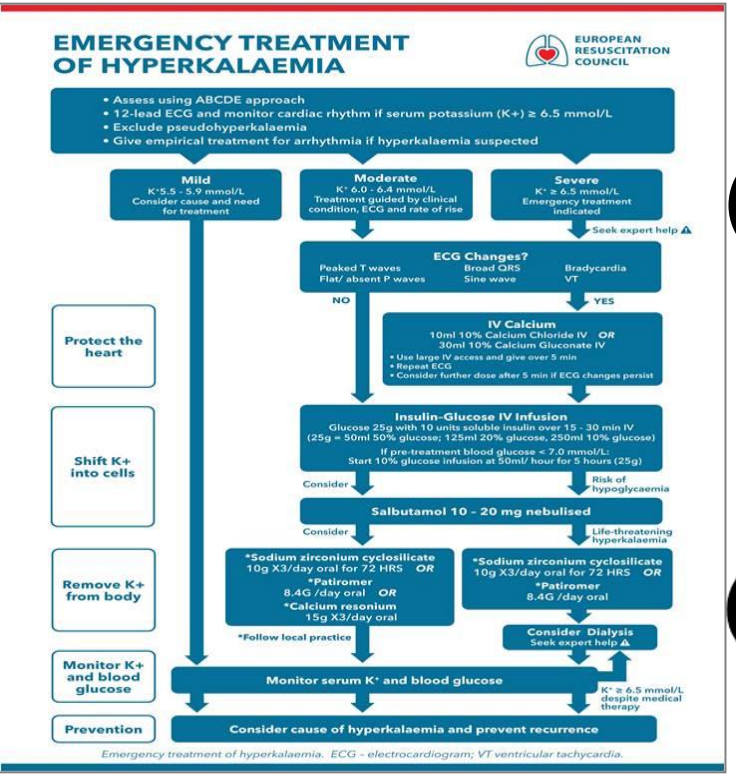
Therapieoptionen

UPDATE DER EUROPÄISCHEN NOTFALL-LEITLINIE 2021 EMPFIEHLT KALIUMBINDER, UM KALIUM AUS DEM KÖRPER ZU ENTFERNEN



Lott C, et al. Resuscitation. 2021;161:152-219

Moderate
K^+ 6,0 - 6,4 mmol/l
Treatment guided by clinical condition, ECG and rate of rise

Severe
K^+ > 6,5 mmol/l
Emergency treatment indicated

Sodium zirconium cyclosilicate 10g x3/day oral for 72 hrs OR **Patiromer** 8.4 g/day oral OR Calcium resonium 15 gx3/day oral

Sodium zirconium cyclosilicate 10g x3/day oral for 72 hrs OR **Patiromer** 8.4 g/day oral

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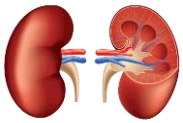
Moderne versus ältere Kaliumbinder: Pharmakologie und Pharmakokinetik

	Patiromer	SZC	SPS/CPS
Wirkmechanismus	Calcium-basierter Ionentauscher	Natrium-basierter Ionentauscher	Natrium/ Calcium-basierter Ionentauscher
Wirkort	Distales Kolon	GI Trakt	GI Trakt
Onset of action (Wirkeintritt in h)	4-7	1	1- 6
Wirk- Dauer, Std.	12- 48	2,2 - 12	4 - 24
Start- Dosis	8,4 g / 1 x Tag	10 g / 3 x Tag für bis zu 2 Tage. Danach 5-15 g / Tag	15 g oral 1 – 4 x / Tag
Abstand zu oralen Medikamenten	3 h	2 h, wenn pH abhängig	3 h
Maximal Dosis	25,2 g	30 g	60 g

GI: gastrointestinal; **SPS/CPS**: Sodium Polystrol Sulfonat; **SZC**: Natrium Zirconium Cyclosilikat

Basierend auf /adaptiert nach: Beccari MV, Meaney CJ. Clinical utility of patiromer, sodium zirconium cyclosilicate, and sodium polystyrene sulfonate for the treatment of hyperkalemia: an evidence-based review. *Core Evid.* 2017;12:11-24.



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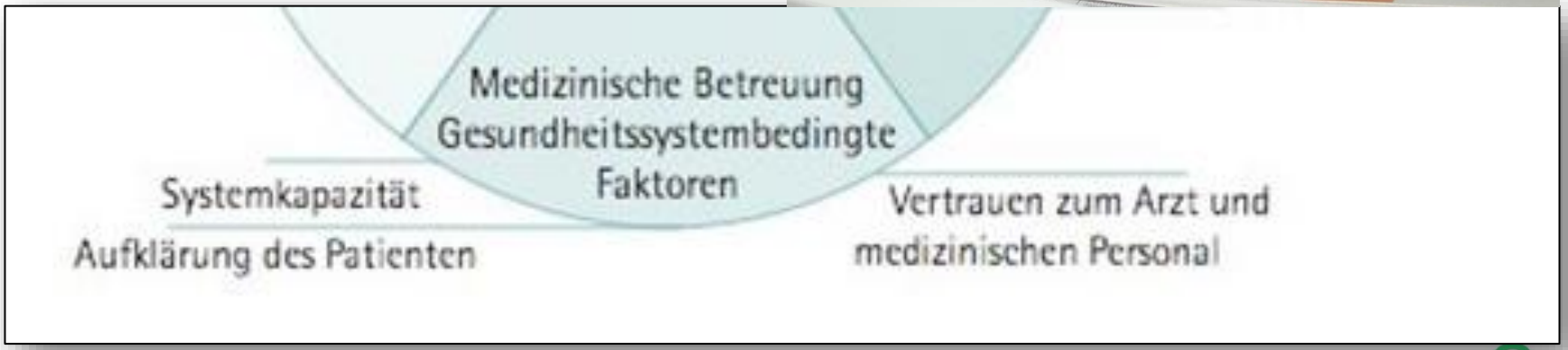
Compliance und Adhärenz



Klinikum Braunschweig

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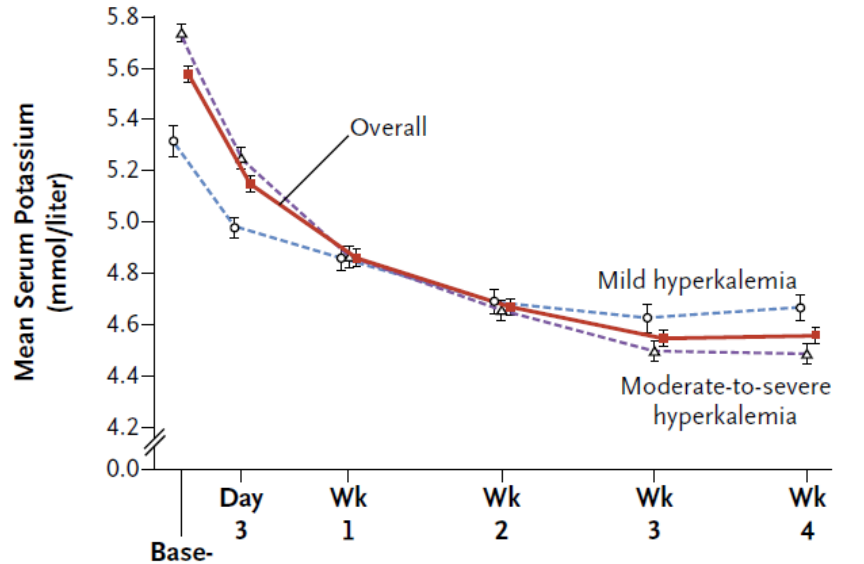
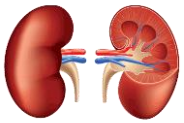
Kaliumbinder: Patiromer



No. at Risk	Base-line	Day 3	Wk 1	Wk 2	Wk 3	Wk 4
Overall	243	217	237	228	221	219
Mild hyperkalemia	92	80	90	87	85	85
Moderate-to-severe hyperkalemia	151	137	147	141	136	134



WEIR et al. : Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors.

NEJM 372(3):211-21, 2015

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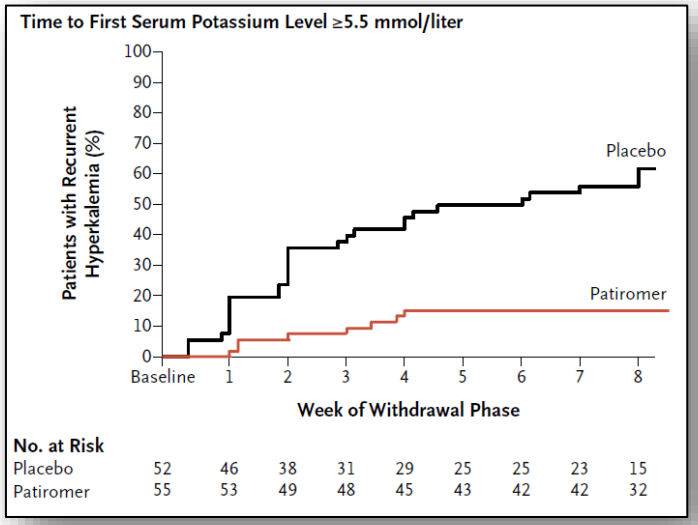
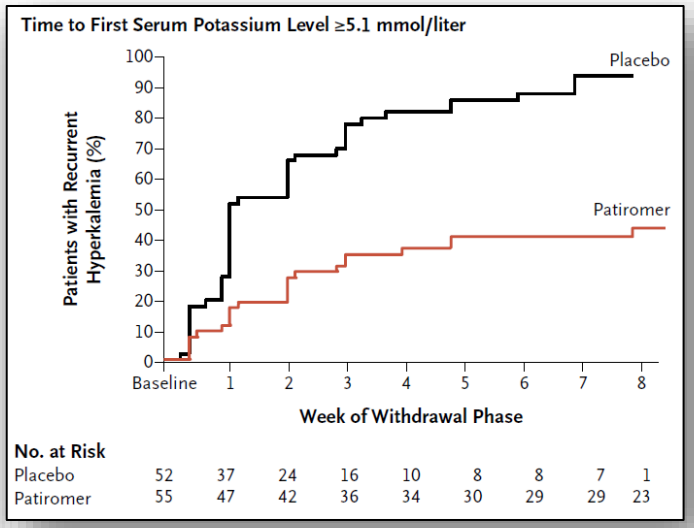
Chronische Kaliumsenkung mit Patiromer





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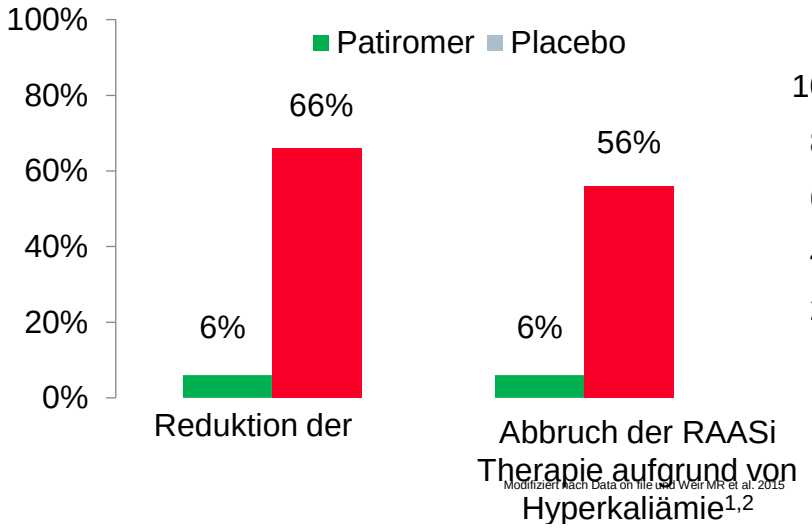
OPAL-HK:

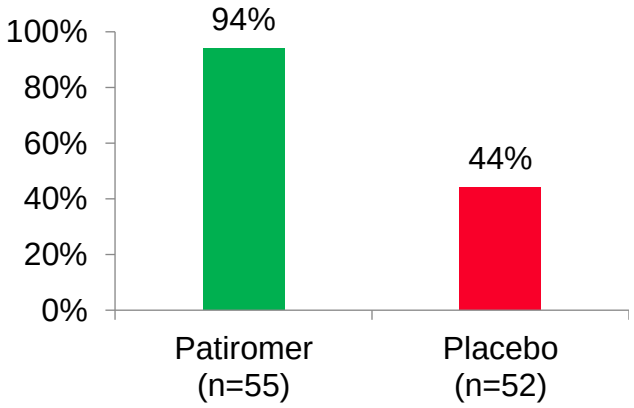
Bei kardiorenalen Patienten mit Hyperkaliämie kann Patiromer eine RAAS – Inhibitor Therapie ermöglichen

Anteil der Patienten mit Dosisreduktion oder Abbruch der RAASi Therapie aufgrund von Hyperkaliämie in Woche 8[1,2]



Modifiziert nach Data on file und Weir MR et al. 2015

Anteil der RAASi-Patienten in Woche 8 (Teil B)[2]



Modifiziert nach Weir MR, et al. 2015

1. Data on file. Redwood City, CA. Relypsa, Inc. Data source: Humedica, Cambridge, MA;
2. WEIR et al. : **Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors.** NEJM 372(3):211-21, 2015

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DIAMOND

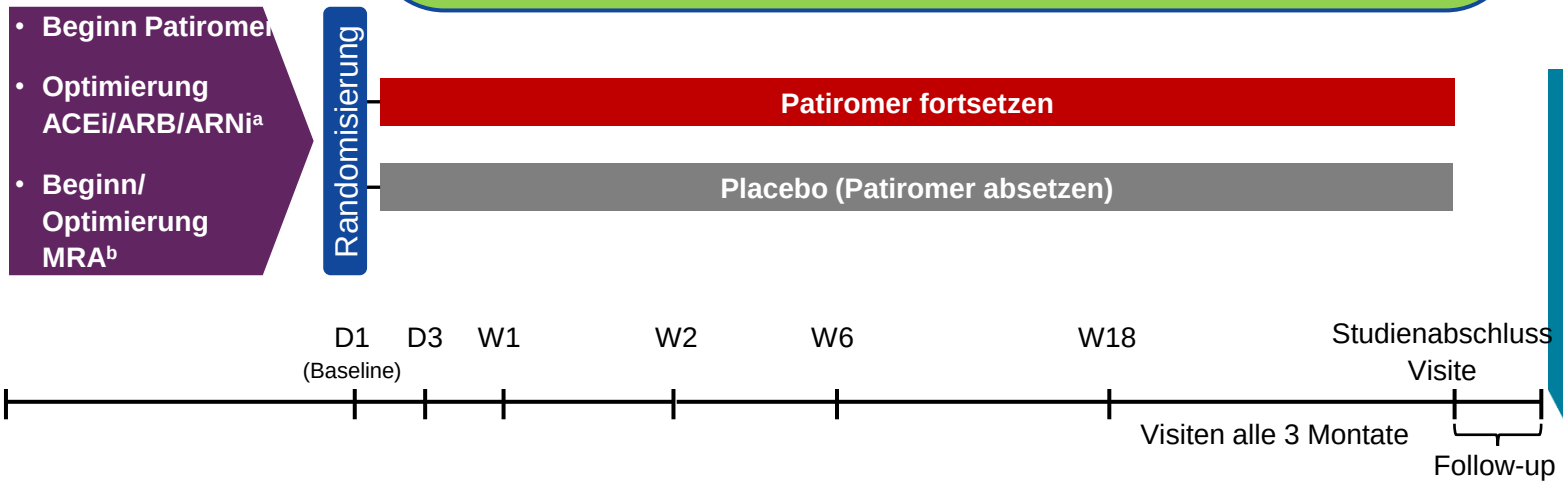
Während der Run-in Phase:
85% der Hochrisikopatienten konnten auf die Leitlinien-empfohlenen RAASi-Dosen optimiert werden[2]

Hyperkaliämie

- Serum K^+ >5.0 mEq/l
- unter RAASi

Normokaliämie

- Serum K^+ 4.0–5.0 mEq/l
- Vorgeschichte von HK, die zu RAASi Dosisreduktion oder Absetzen führte



Screening	Einfach verblindete, Run-in Phase (bis zu 12 Wochen)	Doppelt verblindete Behandlungsphase

ACEi=Angiotensin-Converting Enzym Inhibitor; ARB=Angiotensin II Rezeptor Blocker; ARNi=Angiotensin Rezeptor-Neprilysin Inhibitor; HK=Hyperkaliämie; RAASi=Renin–Angiotensin–Aldosteron-System Inhibitor; W=Woche.
Das Follow-up nach der Studienabschluss Visite umfasste ein K+ Assessment innerhalb von 2 Wochen nach Absetzen von Patiromer/Placebo und/oder ein Follow-up-Telefonat mindestens 2 Wochen nach der Studienabschluss Visite.
[a] ≥50% empfohlene Dosis ACEi/ARB/ARNi.
[b] 50 mg MRA (Spironolacton oder Eplerenon).

1. Butler J, et al. *Eur J Heart Fail*. 2022;24(1):230-238. 2. https://www.viforpharma.com/vifor-pharma-reports-positive-outcome-phase-iiib-diamond-trial-veltassar [Zugriff 11-05-2022]

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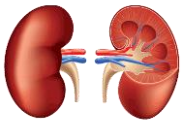
Ergebnisse

1. **Mit Patiromer konnten 85 % der HFrEF-Patienten auf eine Leitlinien-empfohlene RAASi Dosierung eingestellt werden (Run-in Phase).**
2. Eine Patiromer-Behandlung hielt signifikant niedrigere Serum-K^+-Spiegel aufrecht (primärer Endpunkt).
3. Patiromer war im Vergleich zu Placebo mit einem signifikant geringeren Auftreten von Hyperkaliämie-Ereignissen, sowie einem größeren Anteil an Patienten unter Beibehaltung der MRA-Zieldosierung assoziiert.
4. Patiromer reduzierte das Risiko für Hyperkaliämie-Ereignisse um 37 %.



Is patiromer safe and effective in lowering serum potassium among elderly CKD patients receiving RAAS inhibitors?

Kidney Medicine

Methods and Cohort

- Multicenter, open-label RCT
- AMETHYST-DN ≥75 years old (N = 60)
- Patiromer 8.4–33.6 g TDD
- Post hoc Subgroup Analysis
- 52 weeks

Patient Disposition

- **77** Mean Age
- **50%** Men
- **42** mL/min/1.73m² Mean eGFR
- **5.2** mEq/L Mean serum K
- **40** Completed study

Findings

Least squares-mean reduction of serum K⁺

–0.65 mEq/L Week 4

–0.61 mEq/L Week 52

Serum K⁺ after stopping patiromer

4.79 mEq/L after 3 days

4.85 mEq/L after 7 days

4.95 mEq/L after 14 days

Serum K⁺ at the end of 52 weeks

100% of patients had Serum K <5.5

95% of patients had Serum K <5.0

Adverse Effects

10 patients with at least 1 patiromer-related AE

0 cases of hypokalemia or severe hypomagnesemia

Most common AE leading to drug discontinuation

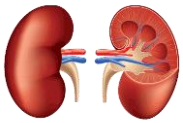
GI symptoms (2) , Chronic kidney failure (2)

Conclusion: Among older patients with hyperkalemia and diabetic kidney disease, treatment with patiromer resulted in significant reductions in serum potassium levels after 4 weeks and lasted through 52 weeks. Patiromer was effective in lowering serum potassium and was well tolerated in older patients.

Reference: Bakris GL, Woods SD, Alvarez PJ, et al. Hyperkalemia management in older adults with diabetic kidney disease receiving renin-angiotensin-aldosterone system inhibitors: a post hoc analysis of the AMETHYST-DN clinical trial. *Kidney Medicine*, 2021.

Visual Abstract by Carlo Trinidad, MD

@hellokidneyMD



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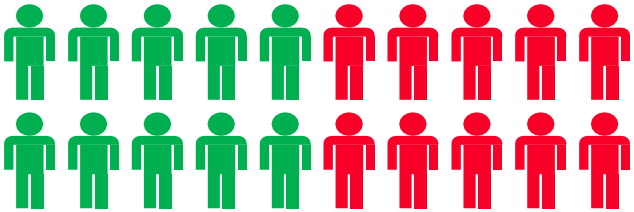
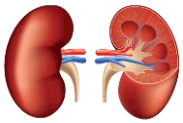
Hyperkaliämie – oft kein Einzelfall

50%



mit Hyperkaliämie (≥5.5 mmol/l)
hatten ≥ Rezidive in 1 Jahr



Einhorn LM, et al. Arch Intern Med. 2009;169:1156–62.

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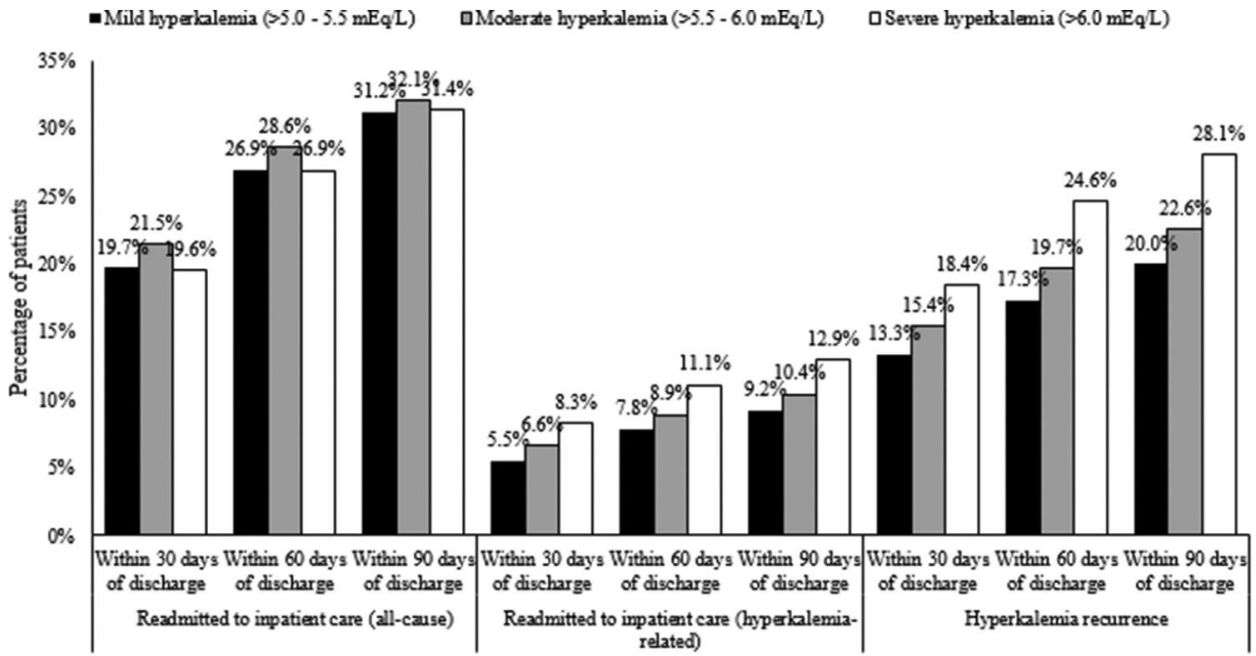
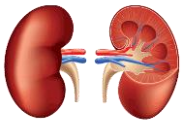
Poststationäre Ereignisse nach Hyperkaliämie



Hyperkalemia Severity	p-values 30 days	p-values 60 days	p-values 90 days	p-values 30 days	p-values 60 days	p-values 90 days	p-values 30 days	p-values 60 days	p-values 90 days
Mild vs. moderate	<0.05*	<0.05*	0.31	<0.05*	<0.05*	<0.05*	<0.01*	<0.01*	<0.001*
Mild vs. severe	0.98	0.97	0.86	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

1 % bei Entlassung Kaliumbinder,
obwohl ~ 18 % Hyprkaliämie



Jill Davis et al.: I**npatient management and post-discharge outcomes of hyperkalemia.**
Hosp Pract 2021: 273-279.

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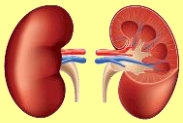
Nephrologische Intervention

Abixanan 2,5 mg	1 – 0 – 1
ASS 100	0 – 1 – 0
Valsartan 40 mg	1 – 0 - 1
Torasemid 10 mg	1 – 0 – 0
Spironolacton 25 mg	1 – 0 - 0
Bisoprolol 2,5 mg	1 – 0 - 1
SGLT2 –Hemmer 10	1 – 0 – 0
Atorvastatin 40 mg tgl.	0 – 0 - 1
+ Patiromer 8,4 g	**1 – 0 – 0**



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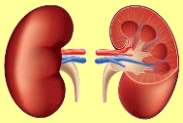
Zwei Monate später

19. 07. 2021:	Kreatinin	1, 4 mg%
	eGFR:	34 ml/min
	Kalium	4,7 mmol/l
	BNP	121 pg/ml

Abixaban 2,5 mg	1 – 0 – 1	
ASS 100	0 – 1 – 0	
Valsartan 40 mg	1 – 0 - 1	
Torasemid 10 mg	1 – 0 – 0	
Spironolacton 25 mg	1 – 0 - 0	**„Free on sick days“**
Bisoprolol 2,5 mg	1 – 0 - 1	
Deapaglifozin 10 mg	1 – 0 – 0	
Atorvastatin 40 mg tgl.	0 – 0 - 1	
+ Patiromer 8,4 g	**1 – 0 – 0**	



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Ambulante Untersuchungsintervalle

Abhängig vom Kalium und dem Patienten …

Kaliumwert	Kontrollintervalle
> 6,5	Stationäre Kontrolle Ambulant: 24 (bis m BGA
6,0 – 6,5	48-72 h
5,5 – 5,9	3 – 7 Tage
5,1 – 5,5	1 - 2 Wochen
< 5,0	Monatlich bei Risiko

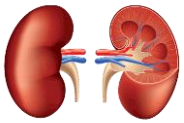
→ **Individuelle Entscheidung (Risikopro**

Patients being considered for treatment with angiotensin-converting-enzyme inhibitors or angiotensin-receptor blockers:

- At treatment initiation
- 1–2 weeks after initiation
- 1–4 weeks after final dose titration
- At regular intervals thereafter based on the patient's individual risk

Patients being considered for treatment with mineralocorticoid receptor antagonists:

- 1 and 2 weeks after initiating or increasing dose
- At 8 and 12 weeks after initiation or increasing dose
- At 6, 9, and 12 months after initiation or increasing dose
- At regular intervals thereafter based on the patient's individual risk



Jordan Weinstein et al.: **Prevention and management o hyperkalemia in patients treated with renin–angiotensin–aldosterone system inhibitors.** CMAJ 2021 December 6;193:E1836-41.

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ESC 2021 EMPFEHLUNG ZUR KONTROLLE UND BEHANDLUNG DER CHRONISCHEN HYPERKALIÄMIE

Kontrolle des Serum-K^+-Spiegels
bei Einleitung oder Erhöhung der RAASi- Therapie[1-3]

↓

3 Tage – 4 Wochen
nach der Einleitung / Erhöhung, danach in regelmäßigen Abständen

Serum-Kalium 4,5 bis 5,0 mEq/l

↓

Initiierung oder Auftitration RAASi möglich
Kaliumbinder einsetzen (Patiromer, SZC), wenn K^+ > 5,0 mEq/l [3]

Serum- Kalium > 5,0 bis < 6,5 mEq/l

↓

Kaliumbinder Patiromer, SZC
zur Wiederherstellung der Normokaliämie [3]

↙ ↘

Maximale RAASi-Therapie
RAASi Dosierung beibehalten, langfristiger Einsatz Kaliumbinder möglich

noch submaximale RAASi-Therapie
Sobald < 5,0 mEq/l mit Initiierung oder Auftitration der RAASi beginnen, langfristiger Einsatz Kaliumbinder möglich

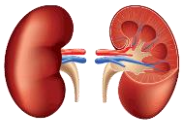
Serum- Kalium > 6,5 mEq/l
oder EKG -Veränderungen

↓

Einleitung der **Notfallbehandlung†**
wenn der K^+-Spiegel ein gefährliches Niveau erreicht Absetzen oder Reduktion der RAASi[3]

RAASi = ACEi/ARNI / (Sartane) / MRA + BB

EKG = Elektrokardiogramm; RAASi = Renin-Angiotensin-Aldosteron-System-Inhibitor



1. Raebel MA. Cardiovasc Ther. 2012;30(3):e156–e166;
2. Yancy CW et al. Circulation. 2013;128:e240-327;
3. McDonagh T.A. et al. Eur Heart J. 2021;42(36):3599-3726. supplementary data;

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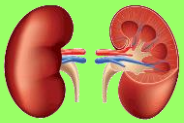
Botschaften

1. **Treat the patient, not the number**
   - DD Pseudohyperkaliämie

2. **RAASi Therapie fortführen bei Nierenfunktionseinbuße!**

3. **Patiromer ist sicher und ermöglicht Therapie mit RAASi**
   → und reduziert relevant Hyperkaliämie – Ereignisse

4. **Additive Diagnostik und Therapie bei Herzinsuffizienz:**
   → Eisenmangel ist häufig(er als gedacht)
   → i.v. Eisencarboxymaltose bessert Symptomatologie



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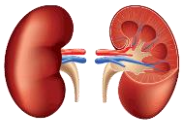
Vielen Dank



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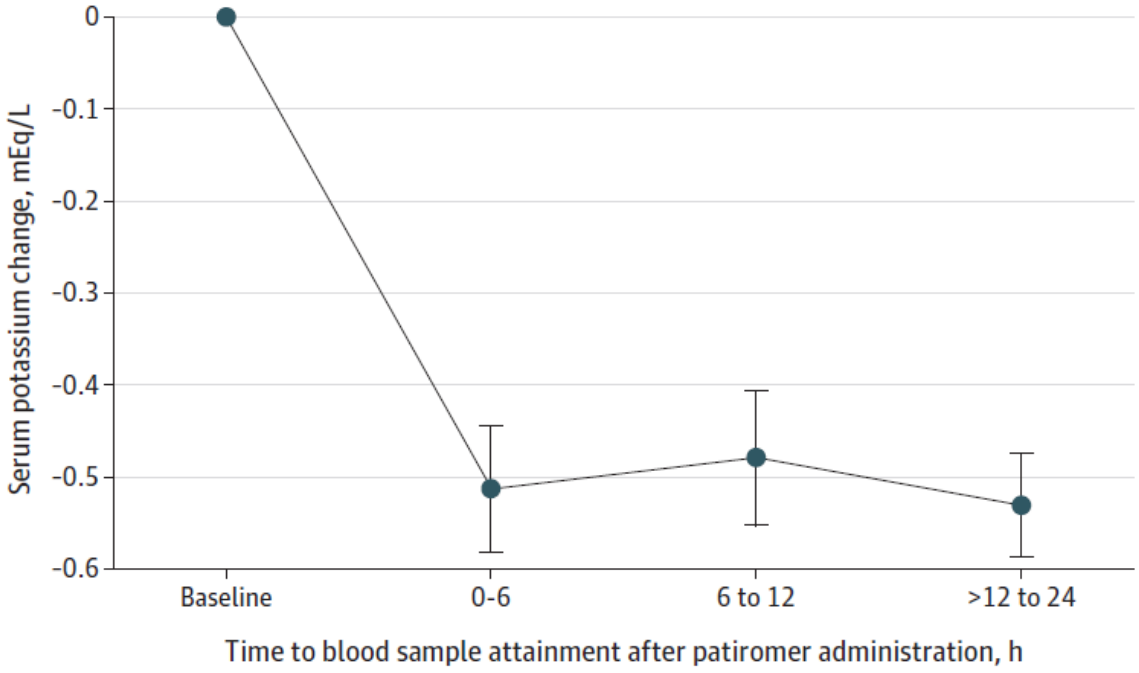
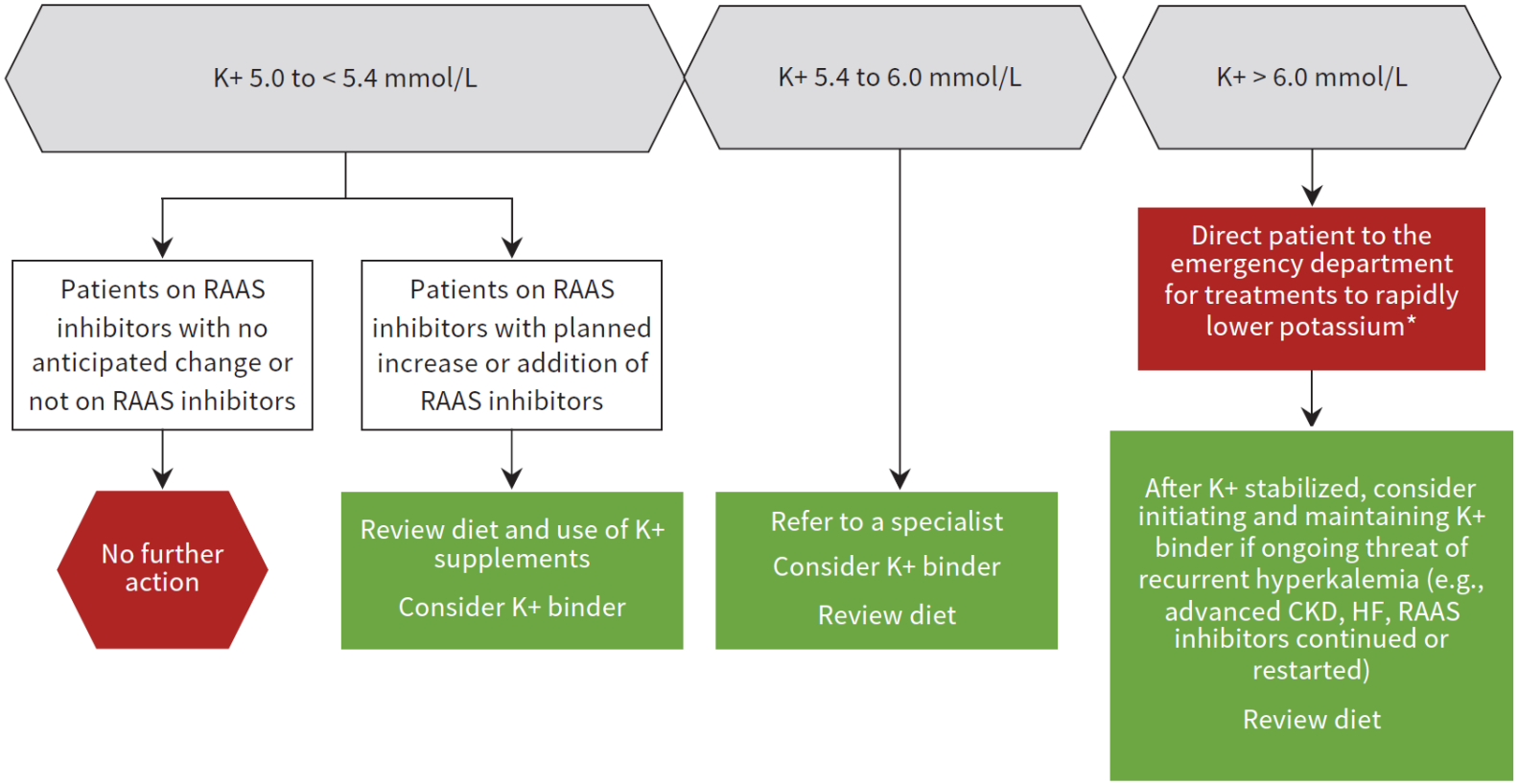
Patiromer in der Notaufnahme

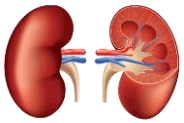
Figure 1. Absolute Serum Potassium Level Reduction Across All Time Intervals



JAMA Network Open. 2022;5(1):e2145236. doi:10.1001/jamanetworkopen.2021.45236

Alternativer Algorithmus





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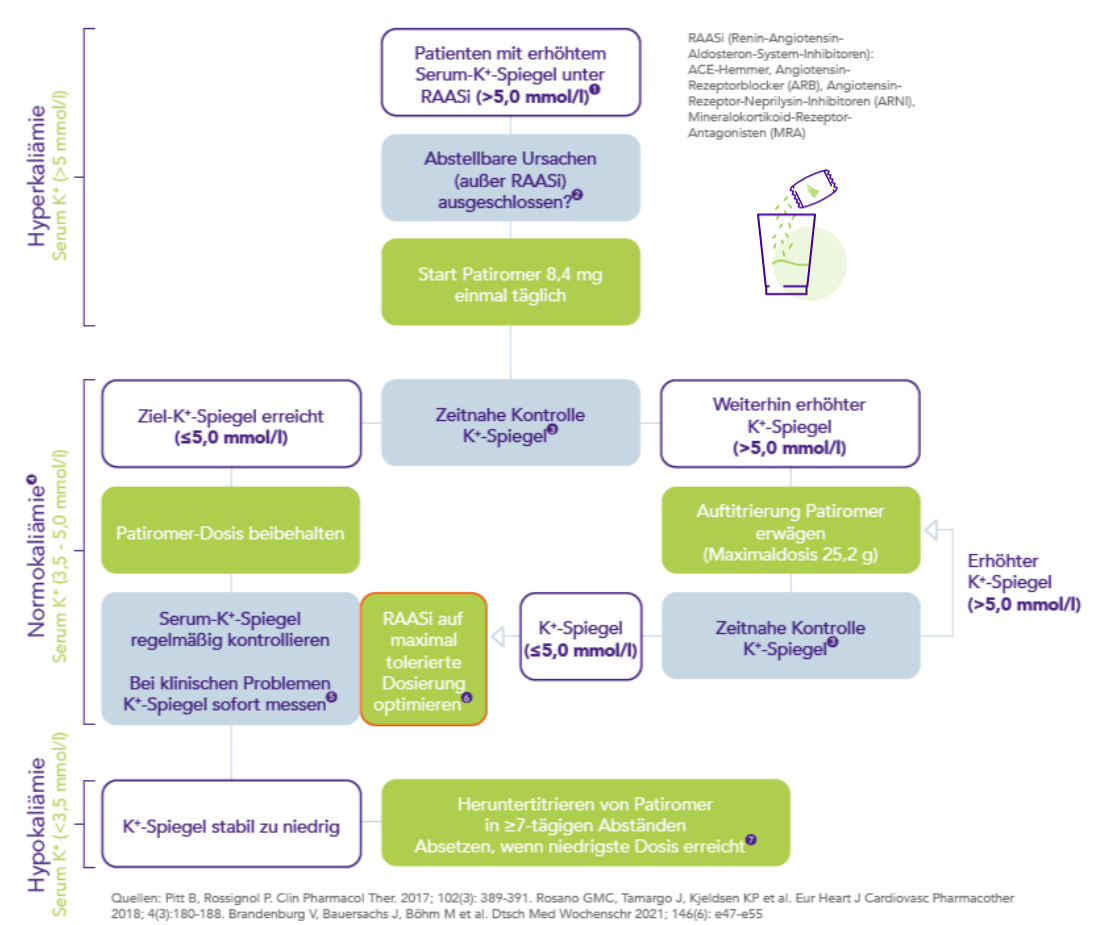
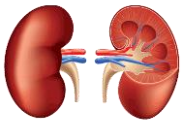
Behandlungsempfehlungen: Einsatz von Patiromer bei chronischer Hyperkaliämie



Quellen: Pitt B, Rossignol P. Clin Pharmacol Ther. 2017; 102(3): 389-391. Rosano GMC, Tamargo J, Kjeldsen KP et al. Eur Heart J Cardiovasc Pharmacother 2018; 4(3):180-188. Brandenburg V, Bauersachs J, Böhm M et al. Dtsch Med Wochenschr 2021; 146(6): e47-e55

Modifiziert nach Pitt B., Rossignol P. 2017



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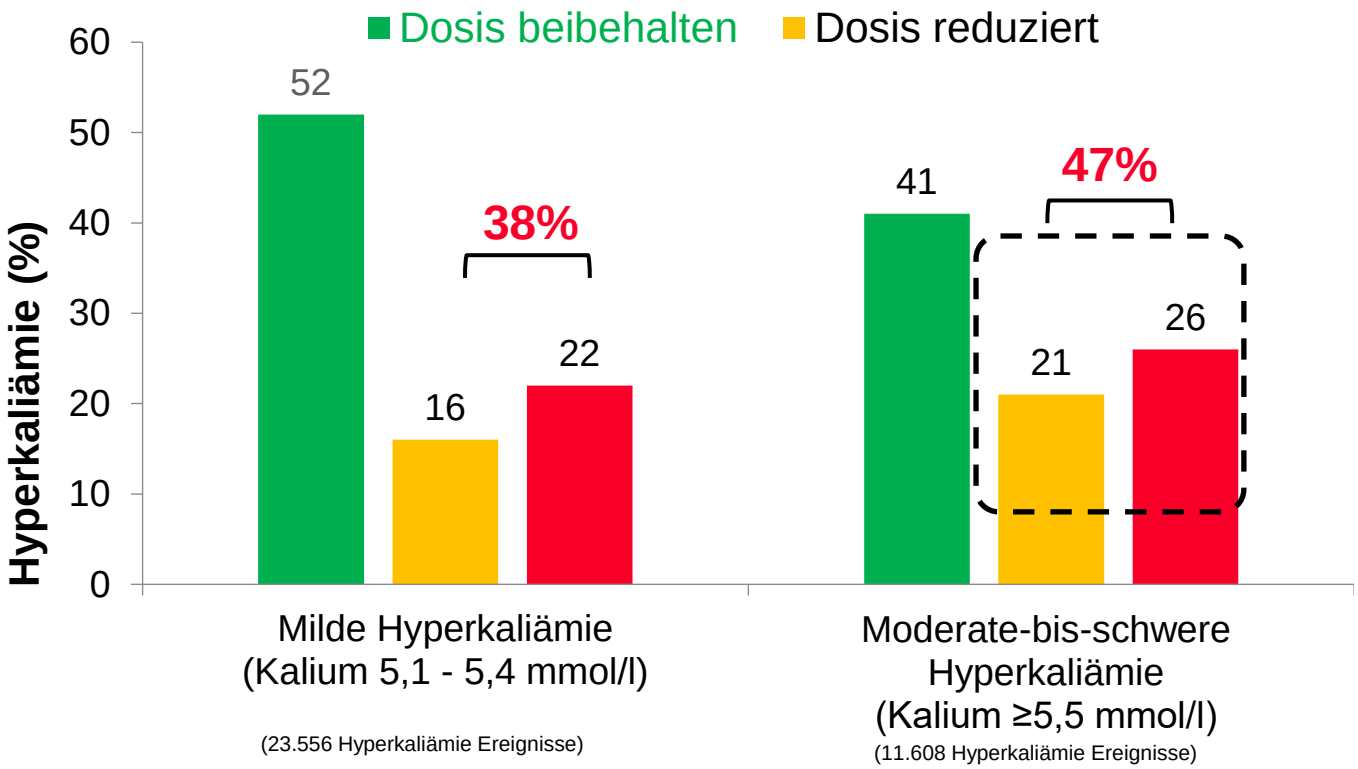
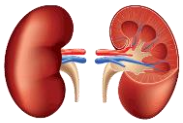
Hyperkaliämie:
Häufige Ursache für Abbruch / Reduktion RAASi-Therapie*

Bei fast der Hälfte der Patienten mit maximaler RAASi-Dosis wurde die Behandlung nach einem Hyperkaliämie-Ereignis reduziert oder abgebrochen





Epstein M, et al. Am J Manag Care. 2015;21:S212–20.

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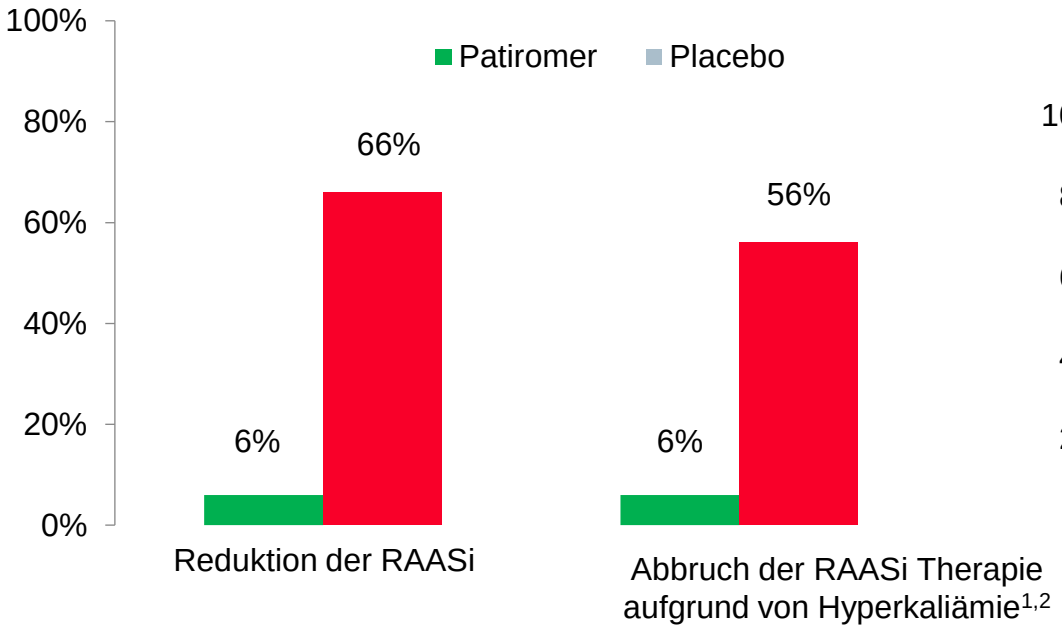
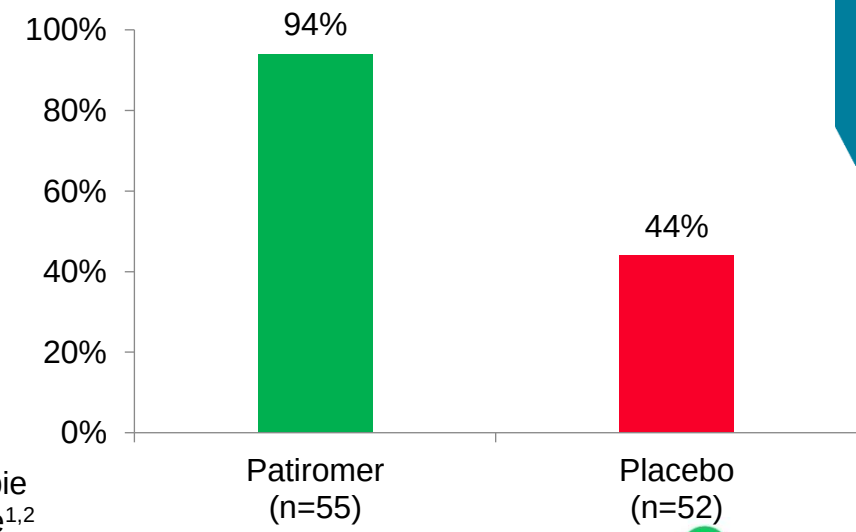
Anteil der Patienten mit Dosisreduktion oder Abbruch der RAASi Therapie aufgrund von Hyperkaliämie in Woche 8[1,2]



Modifiziert nach Data on file und Weir MR et al. 2015

Anteil der RAASi-Patienten in Woche 8 (Teil B)[2]



Modifiziert nach Weir MR, et al. 2015

1. Data on file. Redwood City, CA. Relypsa, Inc. Data source: Humedica, Cambridge, MA;

2. WEIR et al. : **Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors.** NEJM 372(3):211-21, 2015

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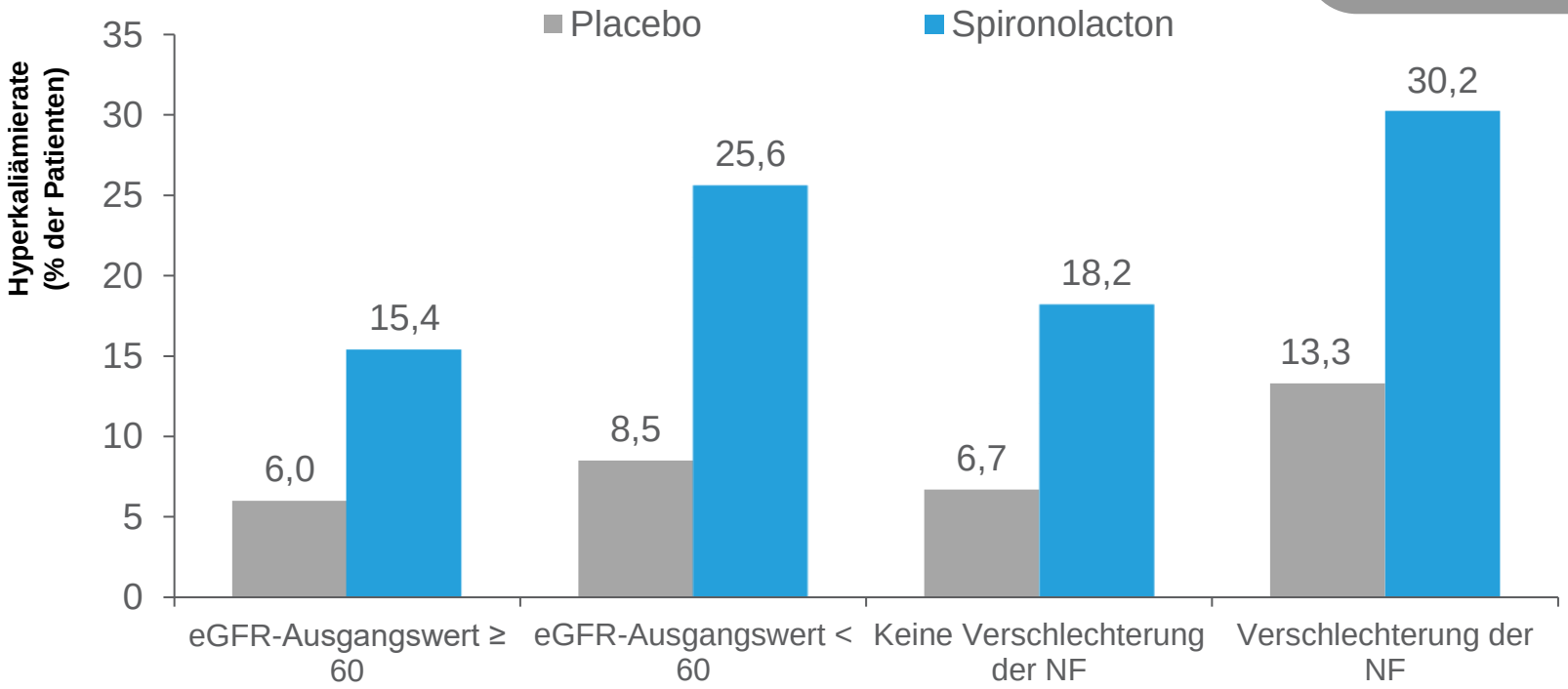
Bei HI-Patienten steigt die Hyperkaliämierate (Serum-K^+ > 5,5 mmol/l) mit abnehmender Nierenfunktion

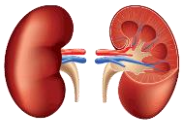
RALES-Studie

Eine beeinträchtigte Nierenfunktion erhöht das Risiko einer Hyperkaliämie sowohl bei Placebo als auch bei mit Sprionolacton behandelten Patienten.



eGFR = geschätzte glomeruläre Filtrationsrate; NF = Nierenfunktion

Vardeny O, et al. *J Am Coll Cardiol.* 2012;60:2082–89.



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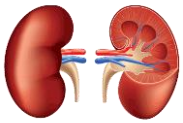
Patiromer : nicht-resorbierbarer Kalium-Binder

Patiromer durchläuft den Magen-Darm-Trakt in 24 bis 72 Stunden

- Patiromer ist bei physiologischem pH-Wert des Dickdarms vollständig ionisiert – für einen optimalen Ionenaustausch
- Carboxylatgruppen von Patiromer binden an K^+
  - hauptsächlich in Dickdarmepithelzellen

- K^+ wird gegen Ca^{2+} ausgetauscht
- Patiromer-Polymere werden über den Darm ausgeschieden
  - Entfernung von überschüssigem K^+

- **Patiromer kann mit oder ohne Nahrung aufgenommen werden,**
  - **wichtig lediglich zeitliche Abstand von 3 h vor bzw. nach der restlichen Medikation um WW zu vermeiden**
  - **Apfelschorle funktioniert bestens**



Li L, et al. J Cardiovasc Pharmacol Ther. 2016;21(5):456–65.

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Nicht vier kleine,
sondern EIN GROSSER SCHRITT

ESC guidelines 2021: Diagnosis and treatment of acute and chronic HF

Therapeutic algorithm of class I therapy indications for a patient with HFrEF

Management of patients with HFrEF

- ACEi/ARNI*
- Beta blocker
- MRA
- Dapagliflozin/Empagliflozin
- Loop diuretics for fluid retention

(Class I)

LVEF≤35% and QRS <130 ms and where appropriate

LVEF >35% or device therapy not indicated or inappropriate

SR and LVEF ≤35% and QRS ≥130 ms

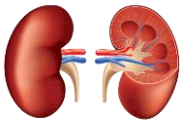
ICD
Non-ischemic (Class IIa)
Ischemic (Class I)

CRT-D/-P**
QRS 130-149 ms (Class IIa)
QRS ≥150 ms (Class I)

If symptoms persist, consider therapies with Class II recommendations

*As a replacement for ACEi. **Where appropriate.

McDonagh TA, et al. Eur Heart J 2021; doi 10.1093/eurheartj/ehab368; [Epub ahead of print].
Gardener, RS | New ESC Guidelines – Guidelines for the diagnosis and treatment of acute and chronic heart failure. ESC 2021.



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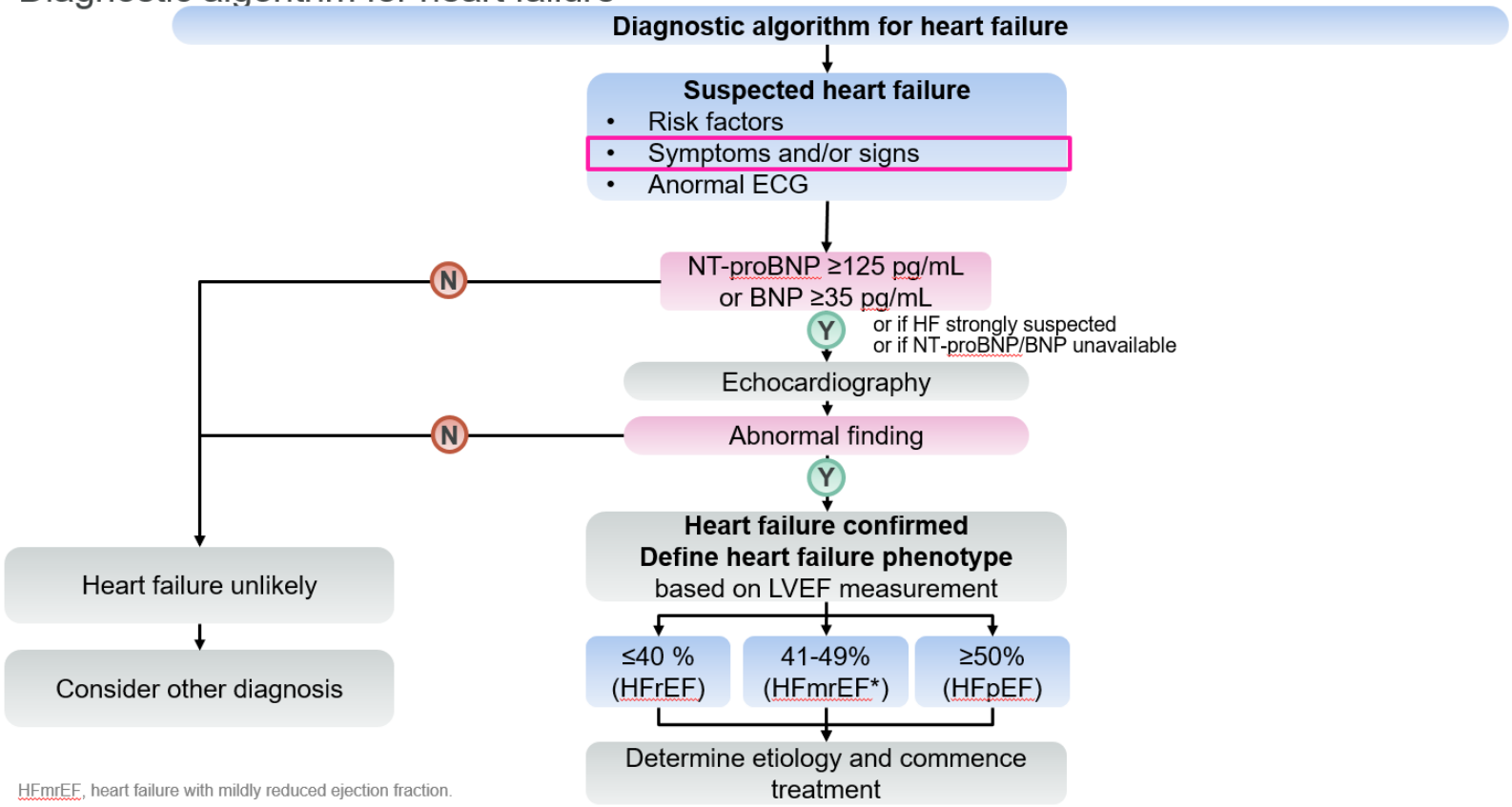
ESC guidelines 2021: Diagnosis and treatment of acute and chronic HF

Diagnostic algorithm for heart failure



HFmrEF, heart failure with mildly reduced ejection fraction.

McDonagh TA, et al. Eur Heart J 2021; doi 10.1093/eurheartj/ehab368; [Epub ahead of print].

Gardener, RS | New ESC Guidelines – Guidelines for the diagnosis and treatment of acute and chronic heart failure. ESC 2021.

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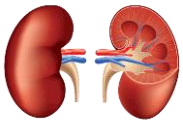
Eisemangel

Recommendations for the management of anaemia and iron deficiency in patients with heart failure

Recommendations	Class[a]	Level[b]
It is recommended that all patients with HF be periodically screened for anaemia and iron deficiency with a full blood count, serum ferritin concentration, and TSAT.	I	C
Intravenous iron supplementation with ferric carboxymaltose should be considered in symptomatic patients with LVEF <45% and iron deficiency, defined as serum ferritin <100 ng/mL or serum ferritin 100–299 ng/mL with TSAT <20%, to alleviate HF symptoms, improve exercise capacity and QOL.[720,722,724]	IIa	A
Intravenous iron supplementation with ferric carboxymaltose should be considered in symptomatic HF patients recently hospitalized for HF and with LVEF <50% and iron deficiency, defined as serum ferritin <100 ng/mL or serum ferritin 100–299 ng/mL with TSAT <20%, to reduce the risk of HF hospitalization.[512]	IIa	B

© ESC 2021



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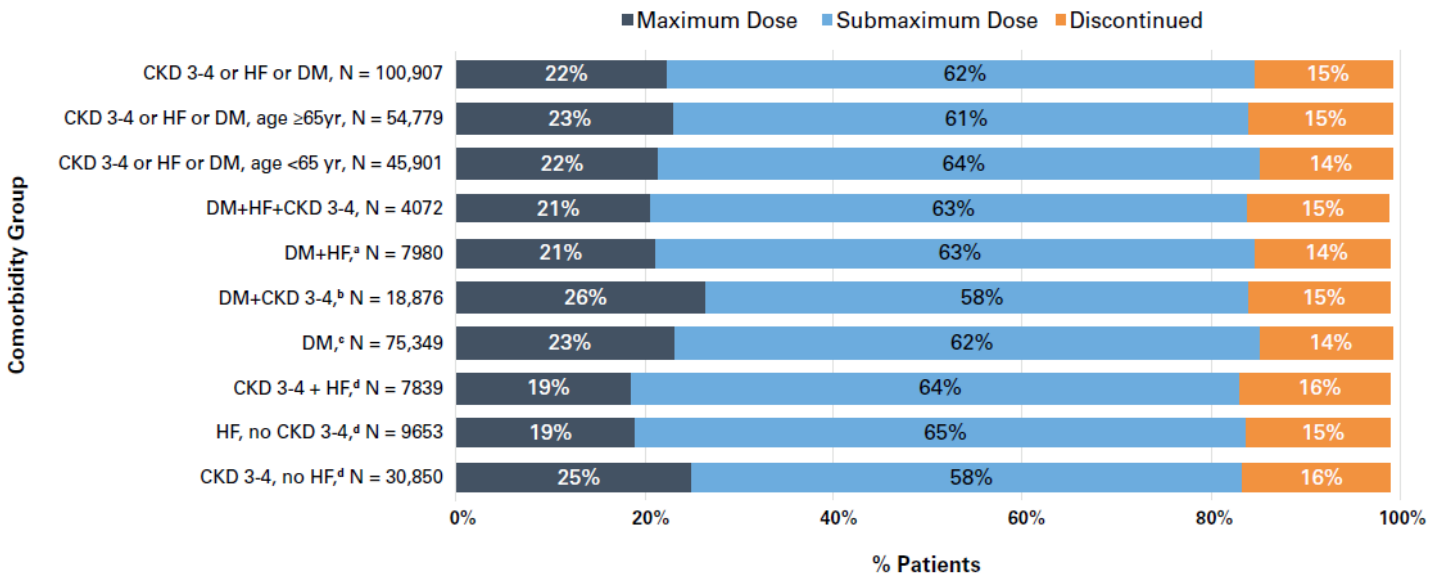
Weniger als 30% der Patienten werden entsprechend den Guideline Empfehlungen mit RAAS Inhibitoren therapiert

Verabreichte RAASi Dosierung nach Co- Morbiditäten Gruppe



M Epstein et al. Am J Manag Care, 2015;21:212-220

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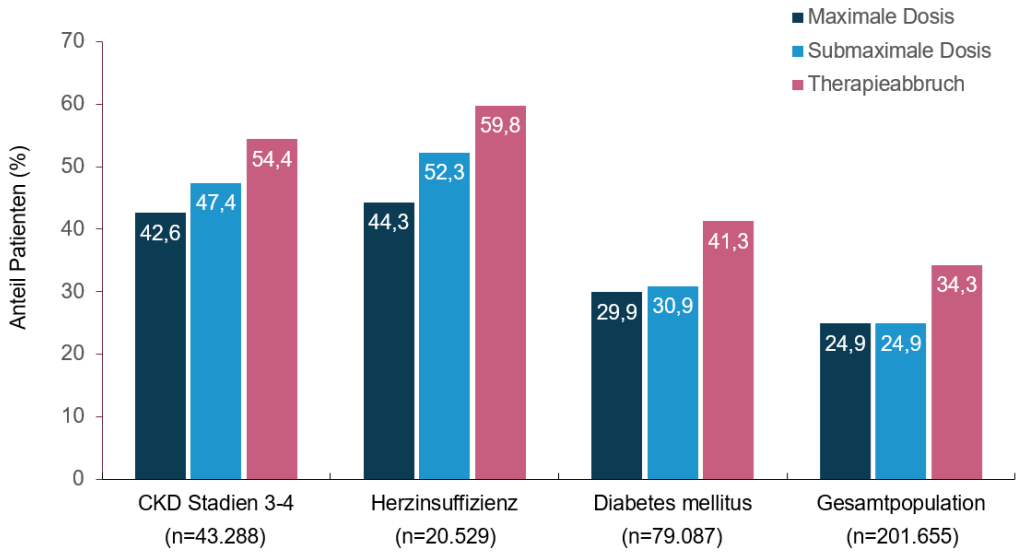
RAAS – Inhibition hinreichend ?

EINE REDUKTION DER RAASi-DOSIS KANN DEN THERAPIE-ERFOLG VERRINGERN

Anteil (%) an Patienten mit schlechtem Therapie-Outcome, aufgetragen nach vorheriger RAASi-Dosis

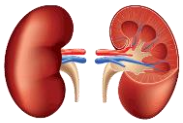


Untersuchte Ereignisse:

- CKD-Progression und Progression bis zur terminalen Niereninsuffizienz
- Schlaganfall und akuter Myokardinfarkt
- Koronararterien-Bypass und perkutane Koronarintervention
- Gesamtmortalität

Modifiziert nach Epstein M et al. 2015

CKD, chronische Nierenerkrankung.
Epstein M, et al. *Am J Manag Care*. 2015;21:S212–20.



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Einsatz von SPS - Kaliumbindern

Management und Kosten (Spanien)

The aim of the study is to determine the severity, current management and cost of chronic hyperkalaemia (HK)

Methods

Retrospective cohort study
Database BIG-PAC:
2011–2018

1499 patients

Chronic HK and CKD, heart failure or diabetes

54.4% women

Mean age 75.8 years

Mean Charlson index 3.1

70.4% of patients on RAASi therapy

Results

	Mild HK	Moderate HK	Severe HK
	992 (66.2%)	351 (23.4%)	156 (10.4%)
RAASi discontinuation	39.8%	49.8%	51.8%
Resin prescription	30.3%	55.7%	89.9%
Annual healthcare cost (per patient)	4468 €	6993 €	12705 €

Treatment adherence very low > elevated potassium persisted in most patients

Conclusion: HK is usually managed by RAASi discontinuation and ion exchange resin treatment. Most patients with HK were not adherent to resins, and those with severe HK remained with high potassium levels, despite bearing elevated health care expenditures.

Olry de Labry Lima, A., et al
Clinical Kidney Journal (2021)
@CKJsocial

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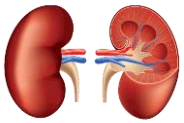
Merke

Bei Patienten mit Herzinsuffizienz ist der wichtigste therapeutische Zielparameter nicht der Blutdruck, sondern die erreichte Medikamentendosis mit Betablockern und Inhibitoren des Renin-Angiotensin-Aldosteron-Systems.

Merke

Die eGFR ist ein Schätzwert für die Nierenfunktion, und die Interpretation eines Abfalls sollte immer im Zusammenhang mit der klinischen Situation, insbesondere Medikamentenumstellungen, beurteilt werden.



Brandenburg, V., et al. (2021). "[Symptom control in heart failure patients - how to handle GFR decrease and hyperkalaemia]." Dtsch Med Wochenschr.

Ausgeprägte Dyskaliämien

Anzahl / Fälle		Labor	mmol/l	Anzahl / Fälle
5521 /1649	**≤ 125**	**Natrium** 138 -145	**≥ 155**	2670 / 660
~ 0,92 % *ICU: 1,2 %*				~ 0,37 % *ICU: 0,6 %*
1303 / 737	**≤ 2,5**	**Kalium** 3,5-4,9	**≥ 6,5**	1265 / 801
~ 0,41 %				~ 0,45 %
		Calcium 2,2-2,6	**≥ 3,0**	231 / 63
				~ 0,04 %
		Kreatinin	**> 3,0 mg/dl**	23789 / 5403
				~ 3,0 %

~ 1 % der stationären Patienten