

FABIO VISTOLI

Valutazione Chirurgica del Ricevente e del Donatore nel Trapianto di Rene da Vivente

STATI GENERALI



RETE NAZIONALE
TRAPIANTI

6.7.8 NOVEMBRE

ROMA



LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

PRINCIPI DELLA VALUTAZIONE

Compatibilità Immunologica

Rischi Funzione Renale

Trasmissione Mal. Infettive/Neoplastiche

Nefrectomia (Intervento)

Ripercussioni Psicologiche/Lavorative

Etica Informativa Donazione

Alternative alla Donazione

Valutazione Cognitiva

Volontarietà

Adattato da Consensus Statement Amsterdam Forum Transplantation 2005;79:491



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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

RAGIONI DI ESCLUSIONE

- 1) Età < 18 anni / Gravidanza
- 2) Crossmatch Positivo / Incompatibilità ABO
- 3) Cause Renali: GFR < 80 ml/min/1.73m² *
Proteinuria / Mal. Glomerulari
An. Urologiche / Mal. Ereditarie
Rischio: Ipertensione / Obesità / DM
- 5) Operatorie: Cardio-Polmonari / Tromboembolismo
- 4) Trasmissione Neoplasia / Malattia Infettiva
- 6) Psico-Sociali / Uso di Droghe



STATI GENERALI
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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

ANOMALIE UROLOGICHE

NEFROLITIASI

Idiopatica

'Single Stone Former'

<1.5cm estraibile

NEFROCALCINOSI

No

CISTI "COMPLICATE"

Resecabile+Sez.Congelata?

ANGIOMIOLIPOMA

Ø <1 cm o Resecabile?

NODULI < 2 cm

Resecabile+Sez.Congelata?

DISPLASIA FIBROMUSC.

Monolaterale e ABPM ok?

A.RENALI MULTIPLE

Val. Chirurgica



STATI GENERALI
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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

VALUTAZIONI AGGIUNTIVE NEL DONATORE CONSANGUINEO

ADPKD	Immagini ± Linkage
S. ALPORT	Audiometria
FSGS Aut Rec (NPHS2)	Genetica
Non Stx-HUS (ad es. CFH, FI)	Genetica
MCGN tipo II	Genetica
ANEMIA FALCIFORME	Foresi Hb/Conc.Urinaria



STATI GENERALI
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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

OBESITÀ

BMI

CONTROINDICAZIONE

$> 35m^2$

ASSOLUTA

$30-35m^2^*$

RELATIVA

**Considerare: OGTT, CVD, Ipertensione, MicroAlb, NASH, Sleep-Apnea S.*

Consensus Statement Amsterdam Forum. *Transplantation* 2005;79:S53



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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

IDONEITÀ CON STORIA DI NEOPLASIA

NEOPLASIA CUTANEA NON-MELANOCITICA

CARCINOMA IN SITU CERVICICE

CARCINOMA COLON DUKES A, F-UP>5 ANNI

Consensus Statement Amsterdam Forum. *Transplantation* 2005;79:S53



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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

RISCHIO PERI-OPERATORIO

POLMONARI	Età, Fumo	SPIROMETRIA (FEV1>70% o FVC>70%) EGA
CHD	Età Fattori di rischio	TEST DA SFORZO
TROMBOSI	Contraccettivi orali Anamnesi TVP	STOP 3 m prima PTT, Res Prot C att, Prot C e S, Alll, Ig aCL e β_2 g, LAC



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LIVING KIDNEY DONOR-TRANSPLANT CANDIDATES

ASPETTI ETICI

Informativa Donazione

- 1) Rischi Operatori e Lungo-Termine
- 2) Probabilità successo
- 3) Alternative alla Donazione

Valutazione Psicologica

- 1) Capacità di comprendere le informazioni
- 2) Volontarietà (no coercizione, pressione)
- 3) Motivazione (no profitto)

Libero Ritiro Consenso

Qualunque momento, favorire “alibi” clinico



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LIVING KIDNEY TRANSPLANT CANDIDATE (KTC)

OBESITY (KDIGO Guidelines)

FRAILITY (KDIGO Guidelines)

WOUND HEALING (KDIGO Guidelines)

ANTICOAGULATION (KDIGO Guidelines)

SURGICAL PLANNING (KDIGO Guidelines)

PERIPHERAL ARTERY DISEASE (KDIGO Guidelines)



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ROMA

LIVING KIDNEY TRANSPLANT CANDIDATE (KTC)

OBESITY (KDIGO Guidelines)

FRAILITY (KDIGO Guidelines)

WOUND HEALING (KDIGO Guidelines)

ANTICOAGULATION (KDIGO Guidelines)

SURGICAL PLANNING (KDIGO Guidelines)

PERIPHERAL ARTERY DISEASE (KDIGO Guidelines)



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OBESITY IN KIDNEY TRANSPLANT CANDIDATE (KTC)

7.1: We recommend KTCs be evaluated for obesity using body mass index (BMI) or waist-to-hip circumference ratio (WHR) at the time of listing and while on the waiting list. (1B)

7.1.1: We suggest that KTCs not be excluded from transplantation because of obesity, *per se*. (2B)

7.1.2: We suggest weight loss interventions prior to transplantation be offered in patients with obesity, including gastric sleeve bariatric surgery for morbid obesity. (2D)

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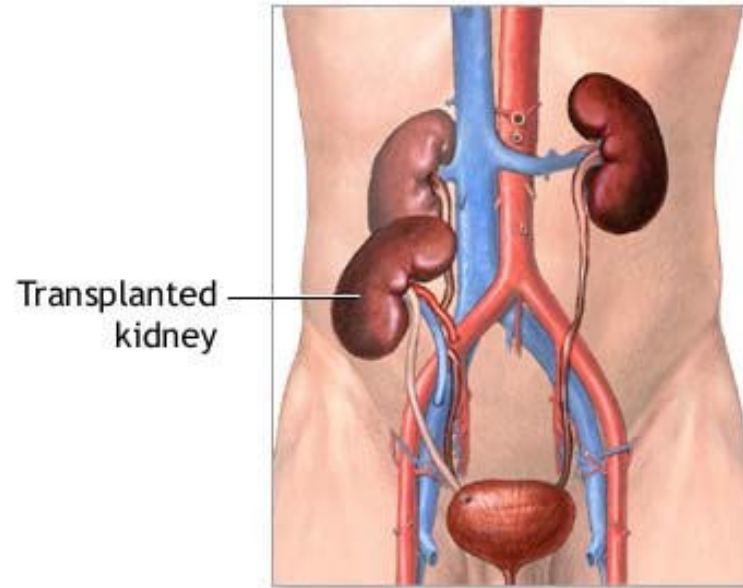
KDIGO Guidelines for Kidney Transplant Candidate (KTC)

Frailty characterized by a loss of function in 5 domains:

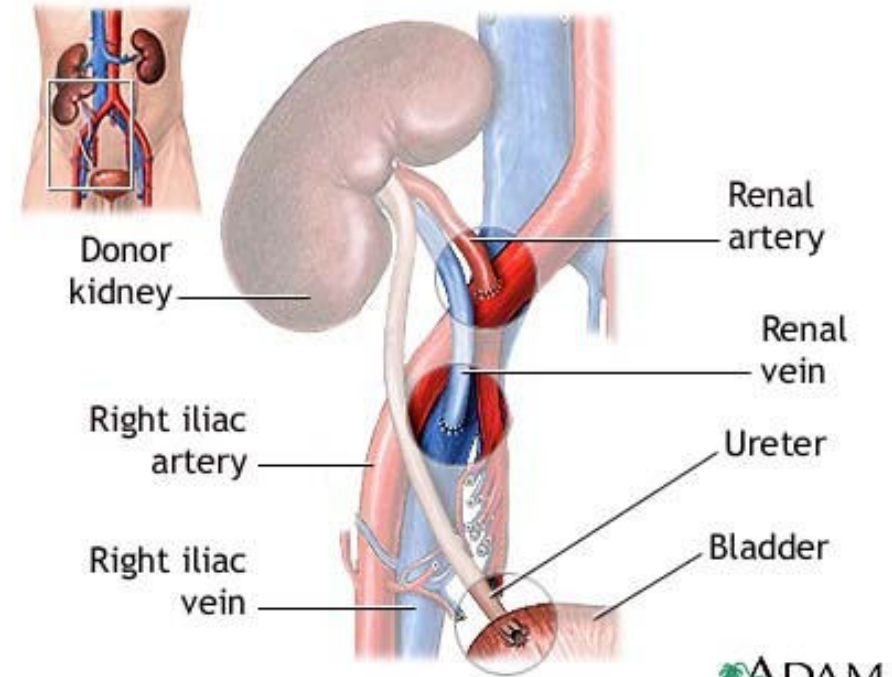
- Shrinkage (unintentional weight loss and sarcopenia),
- Muscular weakness,
- Exhaustion and lack of endurance,
- Slow gait,
- Physical inactivity

7.2: We suggest that patients be evaluated for frailty at listing and while on the waiting list to inform risk and enable optimization strategies. (2C)

Anatomy of Renal Transplantation



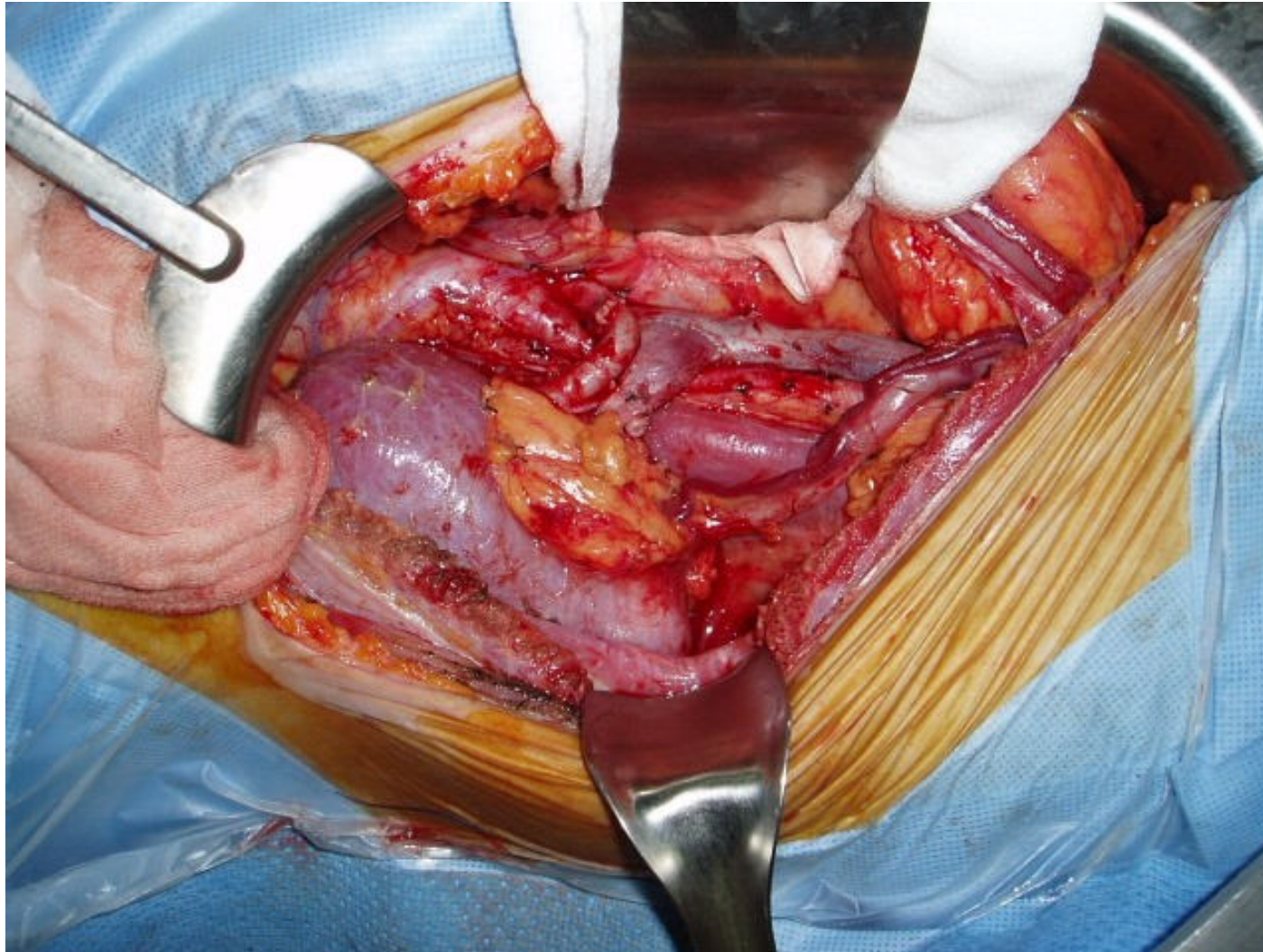
ADAM.



ADAM.



Technique of Renal Transplantation



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SURGICAL PLANNING IN KIDNEY TRANSPLANT CANDIDATE (KTC)

- 7.5:** Assess vascular anatomy and patency for patients with significant peripheral vascular disease (See Chapter 14), prior transplant procedures, venous dialysis catheters, pelvic surgery, or deep venous thrombosis. *(Not Graded)*
- 7.6:** Consider alternative approaches, including transperitoneal organ placement and the need for urologic evaluation, in candidates with prior pelvic surgery including previous kidney transplantation. *(Not Graded)*



SURGICAL PLANNING IN KIDNEY TRANSPLANT CANDIDATE (KTC)

7.7: Evaluate native kidney size in patients with polycystic liver/kidney disease. (Not Graded)

7.7.1: We suggest staged or simultaneous native nephrectomy and transplantation for candidates with polycystic kidney disease (PKD) that is symptomatic, there is a suspicion of malignancy, or if the patient has insufficient room for a transplant. (2D)



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Trapianto di reni con carcinomi uroteliali

- 8 casi
- La recidiva a 15 mesi è stata trattata ancora con resezione parziale
- Il paziente è deceduto 3 anni dopo con un carcinoma bronchiale ma la assenza di uno studio del DNA non consente di escludere che si sia trattato di una metastasi

Mannami M et al

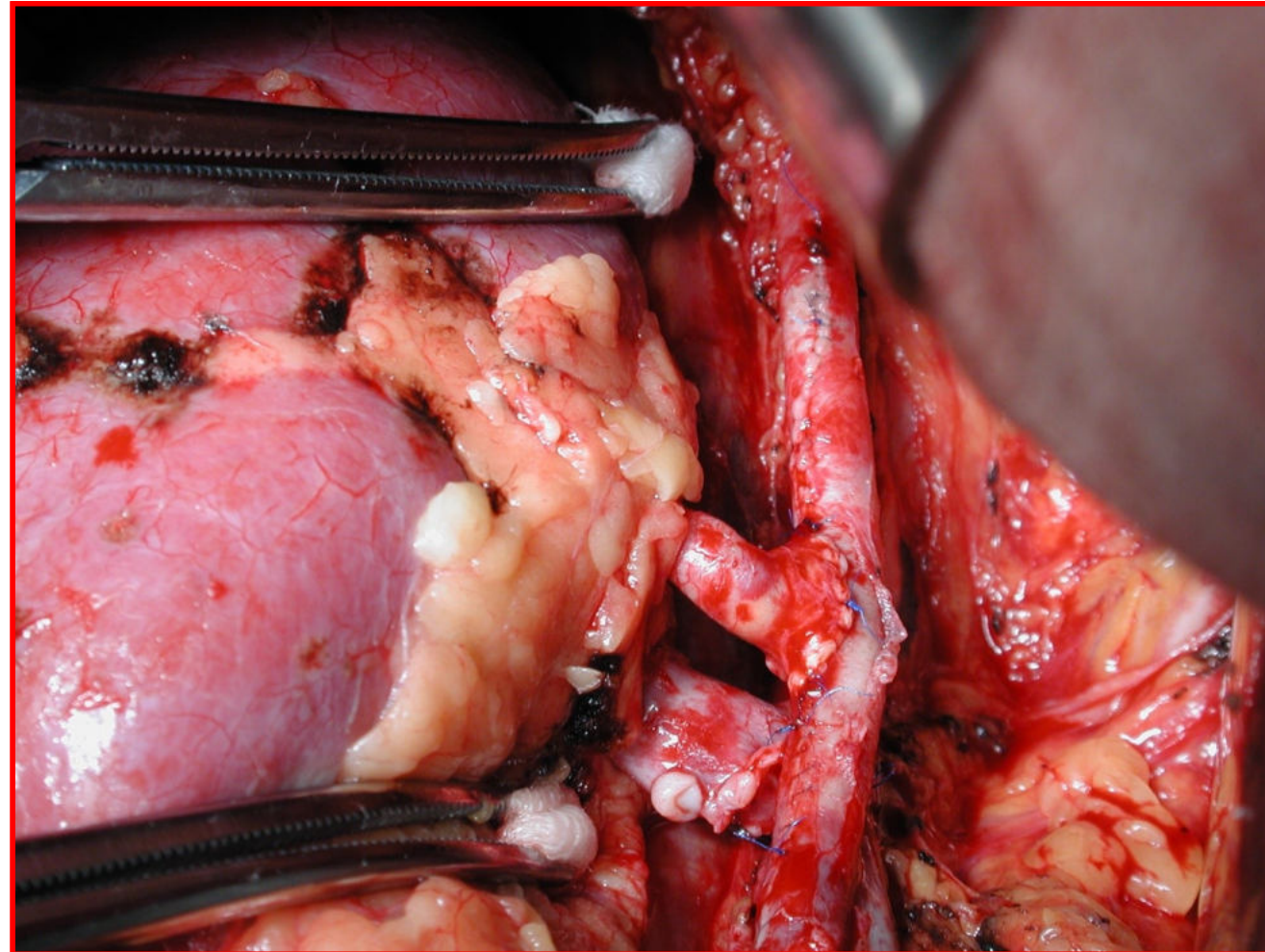
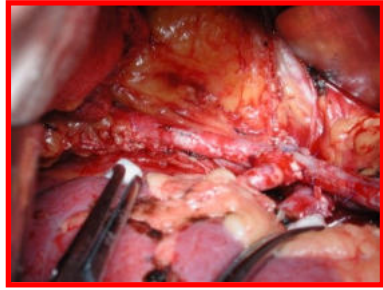
Am J Transplantation 2008,8,811



SURGICAL PLANNING IN KIDNEY TRANSPLANT CANDIDATE (KTC)

- 7.8:** Referral for evaluation by a transplant urologist is indicated for patients with a history or high risk of urologic malignancy, recurrent urinary tract infections, dysfunctional voiding, prior bladder augmentation/division, an ileal conduit, any congenital anomalies of the kidneys or urinary tract, or nephrolithiasis. *(Not Graded)*
- 7.8.1:** We suggest that patients with a history of cyclophosphamide use undergo cystoscopy. *(2D)*
- 7.8.2:** We suggest that pre-transplant unilateral or bilateral nephrectomy be considered for pediatric candidates with high urine volumes (> 2.5 ml/kg/hour) or heavy proteinuria associated with hypoalbuminemia. *(2D)*

PERIPHERAL ARTERY DISEASE IN KIDNEY TRANSPLANT CANDIDATE

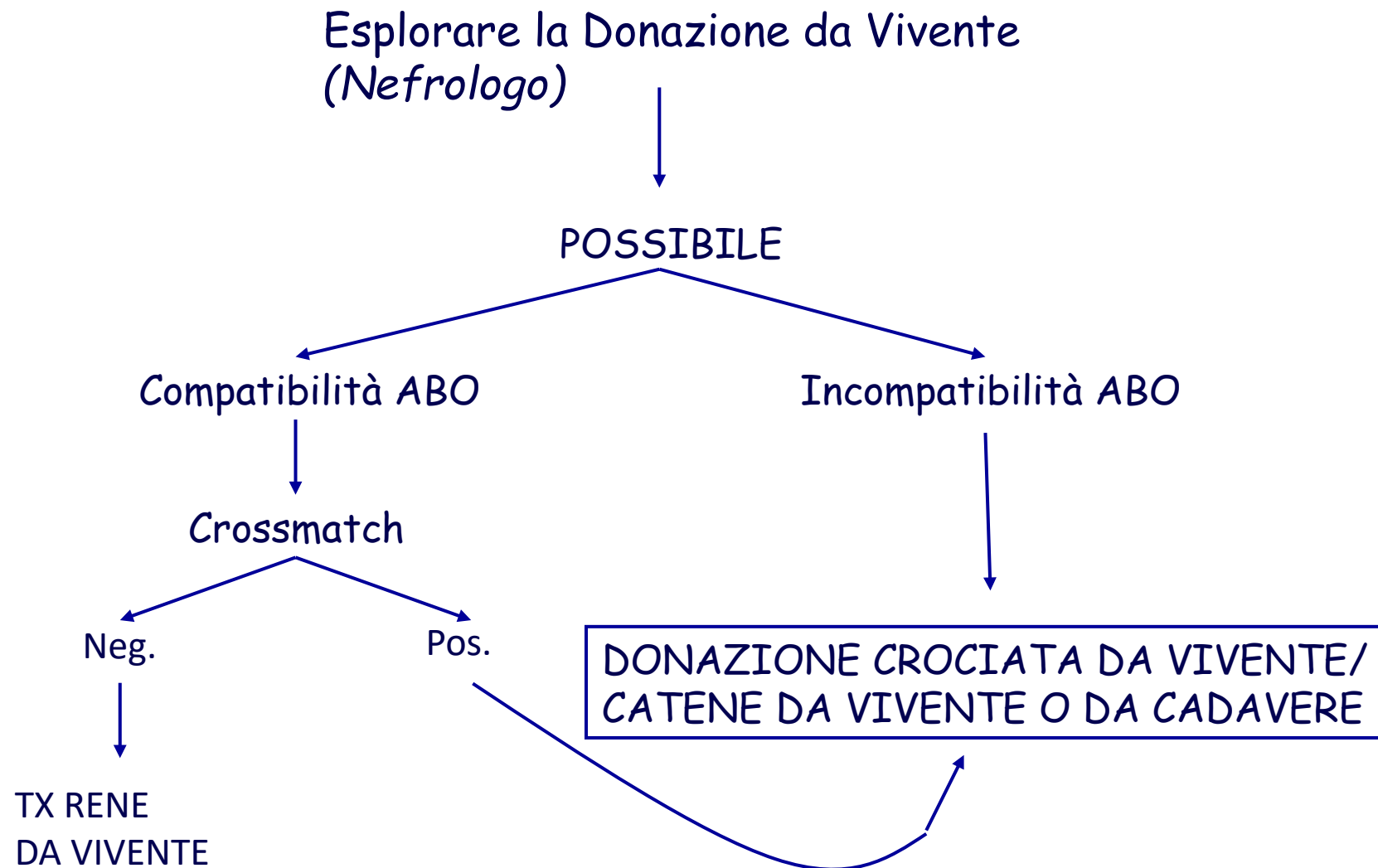


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LIVING KIDNEY DONOR CANDIDATE



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LIVING KIDNEY DONOR CANDIDATE

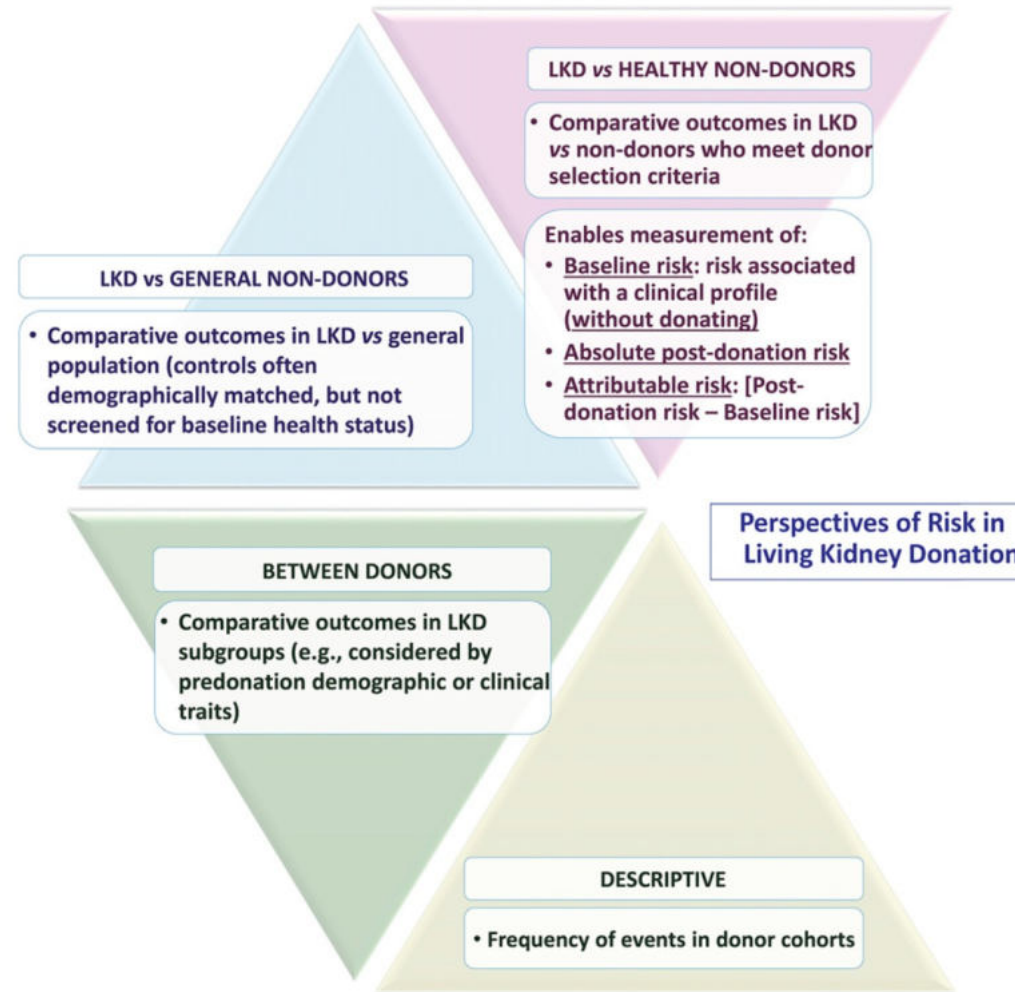


Figure 1. Perspectives of risk in living kidney donation. These perspectives provide a framework for risk assessment and comparison relevant to the design of research studies, interpretation of observations, and patient communication. LKD, living kidney donors

LIVING KIDNEY DONOR CANDIDATE

ACCEPTABLE RISK FRAMEWORK

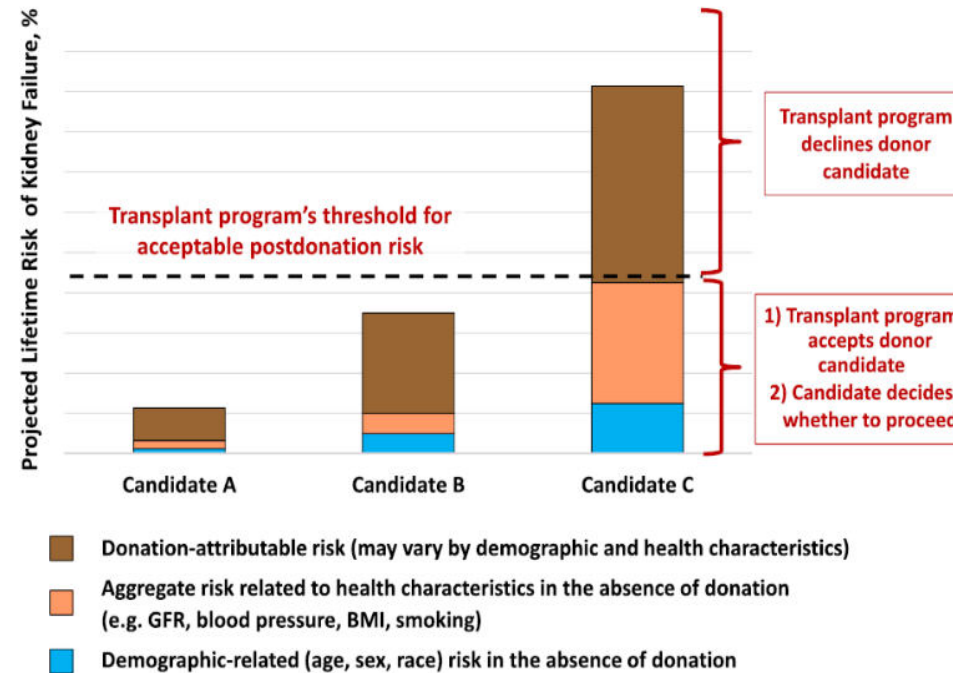


FIGURE 2. Framework to accept or decline donor candidates based on a transplant program's threshold of acceptable projected lifetime risk of kidney failure, quantified as the aggregate of risk related to demographic and health profile and donation-attributable risks. The decision by a transplant program to accept or decline a donor candidate is grounded on whether an individual's estimated projected postdonation lifetime risk is above or below the threshold set (dotted line) by the transplant program. Lifetime risk is comprised of estimated risk in the absence of donation (ie, related to donor demographic and health characteristics, as denoted in blue and beige, respectively) and estimated projected risk attributable to donation (brown). The threshold may vary across transplant programs, but the same threshold should apply to all donor candidates at each program. For example, candidate A would be acceptable because the estimated projected postdonation risk is far below the threshold. Candidate B could be accepted with caution because the estimated projected postdonation risk is close to the threshold, and candidate C would be unacceptable because the estimated postdonation projected risk is far above the threshold.



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LIVING KIDNEY DONOR CANDIDATE

ACCEPTABLE RISK FRAMEWORK

Age (20-80 yrs)	20 yrs	60 yrs
Gender	Male	Male
Race	White	White
eGFR (ml/min/1.73m ²)	90	90
SBP (mmHg)	120	120
Hypert. Medications	No	No
BMI (kg/m ²)	25	25
NIDDM	No	No
ACR (mg/g)	4	4
Smoking History	No	No



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ACCEPTABLE RISK FRAMEWORK

Age (20-80 yrs)	20 yrs	60 yrs
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eGFR (ml/min/1.73m ²)	90	90
SBP (mmHg)	120	120
Hypert. Medications	No	No
BMI (kg/m ²)	25	25
NIDDM	No	No
ACR (mg/g)	4	4
Smoking History	No	No
Pre-donation 15 y risk	0.02%	0.10%
Pre-donation lifetime risk	0.60%	0.20%
Post-donation lifetime risk (x5)??	3.00%	1.00%



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Limitations of Living Donor Kidney Transplantation

- ABO isoagglutinin incompatibility
 - Proposed solution : desensitization protocols
 - Limits of proposed solution : expensive, difficult for recipients with high-titer isoagglutinin, risk for clinical AMR (10-30%) despite accommodation
- donor-specific anti-HLA antibody (DSHA) incompatibility
 - Proposed solution : desensitization protocols
 - Limits of proposed solution : expensive, uncertain prohibitive MFI, risk for clinical (up to 50%) and subclinical AMR, no data yet on long-term follow-up
- sharing of genetic risk factors for inheritable nephropathies in relatives
 - Proposed solution : use non-relatives (spouse, cognate, ...)
- spousal sensitization (especially for wives receiving from husbands)
 - Proposed solution : use cognates
- disparities in GFR between recipient and donor(s) (differences in age and lean BMI)
 - Proposed solution : none

LIVING KIDNEY DONOR CANDIDATE

AGE (SITO-SIN Guidelines)

OBESITY (SITO-SIN Guidelines)

KIDNEY STONES (SITO-SIN Guidelines)

CANCER SCREENING (KDIGO Guidelines)

**SURGICAL APPROACH FOR DONOR NEPHRECTOMY
(KDIGO Guidelines)**



STATI GENERALI
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LIVING KIDNEY DONOR CANDIDATE

AGE (SITO-SIN Guidelines)

OBESITY (SITO-SIN Guidelines)

KIDNEY STONES (SITO-SIN Guidelines)

CANCER SCREENING (KDIGO Guidelines)

**SURGICAL APPROACH FOR DONOR NEPHRECTOMY
(KDIGO Guidelines)**



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Quale Rene Prelevare I

- La scelta è dettata da due “Linee Guida” logiche
 - A) Se i reni sono simmetrici è indicato prelevare il rene più facile da trapiantare
 - B) Se uno dei due reni ha lesioni occorre lasciare al donatore il rene migliore

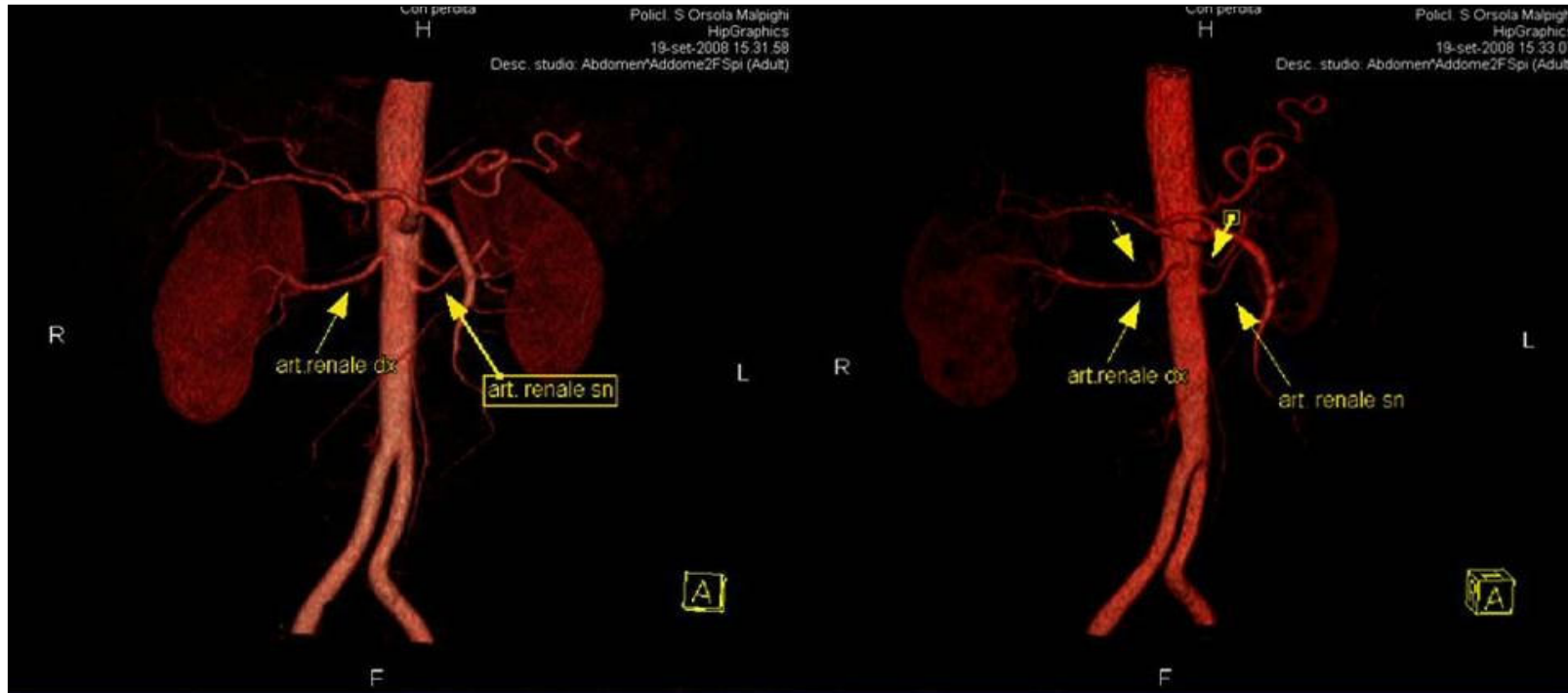


Un Rene è facile o difficile da trapiantare per problemi vascolari

- Facile è il rene con una arteria unica e una vena lunga: il rene sinistro
- Occorre perciò studiare con precisione le arterie renali ovvero eseguire sul donatore o una Angio TAC o una Angio RNM
- I reni con arterie multiple possono essere trapiantati ma le ricostruzioni arteriose aumentano il rischio di infarti polari mentre il lungo tempo necessario ad eseguire anastomosi multiple aumenta quello di DGF



SURGICAL APPROACH FOR DONOR NEPHRECTOMY



**Arterie duplici bilateralmente
ma a dx una delle due arterie è minuscola:
anche se è possibile il suo reimpianto
è probabilmente preferibile impiegare il rene sinistro**

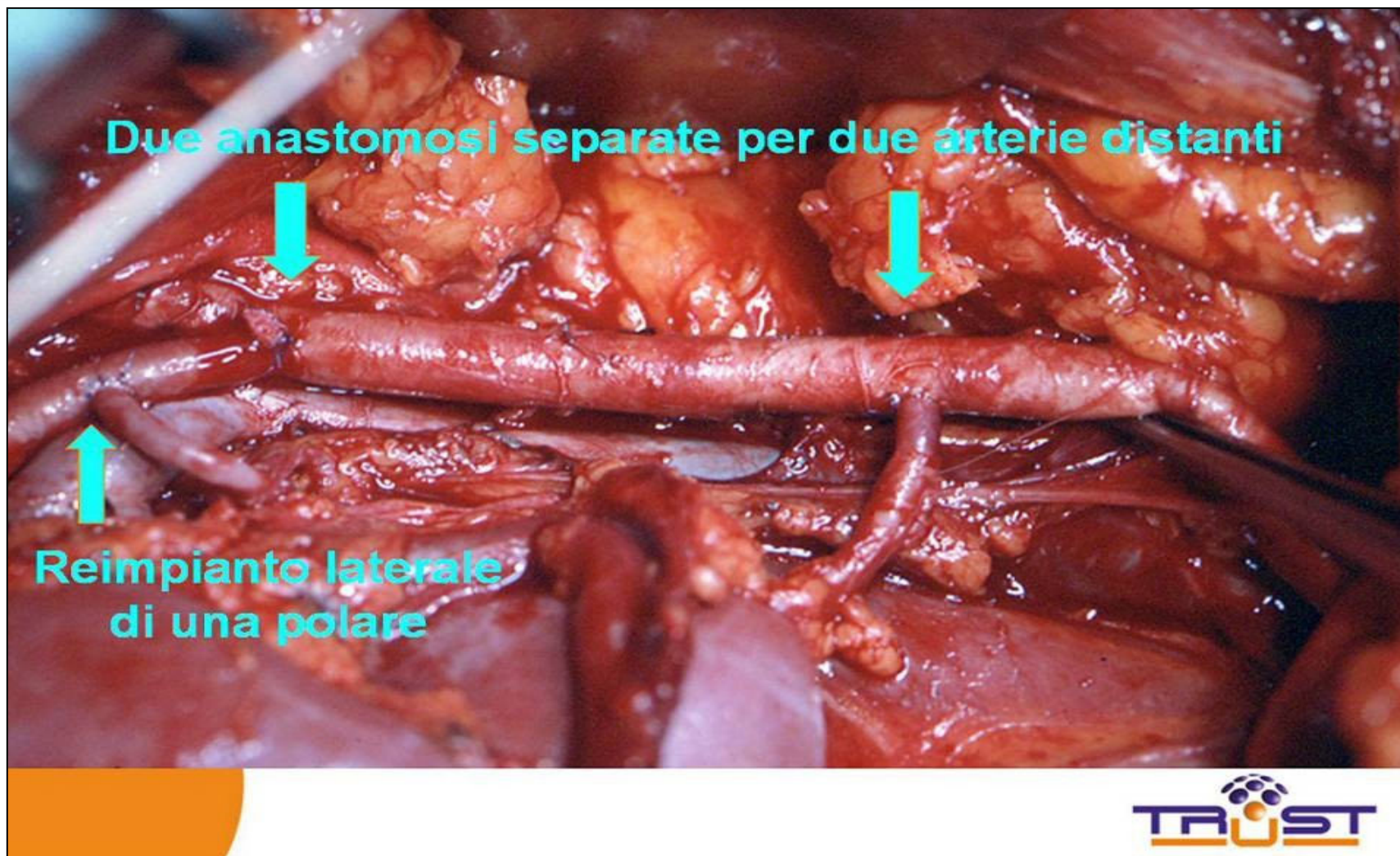


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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

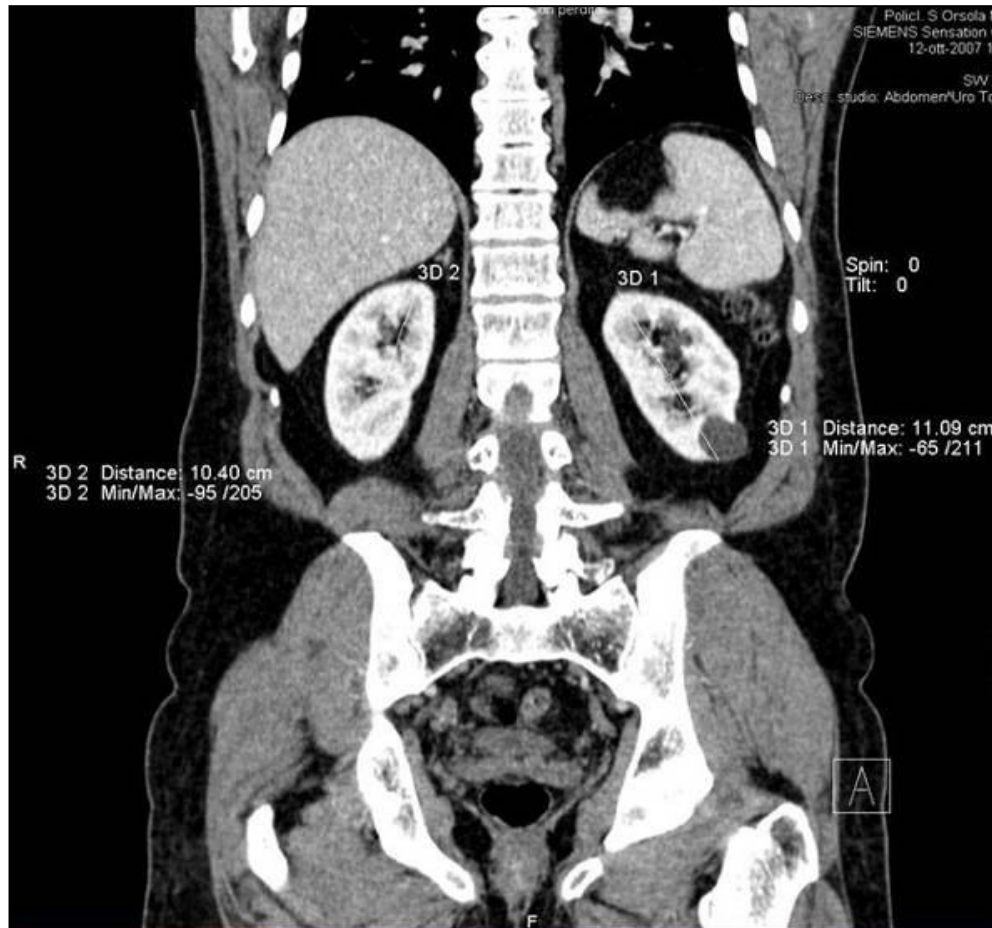


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SURGICAL APPROACH FOR DONOR NEPHRECTOMY



**Piccola cisti
al polo inferiore
del rene sinistro**

**Si preleva quello
lasciando al donatore
il rene dx integro**

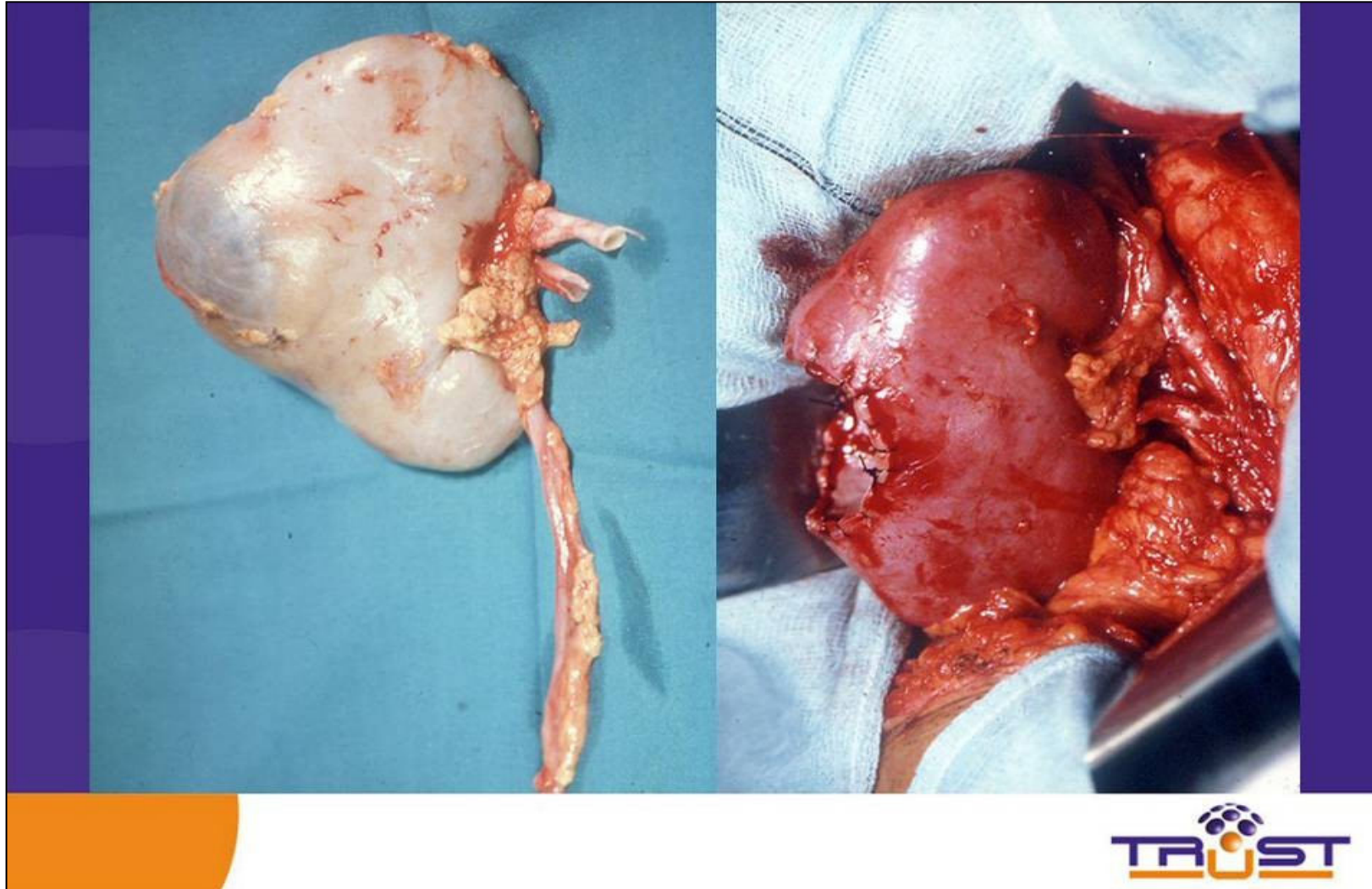


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SURGICAL APPROACH FOR DONOR NEPHRECTOMY



TRUST



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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

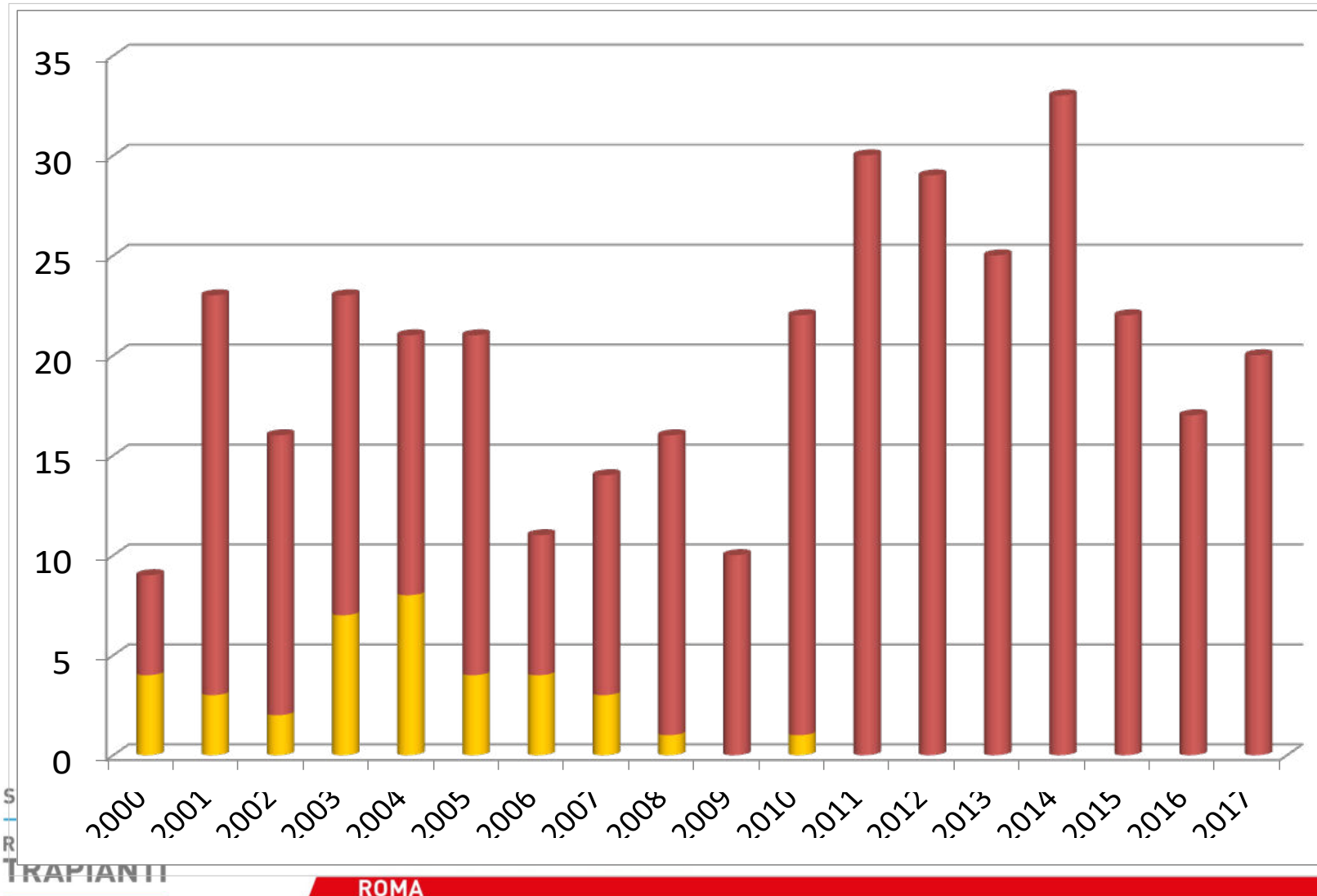
17.1: Renal imaging (eg, computed tomographic angiography) should be performed in all donor candidates to assess renal anatomy before nephrectomy.

17.2: The surgeon should have adequate training and experience for the surgical approach used for the donor nephrectomy.

17.3: We suggest that “mini-open” laparoscopy or hand-assisted laparoscopy by trained surgeons should be offered as optimal approaches to donor nephrectomy. However, in some circumstances, such as for donors with extensive previous surgery and/or adhesions, and at centers where laparoscopy is not routinely performed, open nephrectomy (flank or laparotomy) may be acceptable. (2D)

SURGICAL APPROACH FOR DONOR NEPHRECTOMY

Prelievo laparoscopico Pisa 2000 - 2017



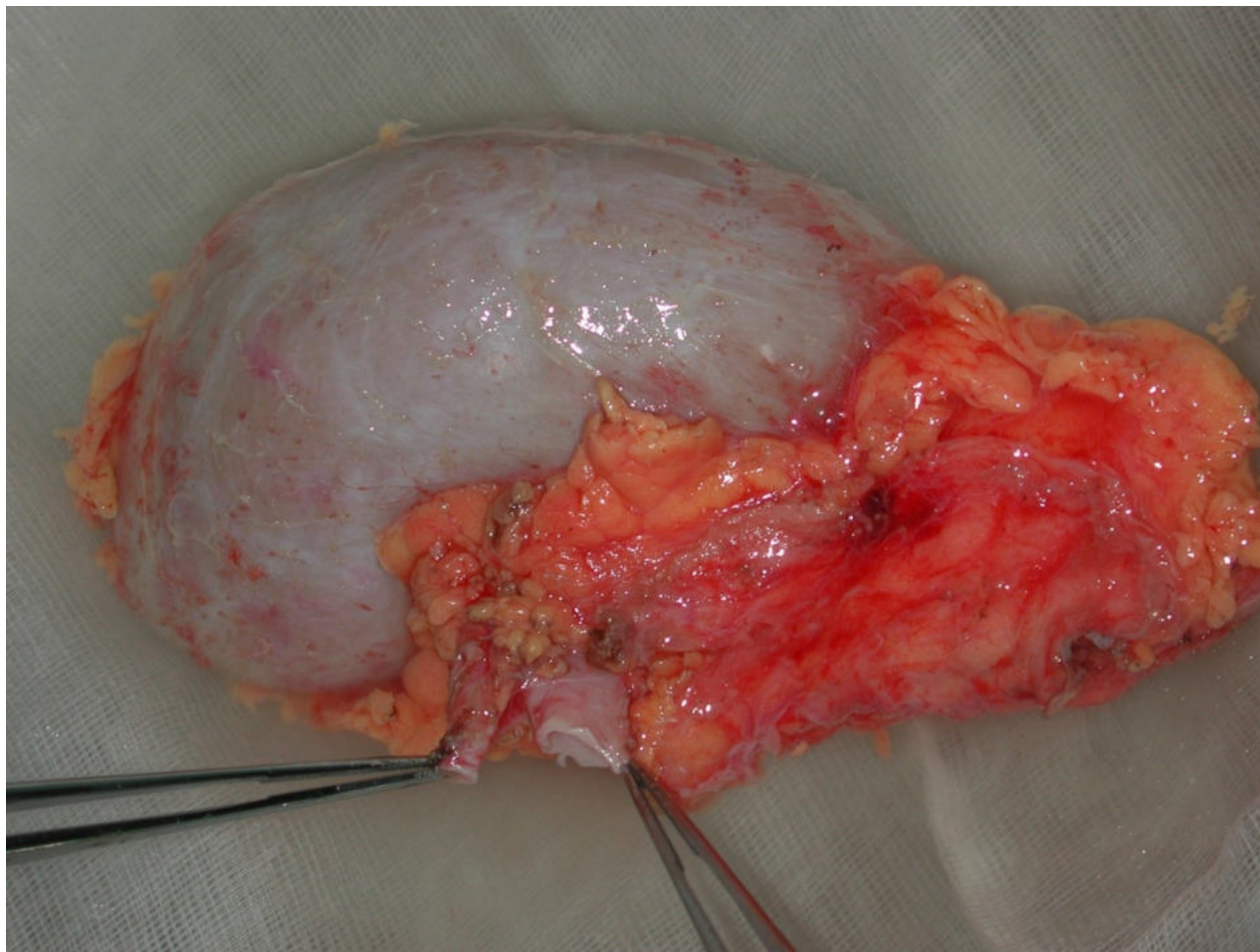
SIR
SIT
TRAPIANTI

ROMA

Ultimi 196 consecutivi in laparoscopia (Pura, HALS,

SURGICAL APPROACH FOR DONOR NEPHRECTOMY

Qualità morfologica del graft
paragonabile al prelievo lombotomica



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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

donazioni laparoscopiche a Pisa

durata intervento 165'

ischemia calda 78''

ischemia fredda 43'

nessuna conversione
nessuna mortalità



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donazioni laparoscopiche a Pisa

minimizzazione ischemia calda 78”

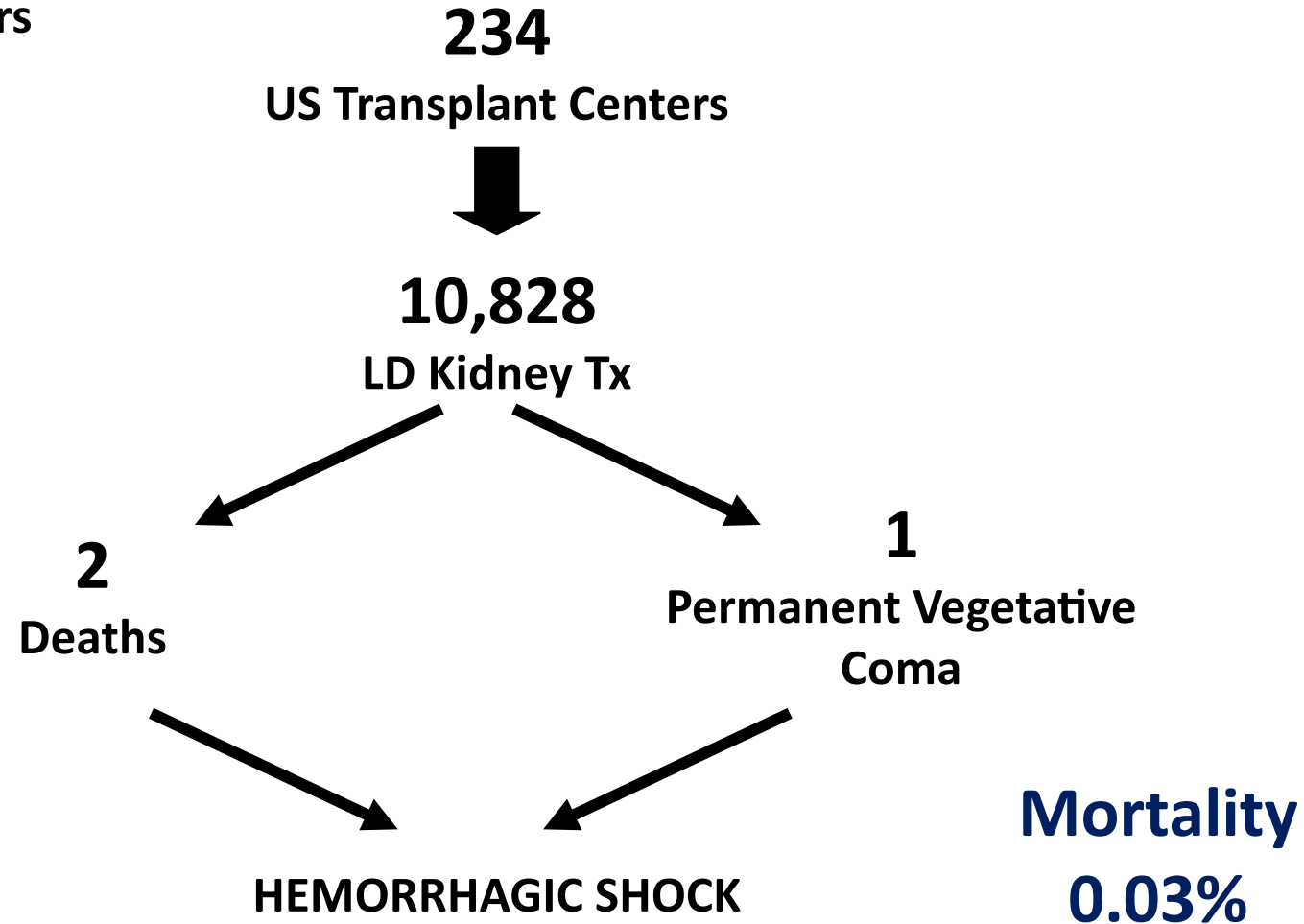
1. pre-loading del graft in endobag
2. utilizzo di 2 stapler per arteria e vena
3. solo peritoneo sull'accesso sovrapubico
4. seconda equipe per la perfusione

SURGICAL APPROACH FOR DONOR NEPHRECTOMY

Matas AJ, Bartlett ST, Leichtman AB, et al.

Morbidity and mortality after living kidney donation, 1999–2001: survey of United States transplant centers

Am J Transplant. 2003;3:830–834



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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

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utility of bone marrow examination in renal transplantation: Nine years of experience from North India. *Transplantation* 2006; 81: 1354.

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Letters to the Editor

e79

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Death of Healthy Volunteers and Professionals on Duty for Cadaveric Graft Shipment

Death of a living organ donor is universally considered a disaster, having devastating effects on public opinion. Deceased donor transplantation poses ethical questions but cannot rise the concerns on donor safety typical of living donation. Hence, it is generally considered "safer."

However, considering the organizational and logistical complexity of cadaveric donation, accidental death of healthy volunteers and professionals caring for graft shipment is a disagreeable price. Perhaps, unconsciously, we all know we have to pay this price for the success of transplantation: what we do not know is exactly how much we do have to pay. Englesbe and Merion (1) reported sporadic fatalities in the United States (Aviation Safety Network [2] IDs 19900911-1 and 20070604-0, wikibase 38890), France (wikibase 43982), Brazil (ID 19760122-1 [3]), and Germany. Englesbe and Merion did not mention another fatality that occurred in Spain (one death: ID 20001125-0). Many more "near-misses" have been reported, for example, from Germany (wikibase 72222) and United Kingdom (ID 20101119-0). Anyway, no registry exists for transplant-related accidents, and surgeon surveys looking for accidents have been performed only in the United States (1). The overall worldwide (excluding Italy) fatality is 28 in the past 30 years. Anyway, this is likely an underestimation because of poor reporting, and ratios of fatal accidents per donated organ are almost impossible to calculate without a registry.

We attempted estimation of this death risk for Italy, whereas between 2004 and 2009, at least nine persons died as a consequence of three mishaps occurred during organ shipment. Englesbe and Merion (1) reported only the one that occurred on February 24, 2004 (20040224-0), where six persons (including two heart

surgeons, one physician assistant, and three pilots) died when their plane crashed into a mountain near Cagliari (Sardinia). On April 22, 2005, a volunteer shipping two kidneys died in a car crash between Siena and Pisa (both in Tuscany) (4). Finally, on February 7, 2009, two pilots died when their aircraft crashed in Trigoria (Rome), shortly after taking off from Ciampino to Modena (Emilia Romagna; ID 20090207-0). In the same period (2004–2009) in Italy, there were 6737 deceased donors leading to 18,722 organ transplants. Consequently, the risk of healthy volunteer or professional when estimated per deceased donor is 0.048% when estimated per organ (5). Admittedly, this is a rough estimation because, at least in Italy, between 2004 and 2009, this risk might have been even greater. Indeed, although at the numerator we could have missed some deaths, the denominator should be probably lower than 18,722, because not all transplanted organs were shipped.

Death of volunteers and health professionals involved in organ transplantation has on medical community a different impact than death of persons fallen transplanted. Deceased donor transplantation and deaths should be surveyed as systematically as live donation is. The creation of an international registry summarizing the ratios of fatalities per transplanted organ could encourage improvement of safety measures and suggest different organization of transplant networks.

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Death of Healthy Volunteers and Professionals on Duty for Cadaveric Graft Shipment

Death of a living organ donor is universally considered a disaster, having devastating effects on public opinion. Deceased donor transplantation poses ethical questions but cannot rise the concerns on donor safety typical of living donation. Hence, it is generally considered "safer."

However, considering the organizational and logistical complexity of cadaveric donation, accidental death of healthy volunteers and professionals caring for graft shipment is a disagreeable price. Perhaps, unconsciously, we all know we have to pay this price for the success of transplantation: what we do not know is exactly how much we do have to pay. Englesbe and Merion (1) reported sporadic fatalities in the United States (Aviation Safety Network [2] IDs 19900911-1 and 20070604-0, wikibase 38890), France (wikibase 43982), Brazil (ID 19760122-1 [3]), and Germany. Englesbe and Merion did not mention another fatality that occurred in Spain (one death: ID 20001125-0). Many more "near-misses" have been reported, for example, from Germany (wikibase 72222) and United Kingdom (ID 20101119-0). Anyway, no registry exists for transplant-related accidents, and surgeon surveys looking for accidents have been performed only in the United States (1). The overall worldwide (excluding Italy) fatality is 28 in the past 30 years. Anyway, this is likely an underestimation because of poor reporting, and ratios of fatal accidents per donated organ are almost impossible to calculate without a registry.

We attempted estimation of this death risk for Italy, whereas between 2004 and 2009, at least nine persons died as a consequence of three mishaps occurred during organ shipment. Englesbe and Merion (1) reported only the one that occurred on February 24, 2004 (20040224-0), where six persons (including two heart

surgeons, one physician assistant, and three pilots) died when their plane crashed into a mountain near Cagliari (Sardinia). On April 22, 2005, a volunteer shipping two kidneys died in a car crash between Siena and Pisa (both in Tuscany) (4). Finally, on February 7, 2009, two pilots died when their aircraft crashed in Trigoria (Rome), shortly after taking off from Ciampino to Modena (Emilia Romagna; ID 20090207-0). In the same period (2004–2009) in Italy, there were 6737 deceased organ donors leading to 18,722 organ transplants. Consequently, the risk of death of a healthy volunteer or professional is 0.13% when estimated per deceased donor and 0.048% when estimated per transplanted organ (5). Admittedly, this is a rough estimation because, at least in Italy and between 2004 and 2009, this risk might have been even greater. Indeed, although at the numerator we could have missed some deaths, the denominator should be probably lower than 18,722, because not all transplanted organs were shipped.

Death of volunteers and health professionals involved in organ transplantation has probably a lower impact on medical community and public opinion than death of living organ donors. Actually, these fatalities are not too different as they are; anyhow, deaths of persons fallen to allow others to be transplanted. We emphasize that deceased donor-related incidents and deaths should be surveyed as systematically as live donation is. The creation of an international registry summarizing the ratios of fatalities per transplanted organ could encourage improvement of safety measures and suggest different organization of transplant networks.

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The authors declare no conflict of interest.

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U.B. had the original idea and participated in writing of the manuscript; and G.A. and D.F. participated in writing of the manuscript and provided final revision for the manuscript.
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6 · 7 · 8 NOVEMBRE

ROMA

SURGICAL APPROACH FOR DONOR NEPHRECTOMY

25 Settembre 2012



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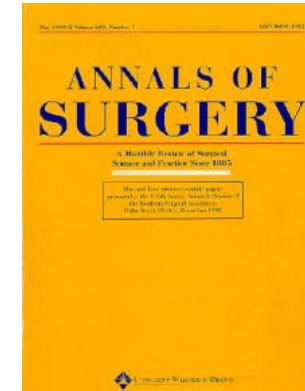
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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

Fatal and Nonfatal Hemorrhagic Complications of Living Kidney Donation

Amy L. Friedman, MD, Thomas G. Peters, MD,† Kenneth W. Jones, MD,† L. Ebony Boulware, MD,‡ and Lloyd E. Ratner, MD§*

Ann Surg 2006; 243: 126–130



Questionnaire sent to the 893 members of the American Society of Transplant Surgeons



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24% response rate

TABLE 1. Technique of Renal Artery Stump Occlusion Used by 213 Respondents to a Survey of Safety in Live Donor Nephrectomy

Technique	Open		Laparoscopic	
	n*	%	n*	%
Single simple tie	18	9	0	0
Multiple simple ties	32	15	0	0
Suture ligature	21	10	0	0
Suture ligature + simple tie	85	40	1	0.5
Oversew	52	24	0	0
Single hemostatic clip (non-locking)	7	3	3	1
Multiple hemostatic clips (non-locking)	13	6	19	9
Single locking hemostatic clip	1	0.5	4	2
Multiple locking hemostatic clips	15	7	39	18
GIA surgical stapler	3	1	64	30
TA surgical stapler	1	0.5	22	10
Other	5	2	1	0.5

*Respondents were not limited to a single choice and some provided multiple responses.



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105 bleedings

66 arterial

39 venous

TABLE 3. Morbidity and Mortality From 66 Cases of Severe Arterial Hemorrhage in Live Donor Nephrectomies

	Known		Unknown
	Yes	No	
Death, n (%)	2 (3)	52 (79)	12 (18)
Transfusion, n (%)	19 (29)	10 (15)	37 (56)
Re-exploration or conversion to open nephrectomy, n (%)	29 (44)	26 (39)	11 (17)
Renal failure, n (% of survivors)	2 (3)	51 (80)	11 (17)

SURGICAL APPROACH FOR DONOR NEPHRECTOMY

TABLE 2. Techniques of Arterial Stump Occlusion Utilized in 66 Cases of Severe Arterial Hemorrhage in Live Kidney Donors

Technique	n (%)
Transfixion	21 (32)
Non-transfixion	45 (68)
Sub-Total	66 (100)

Transfixion	21 (32)
Non-locking	13 (20)
Locking	18 (27)
Suture ligation	4 (6)
Oversew	1 (2)
Reticulating GIA stapler	1 (2)
Sub-Total	21
Non-transfixion	
Non-locking	13 (20)
Locking	18 (27)
Suture ligation	4 (6)
Oversew	1 (2)
Reticulating GIA stapler	1 (2)
Sub-Total	45

Transfixion 21/66

32%

Non-transfixion 45/66

68%



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SURGICAL APPROACH FOR DONOR NEPHRECTOMY

Occlusion of the renal artery by clips, including the Hem-o-lok, is more often associated to severe hemorrhage.

Occlusion of the renal artery using transfixion methods seems to be safer.

Strict control of post-operative pain may contribute to reduce the incidence of delayed post-operative hemorrhage.

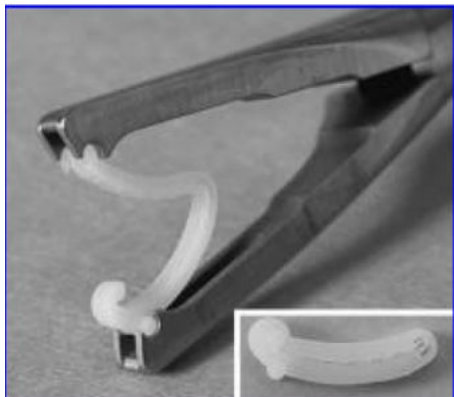


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Reported Failures of the Polymer Self-Locking (Hem-O-Lok) Clip: Review of Data from the Food and Drug Administration*

JOURNAL OF ENDOUROLOGY
Volume 20, Number 12, December 2006

Hem-o-lok Clip Dislodgment Causing Death of the Donor After Laparoscopic Living Donor Nephrectomy



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Transplantation 2008

SURGICAL APPROACH FOR DONOR NEPHRECTOMY



2345 Wakeglen Road, Suite 120
Bannockburn, IL 60015 USA

Phone (USA): (800) 594-9751
International: (312) 453-4652

Important Product Safety Information

April 11, 2006

Re: Contraindication For Use of Hem-o-lok Ligating Clips in Laparoscopic Donor Nephrectomy

Dear Valued Customer and Healthcare Provider:

The purpose of this communication is to provide you with important information regarding the use of our Hem-o-lok® Non-absorbable Polymer Ligating Clips in laparoscopic donor nephrectomy. Teleflex Medical has been made aware of rare incidents in which the ligating clips (sizes L and XL) were reported to have become dislodged following ligation of the renal artery after laparoscopic donor nephrectomy.

Our preliminary assessment is that none of the incidents appears to have involved any defect in or malfunction of the Hem-o-lok® ligating clips. We are aware, however, that laparoscopic donor nephrectomies pose special surgical challenges, including the surgeon's desire to maximize the length of the renal artery removed from the donor in order to facilitate the arterial anastomosis of the transplanted kidney. In rare instances, misapplication of the Hem-o-lok® clips during such laparoscopic procedures may not immediately be apparent, but can have serious, even life-threatening consequences post-operatively. Because of the nature of this risk and the surgical challenges posed by ligation of the renal artery during laparoscopic donor nephrectomies, we are adding a contraindication to the Instructions for Use accompanying Hem-o-lok® Polymer Ligating Clips specifically directed to this procedure—ligation of the renal artery during laparoscopic nephrectomies in living donor patients.

Our decision to contraindicate is limited solely to the use of Hem-o-lok Polymer® Ligating Clips for ligating the renal artery in laparoscopic donor nephrectomies. We recognize that the clips are used in many other types of surgical procedures, and we continue to believe that the clips offer unique advantages when used as directed in other procedures.

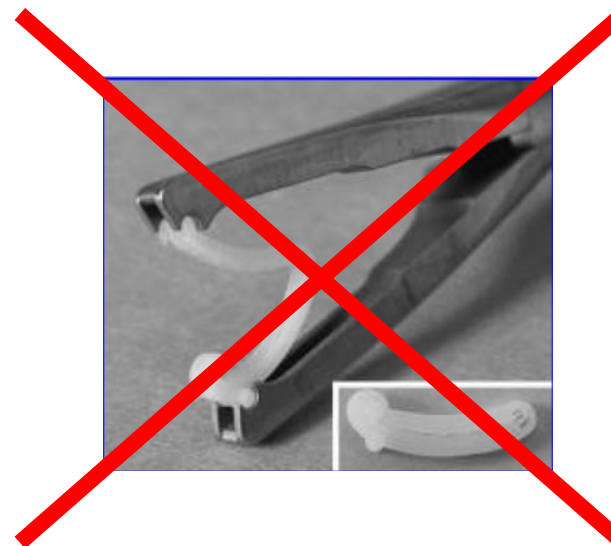
A sample of a revised Instructions for Use is attached for your convenience, and the two modified sections now read as follows:

"CONTRAINDICATIONS":

Hem-o-lok® ligating clips are contraindicated for use in ligating the renal artery during laparoscopic nephrectomies in living donor patients.

"CAUTION":

The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure of the clip. Security of the closure should be confirmed after ligation. The Hem-o-lok Polymer Ligating Clip is not designed for use as a tissue marker. Weck recommends that more than one clip be used to ligate the renal artery in procedures other than laparoscopic donor nephrectomy (see CONTRAINDICATION, above). Application of more than one clip to all other vessels should be left to the surgeon's judgment.



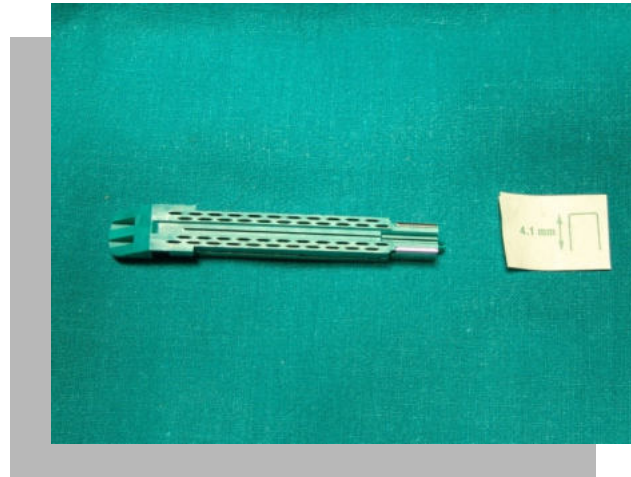
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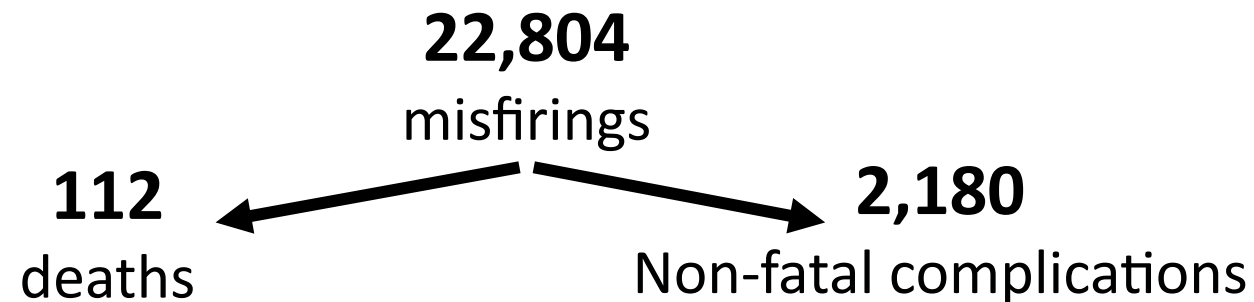
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Surgical stapler-associated fatalities and adverse events to the Food and Drug Administration.

J Am Coll Surg 2004; 199: 374-381



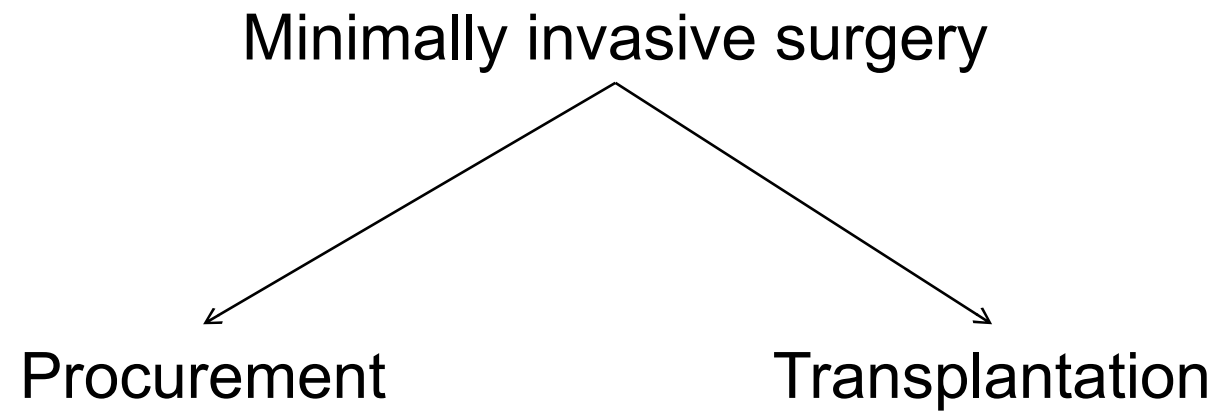
SURGICAL APPROACH FOR DONOR NEPHRECTOMY

17.4: Robotic, single-port, and natural orifice transluminal nephrectomy should generally not be used for donor nephrectomy.

17.5: Nontransfixing clips, (eg, Weck Hem-o-lok) should not be used to ligate the renal artery in donor nephrectomy; instead, renal artery transfixation by suture ligature or anchor staple within the vessel wall should be used.

17.6: In the absence of reasons to procure the right kidney (vascular, urological or other abnormalities), the left kidney should be procured in laparoscopic donor nephrectomy because of the relative technical ease associated with a longer venous pedicle.

SURGICAL APPROACH FOR DONOR NEPHRECTOMY



APPROVED

IN-PROGRESS

Kidney

Pancreas

Liver

Kidney

Pancreas

Liver

+++

±

±

±

±

ND

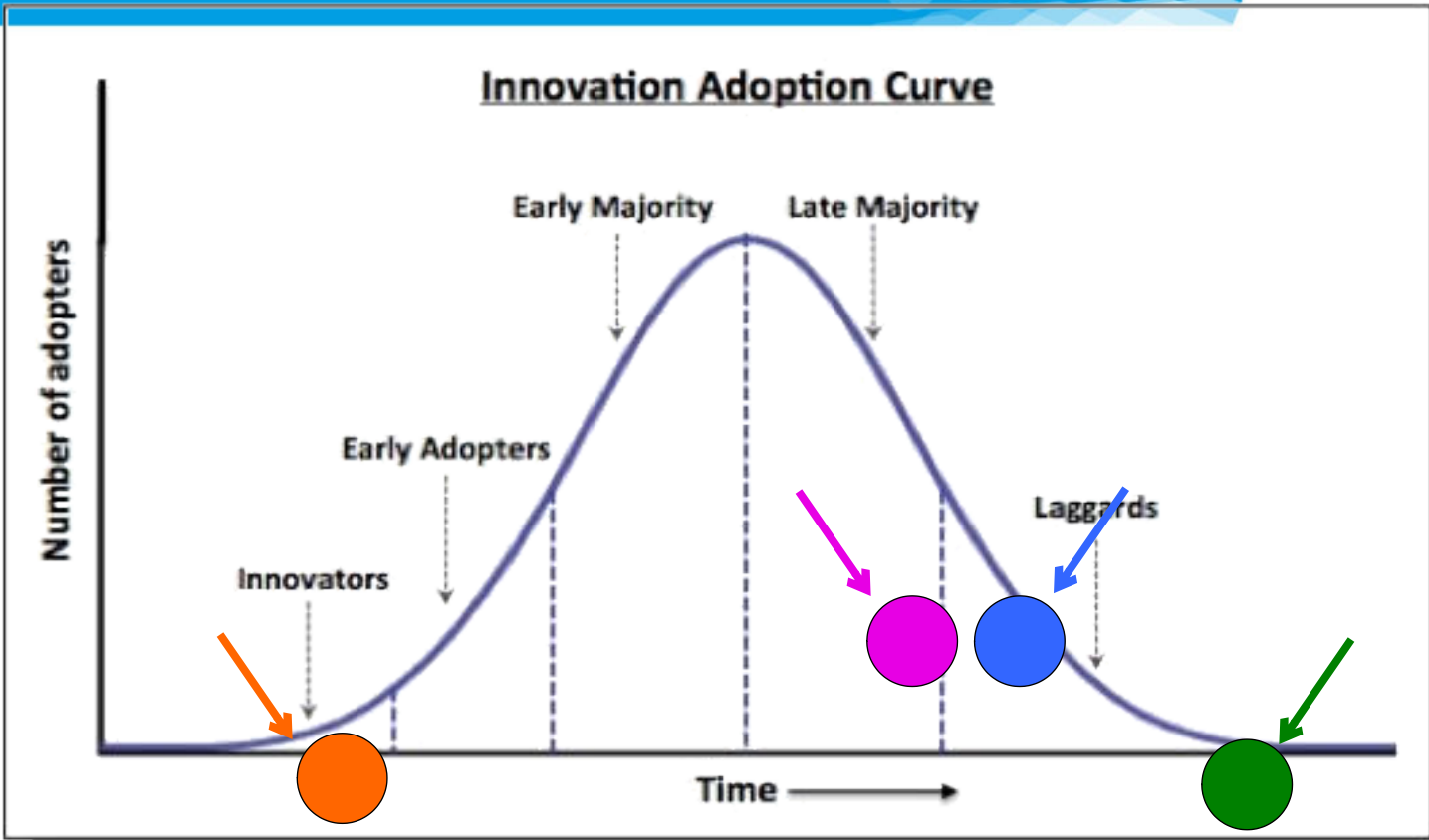
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- Laparoscopic cholecystectomy
- Robotic NS prostatectomy
- Laparoscopic LD nephrectomy
- Laparoscopic/robotic transplantation



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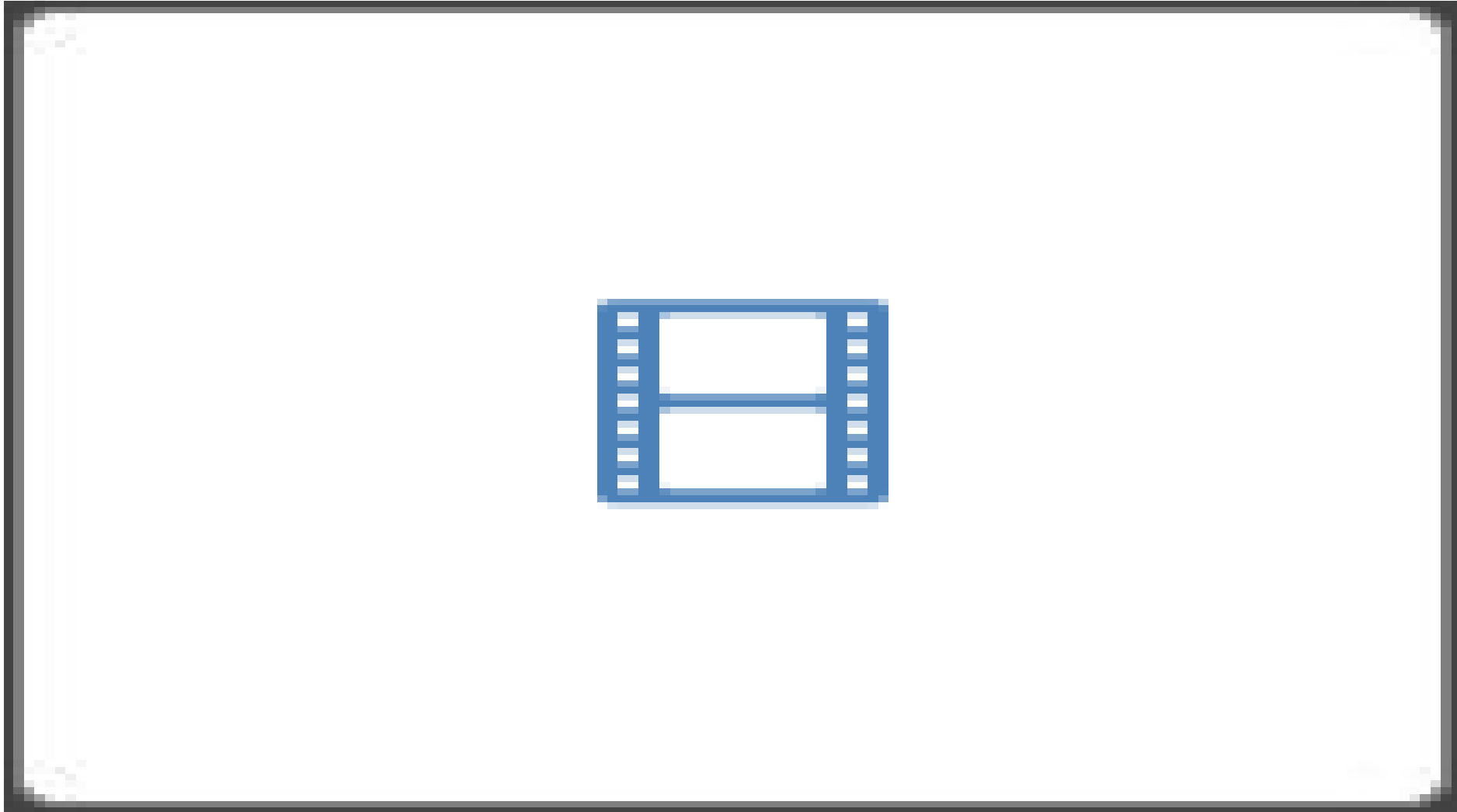
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Robotic Kidney Tx in ADPKD Recipient

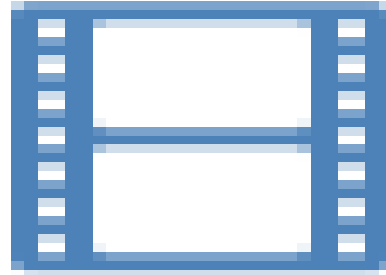


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Robotic Kidney Tx in ADPKD Recipient

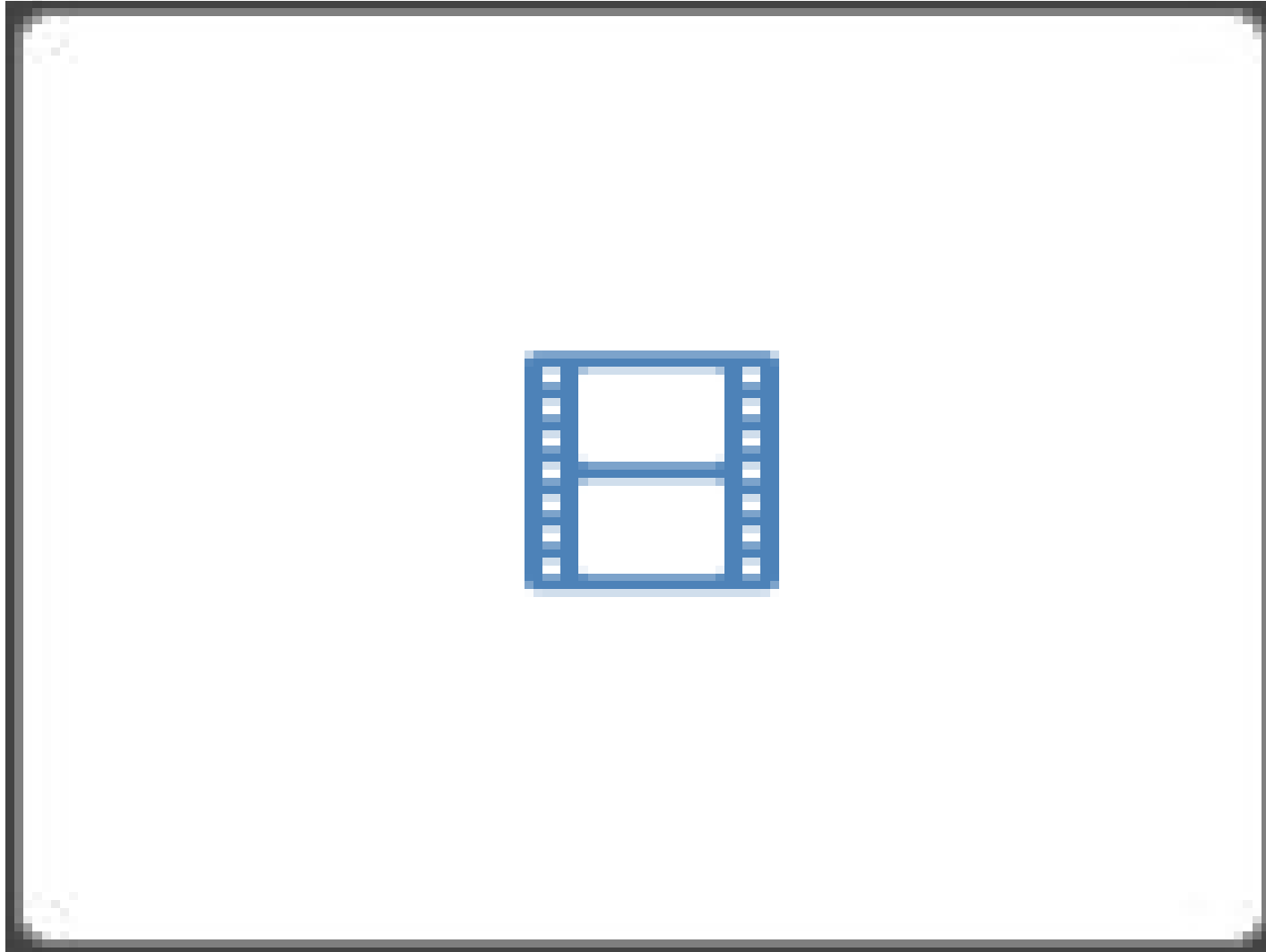


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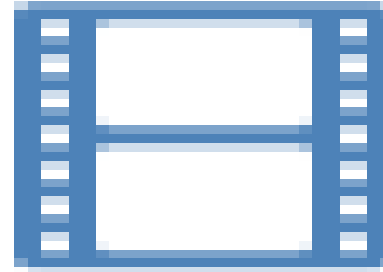
Robotic Kidney Tx in ADPKD Recipient



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Robotic Kidney Tx in ADPKD Recipient

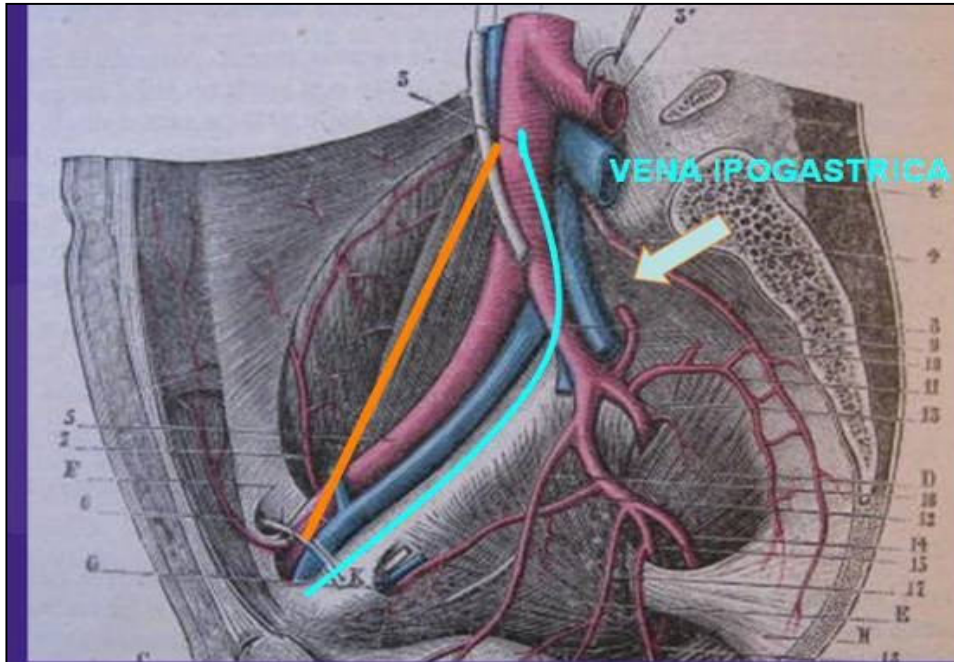


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SURGICAL APPROACH FOR DONOR NEPHRECTOMY



Vena iliaca comune e vena iliaca esterna formano un angolo aperto in avanti e in alto che si annulla legando le vene ipogastriche consentendo di trapiantare reni con vena renale cortissima

E' tecnica delicata per il rischio di emorragie ma permette di annullare in pratica questo problema

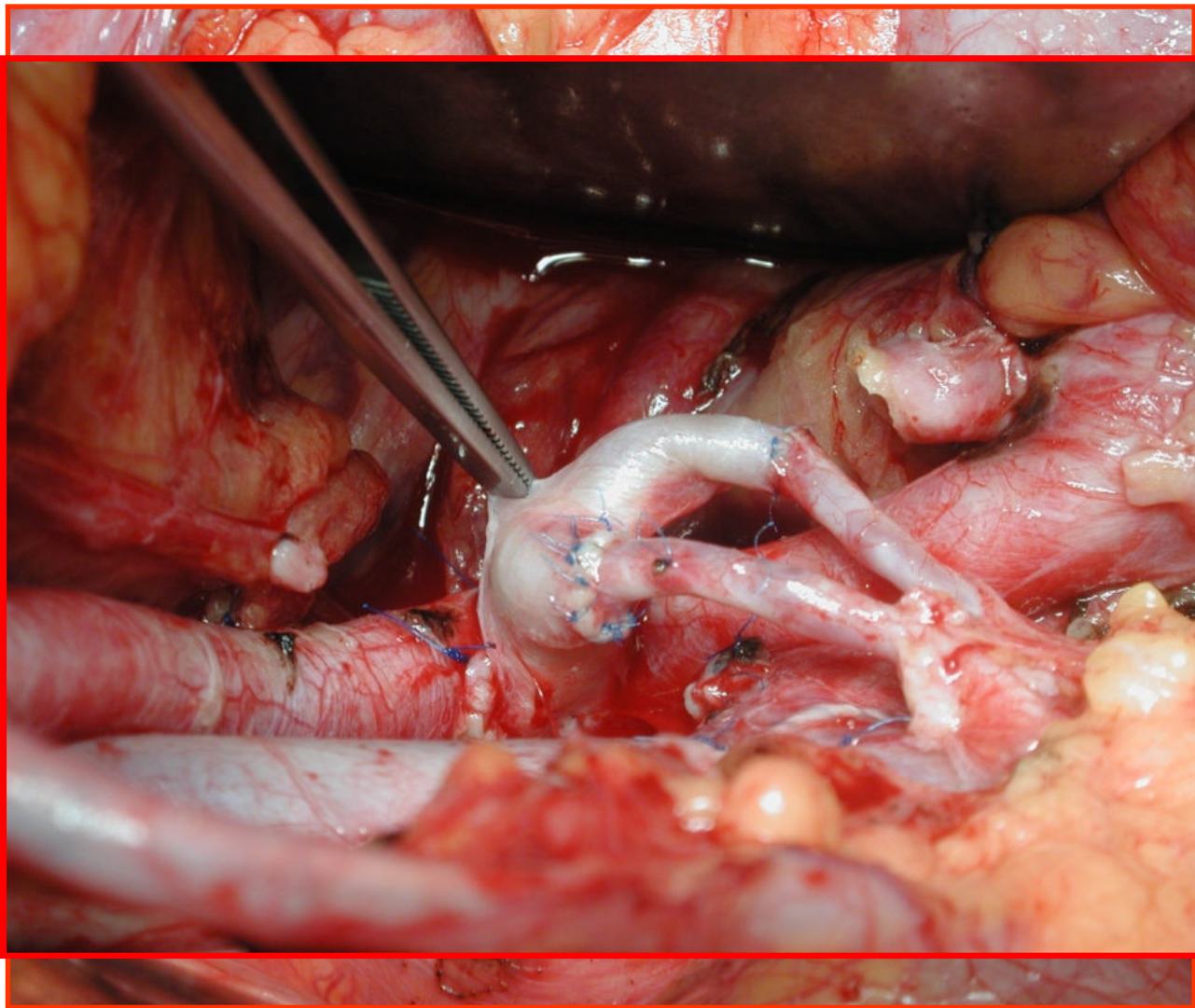
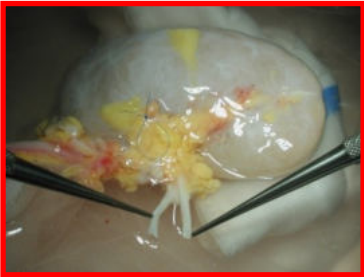
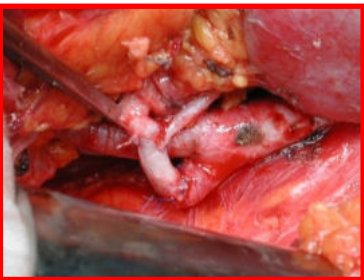
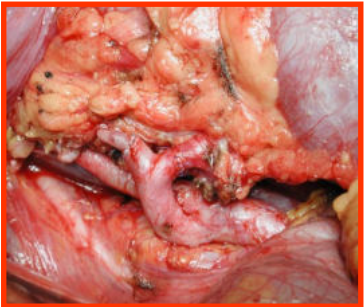


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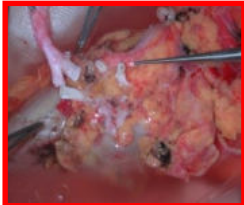
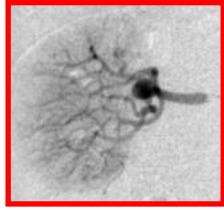
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17.7: We suggest laparoscopic procurement of the right rather than the left living donor kidney may be performed if the surgeon has adequate training and experience. (2D)

17.8: Procurement of a living donor kidney with 3 or more arteries should only be undertaken by surgeons with adequate experience.

17.9: A donor candidate with atherosclerotic renal artery disease or fibromuscular dysplasia involving the orifices of both renal arteries should not donate.



CONCLUSION

LD renal transplantation should be fully developed (in Italy). Ageing of deceased donor population further underscore this need.

DONOR SAFETY accepts no compromise. Surgeons involved in donor nephrectomy, as well as the entire transplant team, should be therefore proficient with the operation, confident with all new technologies, aware of possible complications, and ready to face them.

DONOR DEATH is expected to occur rarely (currently 0.03%), but probably cannot be totally avoided. Surgeons, and the health system, should be therefore prepared to face the negative consequences that this terrible occurrence may have on the public opinion and the medical community.

Minimally invasive techniques may be safely employed in most donors.



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A mind is like a parachute. It doesn't work if it is not open

Frank Zappa



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