Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation möglich und sinnvoll?

Assoc. Prof. Dr. med. Manfred Hecking, PhD
KIM III, Nephrology, Center for Public Health, Department of Epidemiology, Medical University of Vienna
(formerly) MVZ Weiden (Oberpfalz), MVZ Altötting, Kuratorium for Dialysis and Kidney Transplantation (KfH) e.V.

HD & CO RESEARCH GROUP -- https://hd-research.net/

27 March 2025, 17:15-17:45

AGENDA

- **Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation möglich?**

- **Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation sinnvoll?**

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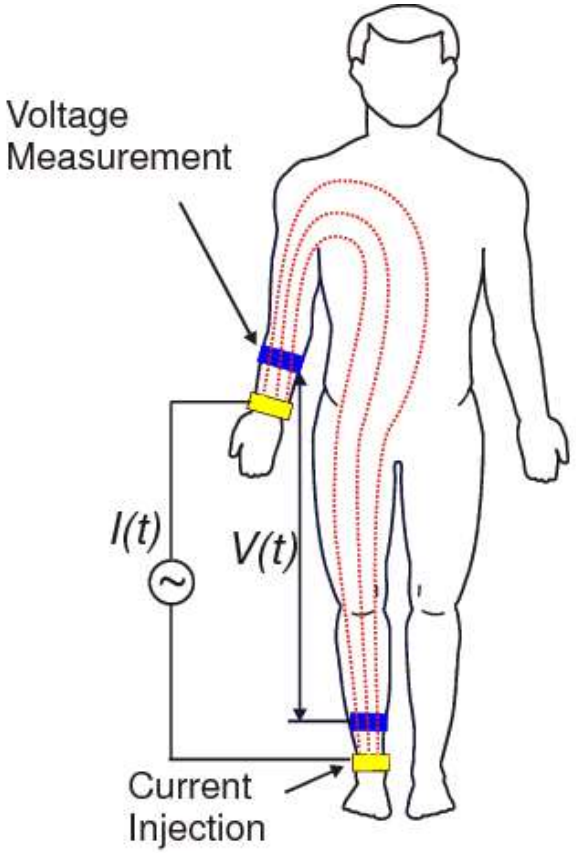
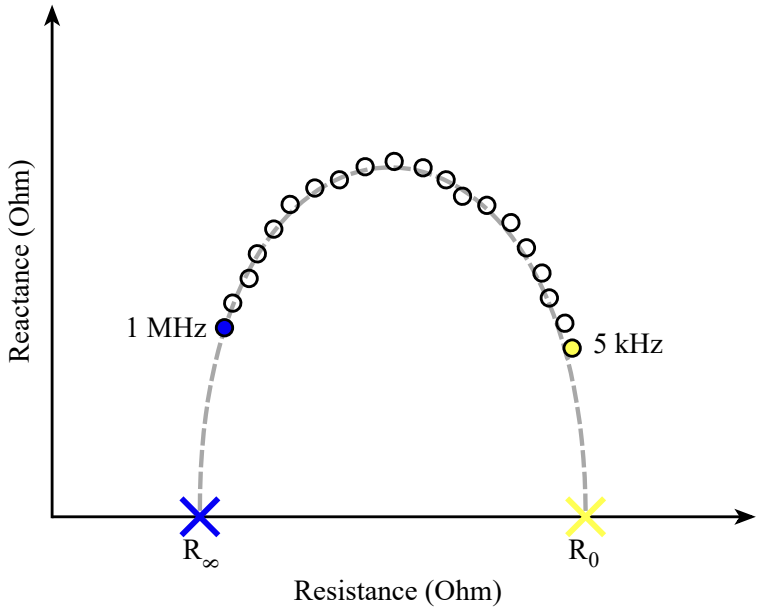
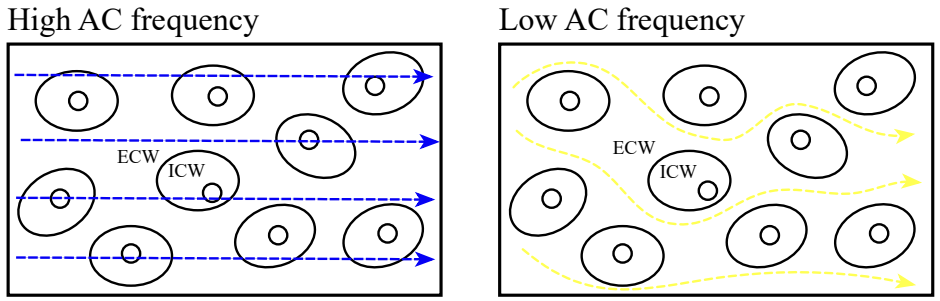
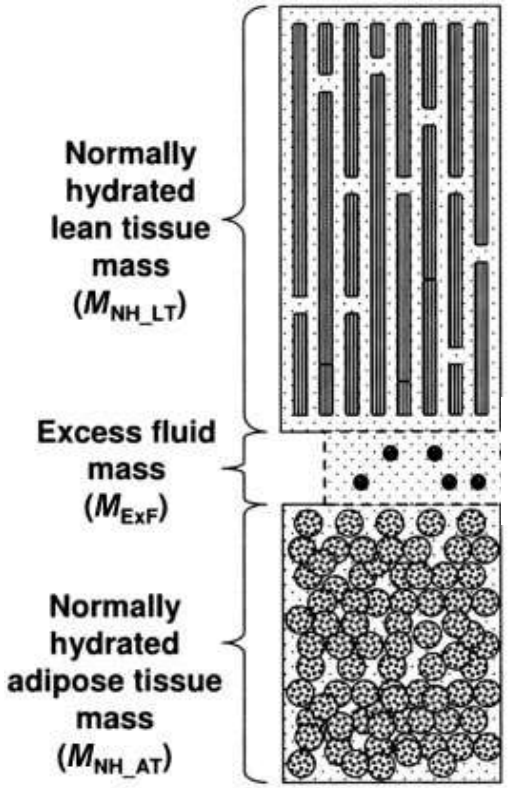
TARGET WEIGHT ASSESSMENT – BIOIMPEDANCE SPECTROSCOPY



Adapted from:
Beckmann et al. 2009 (19964634)



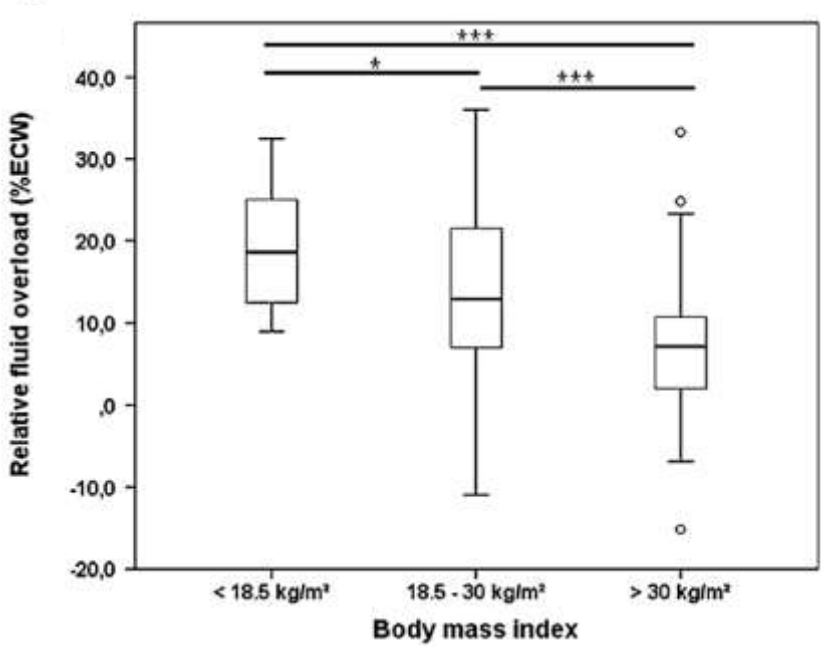




Adapted from:
Chamney et al. 2007 (17209181)

TARGET WEIGHT ASSESSMENT – BIOIMPEDANCE SPECTROSCOPY

Patients with higher BMI have lower Amount of Fluid Overload (are "dry")



Esmerelda was one of the few who really liked dialysis.

Antlanger, M et al., *BMC Nephrology* 2013, 14:266, similar results published by **Ribitsch W, et al.**, *Clin Nephrol* 2012; 77: 376-82 & **Wizemann V, et al.**, *Nephrol Dial Transplant* 2009; 24: 1574-9

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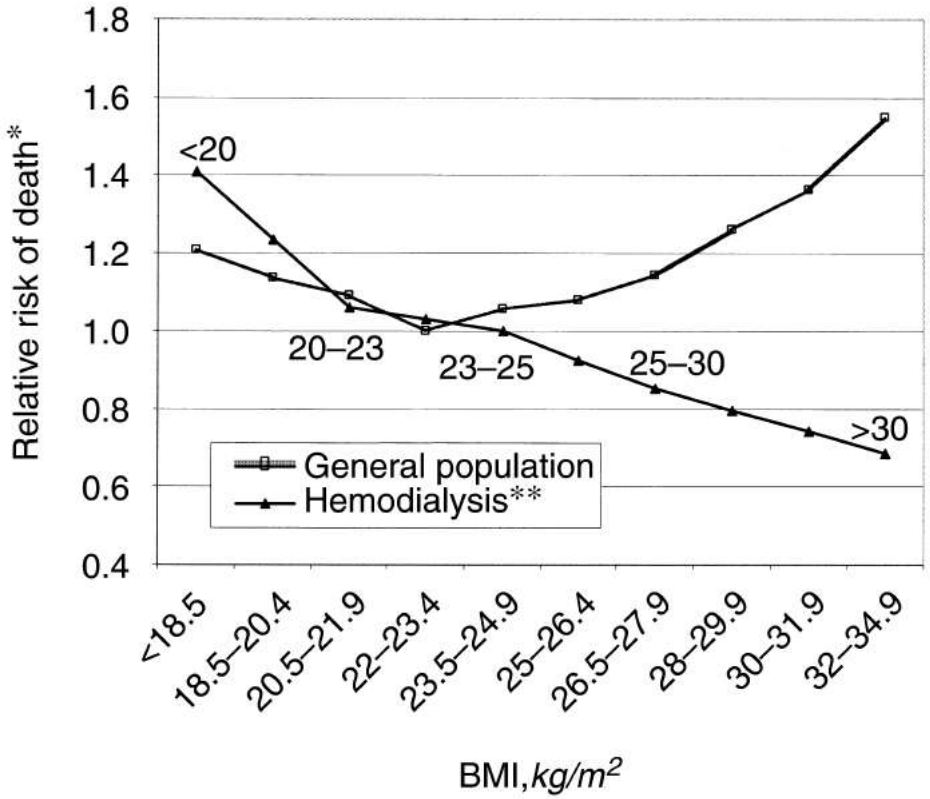


Kalantar-Zadeh, K, et al., Kidney International, Vol. 63 (2003), pp. 793–808

Reverse Epidemiology: A Confusing, Confounding, and Inaccurate Term

Nathan W. Levin,* Garry J. Handelman,*† Josef Coresh,‡ Friedrich K. Port,§ and George A. Kaysen¶

Reverse Epidemiology: A Term with Two Meanings

Josef Coresh

True Epidemiology of Body Mass Index in Hemodialysis Patients

Friedrich K. Port

The Term Reverse Epidemiology Adds Confusion, Not Enlightenment, to the Lipoprotein Level—Vascular Outcome Relationship in CKD Patients

George A. Kaysen

Why Reverse Epidemiology Is a Misnomer and Misleading

Nathan W. Levin and Garry Handelman

Seminars in Dialysis—Vol 20, No 6 (November–December) 2007 pp. 586–592

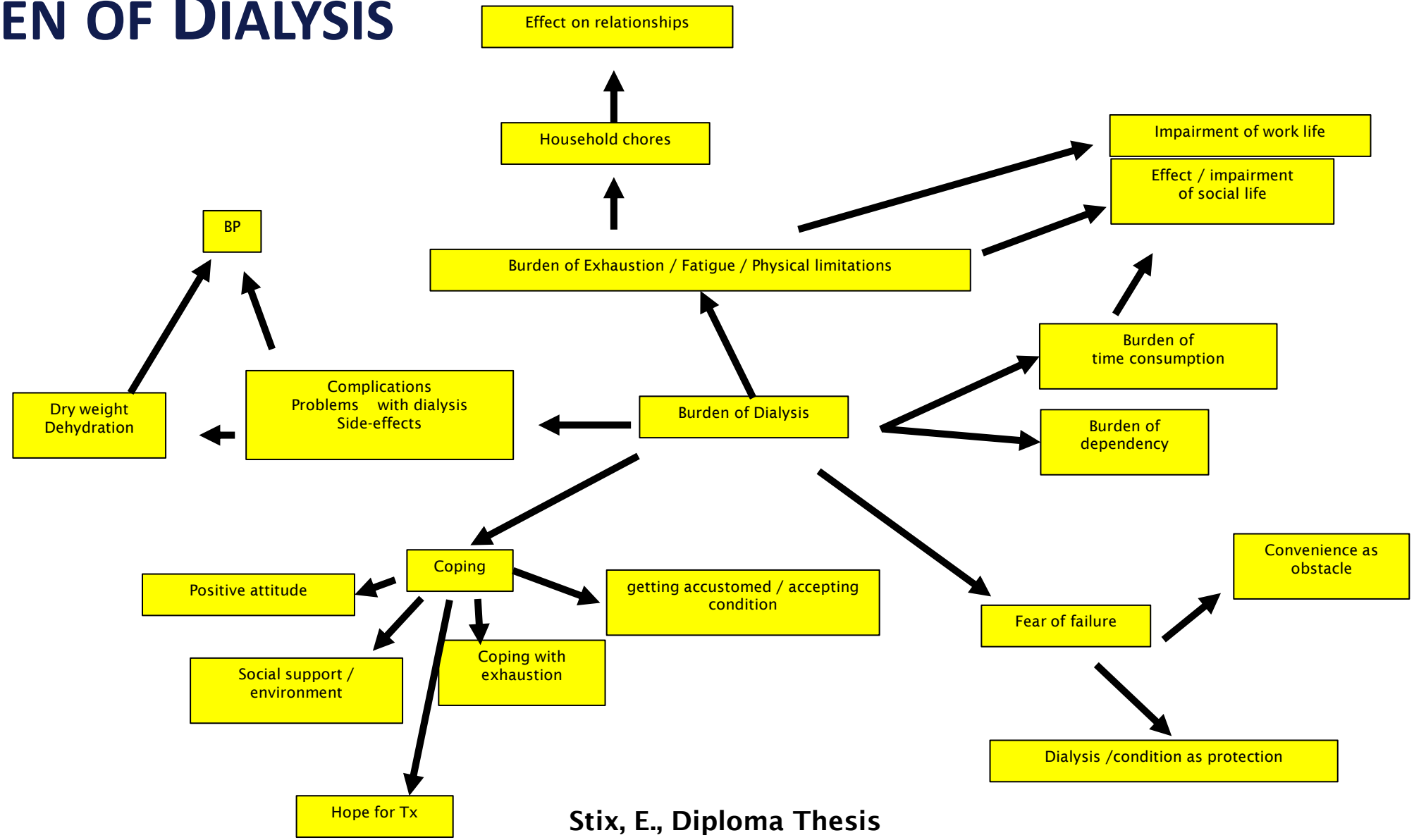
Obesity in HD: "Done"? Qualitative Interview Study...

Analyzed According to Principles of Grounded Theory

	Total	Obesity Class I (BMI: 30-34.9)	Obesity Class II (BMI: 35-39.9)	Obesity Class III (BMI: 40≤)
Total	25	13	10	2
Sex				
Male	14	8	6	-
Female	11	6	4	2
Age				
20s	2	2	-	-
30s	1	-	1	-
40s	3	2	1	-
50s	4	1	2	1
60s	11	6	4	1
70s	4	2	2	-

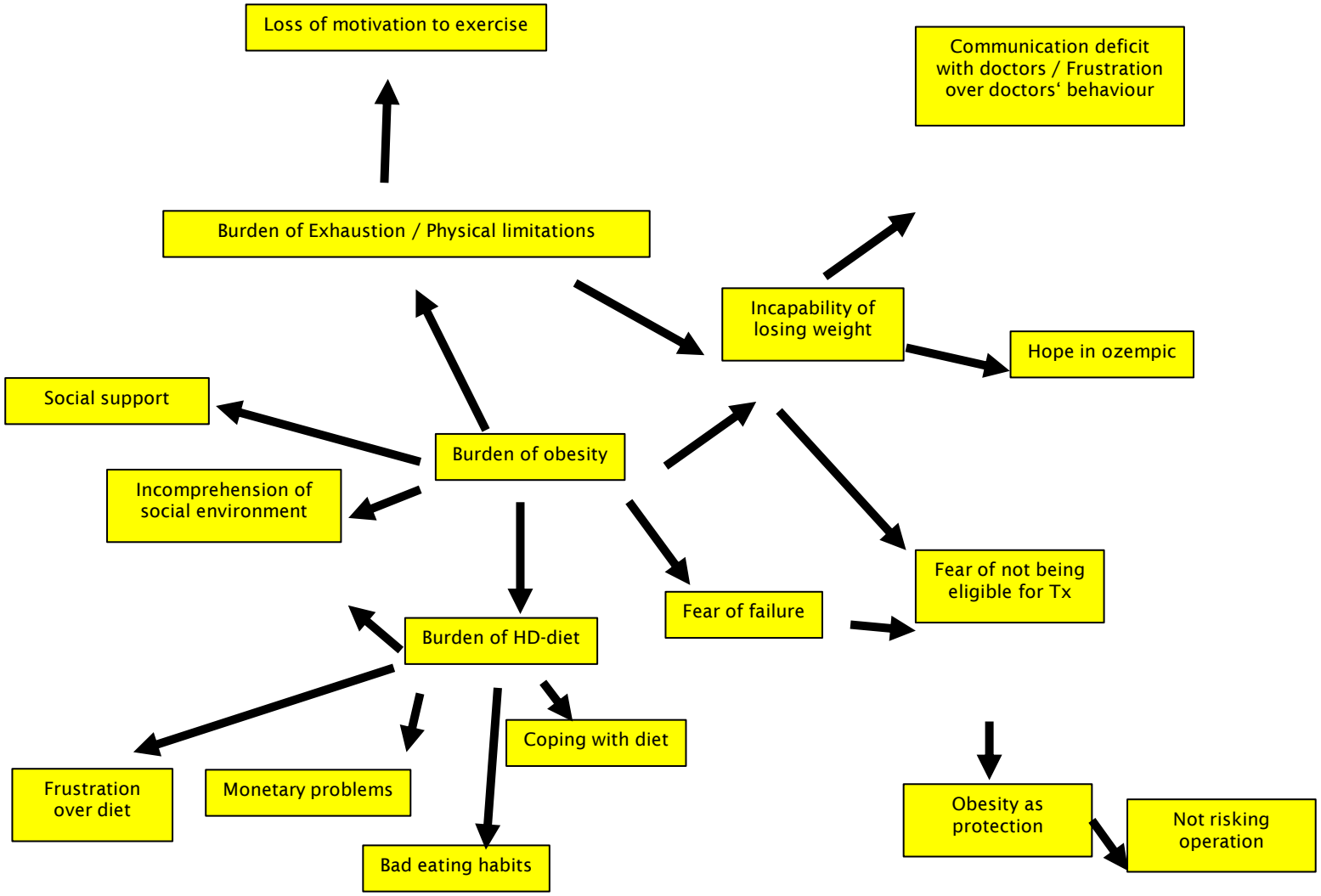
Stix, E.,
Diploma Thesis
Vanek L. et al.,
CJASN, under review

Burden of Dialysis



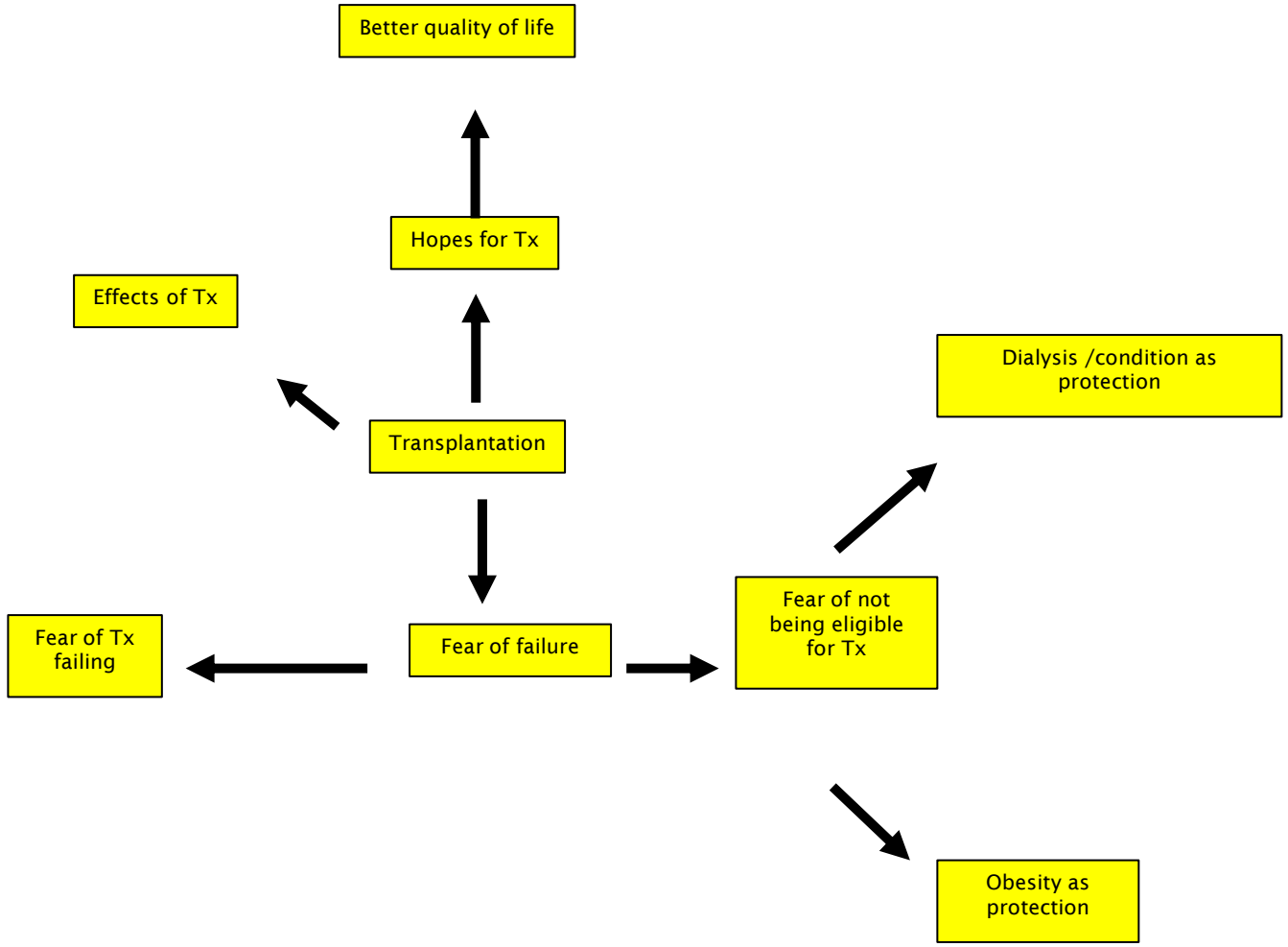
Stix, E., Diploma Thesis
Vanek L. et al., *CJASN*, under review

Burden of Obesity

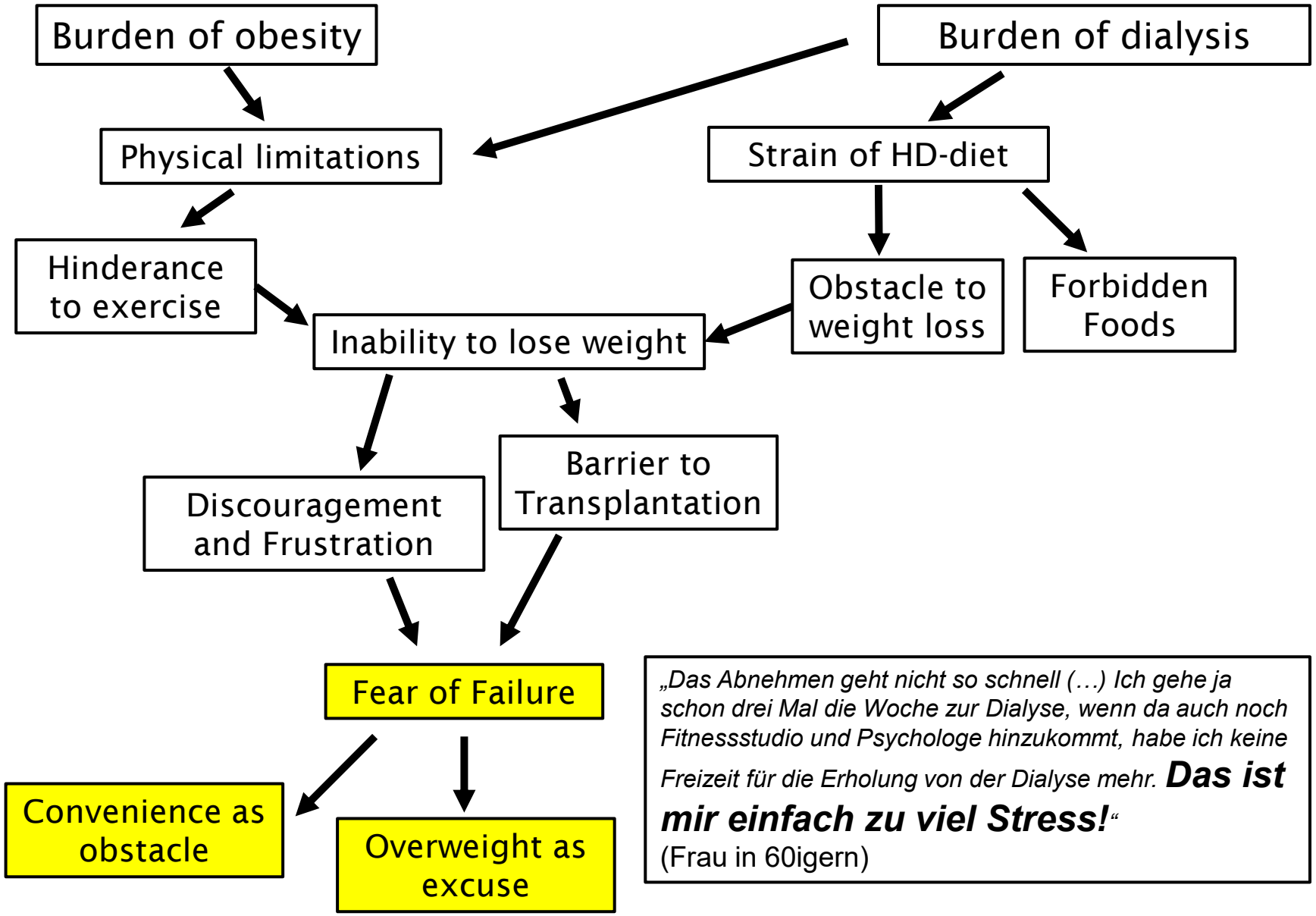


Stix, E., Diploma Thesis; Vanek L. et al., *CJASN*, under review

TRANSPLANTATION



Stix, E., Diploma Thesis; Vanek L. et al., *CJASN*, under review



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(Frau in 60igern)

Stix, E.,
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LIRAGLUTIDE VERSUS SEMAGLUTIDE

Metabolism: Exenatide undergoes primary metabolism in the kidneys and liver through hydrolysis, yielding smaller, inactive peptides subsequently excreted renally. Liraglutide follows a similar pathway involving proteolytic cleavage in various tissues, akin to the metabolism of large proteins. Enzymes like Dipeptidyl Peptidase-4 (DPP-4) and Neutral Endopeptidase (NEP) are likely involved, resulting in smaller, biologically inactive fragments subsequently eliminated. Semaglutide, a polypeptide, undergoes metabolic breakdown into individual amino acids facilitated by serum and tissue proteases.[24][25]

Excretion: Renal elimination primarily governs the clearance of GLP-1 RAs, including Exenatide, Liraglutide, and Semaglutide. The kidneys play a pivotal role in removing these compounds from the body. The rate of renal excretion impacts the duration of action and dosing frequency. Semaglutide, with its extended-release (ER) profile, exhibits a significantly prolonged half-life compared to short-acting formulations.

https://www.ncbi.nlm.nih.gov/books/NBK551568/#:~:text=Excretion%3A%20Renal%20elimination%20primarily%20governs,of%20action%20and%20dosing%20frequency.

LIRAGLUTIDE VERSUS SEMAGLUTIDE

Table 2. Time-change profile of plasma liraglutide concentration following subcutaneous administration of liraglutide in diabetic patients with ESRD on the days of on-hemodialysis and off-hemodialysis.

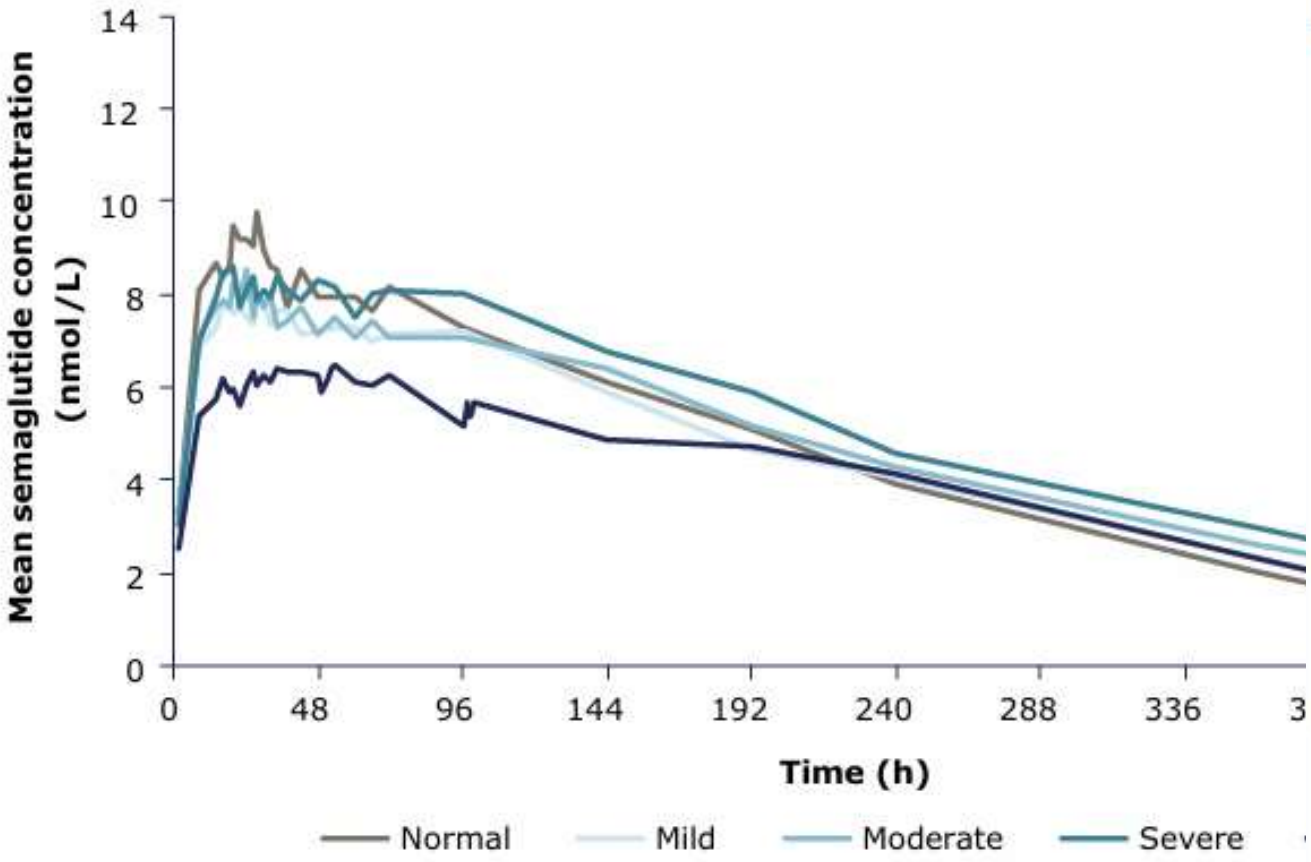
Type of Hemodialysis	Off-hemodialysis (day 2)	On-hemodialysis (day 3)	Mean ratio
	p mol (Mean±SE)	p mol (Mean±SE)	(95% Confidence interval)
2 hr	15479±4413	19224±5280	1.25 (0.96–1.62)
6 hr	18663±5218	21185±6188	1.12 (0.86–1.45)
9 hr	19568±4930	21582±6260	1.08 (0.83–1.40)
12 hr	19392±5053	20483±5289	1.06 (0.82–1.38)
15 hr	18441±5206	20939±6674	1.10 (0.84–1.42)
24 hr	14486±4902	16670±6107	1.14 (0.88–1.49)

n=10.

doi:10.1371/journal.pone.0113468.t002

Osonoi T, et al. (2014)
Effect of Hemodialysis on Plasma Glucose Profile and Plasma Level of Liraglutide in Patients with Type 2 Diabetes Mellitus and End-Stage Renal Disease: A Pilot Study.
PLoS ONE 9(12): e113468. d

LIRAGLUTIDE VERSUS SEMAGLUTIDE



Key Points

Semaglutide exposure was similar between subjects with mild/moderate renal impairment (RI) or end-stage renal disease and subjects with normal renal function; equivalence was not demonstrated in subjects with severe RI, in whom mean exposure was 22% higher. However, when exposures were adjusted for differences in age, sex, and body weight, all comparisons were within the pre-specified 'no effect' limits.

A single subcutaneous dose of semaglutide 0.5 mg was well-tolerated across all renal function groups.

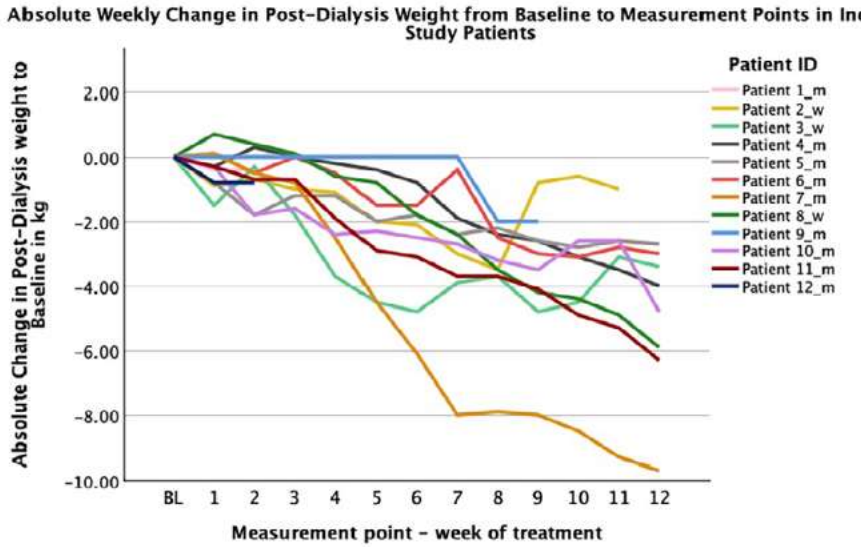
Semaglutide appears to be a useful treatment for subjects with diabetes mellitus regardless of renal status, and may not require dose adjustment.

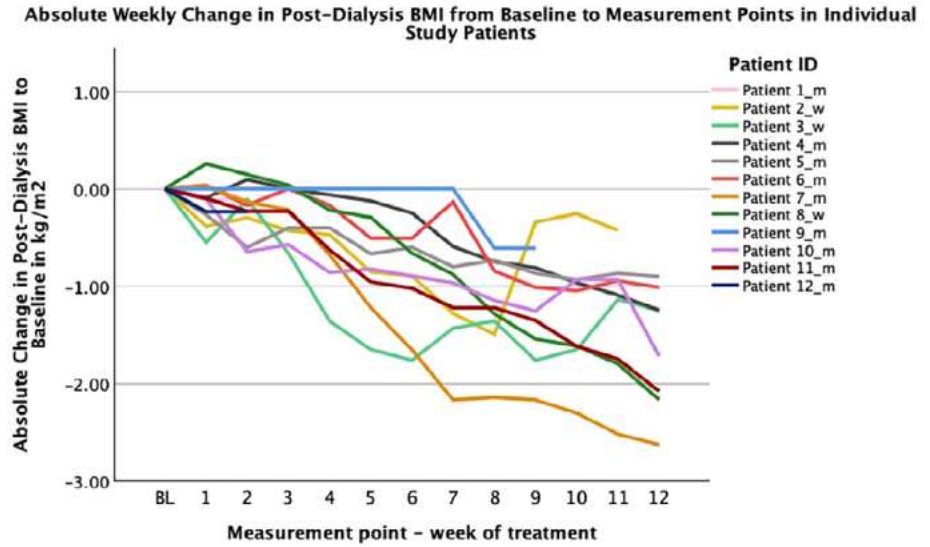
Clin Pharmacokinet (2017) 56:1381–1390

Vanek L, et al.

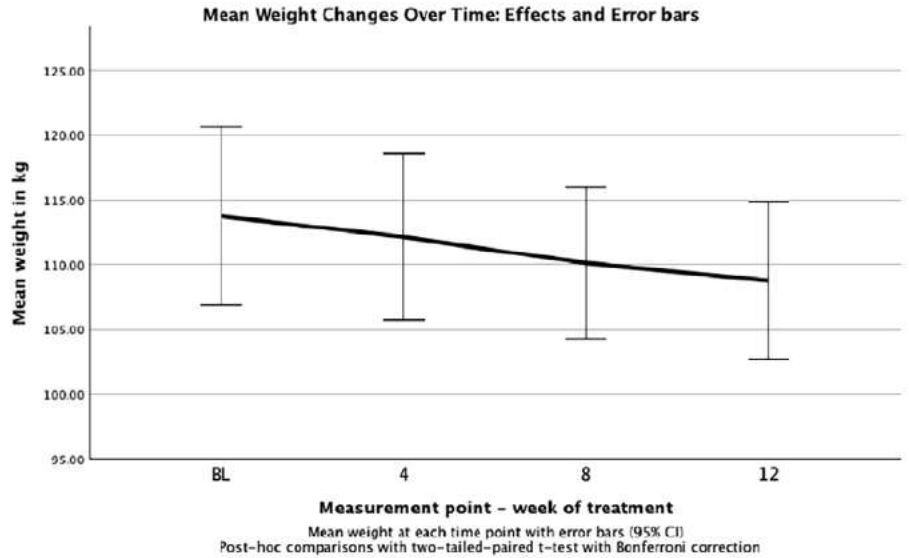
Semaglutide in patients with kidney failure and obesity undergoing dialysis and wishing to be transplanted: A prospective, observational, open-label study.

Diabetes Obes Metab. 2024 Dec;26(12):5931-5941.





(C)



(F)

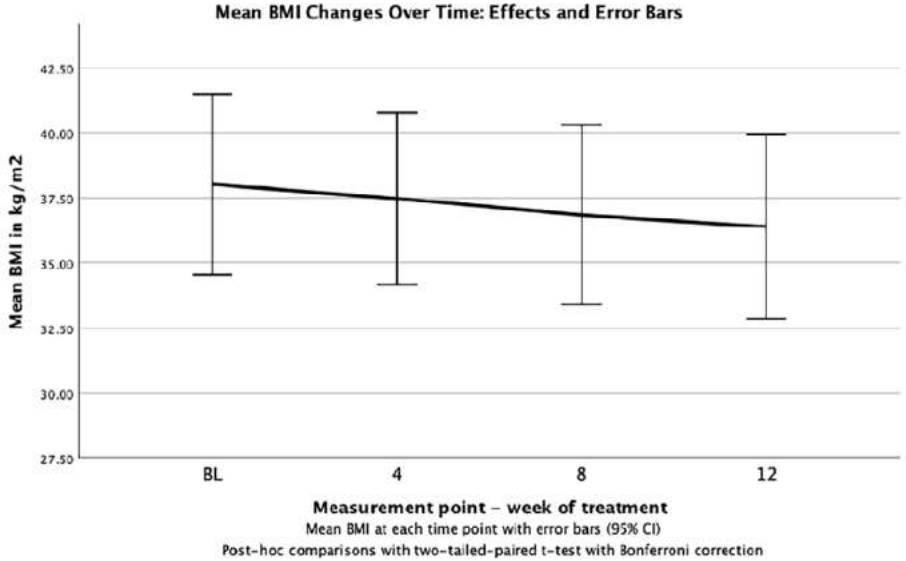


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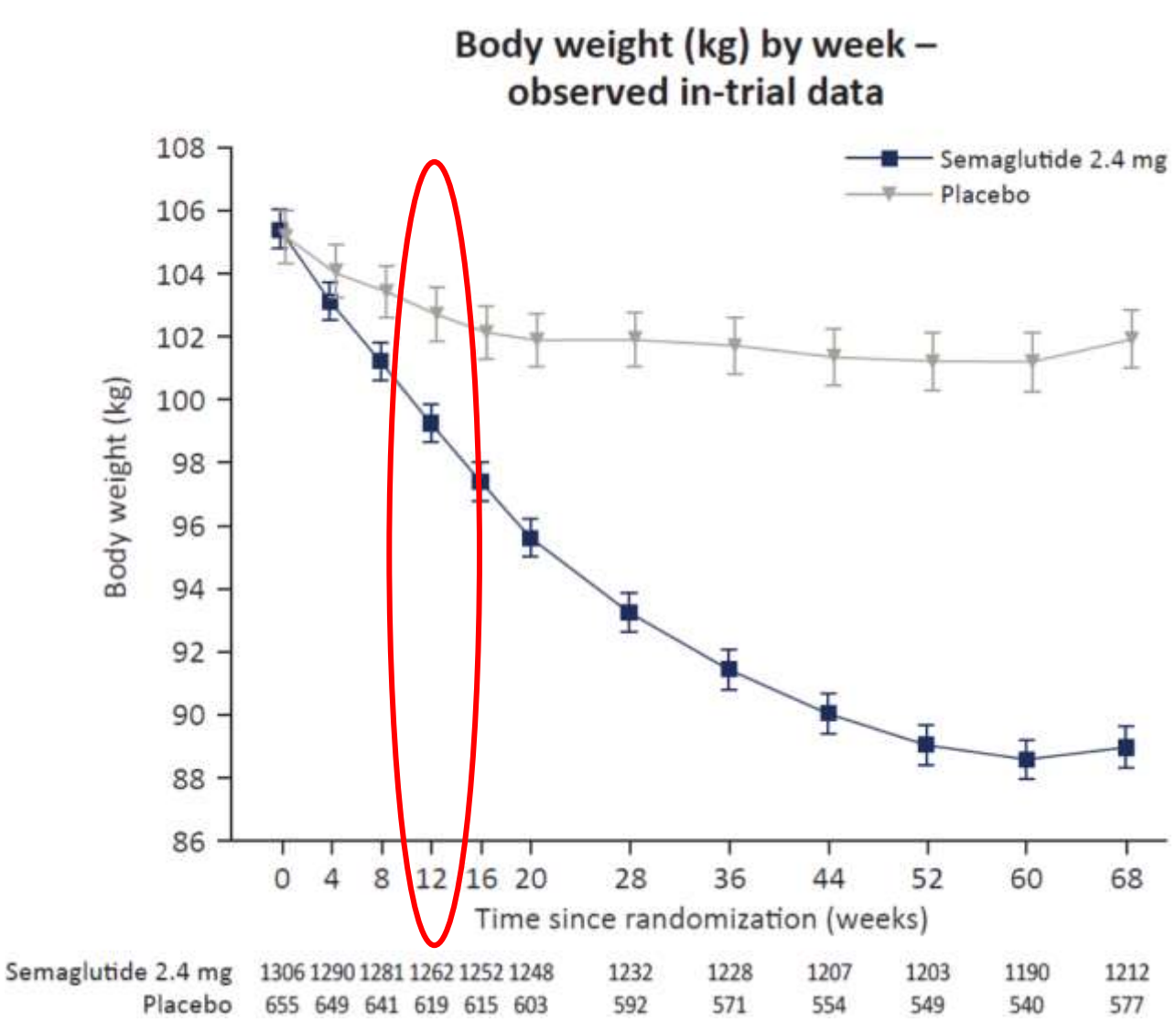
TABLE 4 Changes in blood parameters between baseline and week 12 of treatment.

	Baseline			After 12 weeks of treatment			Paired samples test						
							Paired differences			95% confidence interval of difference		Significance	
	N	Mean	SD	N	Mean	SD	Mean	SD	SEM	Lower	Upper	df	p-Value[a]
Hb g/dL	12	11.55	1.37	9	11.70	2.14	0.19	1.40	0.47	−0.89	1.27	8.00	0.697
MCH pg	12	31.68	3.17	9	31.33	2.04	0.53	1.33	0.44	−0.49	1.56	8.00	0.263
MCV fl	12	99.99	7.41	9	98.60	6.10	2.52	3.51	1.17	−0.17	5.22	8.00	0.063
Hct %	12	36.54	4.17	9	36.80	6.50	1.00	4.23	1.41	−2.25	4.25	8.00	0.498
WBC g/L	12	7.78	2.15	9	7.79	1.73	0.10	1.12	0.37	−0.76	0.95	8.00	0.801
Plt g/l	12	198.25	75.85	9	192.33	88.50	−8.33	27.00	9.00	−29.09	12.42	8.00	0.382
Creat mg/dL	12	10.13	2.38	9	10.22	2.69	0.31	0.87	0.29	−0.36	0.98	8.00	0.316
Blood urea Nitrogen (BUN) mg/dL	12	138.70	37.87	9	121.90	44.93	18.59	18.39	6.13	4.45	32.73	8.00	**0.016**
GFR (CKD-EPI 2021) mL/min/1.73 m^2	12	4.83	1.53	9	4.78	1.48	−0.22	0.67	0.22	−0.73	0.29	8.00	0.347
UA mg/dL	3	5.90	1.66	2	5.75	1.91	0.75	0.07	0.05	0.11	1.39	1.00	**0.042**
Ca mmol/L	12	2.04	0.26	9	1.97	0.36	0.02	0.13	0.04	−0.08	0.12	8.00	0.664



Wilding JPH, et al. *Once-Weekly Semaglutide in Adults with Overweight or Obesity.* NEJM. 2021.

Vanek L, et al.

Semaglutide in patients with kidney failure and obesity undergoing dialysis and wishing to be transplanted: A prospective, observational, open-label study.

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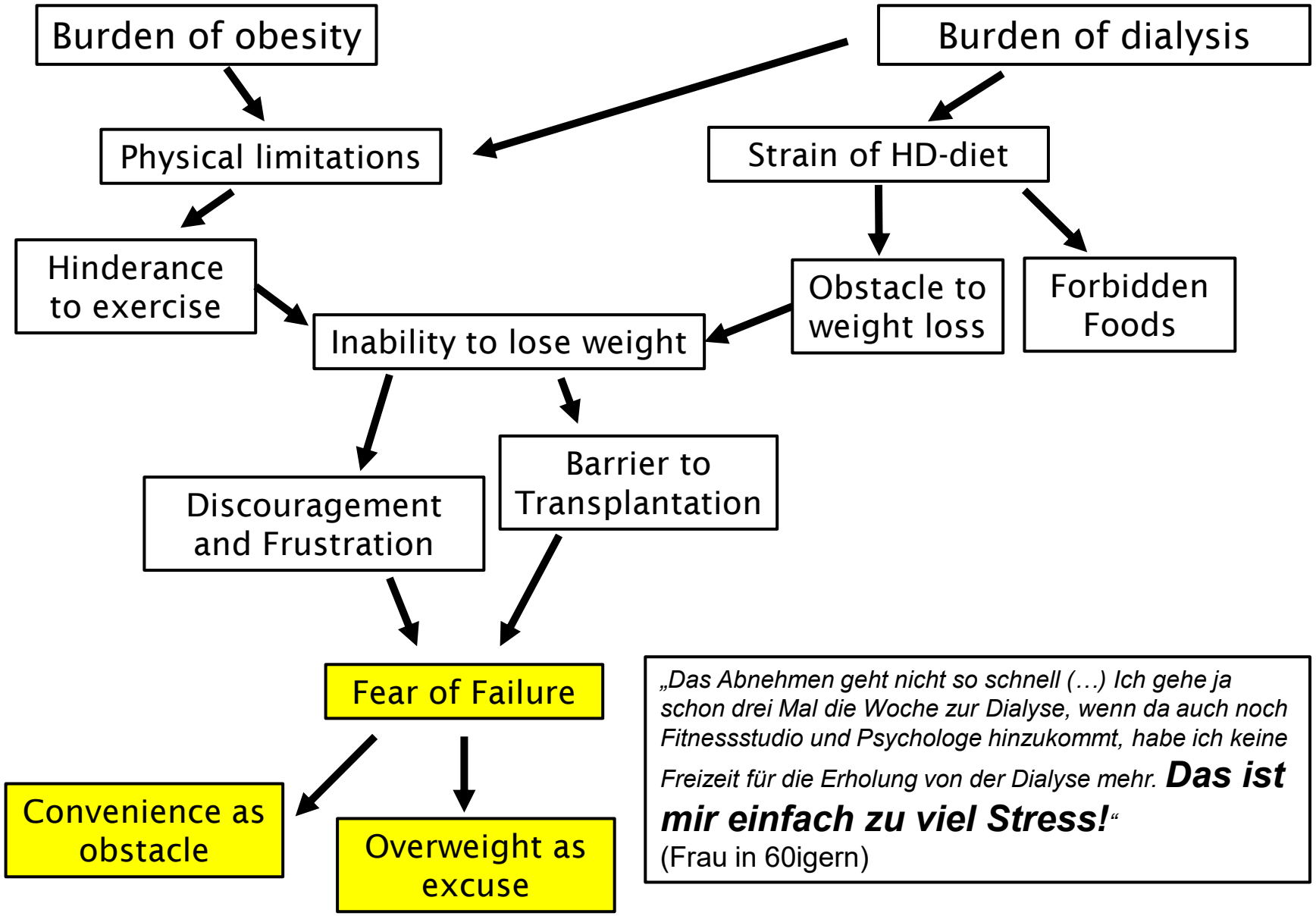

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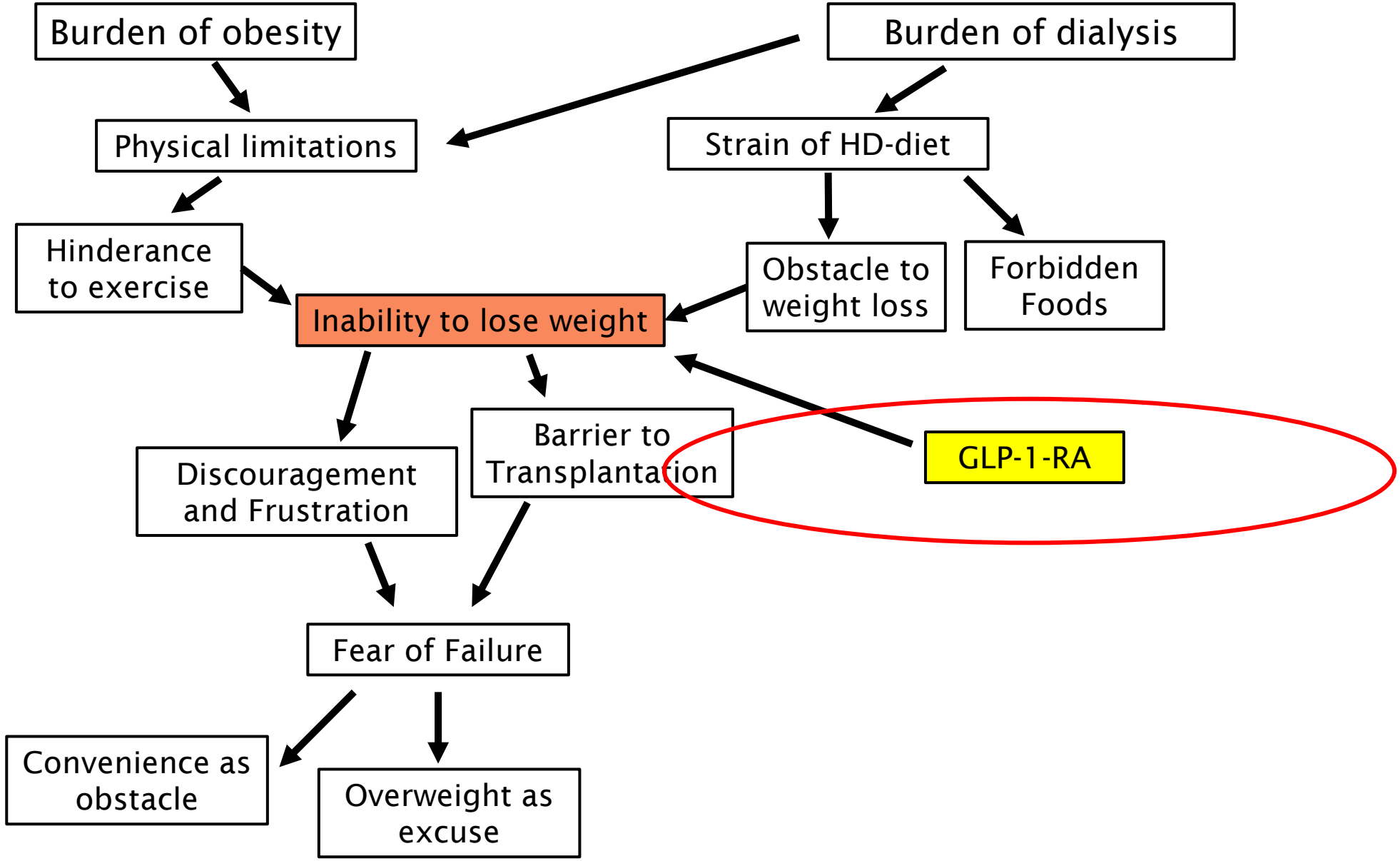
Diploma Thesis
Vanek L. et al.,
CJASN, under review



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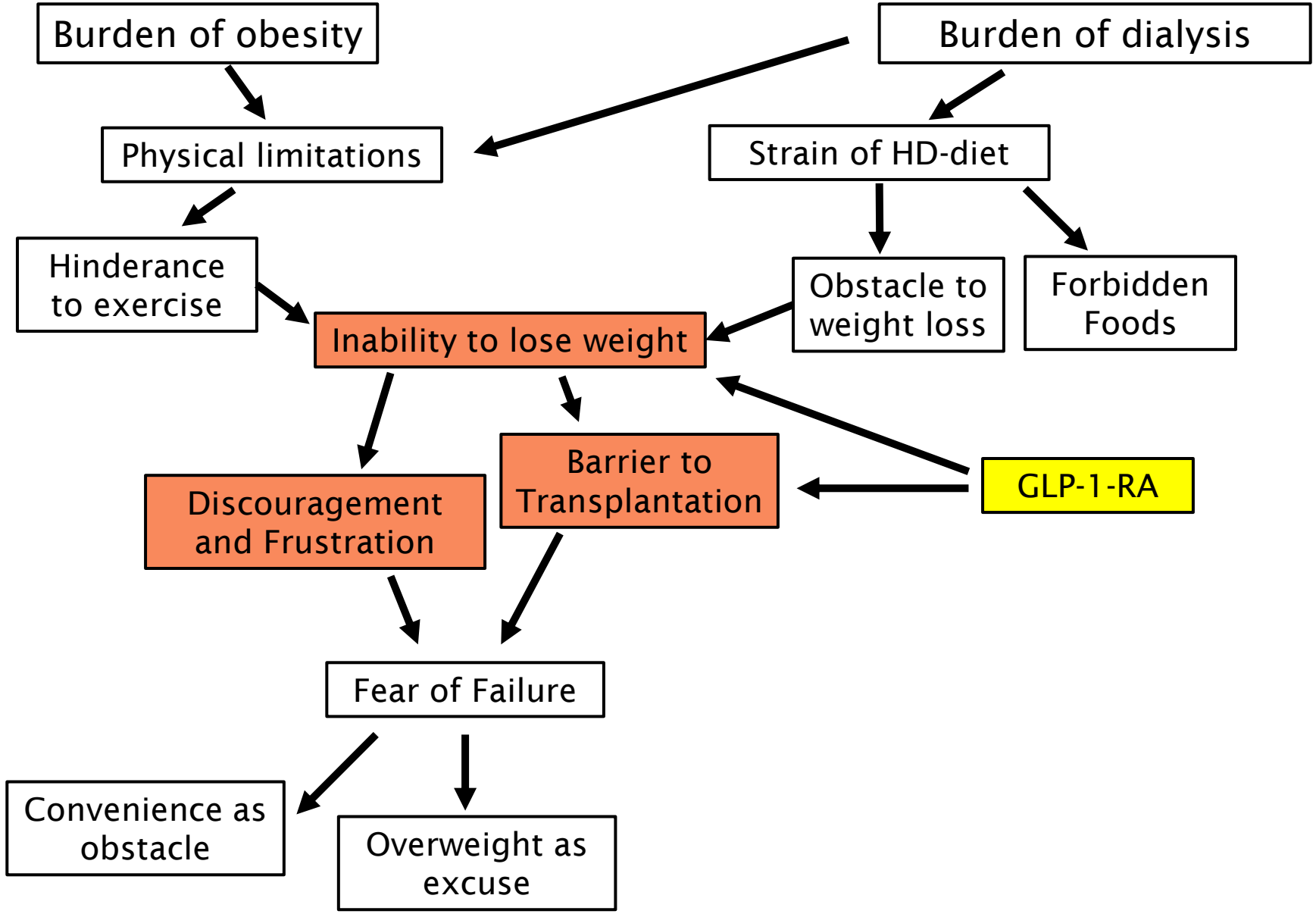

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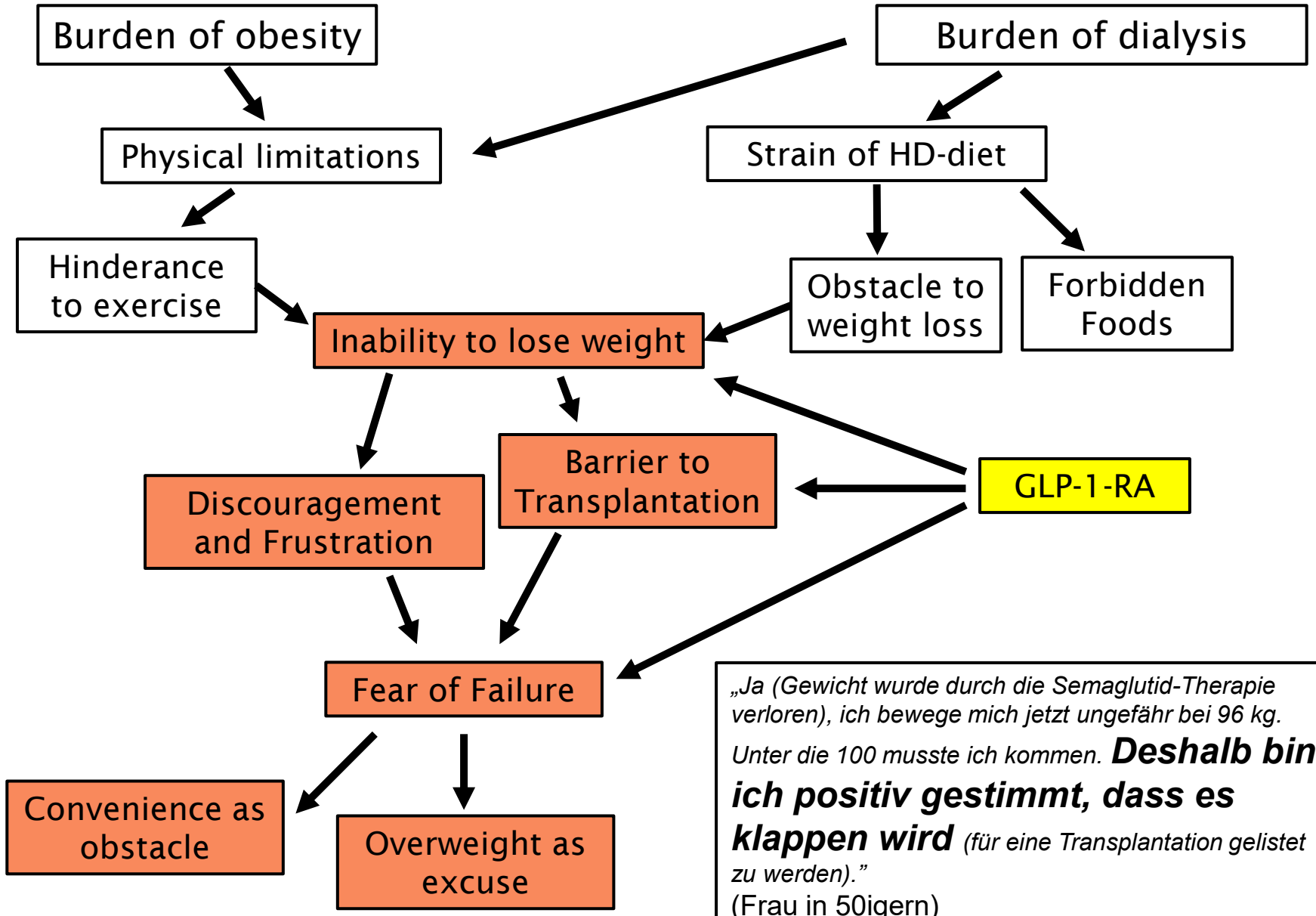
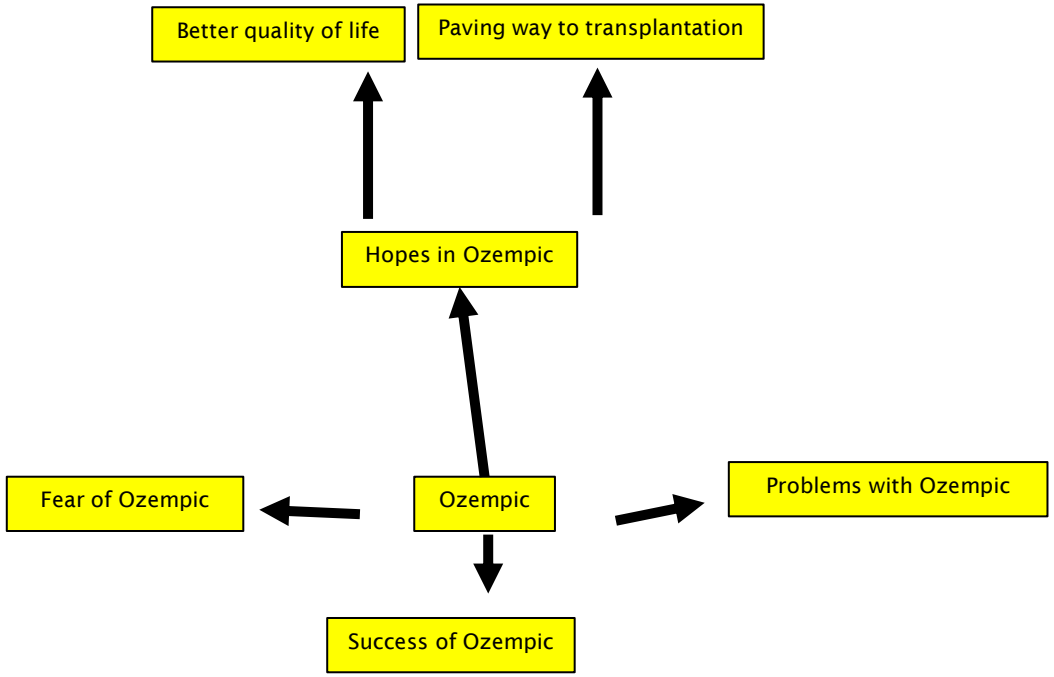


„Ja (Gewicht wurde durch die Semaglutid-Therapie verloren), ich bewege mich jetzt ungefähr bei 96 kg. Unter die 100 musste ich kommen. ***Deshalb bin ich positiv gestimmt, dass es klappen wird*** *(für eine Transplantation gelistet zu werden).”*
(Frau in 50igern)

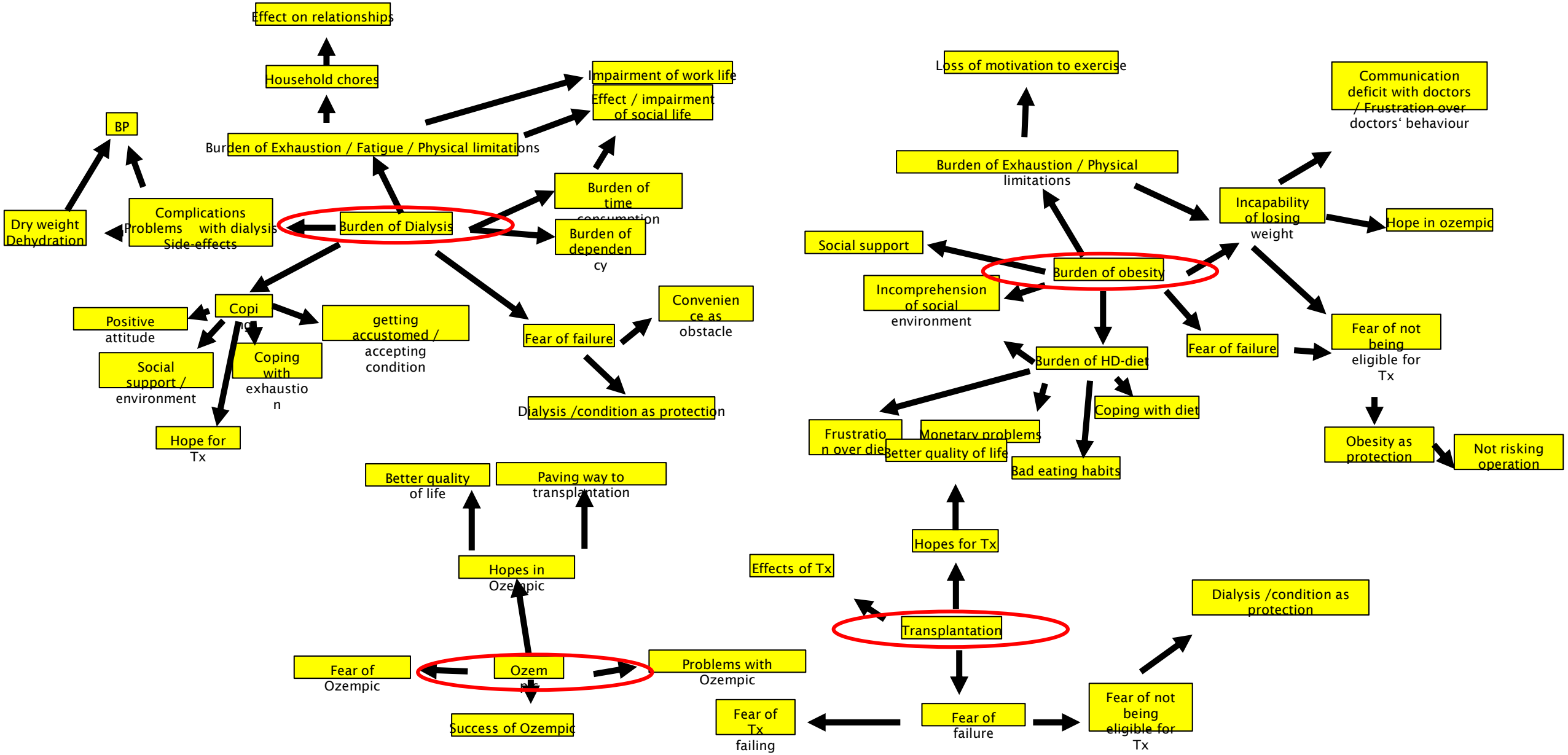
Stix, E.,
Diploma Thesis
Vanek L. et al.,
CJASN, under review

Burden of Obesity in Dialysis Patients and Hopes Associated with Semaglutide Treatment for Transplant Listing: An Interview Study

--Manuscript Draft--



Stix, E., Diploma Thesis; Vanek L. et al., *CJASN*, under review



Stix, E., Diploma Thesis; Vanek L. et al., *CJASN*, under review

STUDY SUMMARY

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Semaglutide in patients with kidney failure and obesity undergoing dialysis and wishing to be transplanted: A prospective, observational, open-label study.

Diabetes Obes Metab. 2024 Dec;26(12):5931-5941.

12 haemodialysis and 1 peritoneal dialysis patients

One patient discontinued treatment due to nausea/vomiting, two patients died of unrelated causes and six patients reported side effects.

Approximately 9 months after the treatment started, three patients were able to seriously reconsider being listed for transplantation.

LIRAGLUTIDE VERSUS SEMAGLUTIDE: SIDE EFFECT SUMMARY(?)

Osonoi T, Saito M, Tamasawa A, et al. Effect of hemodialysis on plasma glucose profile and plasma level of liraglutide in patients with type 2 diabetes mellitus and end-stage renal disease: a pilot study. Barengo NC, ed. *PLoS One*. 2014;9(12):e113468. doi:10.1371/journal.pone.0113468

Idorn T, Knop FK, Jørgensen MB, et al. Safety and Efficacy of Liraglutide in Patients With Type 2 Diabetes and End-Stage Renal Disease: An Investigator-Initiated, Placebo-Controlled, Double-Blinded, Parallel Group, Randomized Trial. *Diabetes Care*. 2015;39(2):dc151025. doi:10.2337/dc15-1025

Vanek L.
kidney fa
observati
doi:10.11

Initial and temporary nausea and vomiting occurred more frequently among liraglutide-treated patients with ESRD compared with control subjects ($P < 0.04$).

	Per Protocol population N =12		Intention-to-treat population N=18	
At least one serious adverse event related to the drug	12	0 (0)	17	1 (6) *
Number of serious adverse event related to the drug per patient	12		17	
0		12 (100)		16 (93)
1		0 (0)		1 (6)*

NAUSEA AND VOMITING GRADING SCALE
NCI CTCAE (Version 4.03)

	GRADE 1 (Mild)	GRADE 2 (Moderate)	GRADE 3 (Severe)	GRADE 4 (Life Threatening)	GRADE 5
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feedings, TPN or hospitalization may be indicated	–	–
Vomiting	1-2 episodes (separated by 5 minutes) in 24 hours	3-5 episodes (separated by 5 minutes) in 24 hrs	≥ 6 episodes separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death

AGENDA

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KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation

Steven J. Chadban, BMed, PhD,[1*] Curie Ahn, MD, PhD,[2] David A. Axelrod, MD, MBA,[3] Bethany J. Foster, MD, MSCE,[4] Bertram L. Kasiske, MD,[5] Vijah Kher, MD, DM,[6] Deepali Kumar, MD, MSc,[7] Rainer Oberbauer, MD, PhD,[8] Julio Pascual, MD, PhD,[9] Helen L. Pilmore, MD,[10] James R. Rodrigue, PhD,[11] Dorry L. Segev, MD, PhD,[12] Neil S. Sheerin, BSc, PhD,[13] Kathryn J. Tinckam, MD, MMSc,[7] Germaine Wong, MD, PhD,[14] and Gregory A. Knoll, MD, MSc,[15*]

7.1.1: We suggest that candidates not be excluded from transplantation because of obesity (as defined by body mass index or waist-to-hip ratio) *(2B)*.

The AJT Report: *News and issues that affect organ and tissue transplantation*

SUE PONDROM

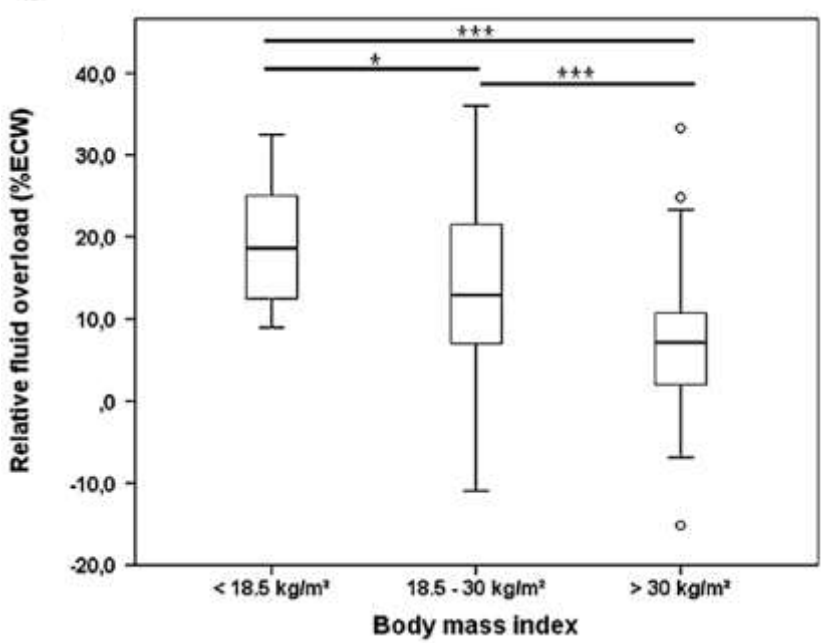
„A recent survey by the American Society of Transplant Surgeons (ASTS) asked kidney transplant centers about their criteria regarding obesity. (...)

Of the 67 kidney centers that responded, 66 used BMI as a selection criterion“

Pondrom S.
Am J Transplant. 2012 Nov;12(11):2865-6.

TARGET WEIGHT ASSESSMENT – BIOIMPEDANCE SPECTROSCOPY

Patients with higher BMI have lower Amount of Fluid Overload (are "dry")



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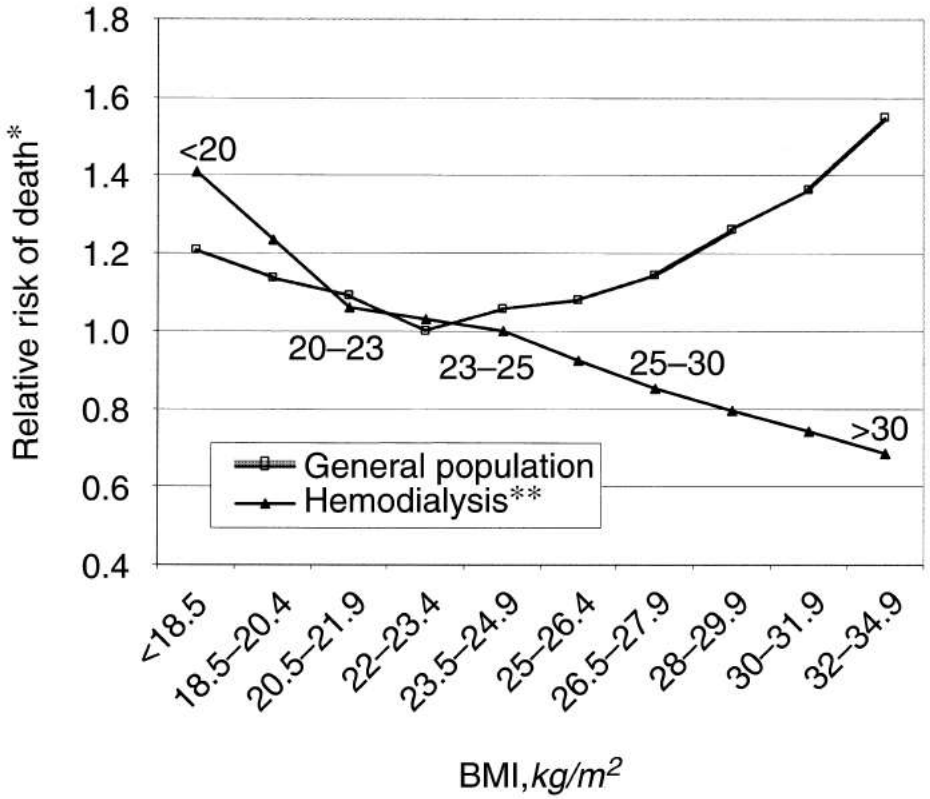
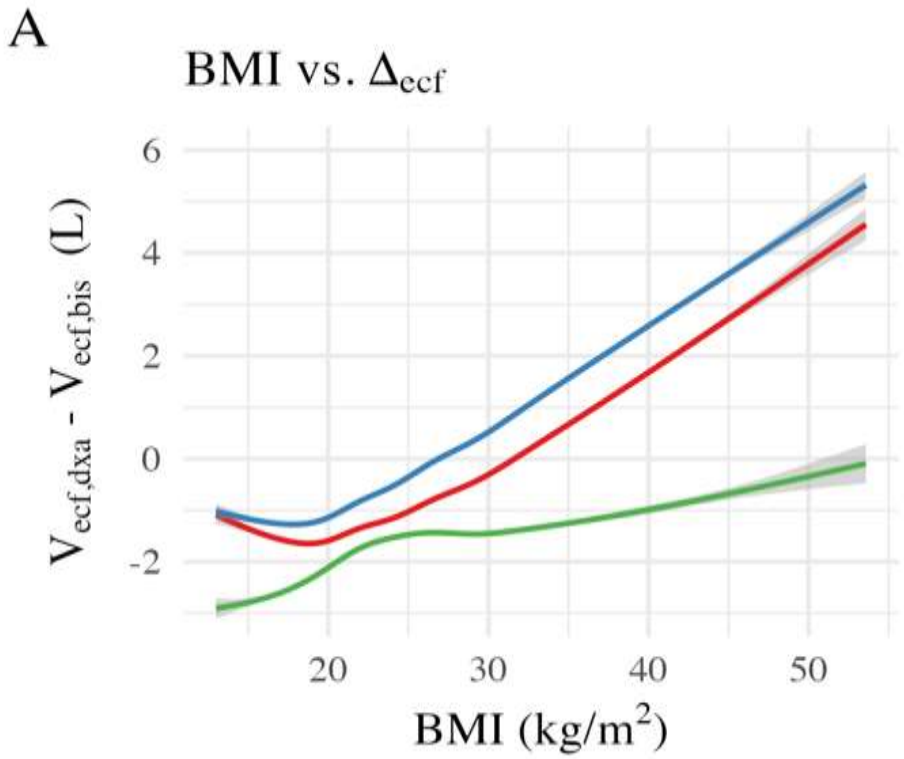


Kalanta-Zadeh, K, et al., Kidney International, Vol. 63 (2003), pp. 793–808

HOWEVER:… BIS UNDERESTIMATES FLUID EXCESS IN OBESITY

(PATIENTS SEEM TO BE DRY ALTHOUGH THEY MAY NOT BE)



Mussnig, S, et al., MS in preparation

Kb, uniform body shape correction with K_b=4.3 according to De Lorenzo et al. (13); Kbmi, adjustment of body shape, resistivity and density based on BMI according to Moissl et al. (3); Kb,i, individualized body shape correction based on lengths and circumferences of arms, legs and trunk; Vecf,dxa, extracellular fluid volume derived from dual x-ray absorptiometry; Vt,dxa, total body volume derived from dual x-ray absorptiometry

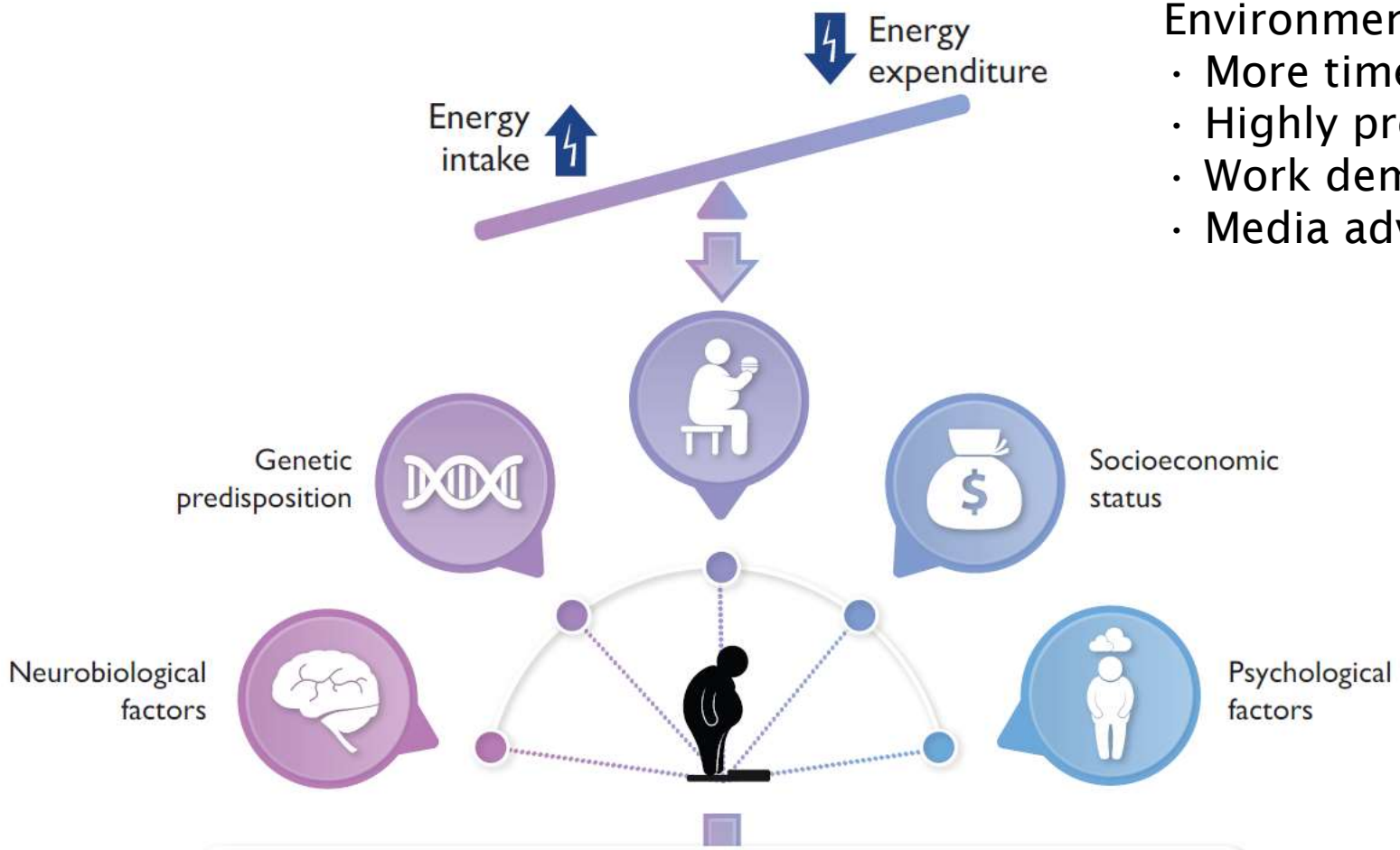
AGENDA

- Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation möglich?

- Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation sinnvoll?

→ SOME (POST-)INTRODUCTORY SLIDES ABOUT OBESITY IN THE NON-DIALYSIS POPULATION

OBESITY & CARDVASCDIS: ESC CLINICAL CONSENSUS STATEMENT



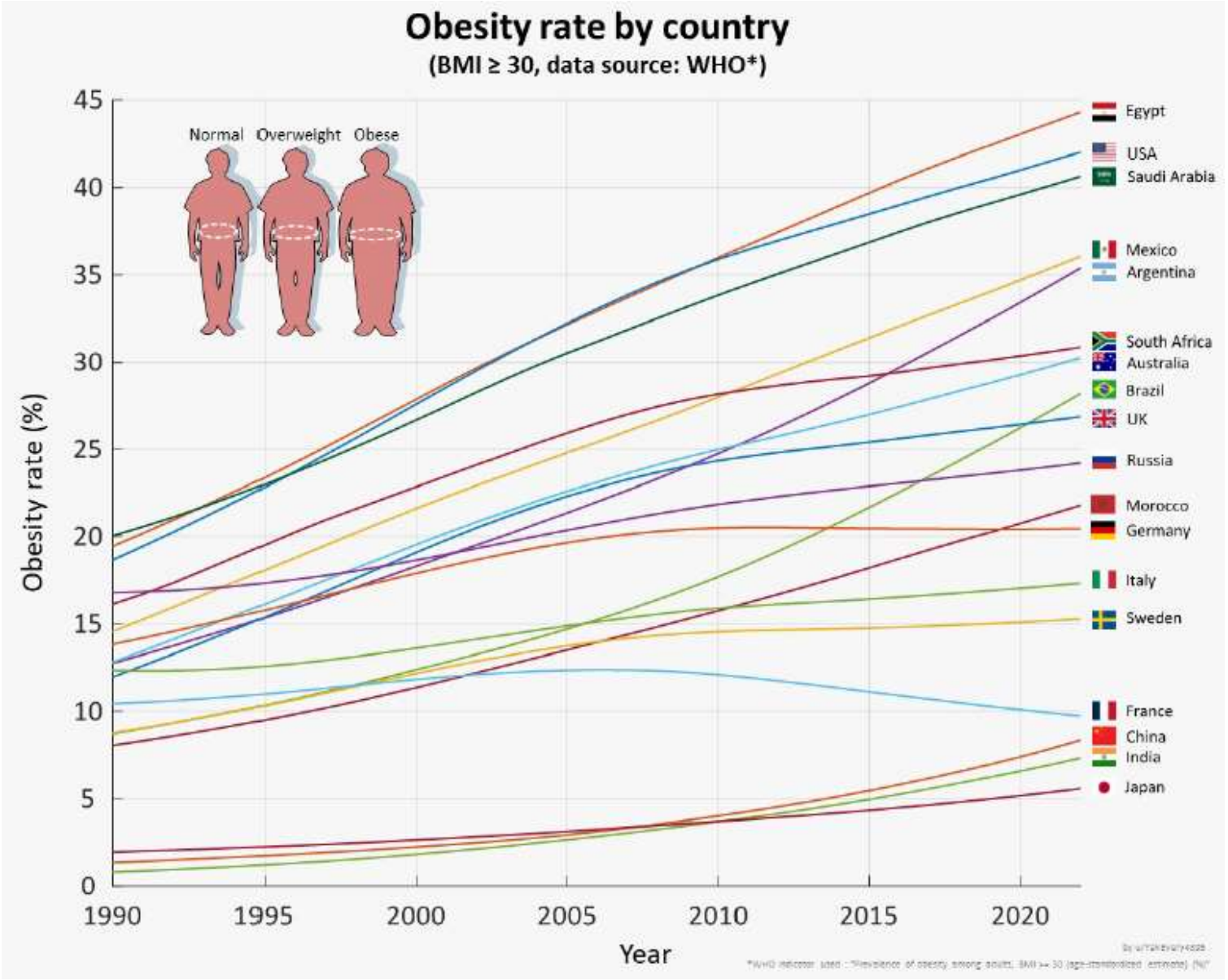
Environmental contributors:

- More time spent sitting in cars and at computers
- Highly processed foods
- Work demands, less exercise
- Media advertising

FOCUS on Socio-Economic Status (SES)

*European Heart Journal (2024) **45**, 4063–4098*
Slide by JJ Carrrero (KDIGO presentation)

Obesity Trends: Increasing in Most Countries



Box 1 WHO classification of overweight and obesity in adults

- BMI 20 to <25 kg/m^2: Normal weight
- BMI 25 to <30 kg/m^2: Overweight
- BMI ≥30 kg/m^2: Obesity
  - BMI 30 to <35 kg/m^2: Obesity Class 1
  - BMI 35 to <40 kg/m^2: Obesity Class 2
  - BMI ≥40 kg/m^2: Obesity Class 3 (severe obesity)

Obesity with BMI ≥35 kg/m2: almost new phenotype from recent decades.

Most obesity-related complications will arise from **overweight and Class 1 obesity**.

BMI is limited as a diagnostic tool.

WHO estimates, 2023
Lancet. 2024 Mar 16;403(10431):1027-1050.
Slide by JJ Carrrero (KDIGO presentation)

ADIPOSITY AND RISK OF DECLINE IN GLOMERULAR FILTRATION RATE: META-ANALYSIS OF INDIVIDUAL PARTICIPANT DATA IN A GLOBAL CONSORTIUM

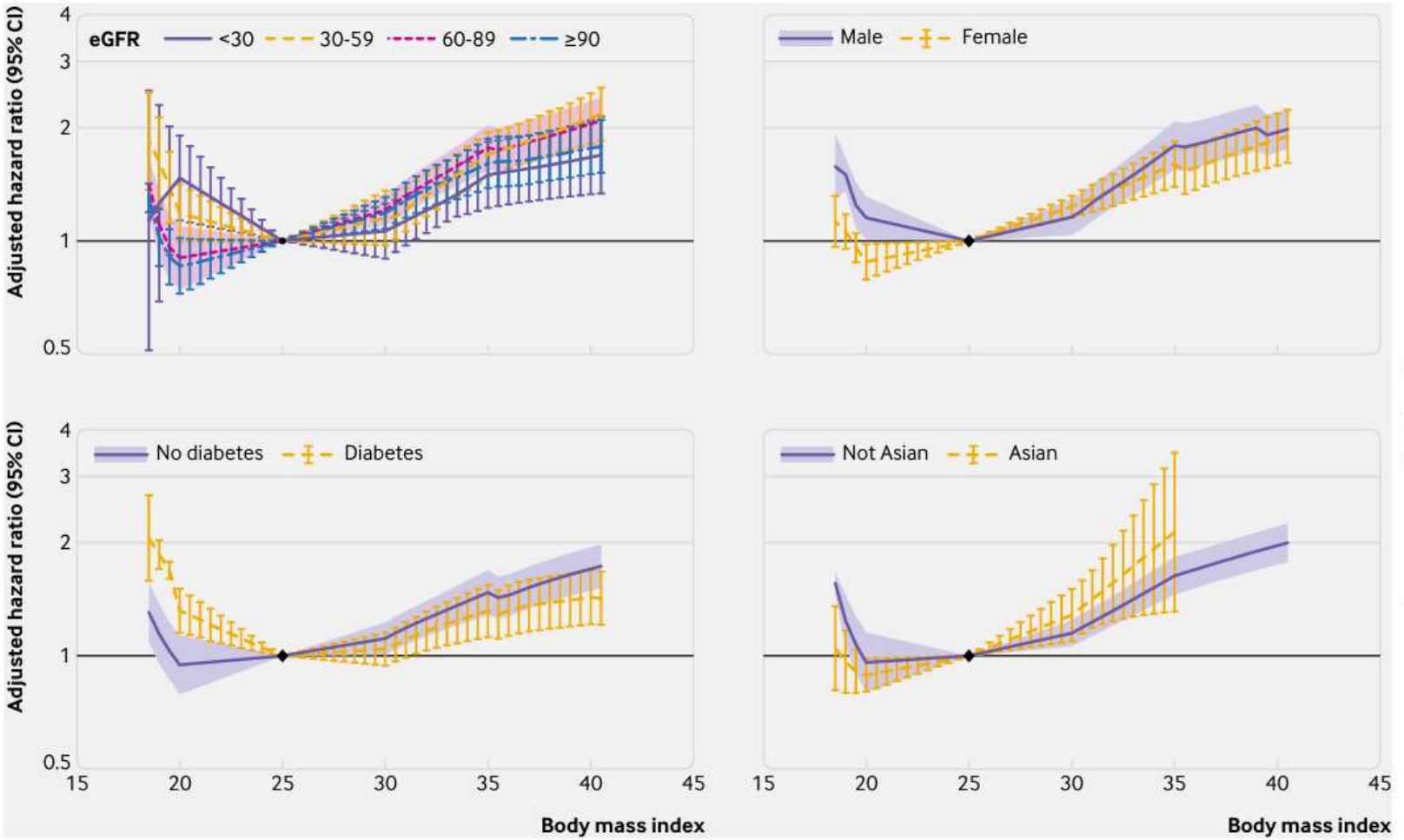
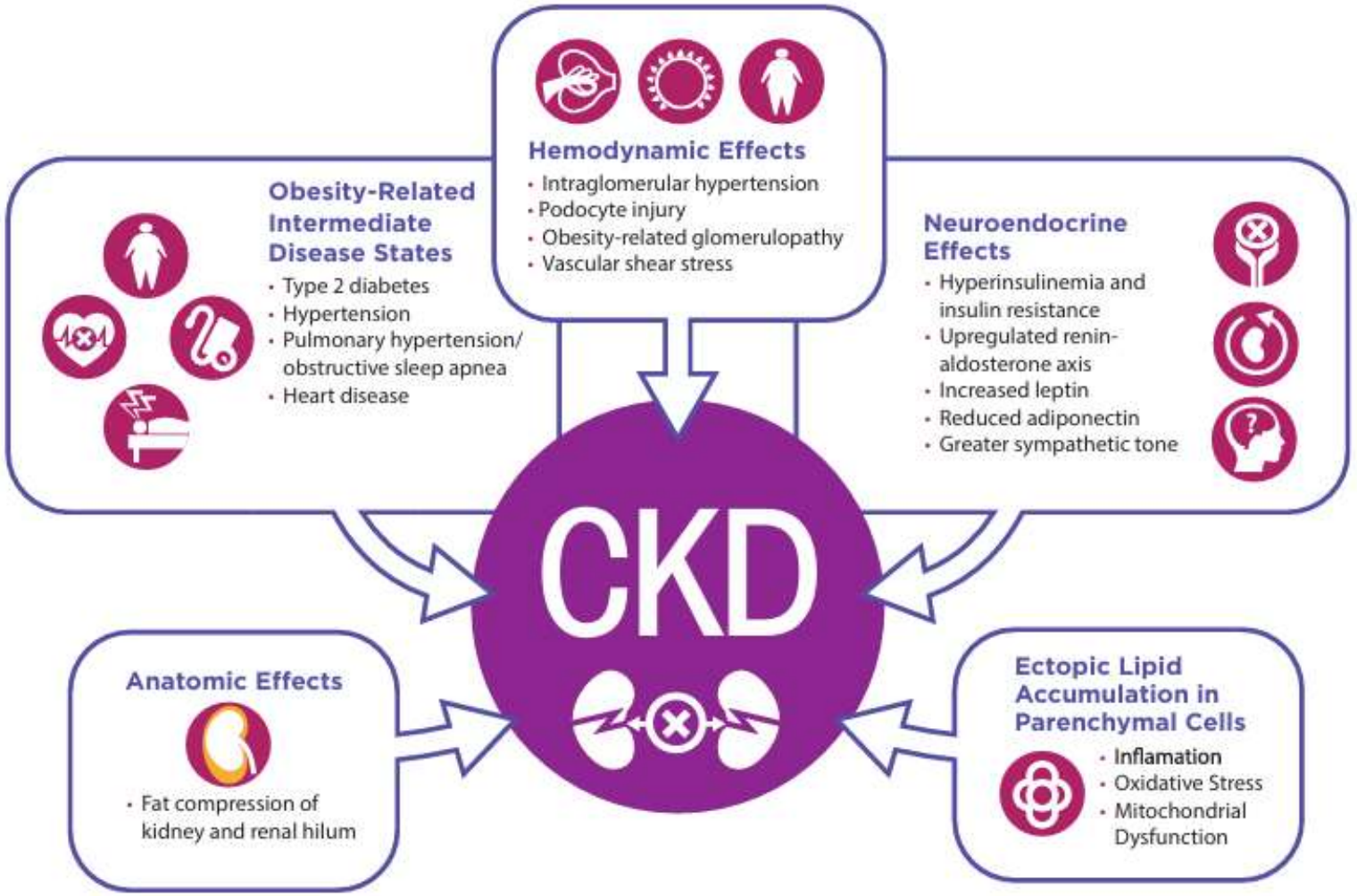


Fig 3 | Body mass index interactions with risk of decline in glomerular filtration rate in general population cohorts, by estimated GFR (eGFR) category, sex, diabetes status, and Asian ethnicity. Meta-analysed hazard ratios and 95% confidence intervals are related to body mass index, modelled by linear splines with knots at body mass indices of 20, 25, 30, and 35 (reference is body mass index 25 in each category)

BMJ. 2019 Jan 10:364:k5301.

Mechanisms Through Which Obesity Leads to Kidney Damage

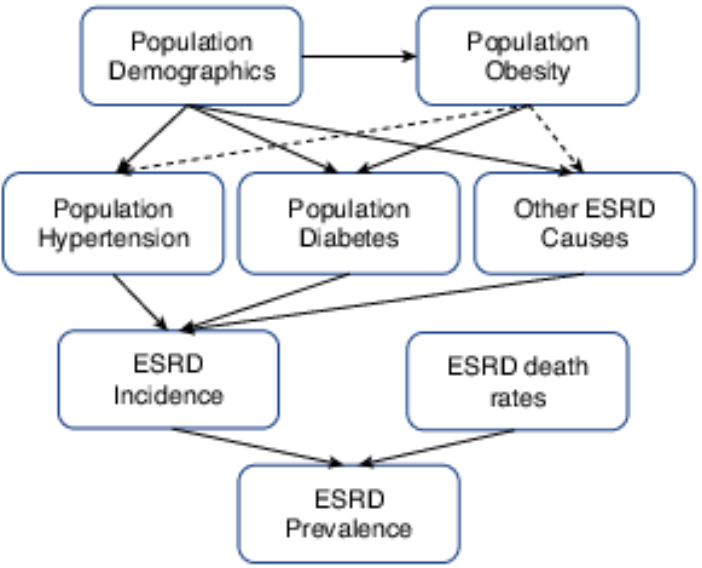


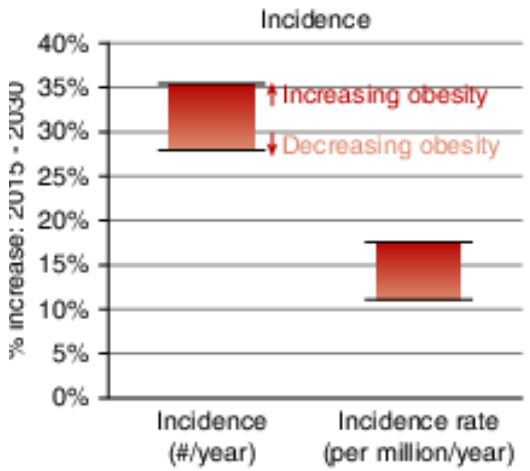
Obstacles and Opportunities in Managing Coexisting Obesity and CKD: Report of a Scientific Workshop Cosponsored by the National Kidney Foundation and The Obesity Society. Am J Kidney Dis. 2022 Dec;80(6):783-793.

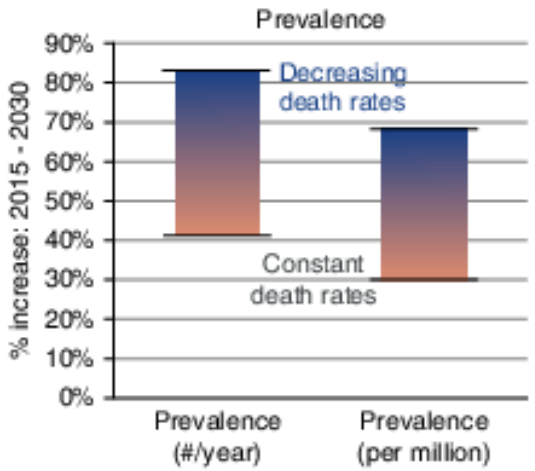
Projecting ESRD Incidence and Prevalence in the United States through 2030

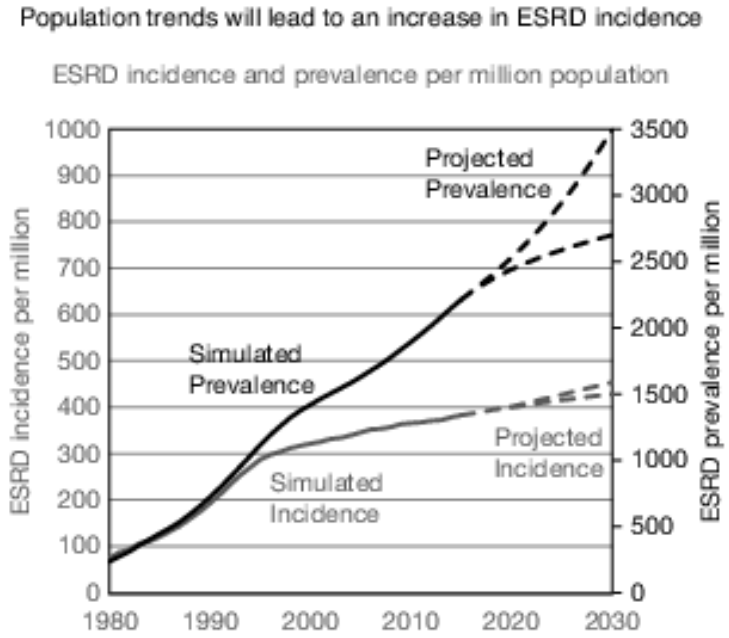
Keith P. McCullough,[1,2] Hal Morgenstern,[2,3,4] Rajiv Saran,[2,5,6] William H. Herman,[2,5] and Bruce M. Robinson[1,7]

Schematic diagram of factors influencing End Stage Kidney Disease (ESRD) prevalence and incidence









J Am Soc Nephrol. 2019 Jan;30(1):127-135.

OBESITY PREVAILS IN THE DIALYSIS POPULATION

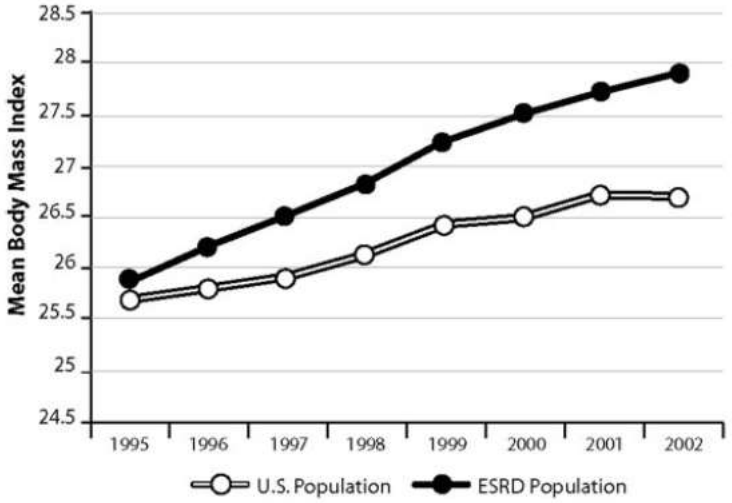
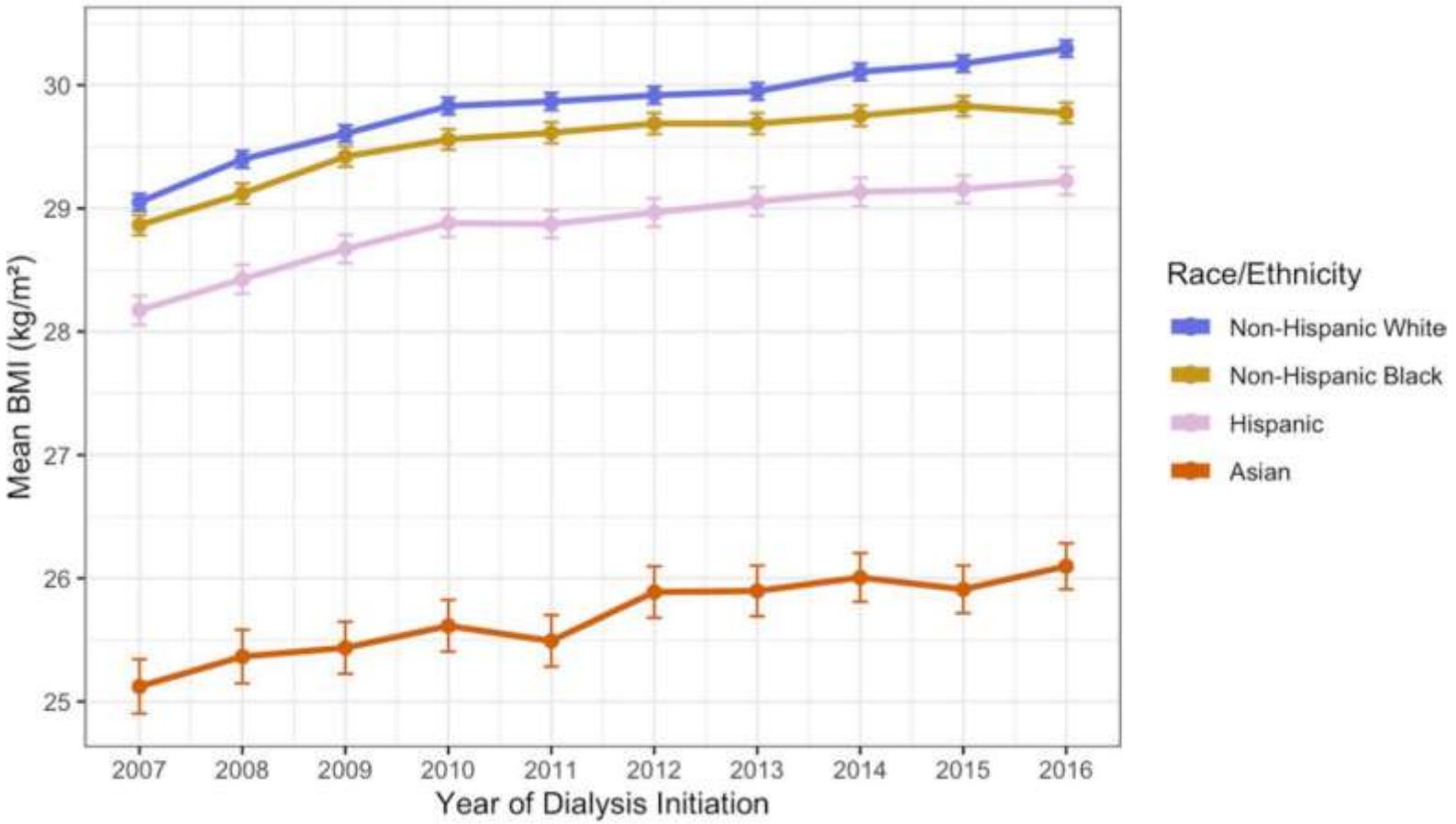


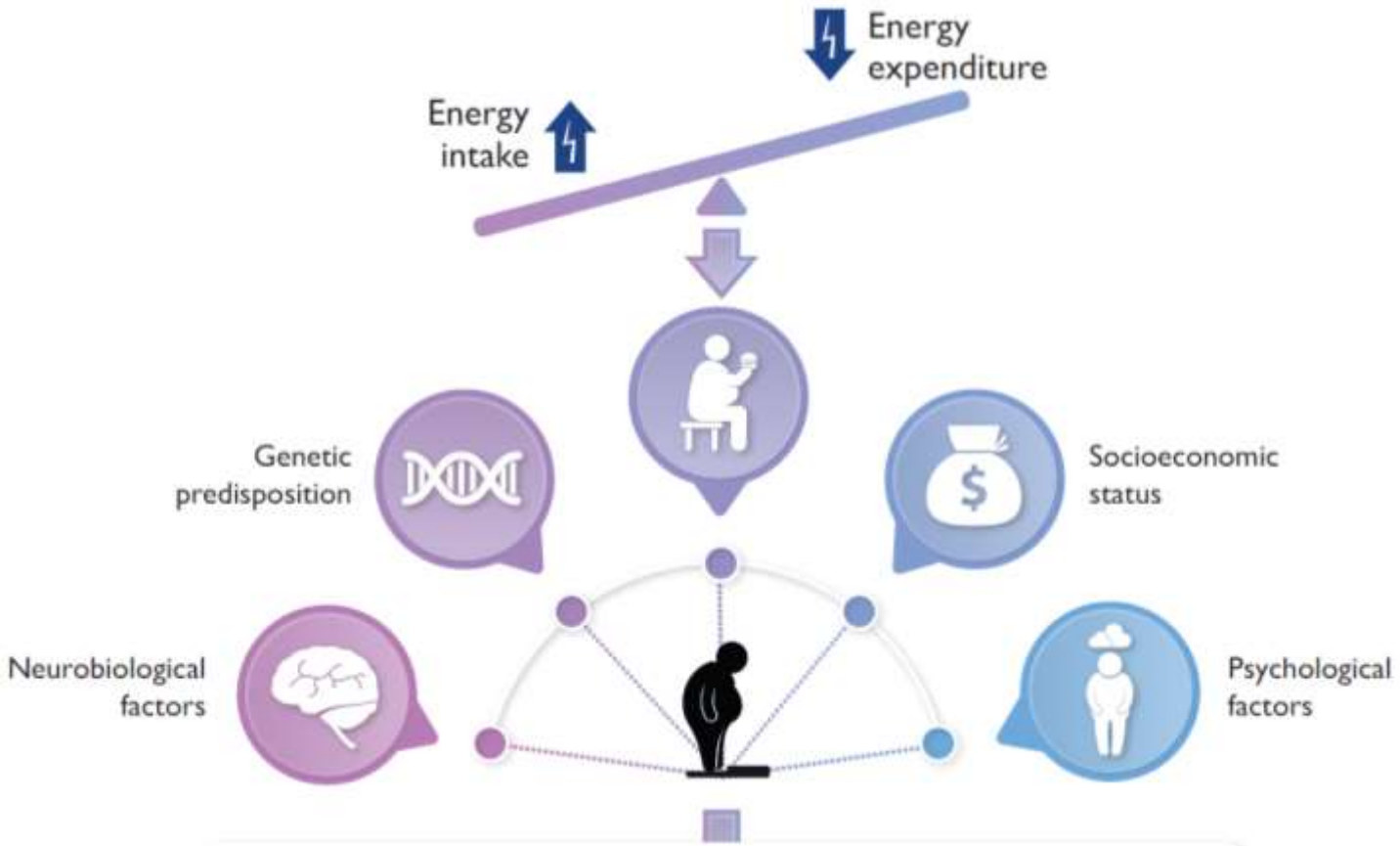
Figure 1. Temporal trends in mean body mass index (kg/m^2) among the incident adult ESRD patient population by year of first permanent dialysis initiation and in the total adult US population (Behavioral Risk Factor Surveillance System) for the corresponding year. Data are age adjusted for the 2000 US census.

J Am Soc Nephrol 17: 1453–1459, 2006



BMI trends of adult incident dialysis patients in the United States by race/ethnicity group (2007–2016).
Figure depicts age and sex-adjusted mean BMI with 95% confidence intervals by race/ethnicity.
In: ***Transplantation . 2022 Nov 1;106(11):e488-e498****. Trends, Social Context, and Transplant Implications of Obesity Among Incident Dialysis Patients in the United States*

OBESITY & CARDVASCDIS: ESC CLINICAL CONSENSUS STATEMENT



About 80%–85% of people with T2DM also overweight or obese.6

Individuals with obesity are nearly three times more likely to develop T2DM than normal weight individuals (20% vs. 7.3%).

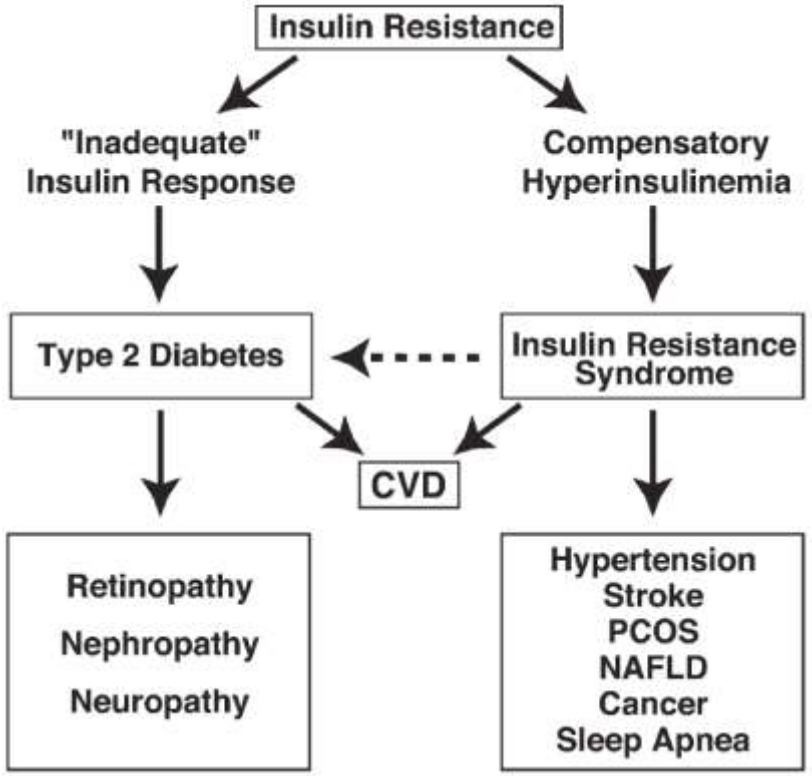
Insulin resistance, a key factor in T2DM development manifesting long before the onset of diabetes,65is also a major feature of obesity.66

Insulin resistance predicts the risk of developing CVD, even in the absence of diabetes,67and promotes atheroma plaque formation.68”

European Heart Journal (2024) ***45****, 4063–4098*

METABOLIC SYNDROME: HISTORICAL PERSPECTIVE

- **Insulin sensitive vs insensitive Diabetes** (Himsworth, *Lancet*, 1939)
- **Syndrome X** (Reaven, *Diabetes*, 1988)
  - Insulin resistance and compensatory hyperinsulinemia
  - Varying degrees of glucose tolerance
  - Plasma TG concentration high & HDL cholesterol concentration low
- **The Insulin Resistance Syndrome = The Metabolic Syndrom**



Reaven GM, *Cell Metab.* 2005 Jan;1(1):9-14.

Erol CERASI, MD, PhD, DHC
Endocrine Services
Department of Medicine
Hebrew University Hadassah
Medical Centre
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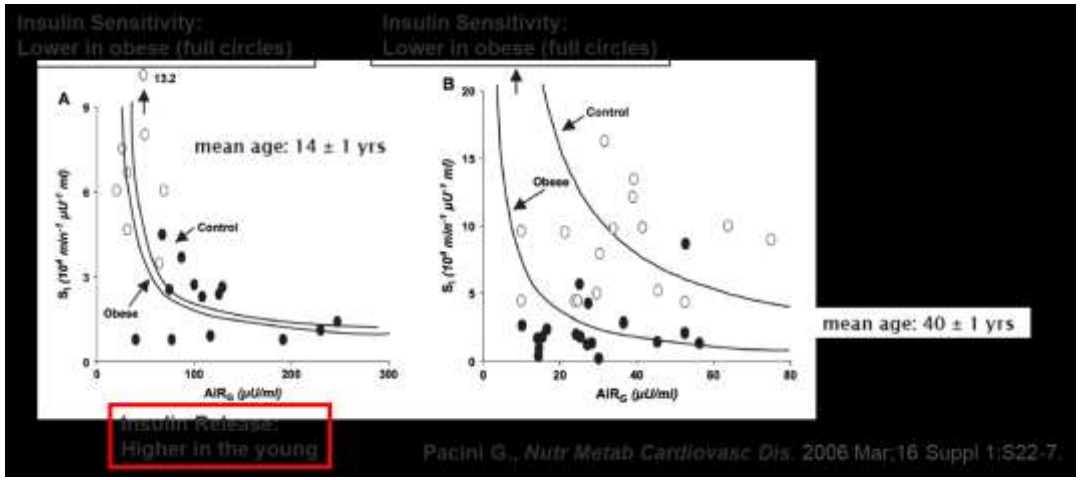
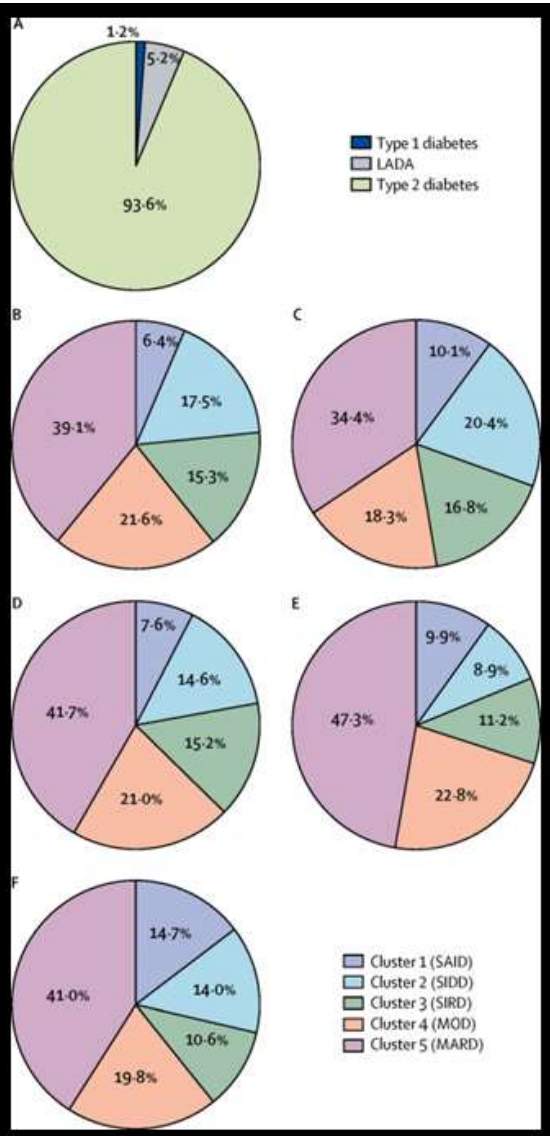
25 YEARS OF PROGRESS IN TYPE 2 DIABETES

β-Cell dysfunction vs insulin resistance in type 2 diabetes: the eternal "chicken and egg" question

by E. Cerasi, *Israel*



DM Physiology: Diabetes Subtypes!!!



Ahlqvist E et al., *Lancet Diabetes Endocrinol.* 2018 May;6(5):361-369

Data-driven cluster analysis (k-means & hierarchical clustering) in newly diagnosed DM

1) Glutamate Decarboxylase Antibodies (GADA, specific for T1DM and LADA)
2) Age at diabetes diagnosis
3) BMI
4) HbA1c
5) HOMA2 estimates of β-cell function
6) HOMA2 estimates of insulin resistance

Cluster 1: Early-onset disease, low BMI, poor metabolic control, insulin deficiency, GADA positive: ***SEVERE AUTOIMMUNE DIABETES (SAID)*** – 6.4% patients

Cluster 2: Similar to cluster 1, but GADA negative: ***SEVERE INSULIN-DEFICIENT DIABETES (SIDD)*** – 17.5% patients

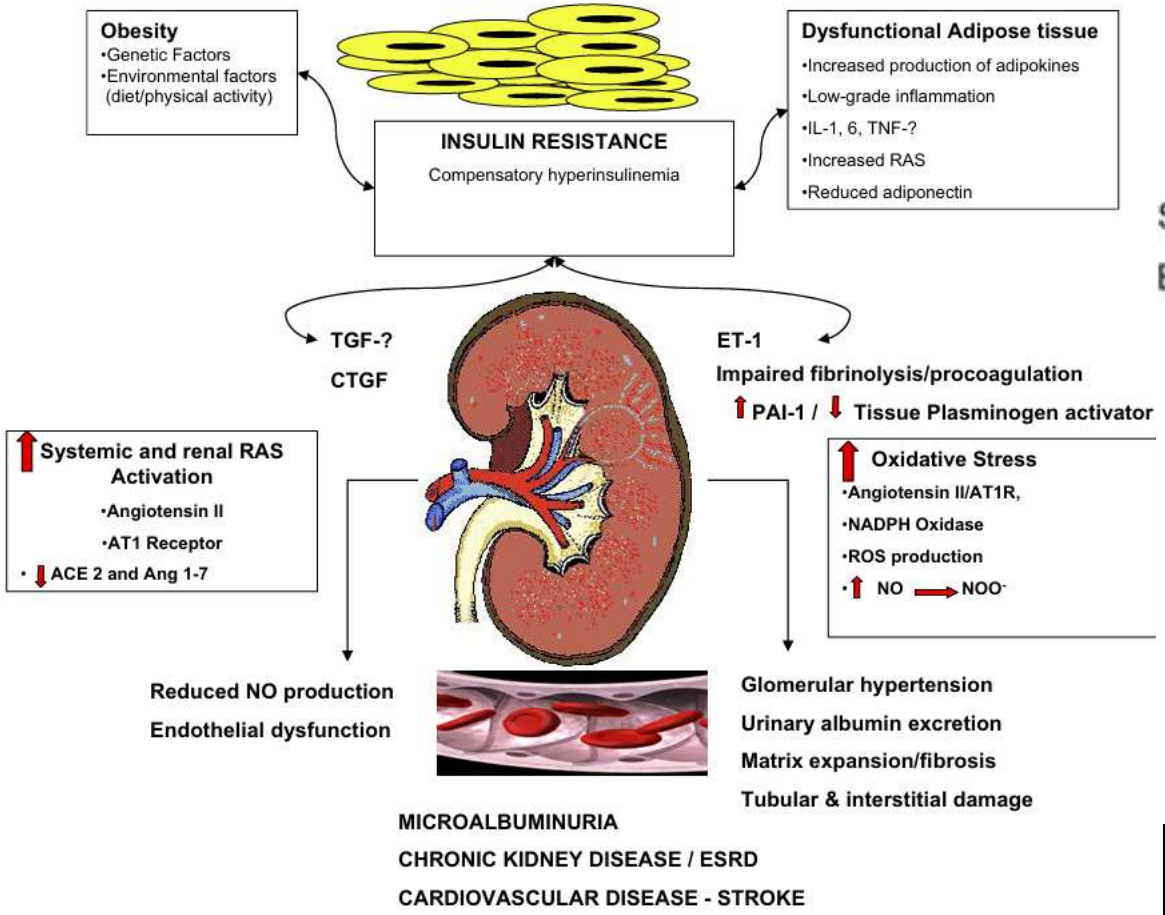
Cluster 3: Insulin resistance (high HOMA2-IR index, high BMI): ***SEVERE INSULINRESISTANT DIABTES (SIRD)*** – 15.3% patients

Cluster 4: obesity, but not insulin resistance: ***MILD OBESITIY-RELATED DIABETES (MOD)*** – 21.6% patients

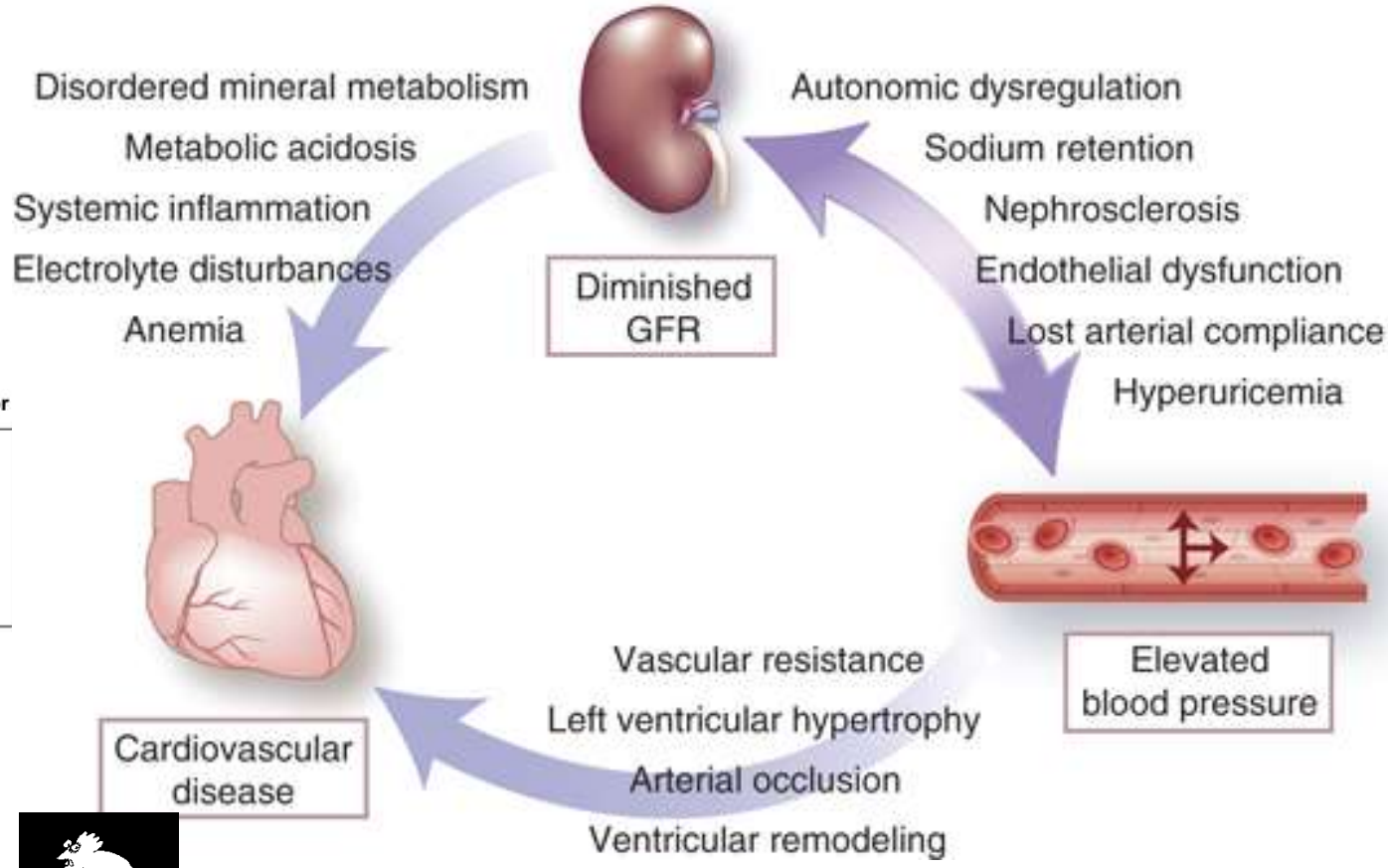
Cluster 5: old, only modest metabolic derangements: ***MILD AGE-RELATED DIABETES (MARD)*** – 39.1% patients

SEVERE INSULINRESISTANT DIABETES higher risk of ***DIABETIC KIDNEY DISEASE!!!***
SEVERE INSULIN-DEFICIENT DIABETES highest risk of retinopathy!!!

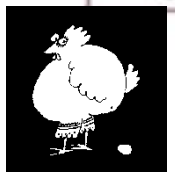
Chicken Vs Egg: Kidney Disease & CVD +/- Insulin Resistance



Lastra et al., *Adv Chronic Kidney Dis*. 2006 Oct;13(4):365-73

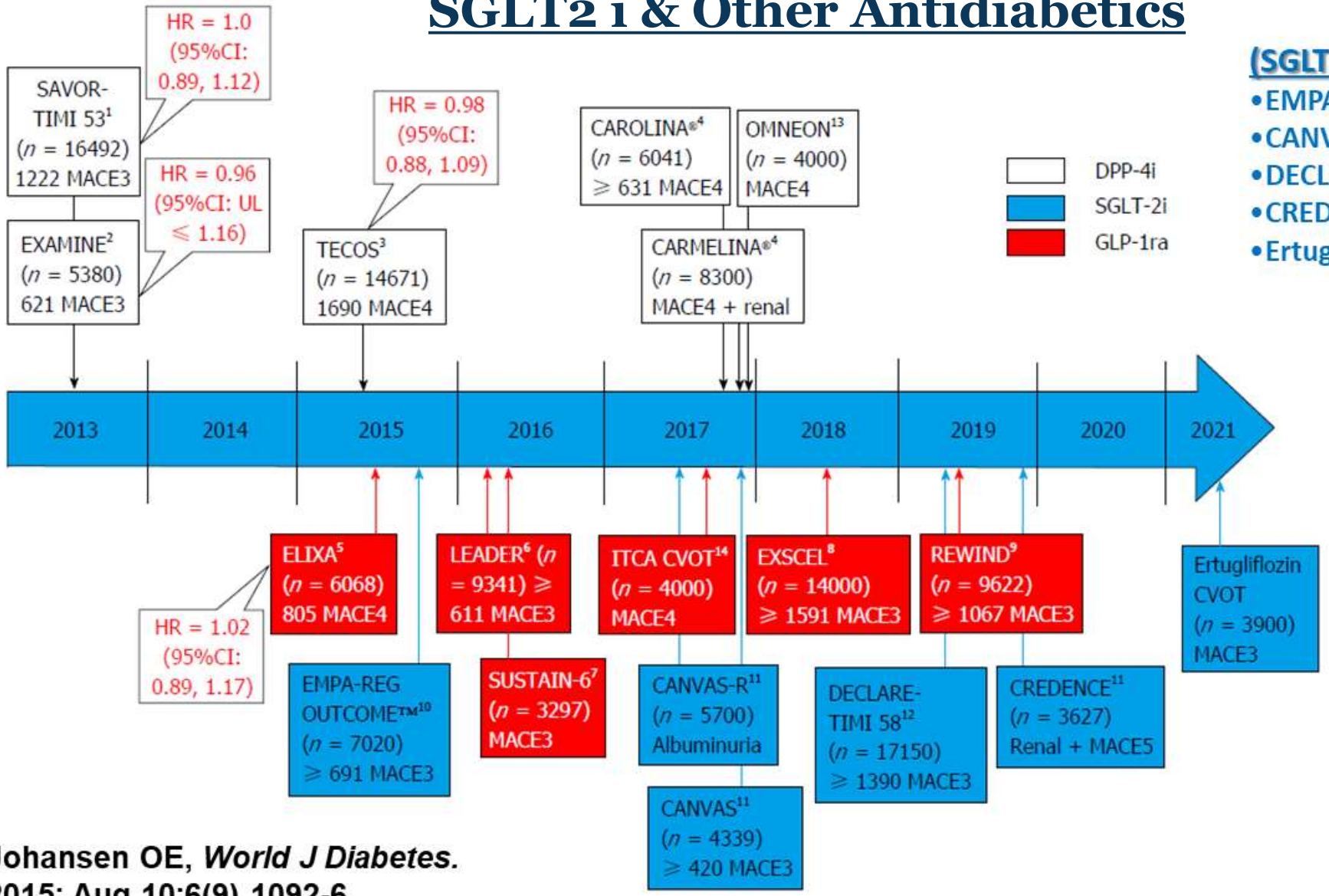


Middleton JP & Pun PH, *Kidney Int*. 2010 May;77(9):753-5



„[…] These and other observations [of high CV mortality] <u>cement an association</u> between CKD and CV disease, but the <u>source</u> of this association <u>remains elusive</u>."

SGLT2 i & Other Antidiabetics



(SGLT2 I – HEMODYNAMIC EFFECT?)

- EMPA-REG OUTCOME: empagliflozin
- CANVAS: canagliflozin
- DECLARE-TIMI: dapagliflozin
- CREDENCE: canagliflozin
- Ertugliflozin CVOT: ertugliflozin

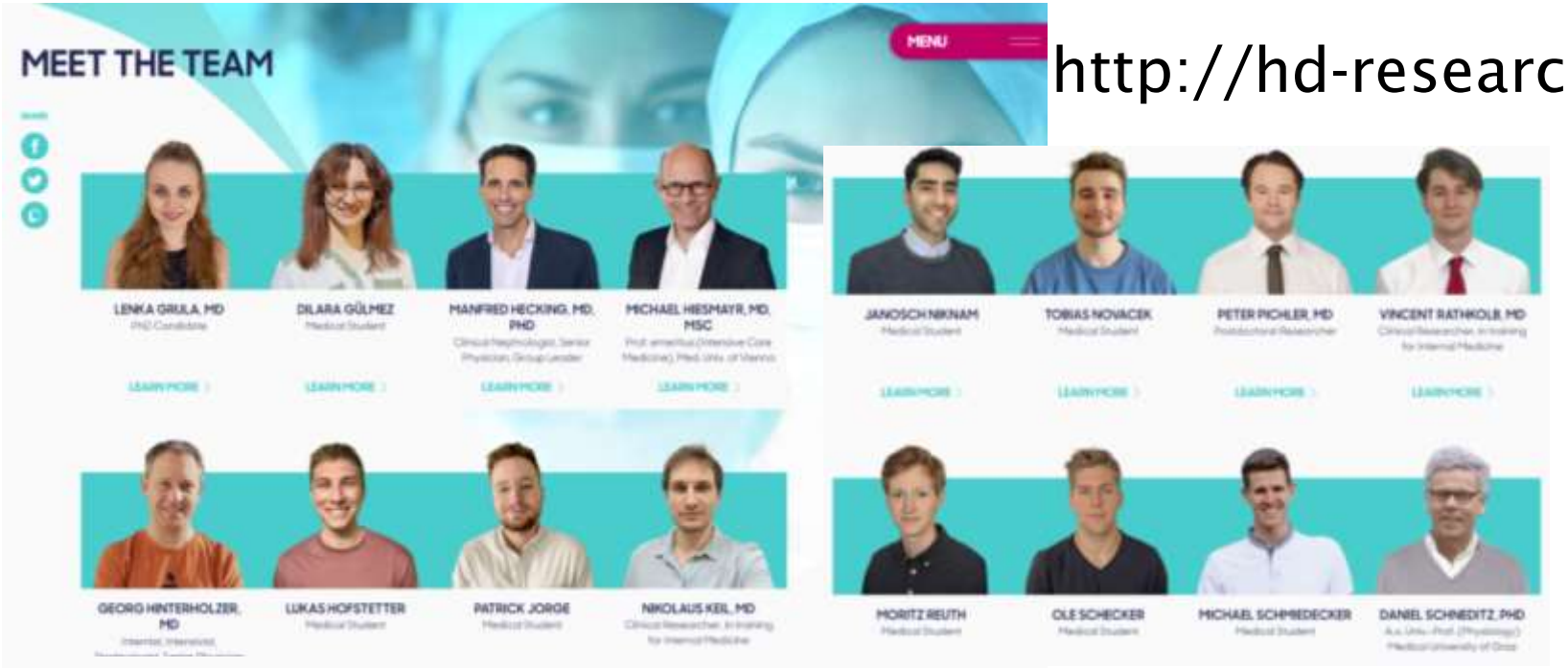
(GLP1 RA – ANTIARTHEROGENIC EFFECT?)

- ELIXA: lixisenatide
- LEADER: liraglutide
- SUSTAIN: semaglutide
- ITCA CVOT: ITCA650 (exenatide)
- EXSCEL: exenatide
- REWIND: dulaglutide

Johansen OE, *World J Diabetes.* 2015; Aug 10;6(9) 1092-6

THANK YOU!

http://hd-research.net



AGENDA

- **Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation möglich?**

- **Sind GLP-Agonisten als Gewichtsreduktionsmaßnahme vor Nierentransplantation sinnvoll? Bitte Abstimmen…**