7th Joint Meeting of ABCD & UKKA 2025, 12th February 2025, Birmingham

Post transplantation diabetes: clinical challenges

Prof. Adnan Sharif

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Honorary Professor, University of Birmingham

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Disclosures

- **Advisory Board:**
  - Sandoz
  - Astellas
  - Atara Biotherapeutics
  - Novartis
  - Takeda
  - Chiesi
  - Alexion
  - Mallinckrodt

- **Honorarium/Grant funding:**
  - Chiesi
  - Napp Pharmaceuticals
  - Sandoz
  - UpToDate.com
  - Takeda

- **Trustee**
  - Global Kidney Foundation
  - Give A Kidney
  - Metchley Park Medical Society

Clinical challenges

Can I prevent PTDM in my high cardio-metabolic risk kidney transplant candidate?

How should I manage a new kidney transplant patient who develops post-op PTDM?

Can I use SGLT2i for my kidney transplant patient with PTDM?

Can I use GLP-1 agonists for my kidney transplant patient with PTDM?

Why PTDM is common after transplantation

Non-modifiable

- Age
- Male sex?
- Deceased-donor kidney?
- Genetic
- HLA matching/type
- Non-Caucasian ethnicity
- Family history of diabetes
- Gestational diabetes
- ADPKD
- Hepatitis C

Modifiable

- Obesity
- Rejection episodes
- Metabolic syndrome
- Serum uric acid level?
- Low androgen levels in males
- CMV infection post-transplant
- Glucose intolerance
- Anti-hypertensives
- Uric acid/Mg abnormality post-transplant
- Immunosuppression

Sharif A, Baboolal K. Nat Rev Nephrol 2010; 6: 415-423
Sharif A. Curr Opin Nephrol Hypertens 2012; 21: 574-9

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Sharif A, Baboolal K. Nat Rev Nephrol 2010; 6: 415-423
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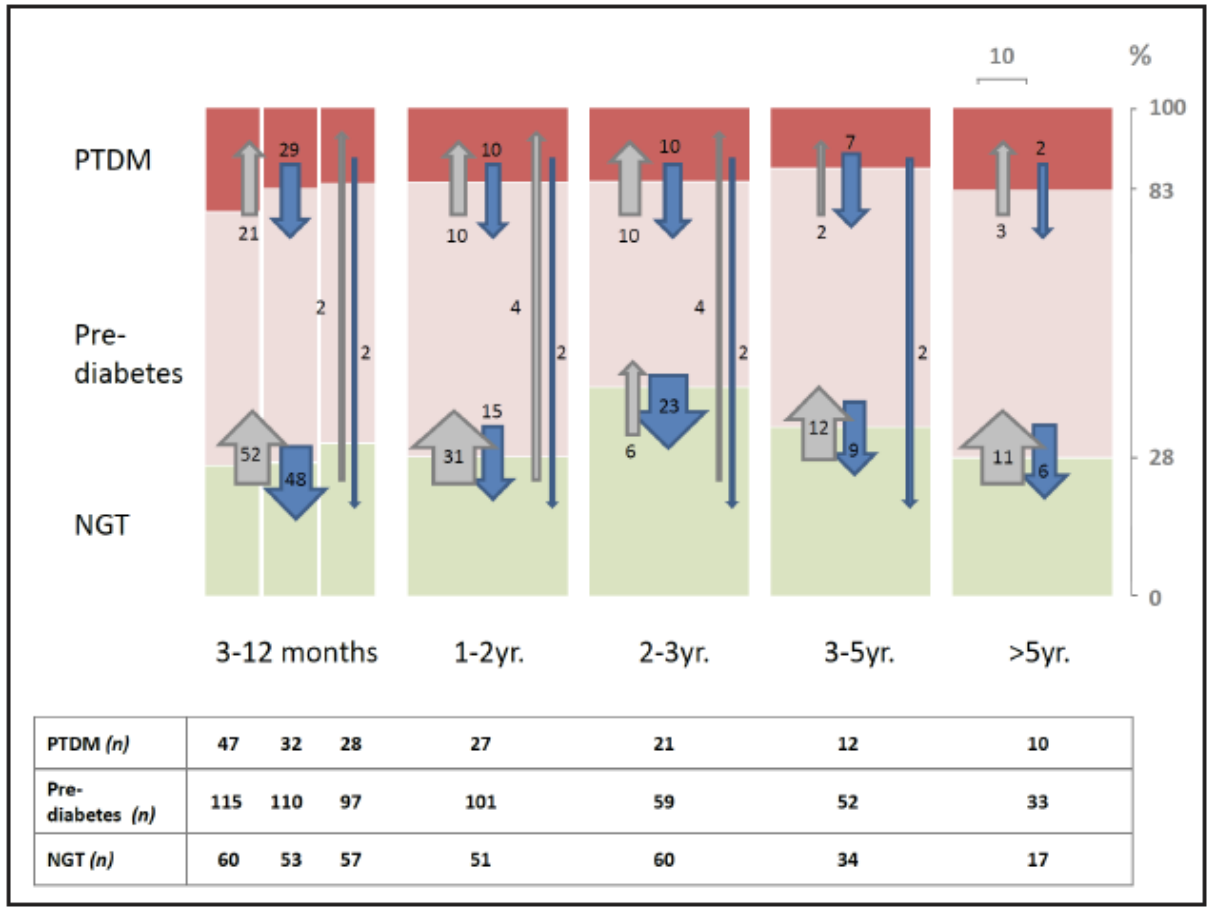
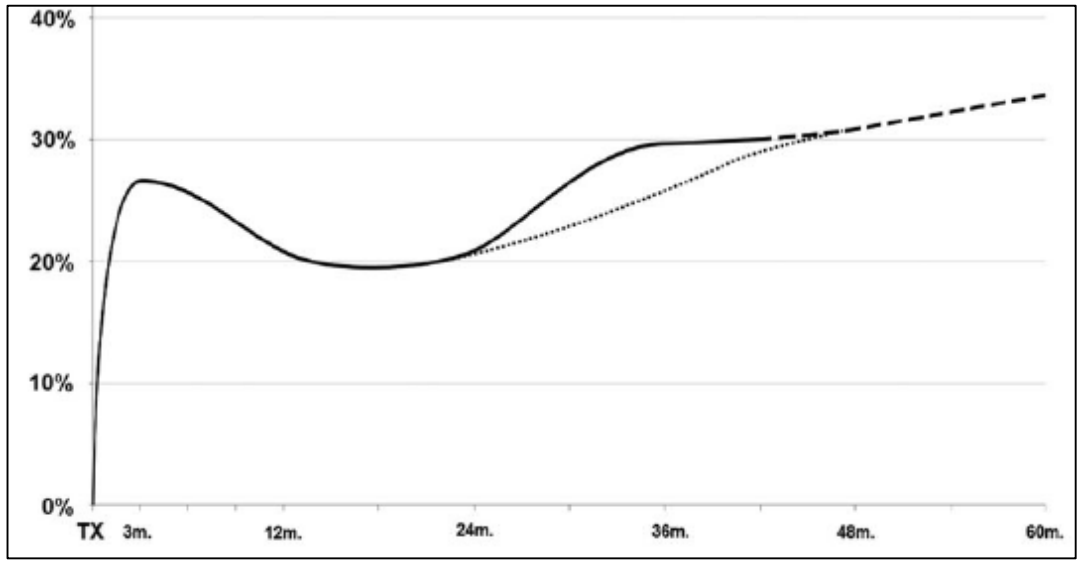
Dynamic and bimodal nature of post-transplant glucose metabolism



PTDM *(n)*	47	32	28	27	21	12	10
Pre-diabetes *(n)*	115	110	97	101	59	52	33
NGT *(n)*	60	53	57	51	60	34	17

PTDM

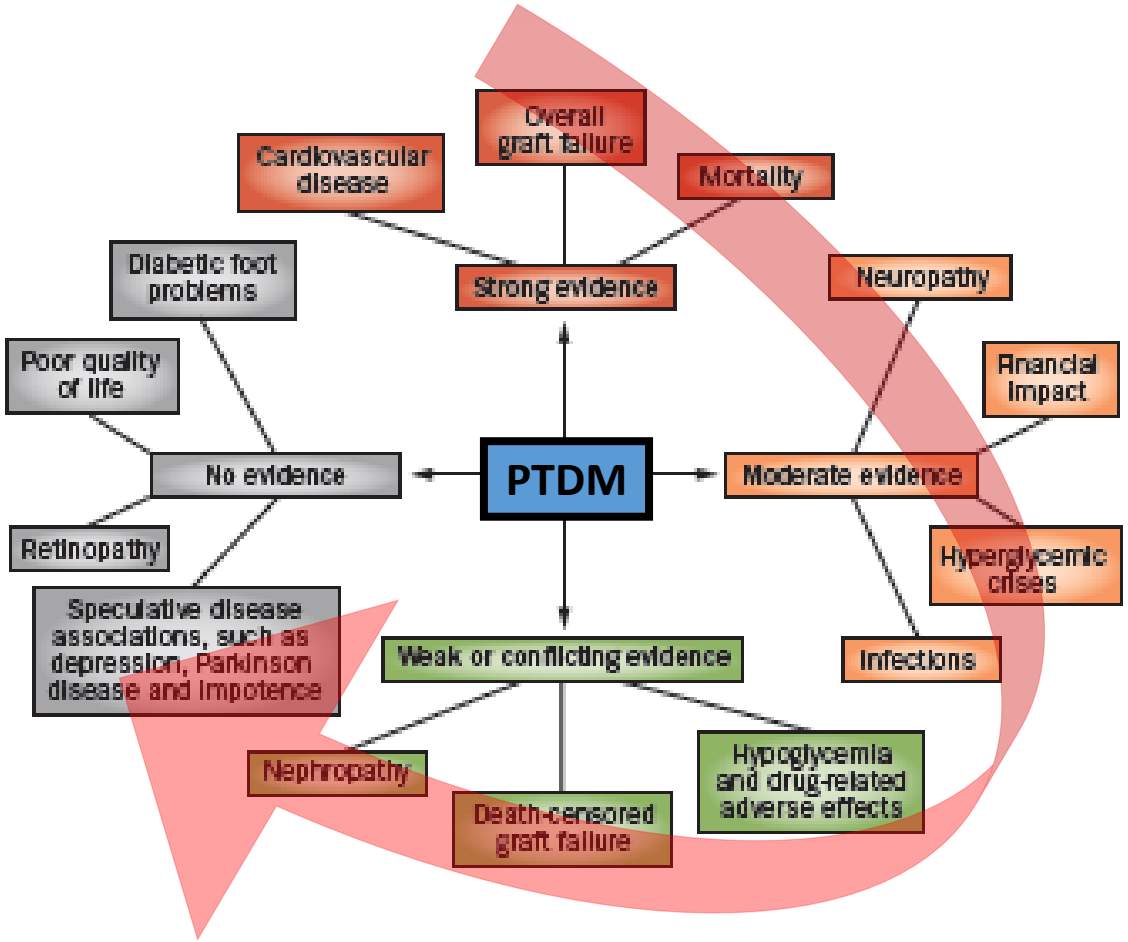


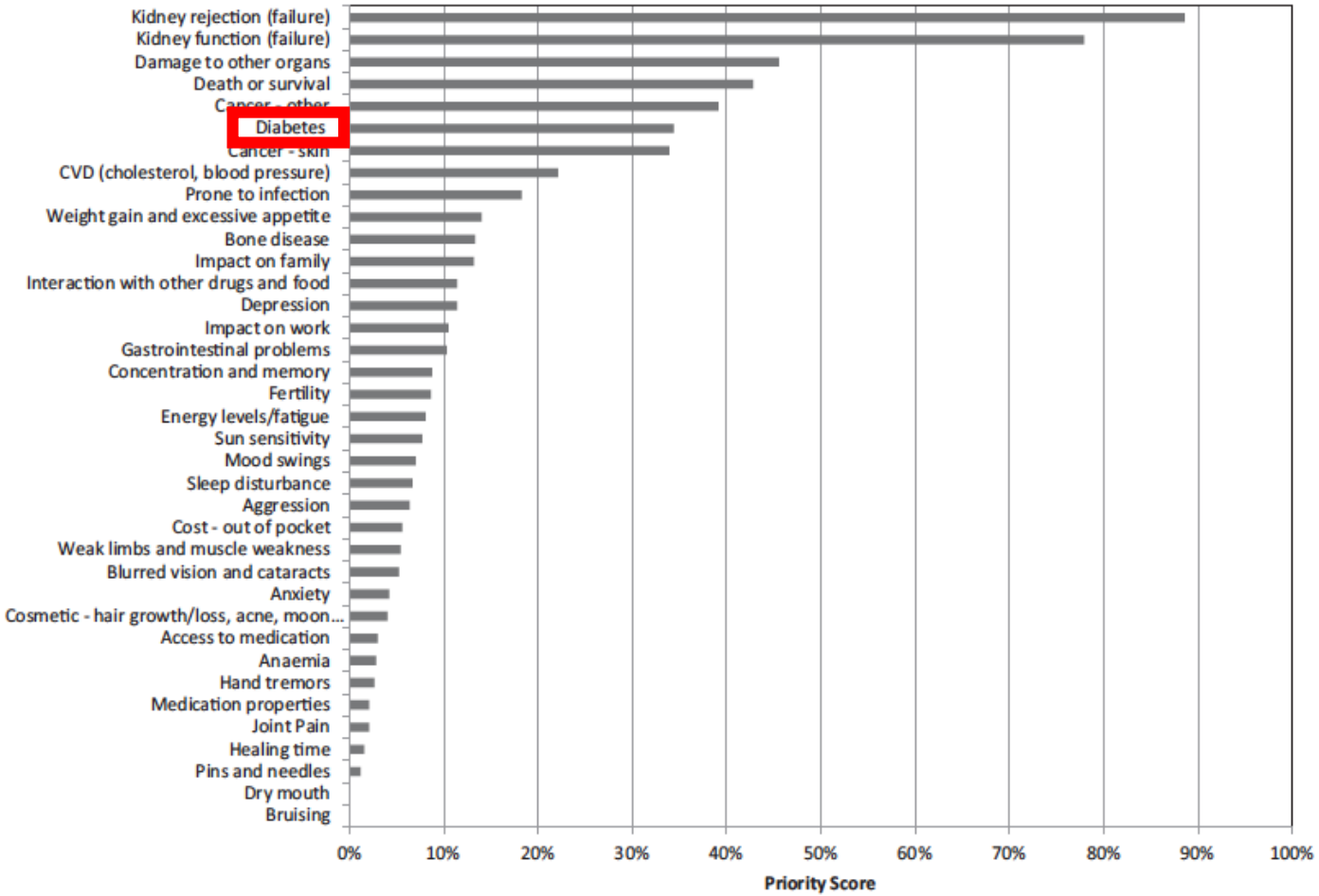
Time from transplant

Guthoff et al. Kidney Blood Pres Res 2017

Porrini et al. NDT 2016

PTDM is associated with inferior post-transplant outcomes





Sharif A, Baboolal K. Nat Rev Nephrol 2012

Howell et al. AJKD 2012

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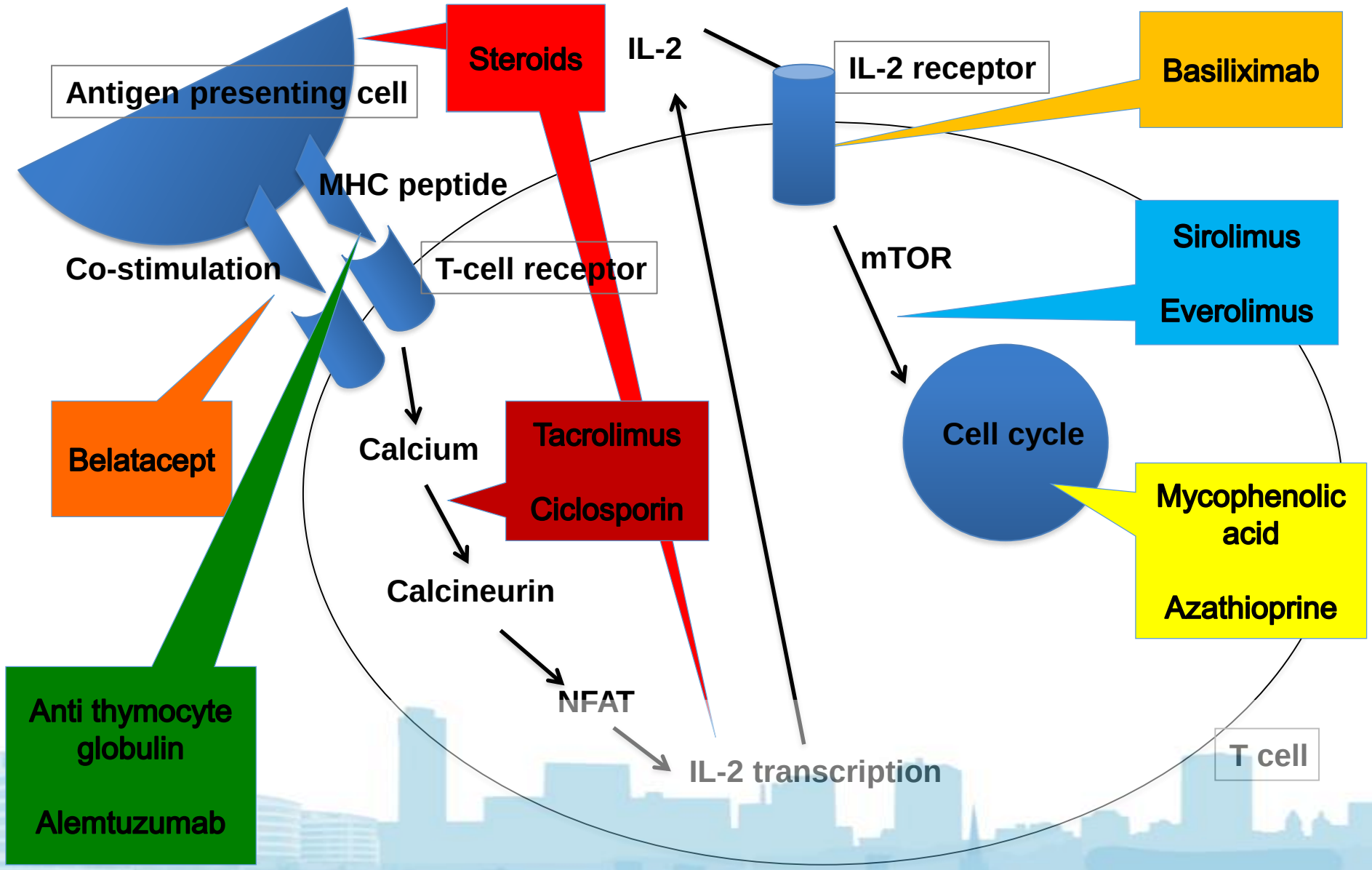
Burgeoning armamentarium of immunosuppression



Transplantation Reviews 38 (2024) 100856

Contents lists available at ScienceDirect

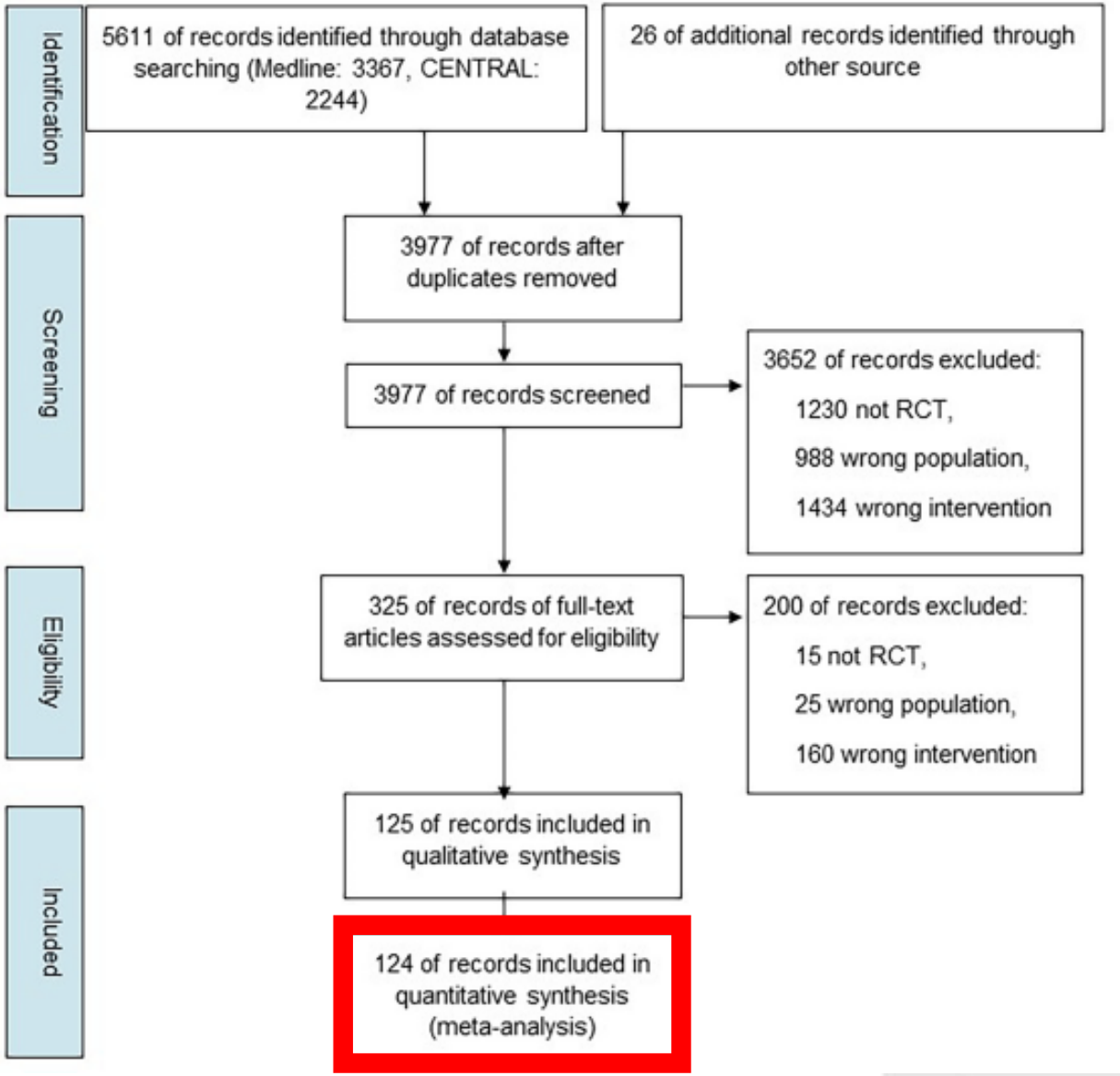
Transplantation Reviews

journal homepage: www.elsevier.com/locate/trre

Review article

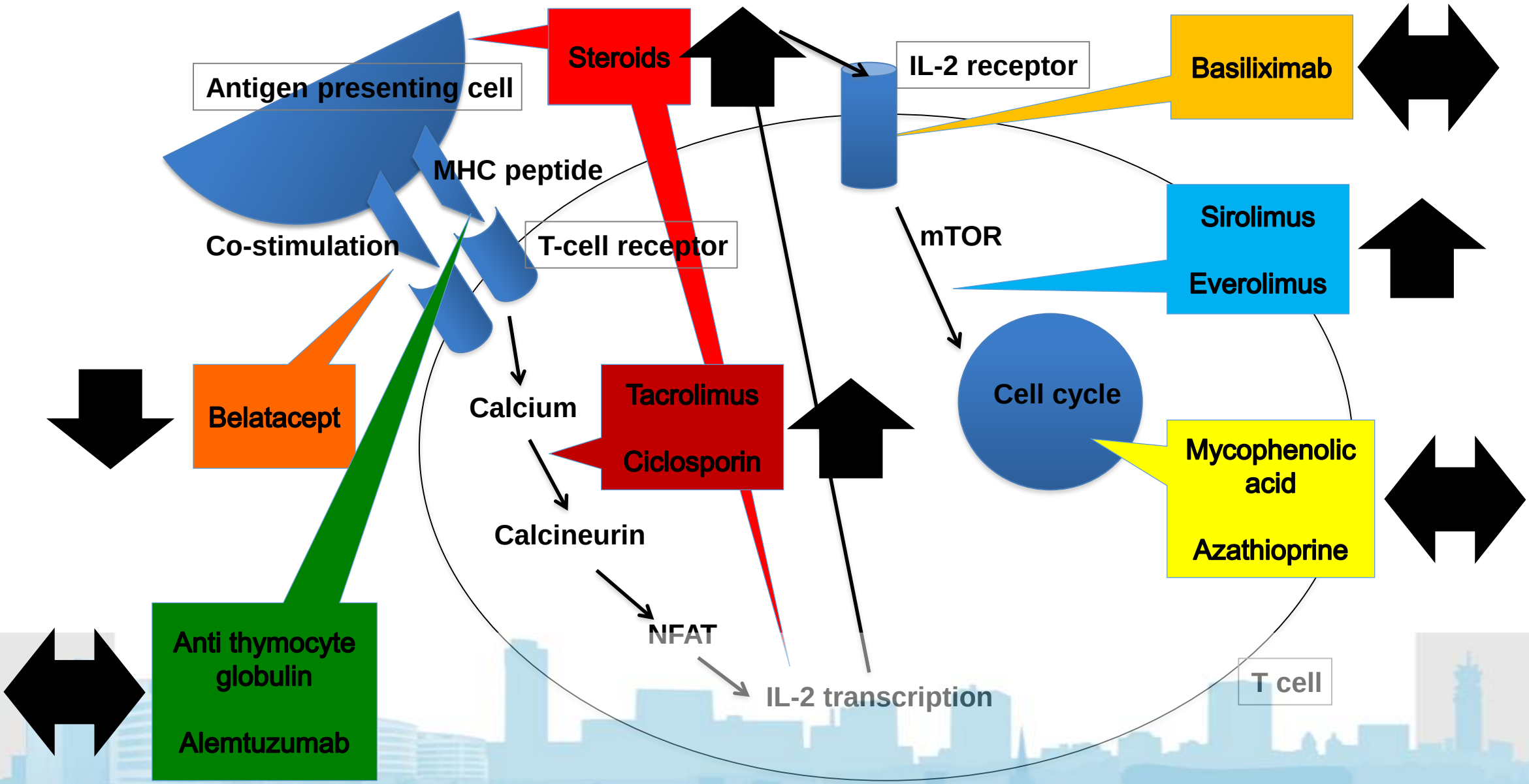
Immunosuppressive drug combinations after kidney transplantation and post-transplant diabetes: A systematic review and meta-analysis

Laia Oliveras [a,g], Ana Coloma [a], Nuria Lloberas [b], Luis Lino [a], Alexandre Favà [a], Anna Manonelles [a,g], Sergi Codina [a,g], Carlos Couceiro [a,g], Edoardo Melilli [a,g], Adnan Sharif [c,h], Manfred Hecking [d], Martina Guthoff [e,i], Josep M. Cruzado [a,g], Julio Pascual [f,**,1], Nuria Montero [a,g,*,1]

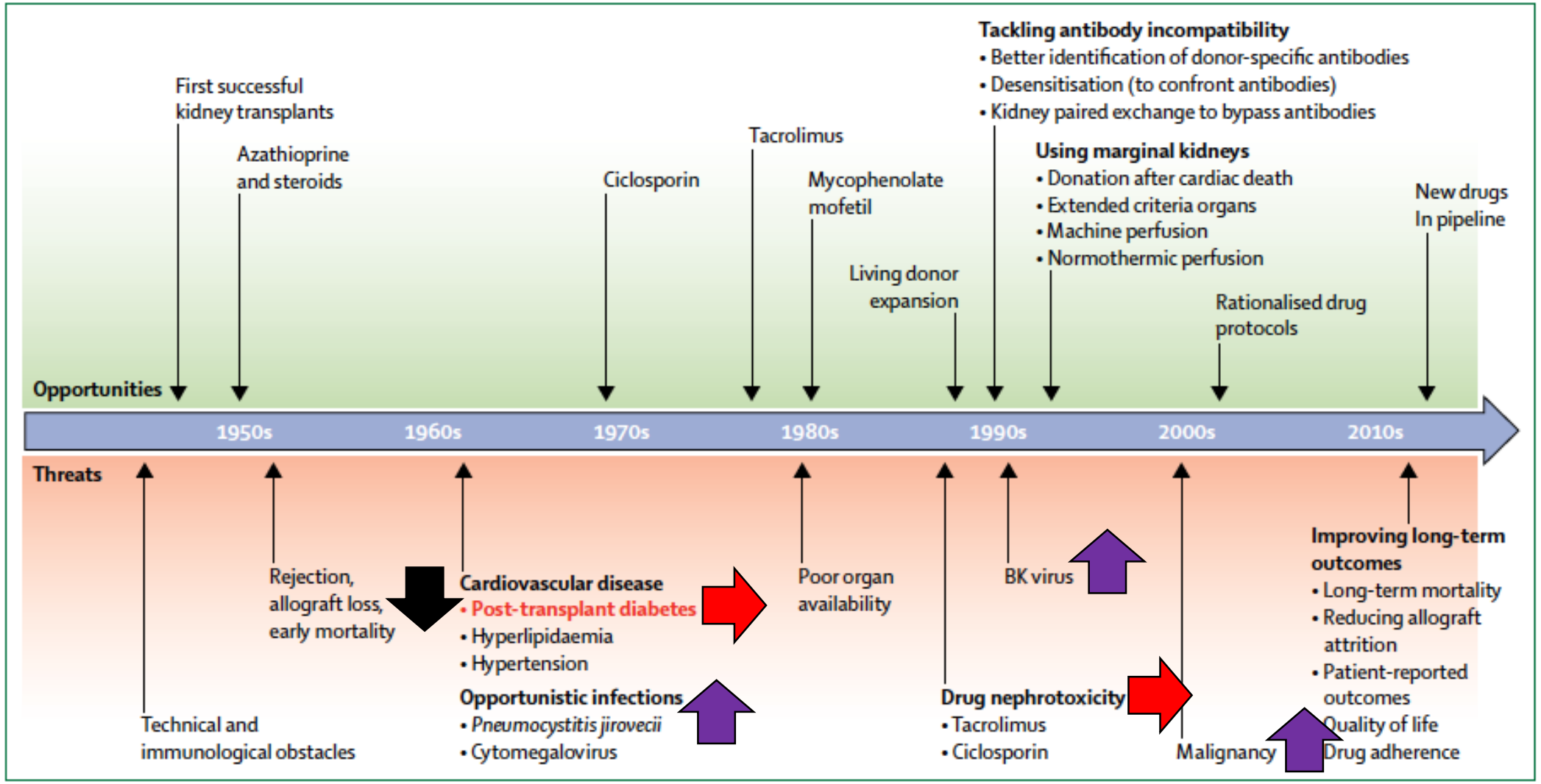


Oliveras et al. Transplant Rev 2024

Burgeoning armamentarium of immunosuppression

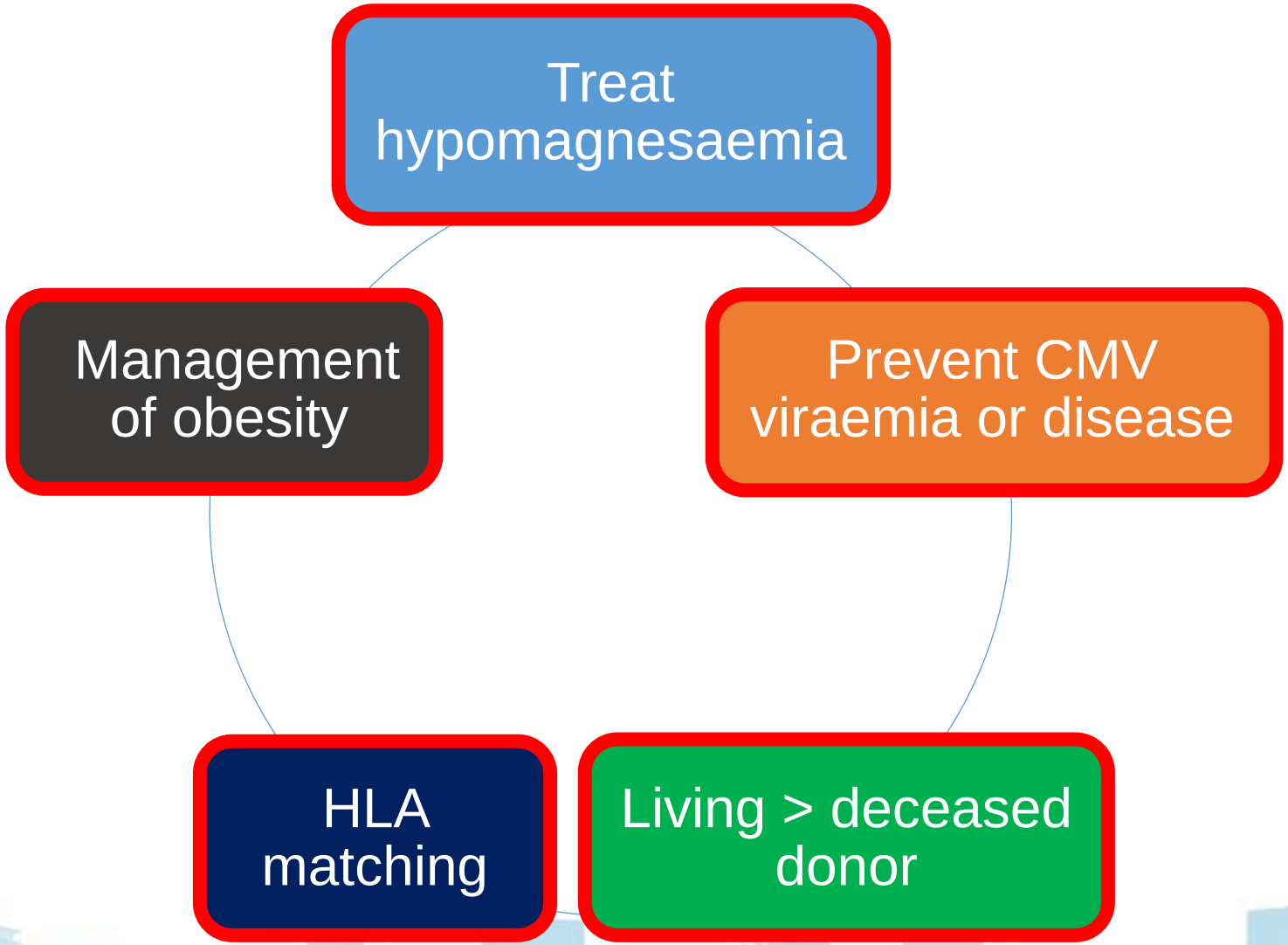


PTDM in the context of competing risks after kidney transplantation



Sharif A, Cohney S. Lancet Diab Endocrinol 2016

Are there any ways to mitigate PTDM?



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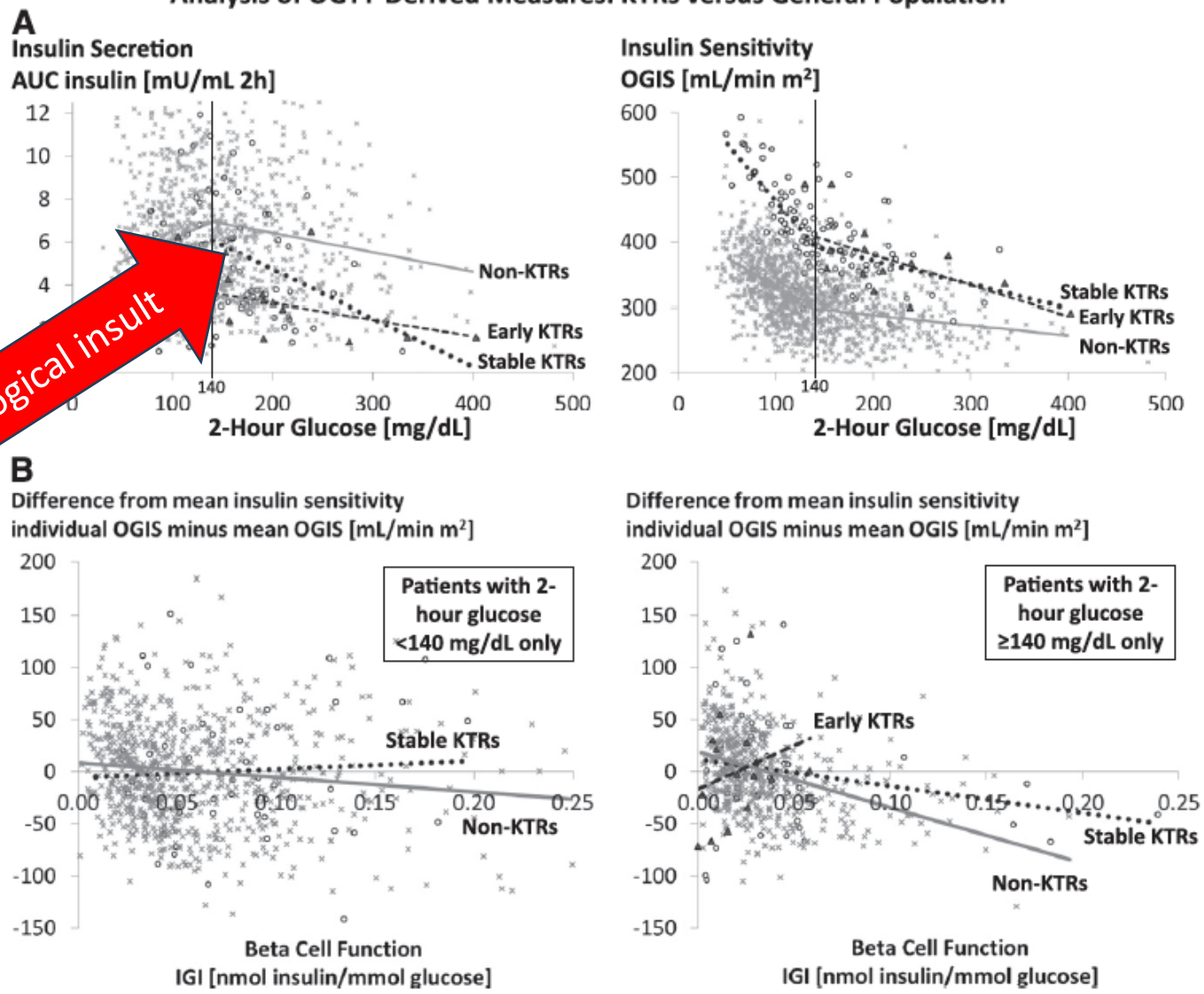
Can I use GLP-1 agonists for my kidney transplant patient with PTDM?

Pathophysiology/Complications
ORIGINAL ARTICLE

Glucose Metabolism After Renal Transplantation

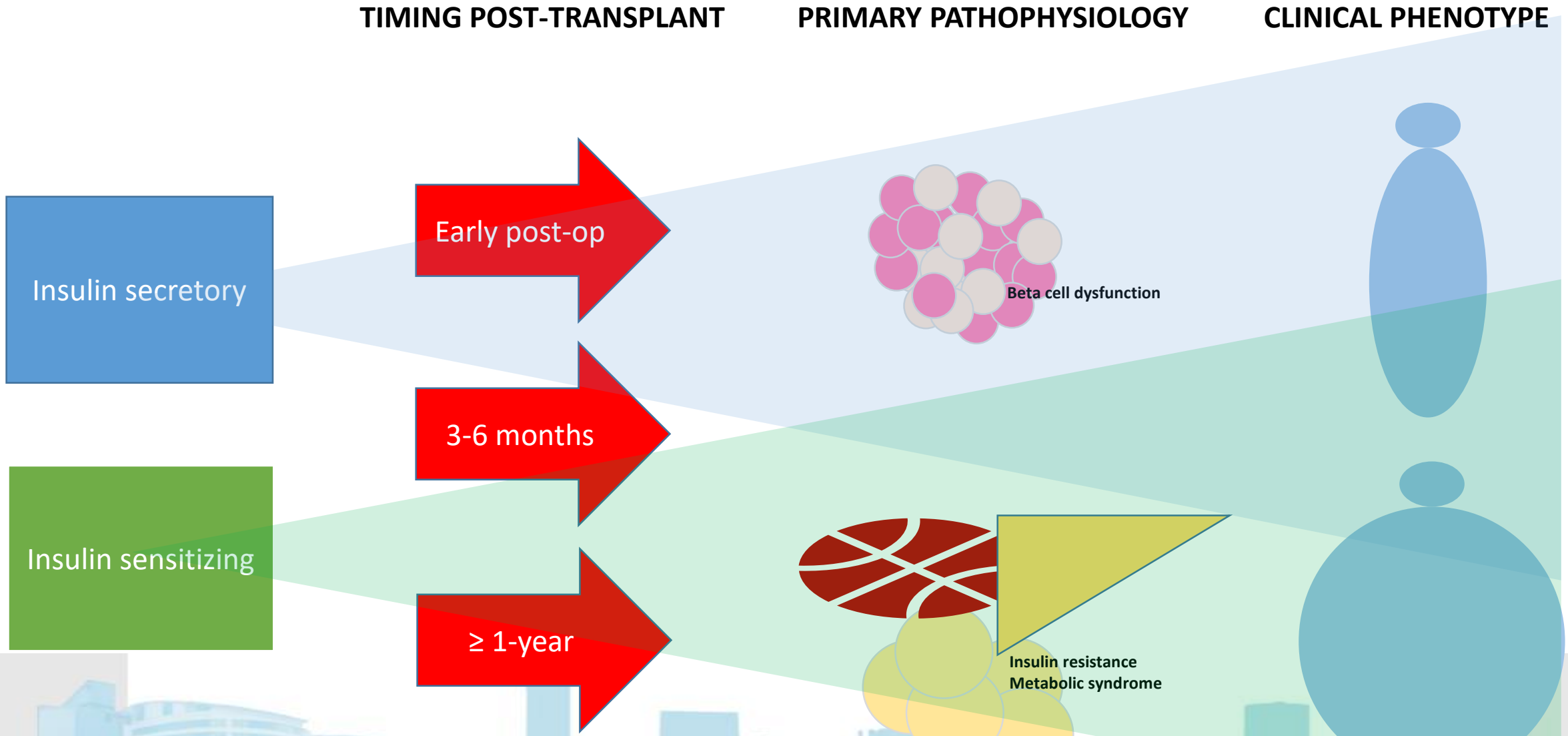
Manfred Hecking, MD[1]
Alexander Kainz, PHD[1]
Johannes Werzowa, MD[1]
Michael Haidinger, MD[1]
Dominik Döller, MD[1]
Andrea Tura, PHD[3]
Angelo Karaboyas, MS[4]
Walter H. Hörl, MD, PHD[1]
Michael Wolzt, MD[2]
Adnan Sharif, MD[5]
Michael Roden, MD[6]
Ermanno Moro, MD[7]
Giovanni Pacini, DSC[3]
Friedrich K. Port, MD, MS[4]
Marcus D. Säemann, MD[1]

Impaired insulin secretion primary pathophysiological insult



Hecking et al. Diabetes Care 2013

Therapeutic options based upon underlying PTDM characteristics



Sharif et al. Transplantation 2022

TIP: Study Design

Treat-to-target trial of Basal Insulin in Post Transplant Hyperglycemia
Efficacy and Safety of a Novel Protocol in Renal Transplant Recipients Receiving a Tacrolimus-based Immunosuppression

Inclusion: NTX, Tacrolimus, No history of DM, Informed Consent

Daily Measurements of Blood Glucose

(At least): Fasting, pre-lunch, pre-supper, post-supper

2 x 25 patients, Randomisation into 2 Study Arms

Arm A (treatment):

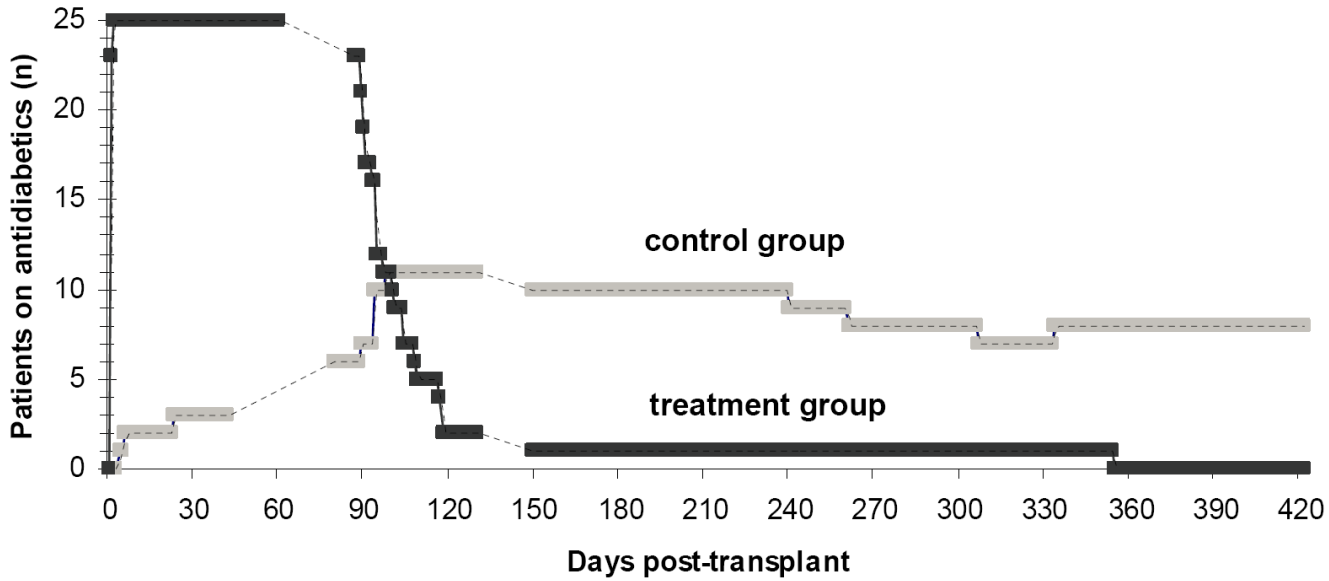
- Treatment starts when evening BG ≥140 mg/dl
- BG target level: 110-120 mg/dl
- Treatment with long acting insulin (Insulatard®)

Arm B (control):

- Corrections at the latest when BG > 250 mg/dl
- BG target level: none, but 250 mg/dl not accepted
- Conventional BG lowering therapy, according to decisions of the ward

Hecking et al. J Am Soc Nephrol 2012

Early insulin for post-op hyperglycaemia prevents PTDM at 1-year

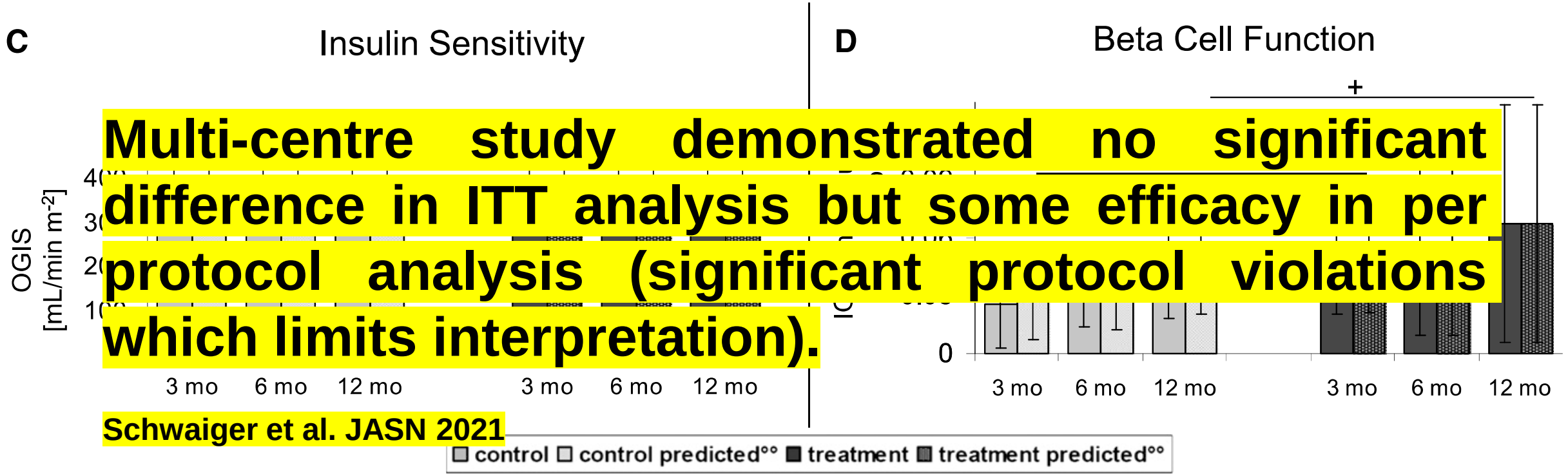


Odds Ratios [95% CI]

	Diabetic versus Non-diabetic	Diabetic + Prediabetic versus Normal
3 months	0.36 [0.11-1.16]	0.29 [0.08-1.09]
6 months	0.13 [0.03-0.53]	0.56 [0.16-1.92]
12 months	[illegible]	0.51 [0.16-1.61]
Overall^^	0.27 [0.10-0.72]	0.43 [0.16-1.14]

Hecking et al. J Am Soc Nephrol 2012

Benefit in treatment group due to improved beta-cell function

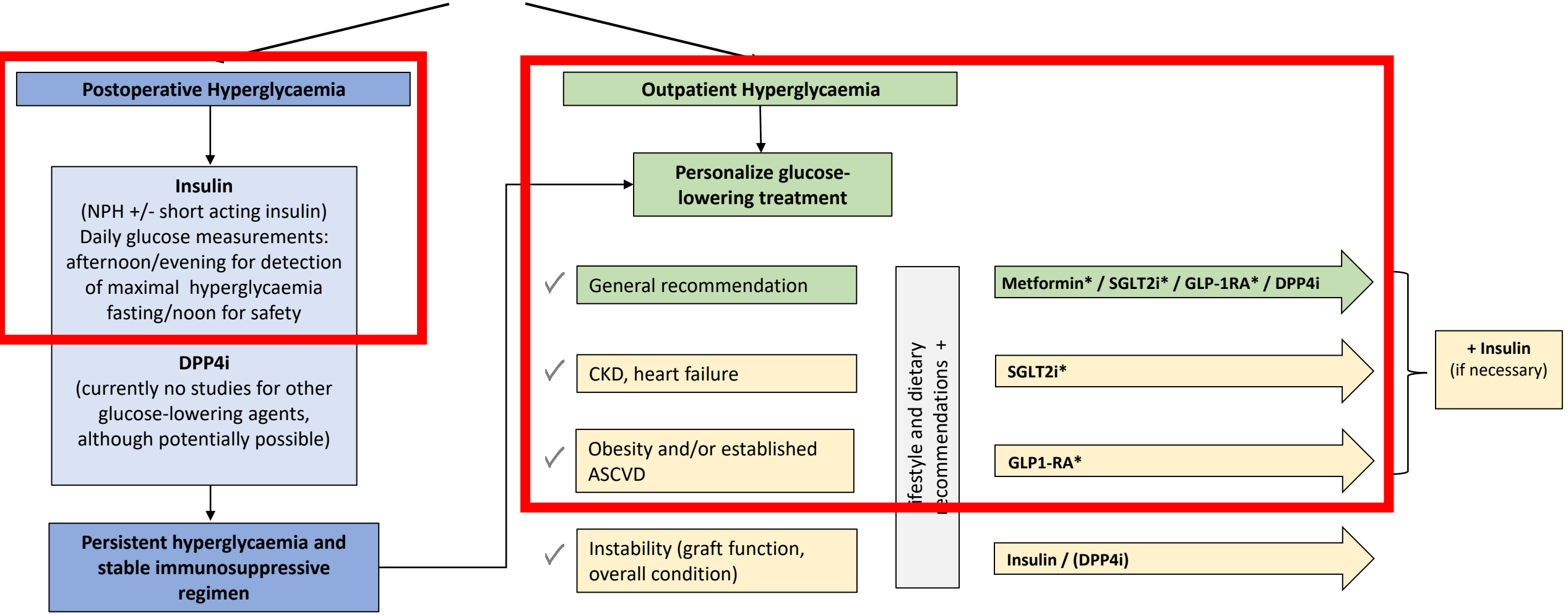


Multi-centre study demonstrated no significant difference in ITT analysis but some efficacy in per protocol analysis (significant protocol violations which limits interpretation).

Schwaiger et al. JASN 2021

Hecking et al. J Am Soc Nephrol 2012

Glucose-Lowering Treatment for Post-Transplant Hyperglycaemia



*Standard 'sick day' rules apply: advise patients to temporarily stop therapy in acute intercurrent illness until medical consult

Sharif et al. NDT 2024

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Benefits and harms of drug treatment for type 2 diabetes: systematic review and network meta-analysis of randomised controlled trials

Interventions	All cause death (OR, 95%CI)	Cardiovascular death (OR, 95%CI)	Non-fatal myocardial infarction (OR, 95%CI)	Non-fatal stroke (OR, 95%CI)	Admission to hospital for heart failure (OR, 95%CI)	End stage kidney disease* (OR, 95%CI)	Health related quality of life score (OR, 95%CI)	Severe hypoglycaemia (OR, 95%CI)	Drug specific adverse events (OR, 95%CI)
SGLT-2 inhibitors	0.88 (0.83 to 0.94)	0.86 (0.80 to 0.94)	0.90 (0.82 to 0.98)	0.99 (0.88 to 1.11)	0.66 (0.60 to 0.73)	0.61 (0.55 to 0.67)	0.30 (0.10 to 0.49)	0.90 (0.79 to 1.02)	Genital infection 3.30 (2.88 to 3.78) Amputation 1.27 (1.01 to 1.61) Ketoacidosis 2.07 (1.44 to 2.98)
GLP-1 receptor agonists	0.88 (0.82 to 0.93)	0.87 (0.81 to 0.94)	0.91 (0.85 to 0.98)	0.85 (0.77 to 0.94)	0.91 (0.83 to 0.99)	0.83 (0.75 to 0.92)	0.17 (0.07 to 0.27)	0.98 (0.90 to 1.06)	Severe gastrointestinal events 1.97 (1.39 to 2.80)
Non-steroidal MRAs	0.89 (0.79 to 1.00)	0.88 (0.75 to 1.02)	0.91 (0.74 to 1.12)	1.00 (0.82 to 1.22)	0.78 (0.66 to 0.92)	0.83 (0.75 to 0.92)	-	0.64 (0.43 to 0.96)	Hyperkalaemia leading to hospital admission 5.92 (3.02 to 11.62)
Tirzepatide	0.83 (0.48 to 1.44)	1.00 (0.35 to 2.85)	0.69 (0.08 to 6.10)	-	0.63 (0.16 to 2.39)	0.68 (0.09 to 4.84)	0.39 (0.13 to 0.65)	1.13 (0.42 to 3.02)	Severe gastrointestinal events 4.59 (1.89 to 11.14)
Metformin	0.84 (0.67 to 1.04)	0.95 (0.48 to 1.88)	0.86 (0.68 to 1.09)	0.97 (0.71 to 1.33)	1.45 (0.28 to 7.36)	1.61 (0.36 to 7.24)	0.04 (-0.25 to 0.33)	1.73 (0.89 to 3.37)	Severe gastrointestinal events 2.22 (0.64 to 7.71)
α-glucosidase inhibitors	0.89 (0.30 to 2.61)	0.99 (0.21 to 4.70)	0.33 (0.06 to 1.92)	9.44 (0.76 to 116.58)	3.25 (0.13 to 82.49)	-	0.03 (-0.34 to 0.39)	1.30 (0.31 to 5.43)	Severe gastrointestinal events 3.40 (0.30 to 38.15)
Thiazolid-inediones	0.95 (0.83 to 1.09)	0.93 (0.77 to 1.12)	0.97 (0.81 to 1.15)	0.85 (0.70 to 1.03)	1.54 (1.27 to 1.88)	0.69 (0.37 to 1.28)	0.20 (-0.13 to 0.52)	1.42 (0.97 to 2.10)	-
DPP-4 inhibitors	1.01 (0.95 to 1.08)	1.00 (0.92 to 1.09)	1.01 (0.92 to 1.11)	0.91 (0.80 to 1.03)	1.05 (0.95 to 1.16)	1.04 (0.93 to 1.16)	0.03 (-0.12 to 0.17)	1.11 (1.00 to 1.23)	-
Sulfonylureas	1.10 (0.97 to 1.26)	1.01 (0.83 to 1.23)	1.00 (0.83 to 1.22)	1.05 (0.84 to 1.32)	0.99 (0.79 to 1.23)	0.68 (0.37 to 1.24)	0.23 (-0.19 to 0.64)	5.22 (3.88 to 7.01)	-
Meglitinides	1.58 (0.51 to 4.92)	0.64 (0.11 to 3.69)	0.28 (0.05 to 1.60)	1.71 (0.26 to 11.40)	-	-	0.17 (-0.29 to 0.63)	3.21 (0.96 to 10.75)	-

SGLT-2 inhibitors = cardio-renal benefits

GLP-1 receptor agonists = cardio-renal benefits

Everything else = majority have no cardio-renal benefits

Shi et al. BMJ 2023

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Prospective post-transplant SGLT-2 inhibitor studies

Study	Study size and design	Duration	Intervention/ Comparator	Primary outcome / Main outcome	Primary outcome results / Outcome results
Schwaiger et al. JASN 2019					ived 2hPG increased during 4 (p=ns), demonstrating clinically
Halden et al. Diabetes Care 2019					echnical error), median change r 24 weeks of empagliflozin
Mahling et al. Kidney Blood Pres Res 2019					dian HbA1c decreased
Shah et al. Indian J Nephrol 2019					re and HbA1c, tacrolimus
Sanchez Fructuoso et al. CKJ 2023	T2DM; multicenter, prospective, observational (interventional)			infections (UTIs) and/or mycoses in diabetic kidney transplant recipients (DKTRs) placed on SGLT2i treatment.	t over 6 months, the most). In 10% patients, SGLT2i were suspended (mostly because of UTI). However, in a post-hoc subgroup analysis, UTIs were similar between DKTRs treated with SGLT2i over 12 months, compared with non-DKTRs (17.9% versus 16.7%). Body weight, blood pressure, fasting glycemia, HbA1c uric acid, urinary protein/creatinine ratio lower after SGLT2i treatment; magnesium and hemoglobin levels higher.

nature communications *Nat Commun* **15**, 10043 (2024).

Article

https://doi.org/10.1038/s41467-024-54171-8

The outcomes of SGLT-2 inhibitor utilization in diabetic kidney transplant recipients

Received: 15 March 2024

Accepted: 5 November 2024

Jia-Yuh Sheu[1], Li-Yang Chang[2], Jui-Yi Chen[3,4], Heng-Chih Pan[5,6,7,8], Chi-Shin Tseng[1,9], Jeff S. Chueh[1,2,9,12] ✉ & Vin-Cent Wu[9,10,11,12] ✉

Sharif et al. NDT 2024

SGLT-2 inhibitor studies in progress (1)

Three strata of patients will be included:

1. Patients with an eGFR ≤25 mL/min/1.73m^2 (non-dialysis or living with a kidney transplant);
2. Dialysis patients with residual diuresis ≥500 mL/24 h (including haemodialysis and peritoneal dialysis);
3. Renal transplant recipients with an eGFR ≤45 mL/min/1.73m^2.

Expectation

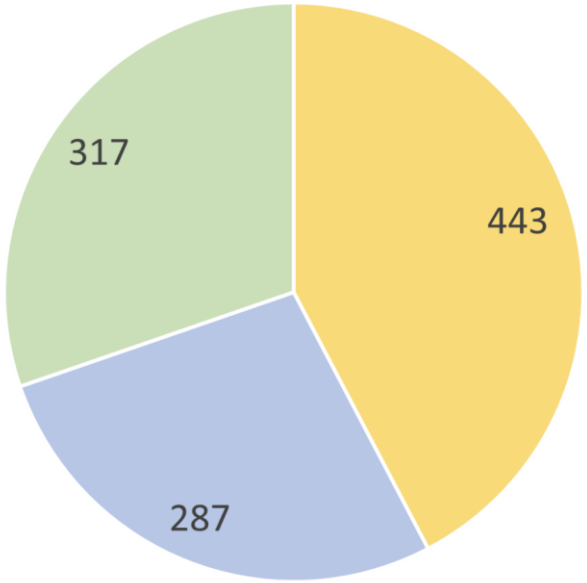
Dapagliflozin reduces clinical end points (all-cause mortality, renal failure, and heart failure-related hospitalizations) in patients with stage 4 or 5 CKD, dialysis patients, and renal transplant recipients with and without type 2 diabetes.

Number of participants

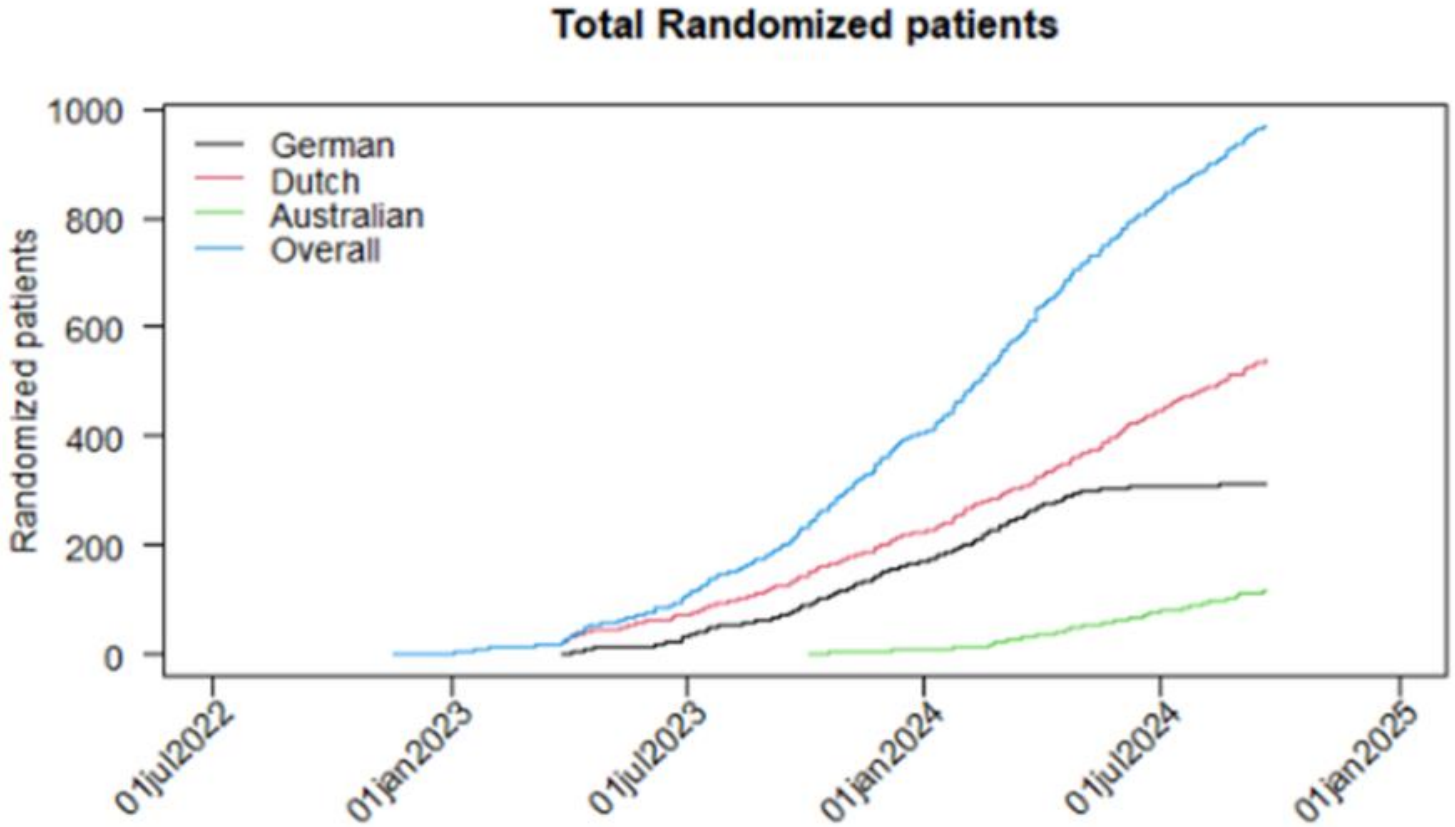
1500 (total study total study duration 48 months but trial is endpoint-driven and will be terminated when 468 primary composite endpoints have occurred).

RENAL LIFECYCLE TRIAL

SGLT-2 inhibitor studies in progress (1)



Participant numbers across patient groups from study start till September 2024 - measured globally



Clinicaltrials.org; NCT05374291

https://renal-lifecycle.com/en/home-en/

SGLT-2 inhibitor studies in progress (2)

Renal **A**nd Card**i**ova**s**cular Protection With **S**glt2 Inhibition In Kidney Transpl**an**t Re**c**ipi**e**nts (**RENAISSANCE**)

*"**We hypothesize** that for adult KTRs who are ≥6 months posttransplant, use of SGLT2i compared with placebo will be safe, well tolerated, and associated with significant reductions in death, deterioration of transplant kidney function and major adverse cardiovascular events (myocardial infarction [MI], stroke and HF).* **We plan a randomized trial (n=900)** to assess the efficacy and safety of SGLT2i for adult KTRs."

Aim 1 - To determine efficacy of SGLT2i to reduce a hierarchical composite defined in hierarchical order as: (1) all-cause mortality, (2) kidney transplant loss (chronic dialysis >90 days, retransplant or sustained eGFR ≤15ml/min/1.73m^2 for >3 months), (3) stroke or non-fatal MI, (4) sustained 40% decline of eGFR, (5) HF events (hospitalization or urgent treatment), and (6) eGFR slope (ml/min/1.73 m^2/year).

Aim 2: To determine SGLT2i safety in KTRs. The primary safety outcome will include all SAEs and items of interest (mycotic infections and UTIs; all other infections requiring ER visit or hospitalization; amputation, bone fracture, diabetic ketoacidosis, episodes of AKI, hypotension, hypoglycemic episodes, and biopsy-proven acute transplant rejection).

In submission: NIH

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Prospective post-transplant GLP-1 receptor agonist studies

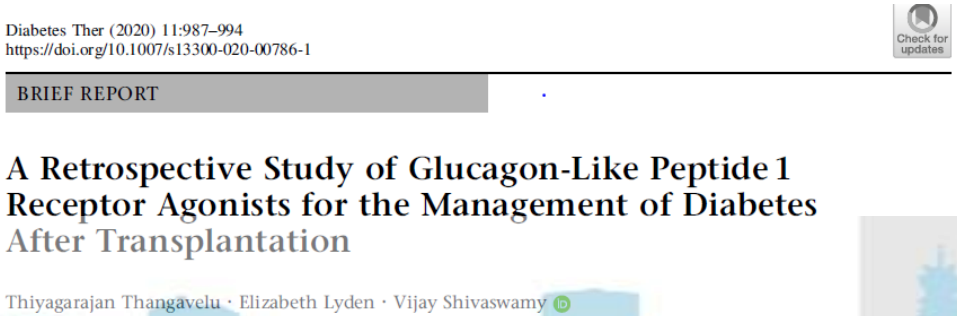
Study	Study size and design	Duration	Intervention/ Comparator	Primary outcome / Main outcome	Primary outcome results / Outcome results
Pinelli et al. Diabetes Care 2013	N=5; prospective, observational (interventional) (case series)	3 weeks	Liragutide	Tacrolimus AUC0–12h	Tac-AUC reduced, Tac trough levels unaltered, reduction of postprandial glucose and body weight
Halden et al Diabetes Care 2016	N=24; RCT	4 weeks	GLP-1 infusion / 0.9% saline. Hyperglycemic clamp	Fasting levels of plasma glucose, glucagon, and insulin, Area under the curve concentrations	Patients with PTDM showed a reduced ability to suppress circulating glucagon levels during the hyperglycemic clamp. First and second-phase insulin secretion was lower compared to the control group

Management of Diabetes Mellitus With Glucagonlike Peptide-1 Agonist Liraglutide in Renal Transplant Recipients: A Retrospective Study

J.-H. Liou[a], Y.-M. Liu[a], and C.-H. Chen[b,c,d,e,*]

The Use of GLP1R Agonists for the Treatment of Type 2 Diabetes in Kidney Transplant Recipients

Aleksandra Kukla, MD,[1] Jennifer Hill, DNP,[1] Massini Merzkani, MD,[1] Andrew Bentall, MD,[1] Elizabeth C. Lorenz, MD,[1] Walter D. Park, BS,[2] Matthew D'Costa, MD,[2] Yogish C. Kudva, MD,[3] Mark D. Stegall, MD,[2] and Pankaj Shah, MD[3]


Diabetes Ther (2020) 11:987–994
https://doi.org/10.1007/s13300-020-00786-1

BRIEF REPORT

A Retrospective Study of Glucagon-Like Peptide 1 Receptor Agonists for the Management of Diabetes After Transplantation

Thiyagarajan Thangavelu · Elizabeth Lyden · Vijay Shivaswamy

Sharif et al. NDT 2024

Safety and Efficacy of Tirzepatide in Patients with Solid-Organ Transplant

Abstract presentation at American Diabetes Association 2024

Table 1. Baseline demographics

Characteristics	Number of patients (n = 16)
Transplant type: Kidney Heart Liver Lung Simultaneous Pancreas and Kidney Heart and Kidney	 5 1 5 3 1 1
Race: Caucasian Hispanic African American Other	 9 2 3 2
Diabetes type: p Type 1 Type 2 Steroid induced hyperglycemia Post-transplant diabetes	 1 10 2 3
Immunosuppression: Steroid Tacrolimus Mycophenolate mofetil	 16 16 16
Age at time of drug initiation Mean ± SD	56.7 ± 13.2
Time from transplant to drug initiation in months Mean ± SD Median (Min, Max)	 53.6 ± 55.2 23.7 (15.9,80.1)

Table 2. Table 2. Changes Observed from Baseline through Last Available Follow-Up

	Baseline	3 months	6 months	Change from baseline to 6 months
A1C, % Mean ± SD Median (Min, Max) Mean percent change P-value	 7.4 ± 2.3 6.5 (6, 8.3)	 6.8 ± 1.3 6.9 (5.7,7.5)	 6.3 ± 0.8 6.5 (5.6,7)	 -1.3 ± 1.9 -0.6 (-7.5,0) -14.8% 0.33
Weight, Kg Mean ± SD Median (Min, Max) Mean percent change P-value	 99.7 ± 16.1 98.8 (89.5,107.9)	 98.6 ± 17.7 99.3 (85.8,109.6)	 92.8 ± 9.9 91.1 (83.4,101.6)	 -5.4 ± 6.2 -4.5 (3.2,-21.3) -6.9% 0.3
Fasting Blood glucose, mg/dl Mean ± SD Median (Min, Max) P-value	 132.7 ± 45.9 122.5 (101.5,142.7)	 115.4 ± 28.5 110 (92.7,134.2)	 107.5 ± 21.7 106 (94.2,122.5)	 -21.4 ± 36.5 -13.0 (-56.5,-2.5) 0.16
Serum eGFR, mL/min/1.73 m^2 Mean ± SD Median (Min, Max) P-Value	 50.3 ± 20.4 49 (35.5, 59.2)	 51.3 ± 20.9 45 (35,64)	 50.3 ± 21.4 46 (41,58)	 0.06 ± 5.6 1 (-8,12) 0.96
Tac level (FK506), ng/ml Mean ± SD Median (Min, Max) P-value	 7.6 ± 2.5 7.5 (6.1,9.7)	 6.9 ± 2.2 6.8 (5.2,9)	 6.0 ± 1.8 6.4 (4.9, 6.8)	 0.21 ± 2.21 0.1 (-3,4) 0.18

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Clinical challenges – summary/conclusions

- Risk can be mitigated but not eliminated.
- Targeting obesity would help.
- Modification of immunosuppression needs balancing against competing risks.

- Go in quick with insulin but safety netting needed for outpatient management.
- Do not alter immunosuppression unless critical need.

- Good short-term safety and efficacy data for SGLT2i use.
- Risk for UTIs probably not any different.
- Two large RCTs either in progress or hopefully soon to start.

- Good short-term safety and efficacy data for GLP-1 agonist use.
- Weight loss benefits are observed post-transplantation.
- No large RCTs in progress.

PTDM society guidelines/consensus statements

Received: 14 August 2020 | Accepted: 9 January 2021

DOI: 10.1111/dme.14523

DIABETIC Medicine

REVIEW ARTICLE

Association of British Clinical Diabetologists and Renal Association guidelines on the detection and management of diabetes post solid organ transplantation

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OXFORD ERA ndt

Nephrol Dial Transplant, 2024, **39**, 531–549

https://doi.org/10.1093/ndt/gfad258

Advance access publication date: 3 January 2024

International consensus on post-transplantation diabetes mellitus

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Chowdhury et al. Diabetic Med 2021

Sharif et al. NDT 2024

Thank you for you attention

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