Insufficienza renale in fase terminale e/o inizio terapia sostitutiva con immissione in lista di attesa di trapianto:

quando iniziare a dare indicazioni al paziente

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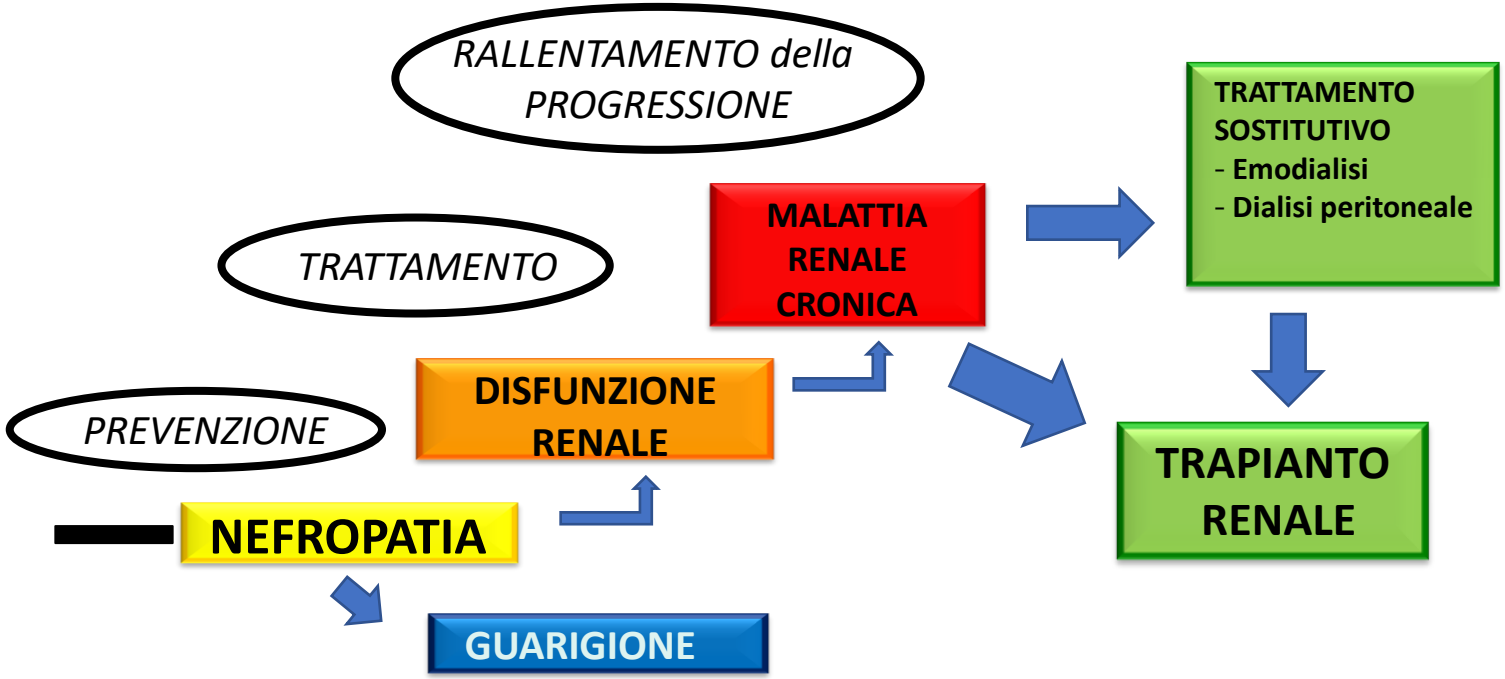
SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna
IRCCS Istituto di Ricovero e Cura a Carattere Scientifico

STORIA "NATURALE" DELLE NEFROPATIE



1.1: DEFINITION OF CKD

1.1.1: CKD is defined as abnormalities of kidney structure or function, present for >3 months, with implications for health. (*Not Graded*)

GFR categories in CKD

GFR category	GFR (ml/min/1.73 m^2)	Terms
G1	≥90	Normal or high
G2	60–89	Mildly decreased*
G3a	45–59	Mildly to moderately decreased
G3b	30–44	Moderately to severely decreased
G4	15–29	Severely decreased
G5	<15	Kidney failure

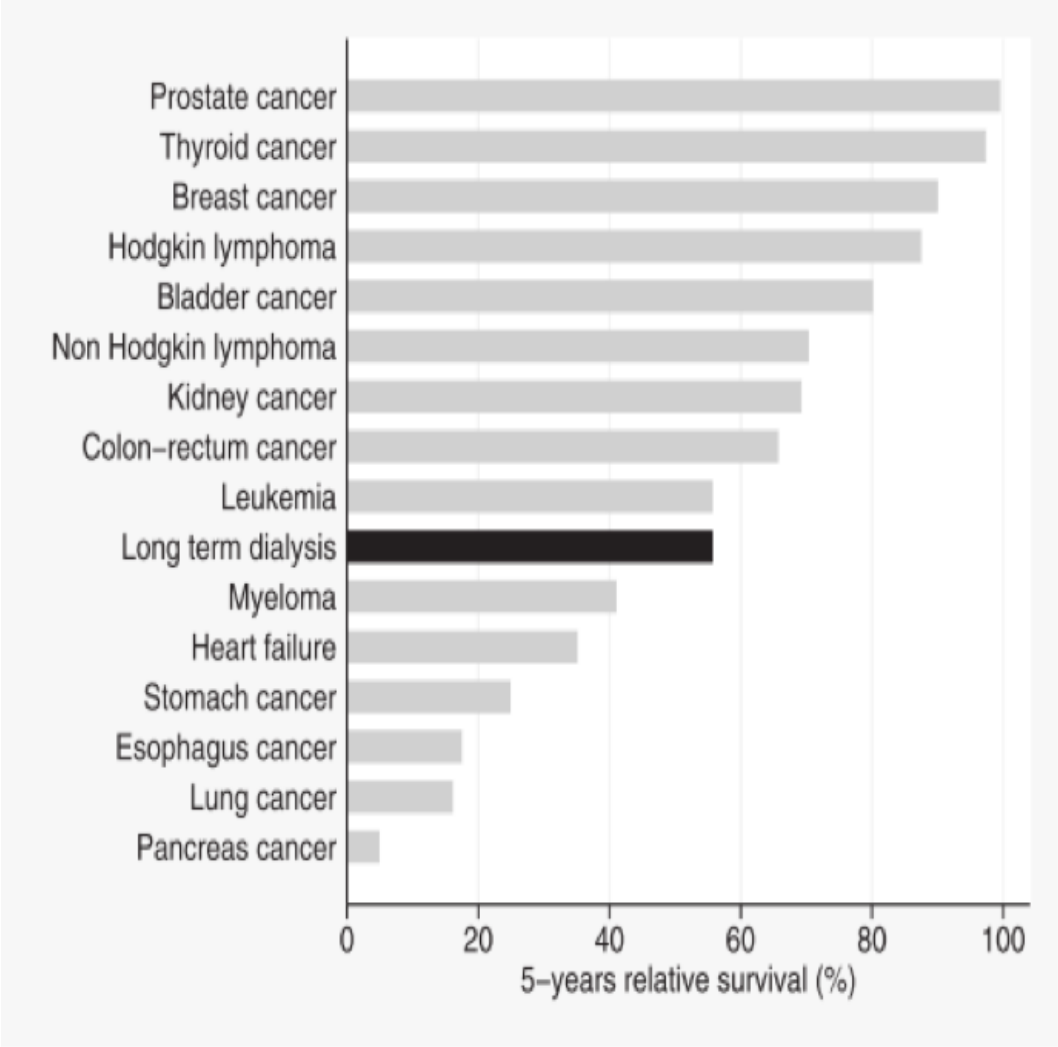
KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease

TRAPIANTO DI RENE

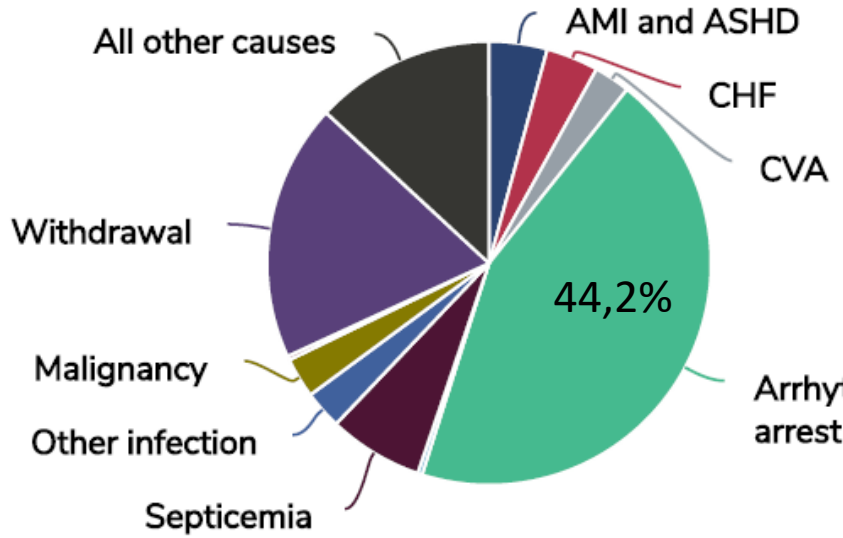
Trattamento di scelta per la malattia renale cronica terminale

- Associato a miglior sopravvivenza
- Associato a riduzione della mortalità cardiovascolare
- Associato ad una miglior qualità di vita
- Associato a minori costi se confrontato con la dialisi

Dialisi e Trapianto di rene - **SOPRAVVIVENZA**

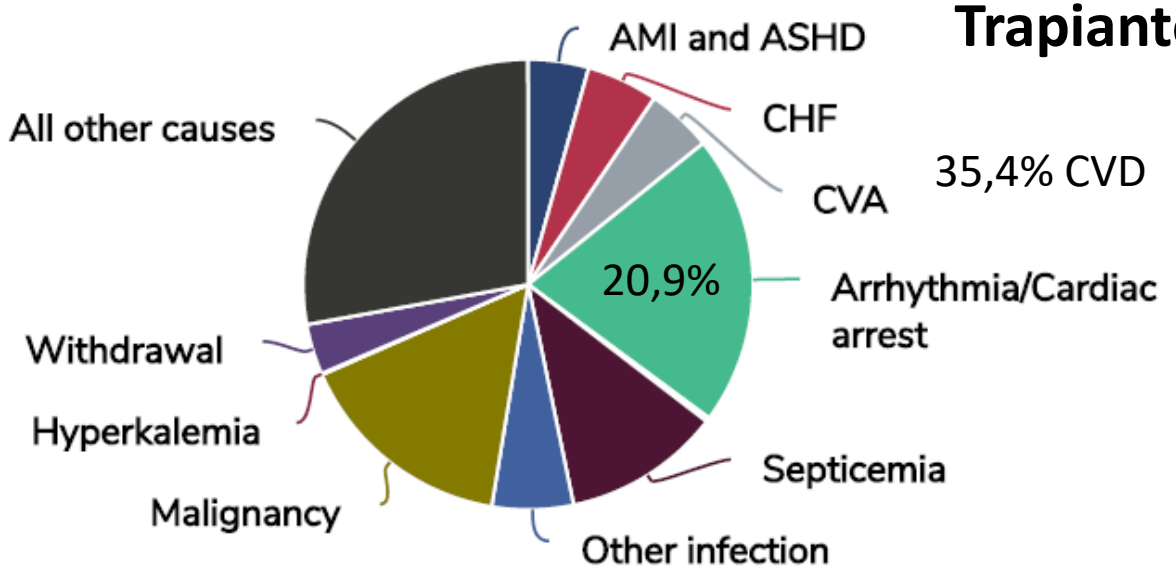


Dialisi



55,2% CVD

Trapianto



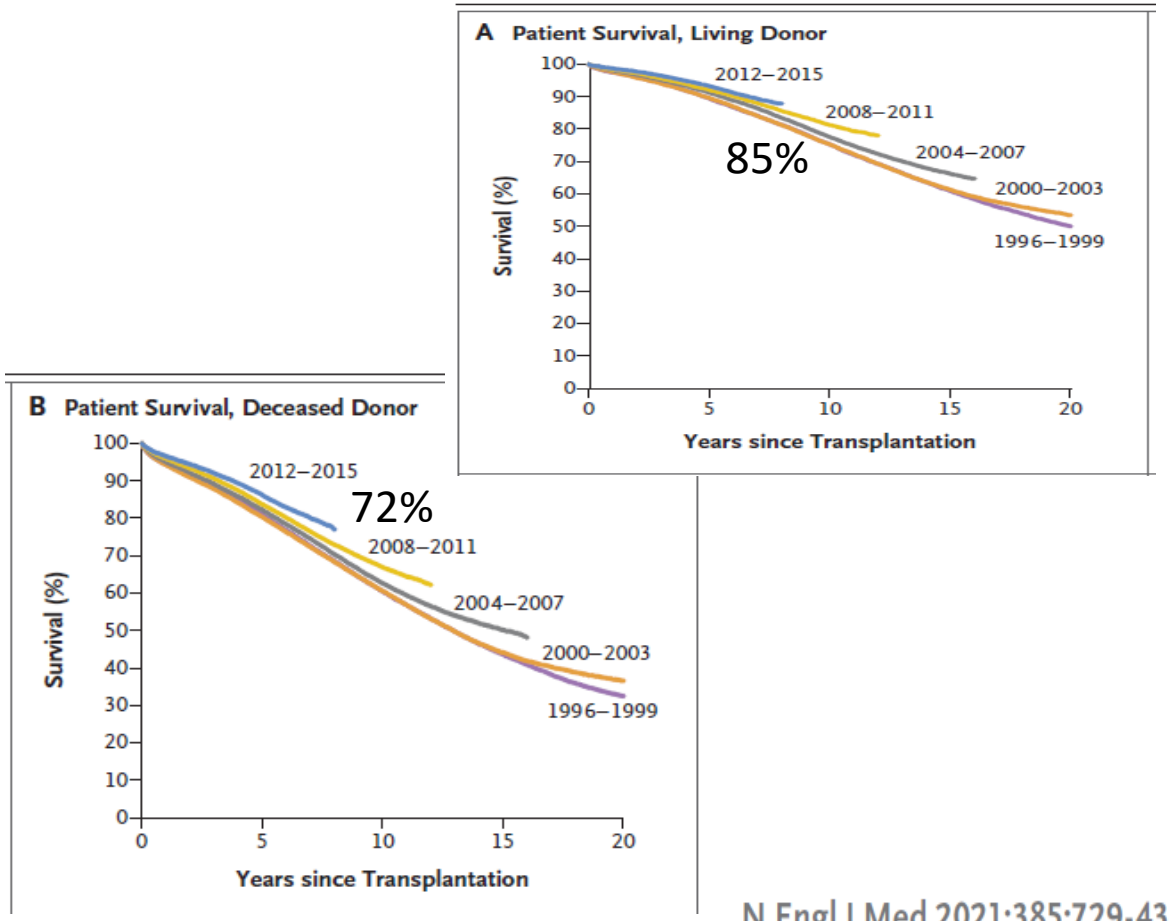
35,4% CVD

USRDS

Dialisi e Trapianto di rene - **SOPRAVVIVENZA**

Long-Term Survival after Kidney Transplantation

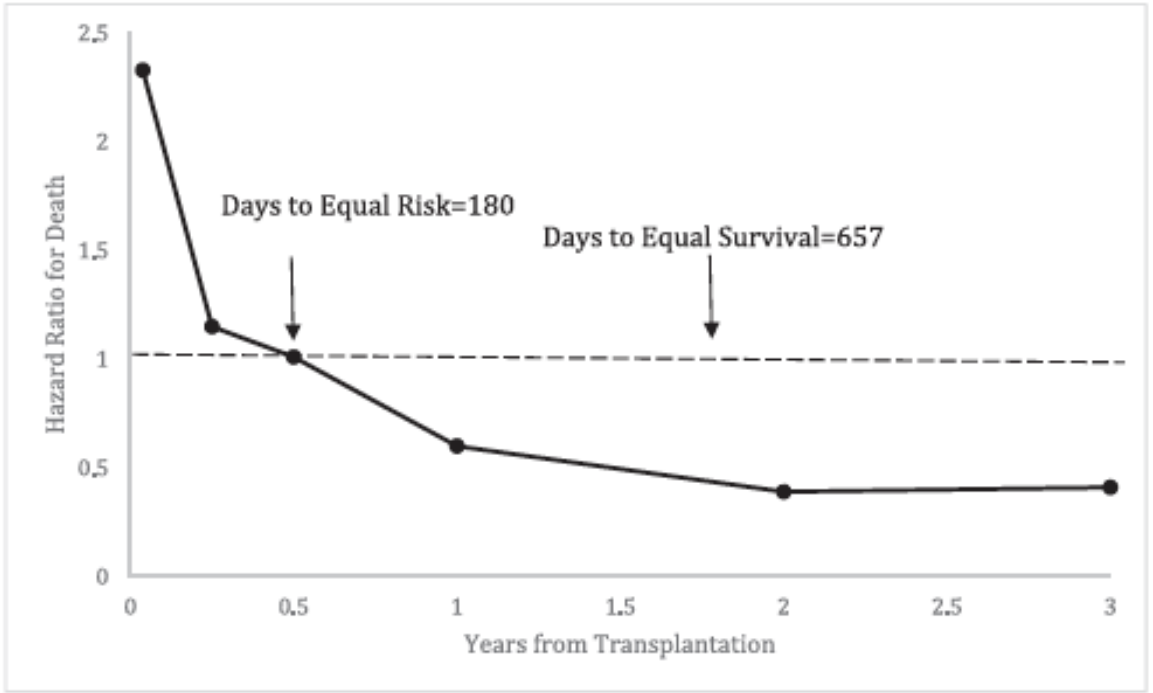
Sundaram Hariharan, M.D., Ajay K. Israni, M.D., and Gabriel Danovitch, M.D.



N Engl J Med 2021;385:729-43.

Association of Kidney Transplantation with Survival in Patients with Long Dialysis Exposure

Caren Rose,† Jagbir Gill,*† and John S. Gill*†*



In summary, kidney transplantation with good-quality deceased donor kidneys was associated with a long-term survival benefit in selected patients with pretransplant dialysis exposure ≥10 years.

Clin J Am Soc Nephrol 12: 2024–2031, 2017.

Trapianto di rene – **MORTALITA' IN LISTA D'ATTESA**

TABLE 2. ANNUAL DEATH RATES AND TOTAL NUMBERS OF DEATHS, 1991–1997.

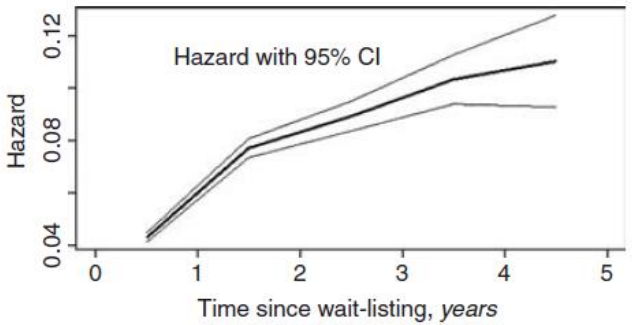
USRDS 300.000 pz dializzati dal '91 al '97

VARIABLE	ALL PATIENTS ON DIALYSIS (N=228,552)		PATIENTS ON THE WAITING LIST (N=46,164)		RECIPIENTS OF CADAVERIC TRANSPLANTS (N=23,275)	
	RATE/100 PATIENT-YR	NO. OF DEATHS	RATE/100 PATIENT-YR	NO. OF DEATHS	RATE/100 PATIENT-YR	NO. OF DEATHS
All patients	16.1	84,713	6.3	4353	3.8	2436
Age*						
0–19 yr	3.6	257	2.2	31	0.9	21
20–39 yr	8.6	7,499	4.3	897	2.3	500
40–59 yr	13.3	30,935	6.5	2372	4.1	1293
≥60 yr	23.2	46,022	10.0	1053	7.4	622
Sex						
Male	16.2	45,366	6.3	2556	3.9	1590
Female	16.1	39,347	6.3	1797	3.5	846
Race						
White	19.3	55,786	7.5	2993	3.9	1859
Black	12.4	25,733	4.8	1168	3.4	478
Asian	9.9	1,783	3.0	108	2.6	64
Native American	13.3	1,411	6.5	84	4.7	35
Cause of end-stage renal disease						
Diabetes	19.9	44,916	10.8	2312	5.6	1091
Other	13.3	39,797	4.3	2041	3.0	1345

*The ages shown are the age at the time of the first treatment for end-stage renal disease in the group of all patients on dialysis (age limit, 69 years), the age at the time of initial placement on the waiting list for patients on the waiting list, and the age at transplantation for transplant recipients.

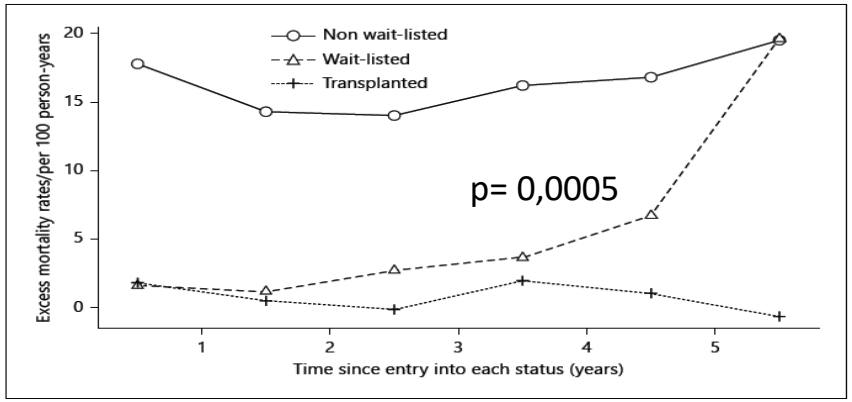
The **annual death rate** for all patients on **dialysis was 2.6 times** as high as that for patients on the **waiting list**, and the annual death rate for patients on the **waiting list was 1.7 times** as high as that for **transplant** recipients.

Wolfe RA, NEJM 1999



The unadjusted annual death rates and hazard for **mortality in dialysis subjects increased with each additional year** on the waiting list

Course of the excess mortality risk over time from entry into each specific status (*REIN Registry 2002–2009*). 21 mila pz in dialisi



In **wait-listed patients**, the **excess death rate** increased rapidly with time; nearly **45% per additional year spent on the waiting list** (95% CI 18–79%, p = 0.0005).

Bouaoun L, Nephron Clin Pract 2013

Trapianto di rene – **SOPRAVVIVENZA**

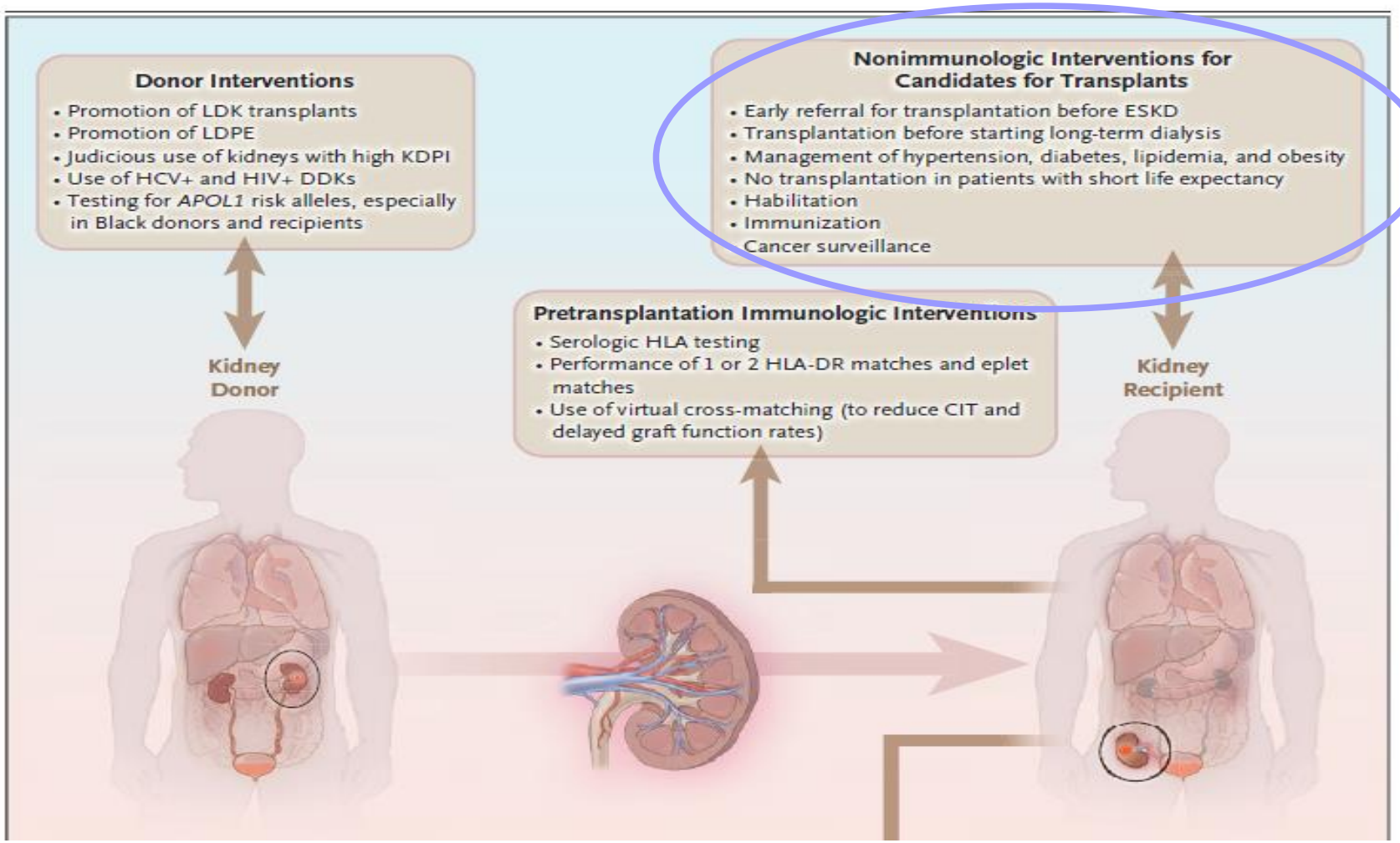


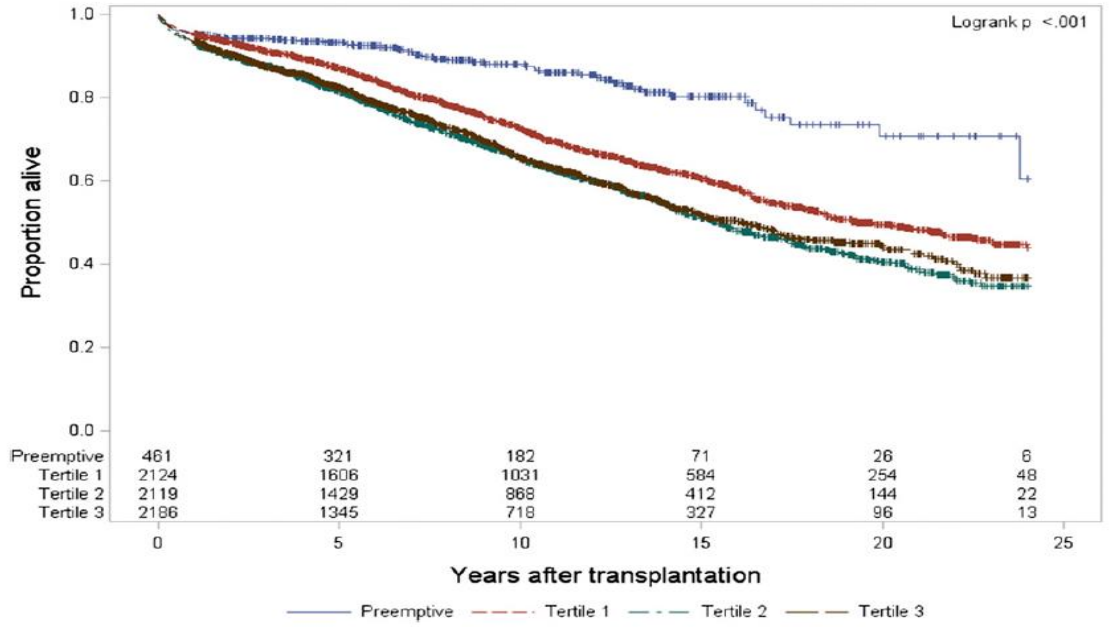
Figure 1. Interventions for Kidney Donors, Candidates, and Recipients That Affect Long-Term Survival.

N Engl J Med 2021;385:729-43.

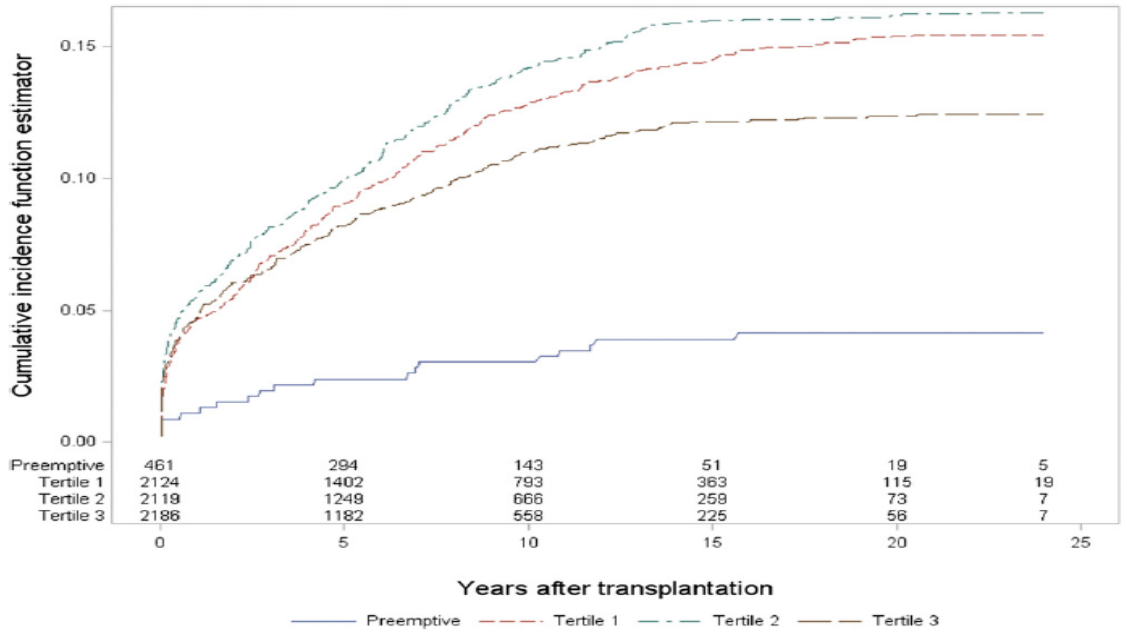
Trapianto di rene – **PRE-EMPTIVE**

- A retrospective cohort study **to investigate the association between pretransplant dialysis vintage and kidney transplant** outcomes included pre-emptive.
- **6979 first kidney allograft** recipients from the Austrian Registry transplanted between 1990 and 2013.

- **Pre-emptive transplantation was associated with a lower risk of graft loss** (hazard ratio, 0.76; 95% confidence interval, 0.59 to 0.98).



Kaplan-Meier curves of all-cause **mortality stratified by duration of pre-transplant** dialysis.



Cumulative incidence curves for death-censored **graft loss stratified by duration of pre-transplant** dialysis.

Haller MC, CJASN 2017

Trapianto di rene – **LINEE GUIDA**

April 2020 ■ Volume 104 ■ Number 4S
Official Journal of The Transplantation Society & International Liver Transplantation Society
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KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation

SECTION 1: ACCESS TO TRANSPLANTATION

We recommend that **all patients with chronic kidney disease (CKD) G4-G5** (glomerular filtration rate [GFR] < 30 ml/min/1.73 m^2) who are expected to reach end-stage kidney disease [ESKD] **be informed of, educated about, and *considered* for kidney Transplantation** regardless of socioeconomic status, sex, gender identity, or race/ethnicity *(1D).*

We recommend **pre-emptive transplantation** with a **living kidney donor** as the preferred treatment for transplant eligible CKD patients *(1A).*

We recommend pre-emptive transplantation (living or deceased donor) in **adults** when the estimated glomerular filtration rate **(eGFR) is < 15-10 ml/min/1.73 m^2 or earlier with symptoms** *(1D).*

We recommend pre-emptive transplantation (living or deceased donor) in **children** when the eGFR is < 15 ml/min/1.73 m^2 or earlier with symptoms *(1D).*

Trapianto di rene – **TIMING**

Management of patients with a failed kidney transplant: what should we do?

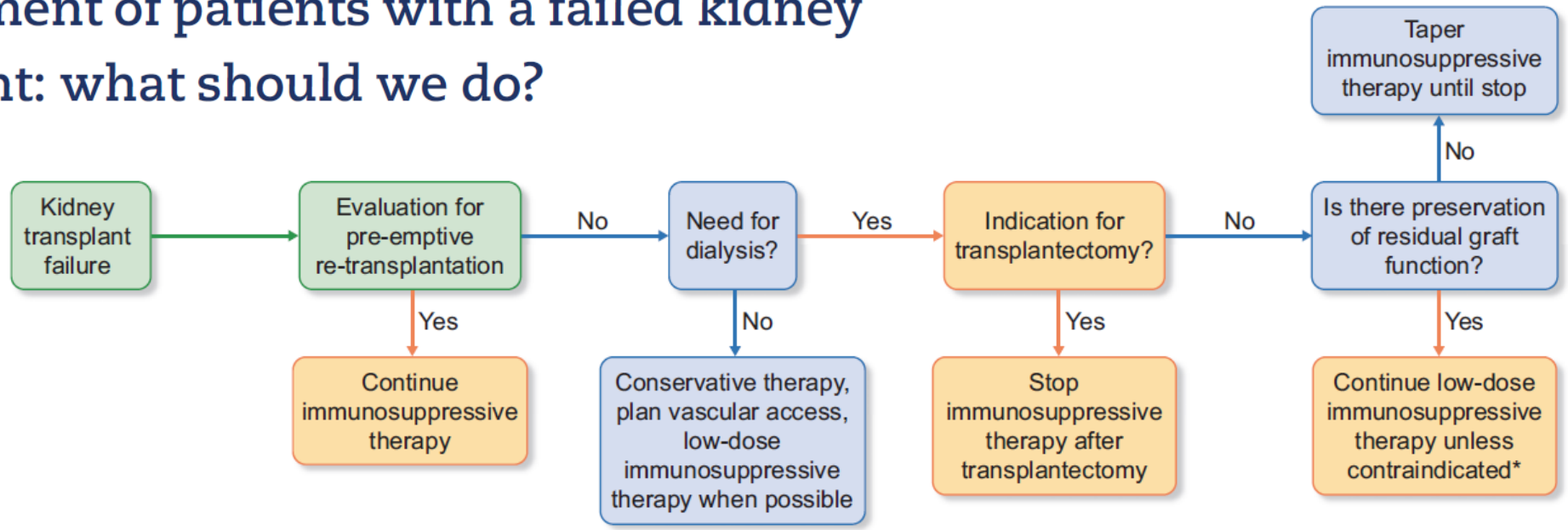

FIGURE 1: Suggested algorithm for the management of immunosuppressive therapy after kidney transplant failure.

*Contraindications to maintaining immunosuppressive therapy: metabolic (diabetes, hypertension), cardiovascular complications, susceptibility to infections, malignant neoplasia, steroid-associated adverse effects

- We suggest that the evaluation of the chance for a **pre-emptive retransplantation** from a deceased or living donor should represent the **first step** in the management of patients with a failing kidney allograft

- The **risk** for **infectious** complications, **cardiovascular disease** and **malignancy** is greater than in the dialysis population due to the frequent maintenance of low-dose immunosuppression

Fiorentino M et al, CKJ 2021

Trapianto di rene – **LINEE GUIDA**

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KIDNEY DISEASE IMPROVING GLOBAL OUTCOMES
KDIGO

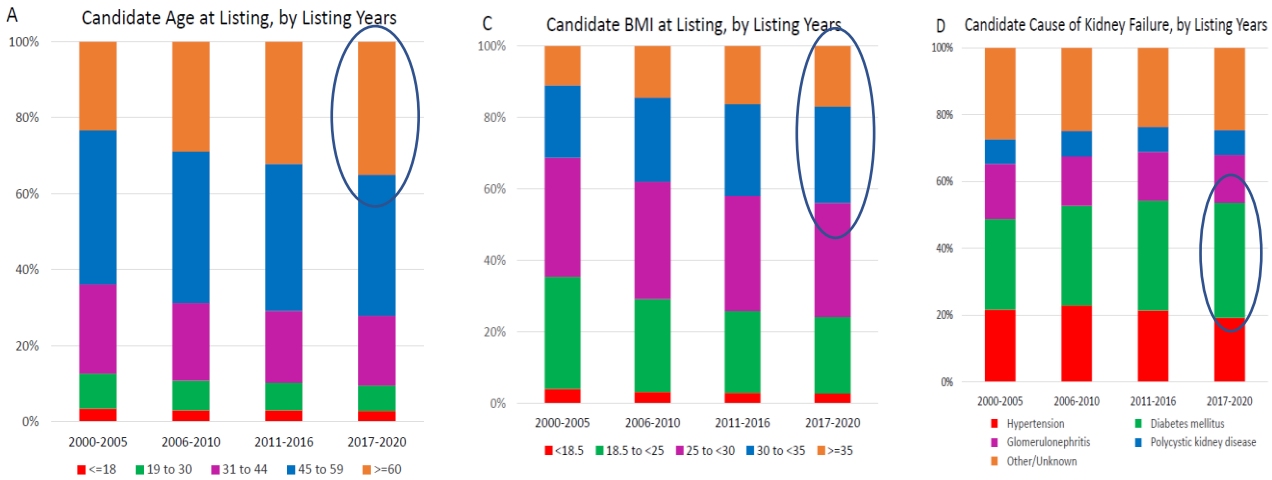
KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation

INTRODUCTION

Transplantation is the kidney replacement therapy of choice for suitable patients with end-stage kidney disease (ESKD). However, not all patients are suitable candidates for transplantation, and suitability is often determined by the perceived risks of transplantation relative to the risks of not receiving a transplant. Estimation of risk is therefore a key part of the transplant candidate evaluation. Should a decision to proceed to transplantation be made, consideration of how to minimize risks and maximize the chances of a successful outcome are additional aspects of the candidate evaluation process.

Wolters Kluwer
www.transplantjournal.com

Trapianto di rene – **CONTROINDICAZIONI ASSOLUTE**



The population in need of transplant is increasingly **complex and diverse**

Lentine K et al, AJKD 2021

• Neoplasia attiva o metastatica *(eccezione per neoplasie indolenti e a basso grado)**
• Infezione croniche gravi o in fase attiva
• Pneumopatie severe ostruttive e/o restrittive
• Disturbo psichiatrico e/o abuso di sostanze
• Cardiopatia severa, non correggibile, sintomatica
• Malattia neurodegenerativa progressiva
• Non aderenza alla terapia
• Qualsiasi condizione clinica con aspettativa di vita inferiore a 1 anno

Trapianto di rene – **SPECIAL ISSUES**

- Nefropatia di base
- Stato vaccinale
- Obesità
- Iperimmunità

Trapianto di rene – **NEFROPATIA DI BASE**

SECTION 9: CAUSE OF END-STAGE KIDNEY DISEASE (ESKD)

- We recommend that the cause of ESKD in candidates be **determined**, where possible, to **inform risks and management after kidney transplantation** *(1A).*

- Advise candidates about the disease-specific risk of recurrence and resultant risk of graft loss *(Not Graded).*

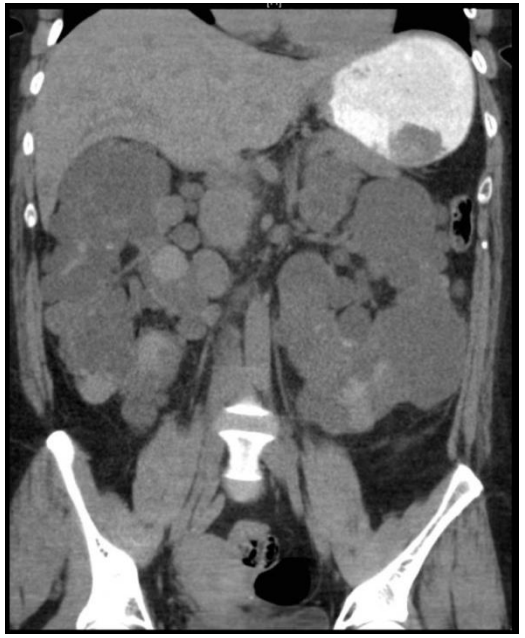
	Overall[#]	IgA Nephropathy	FSGS	Membranous GN	MPGN
Prevalence of GN recurrence					
ANZDATA (1985–2014) (5)	10.3%	10% at 10 y, 15% at 15 y	9% at 10 y, 11% at 15 y	16% at 10 y, 18% at 15 y	16% at 10 y, 19% at 15 y
Mayo/Toronto* (4)	39.5% at 5 y	42% at 3 y, 51% at 5 y	31% at 3 y, 35% at 5 y	45% at 3 y, 55% at 5 y	41% at 3 y, 41% at 5 y
British Columbia (1990–2005) (9)	13% at 10 y, 18% at 15 y	15.4%	9.7%	10%	4.8% (type I MPGN only)
Korea (1995–2010)(11)	17.8%	14.8%	6.3%	0%	12.5%
France (single center) (15)	NR	36% at 10 y	NR	NR	NR
Allograft failure following GN recurrence					
ANZDATA (1985–2014) (5)	55%◆	58%◆	57%◆	59%◆	30%◆
RADR (1987–1996) (14)	5 y GS[θ]:40% (vs. 68% without)	Allograft failure 41%	Allograft failure 65%	Allograft failure 44%	Allograft failure 66%
Mayo/Toronto[#] (4)	HR: 2.6 (1.9, 3.6)	HR: 3.4 (1.2, 9.7)	HR: 5.0 (2.4, 10.1)	HR 1.4 (0.3, 6.8)	HR 6.8 (2.7, 17.2)
British Columbia (1990–2005) (9)	HR: 7.5 (5.5, 10.2)	NR	NR	NR	NR
Korea (1995–2010) (11)	HR: 4.0 (1.7, 9.3)	NR	NR	NR	NR
Clinical predictors of GN recurrence (5, 9, 11, 15, 16)	Primary ESKD secondary to GN, male gender, younger age, non-white ethnicity, steroid-free	Younger age, steroid-free, early steroid-withdrawal, no induction therapy (ATG protective)	Younger age, rapid progression of initial ESKD	Presence (and titer) of anti-PLA2R autoantibody pre-transplant	C3-glomerulopathy subtypes, presence of monoclonal gammopathy, poor response to treatment and rapid progression to ESKD of native disease

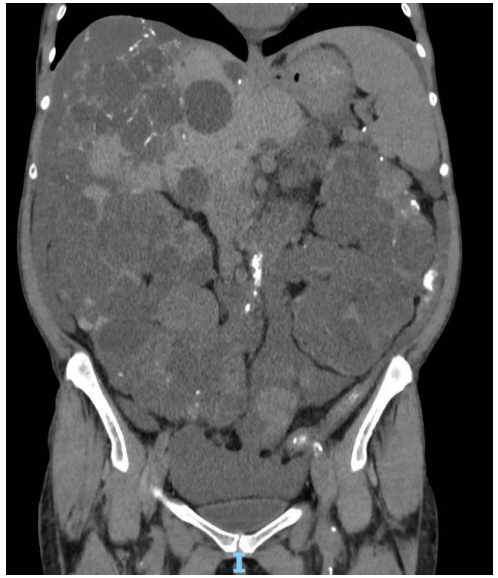
◆*Denotes 5-year graft survival post-disease recurrence. Hazard ratio (HR) of death-censored allograft failure compared to kidney transplant recipients with same GN subtype but without disease recurrence post-transplant. *Denotes cumulative incidence. [#]May include recurrent and de novo GN. [θ]Denotes 5-year actuarial graft survival from time of transplant. GN, glomerulonephritis; HR, hazard ratio; MPGN, membrano-proliferative glomerulonephritis; FSGS, focal segmental glomerulosclerosis; ESKD, end-stage kidney disease; NR, not reported; ANZDATA, Australia and New Zealand Dialysis and Transplant registry; RADR, Renal Allograft Disease Registry; GS, graft survival; y, years; ATG, anti-thymocyte globulin.*

- Test genetici
- monitoraggio laboratoristico
- approcci terapeutici

Lim W et al, Frontiers in Immunology, 2019

Trapianto di rene – **ADPKD**





14,000 tx eseguiti in Italia dal 2002 al 2010 in pz affetti da ADPKD

Nefrectomia?

Trapianto combinato?

Table 2. Answers of Transplant Centers to the Questionnaire; *n* (%)

Nephrectomy before transplantation (attitude of center)	
Conservative approach	32 (91%)
Mononephrectomy	2 (6%)
Binephrectomy	1 (3%)
Embolization	0
Nephrectomy before transplantation (surgical timing)	
Before inclusion in the list	29 (83%)
Contemporary at transplantation	6 (17%)
Main indication to nephrectomy (transplant centers with a conservative approach)	
Ingombro addominale	20 (58%)
Colic/rupture cysts (>1episode/y)	9 (25%)
Recurrent urinary tract infections (>1/y)	1 (3%)
Instrumental investigation before transplantation	
Ultrasonography	5 (14%)
Ultrasonography + CT without contrast	16 (46%)
Ultrasonography + CT with contrast	14 (40%)
Monitoring during period on waiting list	
Ultrasonography (every 1–2 y)	25 (72%)
Ultrasonography + CT without contrast (every 1–2 y)	5 (14%)
Ultrasonography + CT with contrast (every 1–2 y)	5 (14%)
Additional investigations for brain aneurysms (CT/MRI)	
Always	26 (74%)
Only if positive family history	8 (23%)
Never	1 (3%)
Double kidney transplant program	
Relative contraindication	17 (49%)
No contraindication	11 (31%)
Absolute contraindication	0
No experience	7 (20%)
Combined liver-kidney transplant	
No experience	17 (49%)
Sporadic experience	11 (31%)
Regular program	7 (20%)

Mosconi G et al, Transplant Proced 2013

Trapianto di rene – **VACCINAZIONI**

For inactivated vaccines, no specific wait period is required pre-transplantation and candidates can remain active if on a deceased donor waitlist; however, at least two weeks is required for establishment of vaccine immunity. Nevertheless, due to lack of data, there are no recommendations for reimmunization if transplantation occurs within days after vaccination. Vaccine series that are not completed pre-transplant can be generally resumed

Routine Vaccines	Dosing Guidelines*	Comment
Inactive Vaccines		
Diphtheria, Pertussis, Polio, Tetanus, HiB	Generally given in childhood; Ensure these are up-to-date	
Pneumococcal Vaccination: PCV13, PPV23	One dose of PCV13 followed by one dose of PPV23 with a minimum of 8-week interval in between	One booster of PPV23 five years from previous PPV23
Influenza	One dose annually	
Hepatitis B	Three doses at 0, 1, 6 months	Check anti-HBs titer Monitor annually and give booster dose if titers decline <10 IUs/ml
Hepatitis A	Two doses at 0, 2 months	Check titers; If not immune, give vaccination again (i.e., repeat if no response to first series)
Human Papillomavirus	Three doses in both males and females if not previously given (ages 9 to 45)	No boosters
Meningococcal quadrivalent conjugate (Serogroups A,C,Y,W-135)	Two doses given 8 weeks apart; Indicated for travel to endemic areas, prior or planned splenectomy or planned use of eculizumab	Repeat one dose every five years in patients at risk
Meningococcal B vaccine	One dose if planned use of eculizumab	
Shingles (Herpes Zoster Subunit)	Two doses at 0, 2-6 months for those age ≥ 50 years and VZV IgG positive	Unknown if benefit in less than 50 years of age No boosters
Live Vaccines		
Measles, Mumps, Rubella	Two doses given 4 weeks apart. Considered immune after two doses regardless of seroconversion.	Check serology and provide vaccination if negative
Varicella	Two doses given 4 weeks apart. Considered immune after two doses regardless of seroconversion.	Check serology and provide vaccination if negative
Shingles (Herpes Zoster Live)**	One dose in those age ≥ 50 years and VZV IgG positive	Unknown if benefit in less than 50 years of age No boosters

We recommend a **4-week delay in kidney transplantation** if a live vaccine is administered (MMR, VZV, shingles, yellow fever, oral typhoid, oral polio vaccine) *(1B).*

Trapianto di rene – **VACCINAZIONI**

VACCINAZIONE ANTI COVID

KEY RECOMMENDATIONS:

- Vaccination against SARS-CoV-2 is strongly recommended as it may prevent or reduce severity of clinical disease regardless of antibody response.
- We recommend SARS-CoV-2 vaccination in individuals ages 5 years and older, including all solid organ transplant (SOT) candidates, recipients, and living donors as well as vaccination of their household members and caregivers to reduce infection risk for these vulnerable patients.
- We recommend a third full dose of mRNA vaccine, >28 days after most recent vaccine, in patients who are 12 years and older who have received two previous doses of mRNA vaccine, as approved by the FDA and CDC. We encourage a conversation between the provider and the patient which considers the patient's individual situation regarding patient specific vaccination strategies.
- We recommend a second dose of SARS-CoV-2 vaccine in patients who have received 1 dose of Johnson & Johnson/Janssen COVID-19 vaccine >2 months following the first dose. While any of the available vaccines are permitted, data from immunocompetent patients shows a higher antibody response when the second dose is one of the mRNA vaccines. The full dose of either Pfizer or Moderna mRNA vaccines is recommended.
- Patients who have received all doses of their primary series are eligible for an additional booster dose of their vaccine 5 months after completion of the initial series.
- Continued adherence of all transplant recipients to protective measures such as masking and social distancing is recommended regardless of vaccination status.
- We recommend vaccination for SARS-CoV-2 in patients who have recovered from COVID-19, after symptoms have resolved and the period of isolation has ended.
- Whenever possible, vaccination should occur prior to transplantation (ideally with completion of vaccine series a minimum of 2 weeks prior to transplant).
- For post-transplant patients, we recommend administering vaccination beginning as early as 1-3 months after transplantation. This can be individualized based on immunosuppression.
- We do not recommend routinely checking antibody responses to the vaccine.
- We do not recommend routine adjustment of immunosuppressive medications prior to vaccination outside of clinical trials.
- We recommend each center develop approaches to educate patients on the importance of vaccination and consider tracking vaccination rates.
- We support the development of institutional policies regarding pre-transplant vaccination as we believe that this is in the best interest of the transplant candidate, optimizing their chances of being safely transplanted, especially at times of continued greater virus circulation.

AST | AMERICAN SOCIETY OF TRANSPLANTATION

COVID-19 Vaccine FAQ Sheet
(updated 1/28/22)

Trapianto di rene – **OBESITA'**

Preventive Nephrology: The Role of Obesity in Different Stages of Chronic Kidney Disease

Wolfgang Pommer

Department of Nephrology, The First Affiliated Hospital of Jinan University, Guangzhou, China; Kuratorium für Dialyse und Nierentransplantation, KfH-Bildungszentrum, Neu-Isenburg, Germany

Table 1. Effect of overweight (BMI >30) in different stages of CKD (for details, see text)

Condition	CKD 1–4	CKD 5 and CKD 5D	Kidney transplantation
Renal function	Origin of specific obesity-associated nephropathy Decrease of GFR by hyperfiltration, inflammation, albuminuria ? Contributes to GFR decline in nonobese nephropathies	? Modifies decline of renal residual function	? Impaired graft function
Risk modification	Depending on metabolic aspects (diabetes control, hypertension, lipid profile) Endocrine status (fertility, adrenal function, hypothyroidism, pituarity functioning) Genetic factors	Improved survival independent of co-morbidity ? Benefits may be different in the age groups and within dialysis modalities	Increased risk of surgical complications Decreased graft survival ? Increased mortality risks due to metabolic complications
Preventive measurement	Diet modification Exercise Behavior changes Psychological counseling Social support	Adequate dialysis Sufficient nutritional intake (calories, protein) Regular assessment of body weight and conditions which may cause weight loss	Aggressive treatment of comorbidity risks (glucose control, lipids, smoking, hypertension) Diet modification Exercise/counseling
Therapeutic aspects	Medication Bariatric surgery	Standard nutritional recommendation according to treatment modality Nutritional intervention to avoid weight loss (<25 BMI)	? Adaption of immunosuppressive regimen (steroids) ? Bariatric surgery
Further aspects	Definition of benefits and risks of complications by bariatric surgical intervention	Normalization of body weight in transplant candidates (BMI <30–35) Definition of the role of bariatric surgery	Special donor care to reduce overweight and prevent OAN

?, denotes limited evidence; OAN, obesity-associated nephropathy.

Kidney Dis 2018;4:199–204

Why Obesity is a problem?

- **Increased risk of death**
- **Delayed graft function**
- **Acute rejection**
- **Wound infection**
- **Dehiscence**
- **Prolonged hospital stay**

The absence of a REAL BMI CUT-OFF

TARGET
BMI ≤ 30 Kg/m2

Trapianto di rene – **IPERIMMUNI**

Panel, Gruppo e Tipizzazione (dm44074)

Gruppo: 0 Pos

Locus	1	2
A	11	24(9)
B	8	8
C	7	7
DR	17(3)	7
DRW		
DQA		
DQB	2	2
DPA		
DPB		

Sieri presenti	23
Ultimo siero	07-02-2022
Scadenza	09-06-2022

	Data	PRA	Tipo
Last	04-08-2021	99	cPRA I
Max	11-02-2019	100	CDC

	Data	PRA
Max CDC	11-02-2019	100
Ultimo CDC	09-11-2020	95
Primo CDC	28-09-2016	98
Max cPRA I	04-08-2021	99
Ultimo cPRA I	04-08-2021	99
Primo cPRA I	28-09-2016	99
Max cPRA II	07-05-2018	99
Ultimo cPRA II	04-08-2021	98
Primo cPRA II	28-09-2016	99

Pra CDC >= 50	10
Pra CDC >= 80	10
cPRA I >= 80	11
cPRA II >= 80	11

		CDC			CDC+DTT		Flow PRA		Citofluorimetria Luminex						
							Classe I	Classe II	Classe I				Classe II		
	Data	PRA %	Spec Ab	IgM	PRA DTT %	Spec Ab	FlowPRA %	FlowPRA %	Met.	Screen	CPRA %	Spec	Screen	CPRA %	Spec	Stato
	07-02-2022															
	12-11-2021						99	99								
	04-08-2021								Isa	+	99	A1, A2, A3, A23, A25, A26, A29, A30, A31, A32, A33, A34, A36, A43, A66, A68, A69, A74, A80, B7, B13, B18, B27, B35, B37, B38, B39, B41, B42, B44, B45, B46, B47, B48, B49, B50, B51, B52, B53, B54, B55, B56, B57, B58, B59, B60, B61, B62, B63, B64, B65, B67, B71, B72, B73, B75, B76, B77, B78, B81, C2, C4, C5, C6, C8, C9, C10, C12, C14, C15, C16, C17, C18	+	98	DR1, DR4, DR8, DR9, DR10, DR11, DR12, DR13, DR14, DR15, DR16, DR103, DRW51, DRW53, DQB4, DQB5, DQB6	

IPERIMMUNE: Presenza di anticorpi anti-HLA in grado di reagire contro più dell'80% della popolazione (*panel reactivity antibodies* superiore a 80% - o PRA>80%)

- **Gravidanze**
- **Trasfusioni**
- **Trapianti**

- Minore probabilità di trapianto perché un numero di potenziali donatori presenterà antigeni HLA verso cui il candidato iperimmunizzato avrà prodotto anticorpi
- Tempo lungo di lista di attesa
- In caso di trapianto, minore probabilità di successo, anche dovuta all'aumentata attesa in dialisi

Programma Nazionale Iperimmuni

Desensibilizzazione

TAKE HOME MESSAGES

Il trapianto di rene è il trattamento sostitutivo della funzione renale di prima scelta, da valutare in tutti i pazienti con ESRD, in considerazione del miglior outcome

Informare il paziente con malattia renale cronica con GFR < 30 ml/min/1.73 m^2 della possibilità di trapianto, valutando la percorribilità di pre emptive con donatore vivente

Una appropriata selezione del ricevente di trapianto è cruciale per il successo del trapianto stesso e richiede una complessa e approfondita valutazione multidisciplinare clinica, chirurgica, psicologica e sociale.