GUIDELINES

Recommendations for Evaluation and Selection of Deceased Organ Donor: Position Statement of ISCCM

Kapil G Zirpe[1], Anand M Tiwari[2], Rahul A Pandit[3], Deepak Govil[4], Rajesh C Mishra[5], Srinivas Samavedam[6], Palepu B Gopal[7], Atul P Kulkarni[8], Subramanian Swaminathan[9], Subhal B Dixit[10], Arindam Kar[11], Rajesh K Pande[12], Dhruva Chaudhry[13]

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Abstract

There is a wide gap between patients who need transplants and the organs that are available in India. Extending the standard donation criterion is certainly important to address the scarcity of organs for transplantation. Intensivists play a major role in the success of deceased donor organ transplants. Recommendations for deceased donor organ evaluation are not discussed in most intensive care guidelines. The purpose of this position statement is to establish current evidence-based recommendations for multiprofessional critical care staff in the evaluation, assessment, and selection of potential organ donors. These recommendations will give "real-world" criteria that are acceptable in the Indian context. The aim of this set of recommendations is to both increase the number and enhance the quality of transplantable organs.

Keywords: Brain death, Donor age, Donor evaluation, Expanded criteria donor, Intensivist, Transplantation.

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Introduction

Organ transplantation is a lifesaving procedure for many patients with end-stage organ failure. In India, in 2018, the deceased donor organ donation rate was 0.65 per million population.[1] The growing disparity between the increasingly huge demand for organ transplants and the low incidence of actual transplants is concerning. One of the important causes for disparity is the determination of contraindication and failure to evaluate potential donor. The coronavirus disease-2019 (COVID-19) pandemic has further led to a significant decrease in organ donations globally, and India is no exception.[2] The organ supply crisis imposes a compelling obligation on the transplant community to maximize the use of organs obtained from all deceased donors. The relative scarcity of organ donors has sparked debate on the use of borderline donors, emphasizing the importance of evaluating expanded criteria for potential donors. Deceased donation program will achieve momentum with timely identification and early referral of all potential donors (Fig. 1).[3]

Objective

The purpose of this position statement is to establish recommendations for multiprofessional critical care staff in the evaluation, assessment, and selection of potential organ donors. These recommendations will give "real-world" criteria that are acceptable in the Indian context. The aim of these set of recommendations is to increase the number and enhance the quality of transplantable organs.

Methodology

Evaluation and recommendation for each individual organ is mentioned as per available current literature and evidence. The major database for the review was MEDLINE, which was accessible using the PubMed service. The PICO methodology of structured inquiries was used in the search. Using the MeSH (Medical Subject Headings),

[1]Department of Neuro Trauma Unit, Grant Medical Foundation, Pune, Maharashtra, India

[2]Department of Neuro Trauma Unit, Ruby Hall Clinic, Pune, Maharashtra, India

[3]Department of Critical Care Medicine, Fortis Hospital, Mumbai, Maharashtra, India

[4]Institute of Critical Care and Anesthesia, Medanta – The Medicity, Gurugram, Haryana, India

[5]Department of MICU, Shaibya Comprehensive Care Clinic, Ahmedabad, Gujarat, India

[6]Department of Critical Care, Virinchi Hospital, Hyderabad, Telangana, India

[7]Hyderabad, Telangana, India

[8]Division of Critical Care Medicine, Department of Anaesthesia, Critical Care and Pain, Tata Memorial Hospital, Homi Bhabha National Institute, Mumbai, Maharashtra, India

[9]Department of Infectious Diseases, Gleneagles Global Hospital, Chennai, Tamil Nadu, India

[10]Department of Critical Care, Sanjeevan and MJM Hospital, Pune, Maharashtra, India

[11]Calcutta Medical Research Institute, Kolkata, West Bengal, India

[12]Department of Critical Care, BLK Superspeciality Hospital, New Delhi, India

[13]Department of Pulmonary and Critical Care Medicine, University of Health Sciences, Rohtak, Haryana, India

Corresponding Author: Anand M Tiwari, Department of Neuro Trauma Unit, Ruby Hall Clinic, Pune, Maharashtra, India, Phone: +91 7798255626, e-mail: dranandtiwari@gmail.com

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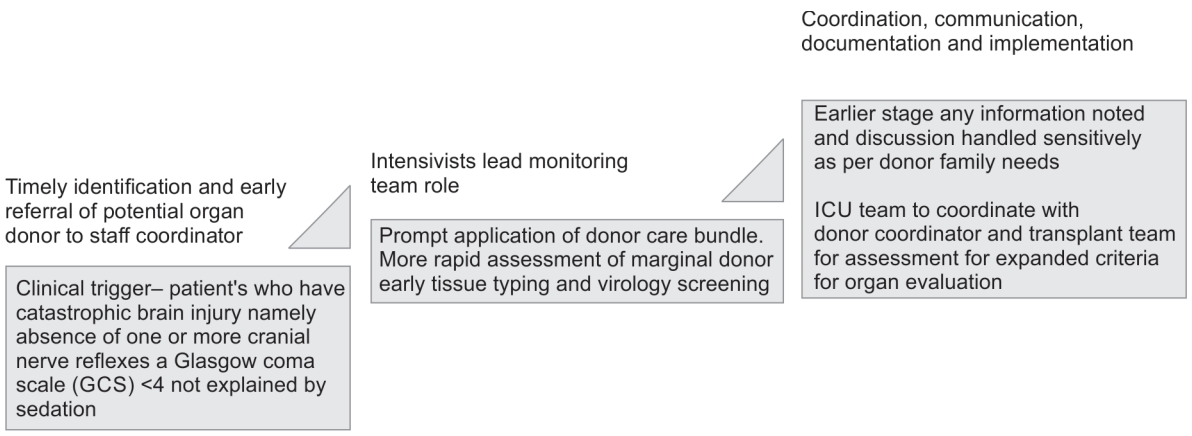

Fig. 1: Steps for improving the identification, referral, and evaluation of potential donor

the following key word combinations were used: (Organ donation OR brain death AND (Organ donor OR donor), (recommended OR consensus), OR lung transplantation OR management), donor OR donor management OR donor with expanded criteria), (organ donor AND kidney donor), brain-death organ donor AND management OR kidney transplantation), (organ transplantation) (cadaveric donor AND timing AND liver transplantation), (increased donor pool AND liver OR marginal donor liver) AND outcome or Extended criterion donor), (OR cardiac transplantation OR heart donor management) OR Pancreas transplant OR decease donor Intestinal transplant) OR deceased donor COVID or Deceased donor with VITT).

Identification, screening, selection, and recommendation are done as per steps shown in Figure 2.

The recommendation when graded as Grade A indicates benefits outweighing the risk, Grade B indicates that the benefits are likely to outweigh the risk, although more research is needed, and Grade C indicates that the benefits and risks must be assessed on a case-to-case basis.

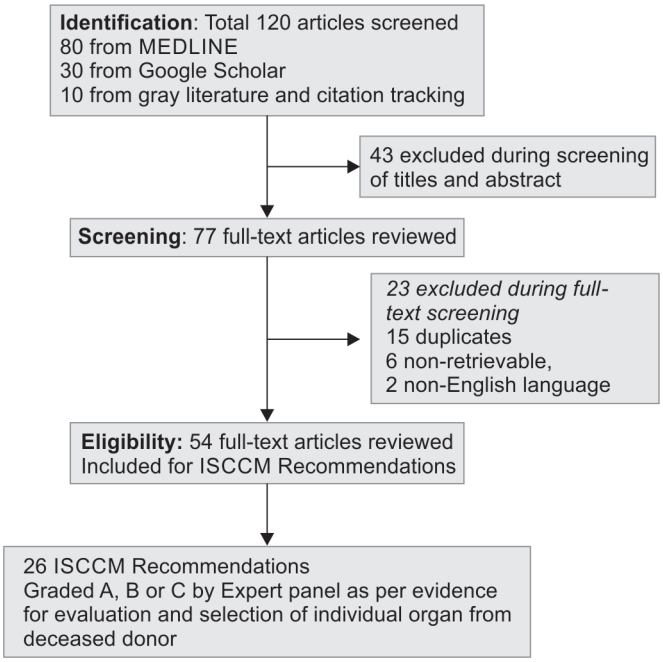

Fig. 2: Methodology

Evaluation and Selection of Potential Brain-dead Donor

The intensivist plays a critical role in identifying potential donor. In the intensive care setting, however, potential brain-dead donor detection and referral may be suboptimal. Lack of specific training and the need to provide concurrent urgent care to other critically ill patients are the factors that influence lower detection and referral rates.[4] A long period of time between the first clinical test for brain dead (BD) diagnosis and organ procurement may be an important risk factor for cardiac arrest in deceased potential donors and consequent loss of potentially available organs.[5]

Recommendation 1: *Indian Society of Critical Care Medicine (ISCCM) recommends early detection and assessment of potential brain-dead donor (Grade A).*

Families of potential donors' refusal to give consent is a first rate-limiting step in conversion rate after the timely detection of deceased donors. Rates of consent vary greatly across the globe. Consent for organ donation is, by definition, more complicated than consent for most medical procedures.[6] There is a link between the information discussed during the request for organ donation and the rate of consent for organ donation.[7]

Recommendation 2: *ISCCM recommends communication be carried out in a private setting, in a stepwise fashion with temporal separation (decoupling) regarding notification of brain death acceptance by the family and request for organ donation. Furthermore, there should be a distinction between the treating team announcing brain death and the one initiating the conversation about organ donation. To maintain public trust and avoid potential conflicts of interest. Once initiated, the treatment team may attend additional family meetings (Grade A).*

ISCCM recommends trained intensivist to play key role along with donor coordinator regarding communication and obtaining consent (Grade B).

Deceased organ donors (brain death) are divided into two categories: standard criteria donors (SCD) and expanded criteria donors (ECD) (Fig. 3).

The term "expanded criteria donor" (ECD) was coined by Kauffman et al.[8] in 1997 to characterize transplantable organs that do not match the requirements for standard donor organs. ECD provides an opportunity to close the growing gap between the demand for and supply of donated organs.[9]

Recommendation 3: *ISCCM recommends that intensivists should aim to increase organ availability; and adopt new approaches for screening and selection, based on emerging evidence, that permits the successful harvest of deceased donor organs that were previously considered unusable (Grade B).*

Intensivist-led team should perform continuous evaluation of the deceased organ donor, multidisciplinary briefings, and thorough clinical information sharing with surgeons and other specialists. This is in an attempt to improve donor care by evaluating specific organs and monitoring their performance.

Recommendation 4: *ISCCM recommends that intensivist should play a central role in evaluating the deceased donor. Intensive care team should obtain detailed clinical and behavioral history, ensure cause of brain death, perform meticulous physical examination and follow investigations (biochemistry and radiological) as suggested in* Table 1 *(Grade A).*

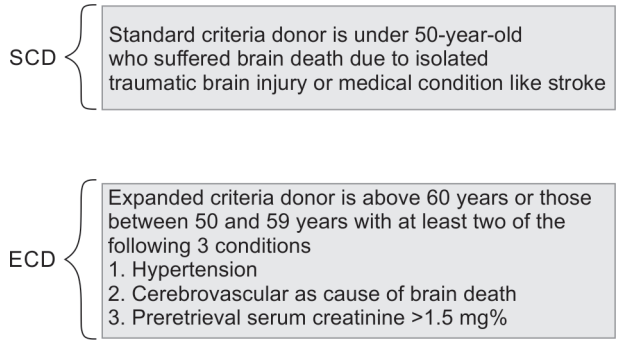

Fig. 3: Categories of deceased organ donor

Tests and evaluation of deceased donors are done with aim to minimize the risk of transmission of two major diseases: infections and malignancy to the recipient. As a result of intensive care and invasive resuscitative measures, bacterial and fungal colonization or infection is frequently detected in potential organ donors.[10] Goal of screening by intensive care team is to identify and look for unacceptable risk of transmission pragmatically, and not for all kinds of infections. The suggested list of absolute contraindications is shown in Table 2.

Recommendation 5: *ISCCM recommends that blood cultures be taken from deceased donor. Donor with active bacterial infections should receive organism specific antibiotics for 48 hours before organ procurement. This should be communicated with the transplant intensivist/ transplant surgeon, so that the recipient receives pathogen specific antibiotics for 7–10 days (Grade B).*

It is necessary to define the acceptable risk of employing previously judged poor organs as well as a risk-benefit analysis that patients can understand.[11] Regulatory bodies like the National Organ and Tissue Transplant Organization (NOTTO) will also have to recognize the need to increase awareness of ECD as applicable to various organs so that many patients waiting for organ transplants will get organs from deceased donors, leading to increased number of lives saved.

Recommendations for Specific Organs from Deceased Donor

Kidney

Kidney transplantation is the therapy of choice for individuals with end-stage renal illness; successful kidney transplantation improves both quality and length of life, even when dialysis is an option.[12,13]

Table 1: Highlights of donor evaluation parameters

All donors	Blood, urine sputum culture Electrolytes CBC, hemodynamics Intake/output Medication and vasopressor Chest X-ray	Age, ethnicity, height, weight, clinical course, medical/social history Physical assessment, ABO blood group and Rh typing, HLA typing, Infectious disease testing
Kidney	Urine analysis, biopsy if indicated	
Liver	AST, ALT, alkaline phosphatase, total and direct bilirubin, Gamma-glutamyl transferase	PT/INR, PTT, biopsy if indicated
Heart	12-lead ECG, 2D ECHO heart cardiac enzymes CPK-MB, NTpro-BNP	Cardiology consult Cardiac catheterization based on donor characteristics
Pancreas	Serum amylase, serum lipase	
Lungs	ABG, sputum Gram stain, culture	Chest X-ray, bronchoscopy
Notes- Additional	Any organ system COVID-19 RT-PCR	Based on donors' clinical presentation USG, CT scan, MRI, X-ray additional laboratory work

CBC, complete blood count; HLA, human leukocyte antigen; PT, prothrombin time; INR, international normalized ratio; PTT, partial thromboplastin time; ECG, electrocardiography; 2DECHO, two-dimensional echocardiography; CPK, MB, creatine phosphokinase myocardial band; NTpro-BNP, N-terminal prohormone B-type natriuretic peptide; COVID-19 RT-PCR, coronavirus disease-19 reverse transcription polymerase chain reaction; USG, ultrasonography; MRI, magnetic resonance imaging

Table 2: List of infections and malignancies in deceased donor, which are absolute contraindications

Infections	*Malignancies*
Severe systemic infections, intracellular pathogens like *Listeria* and *Trypanosoma*	Metastatic malignant neoplasm
Untreated and unknown origin	Acute leukemia in progress
Uncertain encephalitis of viral origin	Acute lymphoma
Febrile meningoencephalitis of unknown origin	Melanoma with <5-year follow-up
Active infection due to fungi or another opportunistic organism	Pulmonary microcytoma
Infection with no treatment options, like rabies, dengue within their infectious/transmissible period	Multiple myeloma in progress

Expanded criteria donor for kidney includes deceased donor above 60 years or those between 50 and 59 years with at least two of the following three conditions.[9]

- Hypertension
- Cerebrovascular as cause of brain death
- Pre-retrieval serum creatinine >1.5 mg%

Recommendation 6: *ISCCM recommends evaluation and use of kidney from expanded criteria donor in selected patients (Grade B).*

Dual kidney transplantation (DKT) is a safe and effective method of using kidneys from deceased donors over the age of 70. Despite older donors having higher serum creatinine levels, diabetes, kidney donor profile index (KDPI), and kidney donor risk index (KDRI), DKT provides comparable graft survival and graft function to a single expanded criteria donor kidney transplant (ECD KT).[14]

Recommendation 7: *ISCCM recommends double kidney transplant from donors above 70 years, after meticulous evaluation and selection and communication with recipient whose outcome is poor without procedure (Grade C).*

Kidneys from select donors with acute kidney injury (AKI): According to the findings by Heilman et al.,[15] there is a significant opportunity to increase the use of kidneys from donors who had AKI. They reported one of the largest studies involving transplanting kidneys from deceased donors with severe AKI. There was no significant difference in graft survival when comparing outcomes of recipients who received kidney from donors with and without AKI group.

Recommendation 7: *ISCCM recommends KT from deceased donor with AKI in selected cases (Grade B).*

Preimplantation Kidney Biopsy

Even when evaluated by specialist pathologists, the overrepresentation of glomerulosclerosis (GS) in wedge biopsies remains a problem. To maximize the use of ECD kidneys, standardizing the type of biopsy to one with the least sampling error and developing a specialist on-call pathology service should be considered.[16]

Recommendation 8: *ISCCM recommends preimplantation tissue biopsy in indicated cases to be confirmed and reported by specialist pathologist before organ refusal (Grade C).*

Kidney Transplantation from a Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)-positive Patient

Koval et al. reported a case series of 10 cases of kidney transplantation from selected donors with detectable (SARS-CoV-2) RNA that resulted in successful short-term outcomes.[17] There were no clinical signs of SARS-CoV-2 infection in recipients, and there were no transmission events to organ procurement teams.

Meshram et al., published a preliminary report on kidney donation in a virologically negative and recovered deceased donor who was admitted with a critical COVID-19 infection.[18]

Recommendation 9: *In the absence of sufficient data, ISCCM suggests balancing the risk of SARS-CoV-2 transmission, its potential effects on allograft quality, and the risk to procurement teams with the recipient's risk of mortality and other waitlist complications (Grade C).*

Liver

Age limit-deceased donation after brain death (DBD) liver transplantation has no upper age limit for donors. Aging of the liver has fewer functional consequences.[19]

Recommendation 10: *ISCCM recommends not to consider age limit as criteria for refusal of deceased liver donor. ISCCM suggests that liver from older donors should be accepted, if other selection criteria are fulfilled (Grade B).*

Electrolyte imbalance, notably hypernatremia, is common in patients diagnosed with brain death. Serum sodium >160 mEq/L is presumed to be associated with primary graft failure. Hypernatremia was identified to be a risk related to graft loss in retrospective investigations, which were database review. However, Magnus et al., reported no clinical impact of serum sodium on post-transplant liver function.[20] They reviewed organ procurement records of 1,013 consecutive deceased liver donors with no negative impact from donor hypernatremia.

Recommendation 11: *ISCCM recommends correction of sodium level if >160 mEq/L in deceased donor but higher level is not contraindication for deceased donor organ transplant (Grade B).*

Viral infections [Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), Hepatitis B surface antigen (HBsAg)]: Survival appears to be equivalent to HCV-negative donors when HCV-positive patients are transplanted with organs from HCV-positive donors.[21,22] There is limited clinical experience with HBsAg-positive donor grafts, since most transplant centers avoid using these grafts. E. Cholongitas et al., published a systematic review regarding liver graft from anti-hepatitis B core-positive donors.[23] They concluded that the liver can be used if the recipient is anti-HB-positive since the recipient's own surface antibodies will prevent hepatitis B reactivation. Antiviral medicines and immunoglobulin should be utilized if the recipient's status is negative. The prevalence of HIV varies globally. The HIV Organ Policy Equity (HOPE) Act of the US in 2013 deemed HIV as no longer an absolute contraindication to organ donation, allowing organ transplantation from a deceased HIV-positive donor to a HIV-positive recipient with end-stage organ failure. There is, however, a lack of clinical experience owing to concern regarding drug-resistant HIV transmission and a low success rate.[24]

Recommendation 12: *ISCCM recommends that liver from deceased donors who are B serology positive (except HBsAg positive) and with evidence of resolved HBV infection (positive anti-HBc alone or associated with anti-HBs) can be considered for donation in HBV carrier with minimum risk and implementation of specific antiviral prophylaxis and similarly HCV-positive deceased donor can be considered for HCV-positive recipient (Grade C). ISCCM recommends against using liver from deceased donor with HIV-positive status (Grade B).*

Model for End-stage Liver Disease (MELD Score)

Kitajima et al., reported a study comparing the outcomes of living donor primary liver transplantation (LDLT) versus deceased donor primary liver transplantation (DBD-DDLT).[25] Results of the study showed that LDLT, when compared to DBD-DDLT and donation after circulatory death-deceased donor liver transplant (DCD-DDLT), is associated with a higher risk of early graft loss, especially in patients with a MELD score of 15–29. Currently, the DCD protocol does not exist in Transplantation of Human Organ and Tissue Act (THOTA) in India. In practice, only tissues are donated following cardiac death in India. A recent meta-analysis

reported no difference in patient survival between DCD and DBD, but DCD was linked to an increased risk of graft loss.[26]

Recommendation 13: *ISCCM recommends preferring deceased donor liver transplant (DDLT) from brain death patient over the donor with circulatory death (Grade B).*

Risk of COVID-19: COVID-19 transmission from deceased donor to the recipient is a possibility. Only if the donor is COVID-19 negative and the receiver is from the same city should elective DDLT be performed. At all costs, air travel should be avoided. All donors (dead and living) and recipients should be screened for COVID-19 at the time of an emergency transplant.[27]

Recommendation 14: *ISCCM recommends RT PCR test screening for COVID-19 in all deceased donor before elective or emergency organ transplant (Grade A).*

Heart

Heart transplant is the only treatment for patients with end-stage heart failure (Table 3).[28]

Deceased Donor Characteristics

Age: The 29th adult transplant worldwide report from registry of international heart and lung transplant says that the median age of heart allograft donor has increased from 31–42 years.[29]

Gender: In heart transplant patients, negative impact was observed in male recipients who were over 45 years of age and received heart from deceased female donor.[30]

Weight or body mass index (BMI): Donor criteria for heart transplant allow allograft from donors within 20–30% of recipient weight. A study by Patel et al., reported that post-transplant survival was not affected by weight ratio, except in patients with increased pulmonary vascular resistance who received undersized heart.[31]

Donor risk factors: Diabetes and hypertension have a significant impact on post-transplant survival; both conditions have vascular effects and negative impact on recipient outcome if donor was male. These effects were not seen with female deceased donors.[32]

Donor with left ventricular hypertrophy: Increase in left ventricular wall thickness >1.4 cm was associated with poor outcome.[33]

Deceased donor monitoring: Both initial echocardiography and subsequent (pulmonary artery catheterization) PAC-guided assessment and management of potential heart donors should be considered standard practices.[35,36] Initial cardiac dysfunction on echocardiography in a deceased donor should not be criteria for refusal of organs such as the heart and kidney. Serial echocardiographic monitoring has shown a median period of roughly 48 hours from autonomic storm to recovery of cardiac function.[37]

Recommendation 15: *ISCCM recommends considering age, comorbid conditions, body weight, and morphological examination of heart in all deceased donors with aim of including marginal donors before refusal (Grade B).*

Recommendation 16: *ISCCM recommends extending donor criteria to include undersized hearts in select recipients (Grade B).*

Recommendation 17: *ISCCM recommends that for evaluation of heart function before refusal, both initial and serial echocardiographic examination be taken in to account (Grade B).*

Recommendation 18: *ISCCM recommends against using deceased donor heart with documented left ventricular thickness >1.4 cm (Grade A).*

Lungs

The old criteria for categorizing donor lungs as standard criteria were created arbitrarily based on clinical impression and experience rather than evidence from clinical trials. Extended criteria donors for lung transplantation will continue to evolve as depicted in Table 4.

Table 3: Expanded criteria for acceptable heart donors[34]

Age up to 65 years	Long-distance procurement
Undersizing/oversizing >20% of body weight	High-dose pressor requirement
Prolonged hospitalization	Correctable valvular dysfunction by echocardiography
History of chest trauma	Bypassable one- or two-vessel coronary artery disease
Elevation of myocardial enzymes level	Prolonged cardiopulmonary resuscitation >5 minute
Transient hypotension	Open cardiac massage
Wall motion abnormality by echocardiography	Persistent conduction disturbance
Cold ischemic time 4–5 hours	

Table 4: Lung transplant donor criteria[38]

Standard criteria donor	*Expanded donor criteria*
Age <55 years, ABO compatibility	Age >55 years healthy
Clear chest radiogram	
PaO_2 >300 on FiO_2—1, peep—5	PaO_2 <140 on FiO_2—0.4 or <300 on FiO_2—1
Less than or equal to 20 pack-year smoking history	Smokers more than 20 pack-year
Absence of chest trauma	Absence of history of lung disease
No previous surgery on side of harvest	Mild asthmatic donors
No aspiration or sepsis Absence of purulent secretions at bronchoscopy Sputum Gram stain free of significant no. of bacteria, fungus and WBC	

Age: Multiple studies are published with emerging evidence that lungs from older donor aged between 55 and 70 years; with absent or infrequent smoking history, showed survival non-inferior to donors in standard age group.[39,40]

Smoking: There is conflicting evidence about the use of lungs from donors who were smokers, with some trials showing similar survival.[41–43]

History of asthma: Deceased donors, who died of status asthmaticus, and have high pulmonary vascular resistance are contraindicated, asthmatics who required regular medication are high risk donors, and those with known exercise-induced asthma are considered moderate risk.[44]

History of malignancy: Donors who had localized basal cell carcinoma, *in situ* cervical cancer, primary central nervous tissue malignancy, which rarely metastasize, may be considered as donors.[45]

Recommendation 19: *ISCCM recommends careful selection of extended criteria donor for lung transplantation. Donors who are old and are chronic smokers should be strictly avoided (Grade B).*

Recommendation 20: *ISCCM recommends careful screening of history and CT scan for deceased donor for lung to rule out aspiration pneumonia before considering lung transplant (Grade A).*

Recommendation 21: *ISCCM recommends following individual institutional protocol with RT-PCR and HRCT to rule out COVID-19 in deceased donor.*

Recommendation 22: *ISCCM recommend against transplant from deceased donor with high pulmonary vascular resistance (Grade A).*

Pancreas

Pancreatic transplant alone (PTA) is a management option in diabetic patient with normal renal function, while diabetic patient with chronic kidney disease (CKD) may need deceased kidney transplant or simultaneous pancreas and kidney transplant (SPKT) or pancreas after kidney transplant (PAKT).[46] Transplantation of islets of langerhans is a good alternative to whole pancreas transplant in selected patients.[47]

Recommendation 23: *ISCCM recommends careful deceased donor evaluation with age <55 years, with morphological assessment prior to considering the donor for pancreatic transplantation (Grade B).*

Intestinal

Adult intestinal transplantation is challenging and moving slowly from rarely performed procedure in mainstream when compared to solid organ transplant.[48] One multicenter international survey reported that physicians refrain from intestinal transplant as therapeutic option.[49] Intestinal transplant tissue poses a large lymphoid load and immunological reactivity to recipient. Intestinal transplant proved to be cost-effective when compared to home parenteral nutrition in patients with irreversible intestinal failure.[50]

Recommendation 24: *ISCCM recommends that donor age for intestinal transplant be less than 50 years, no history of blunt abdominal trauma, ICU stay <1 week, and serum sodium level <155 (Grade A).*

ISCCM recommends careful donor selection with evaluation of bowel length and functioning by CT enterography apart from other tests mentioned in Table 1 *(Grade A).*

Recommendation 25: *Cold ischemic time limit for deceased donor* (Fig. 4).

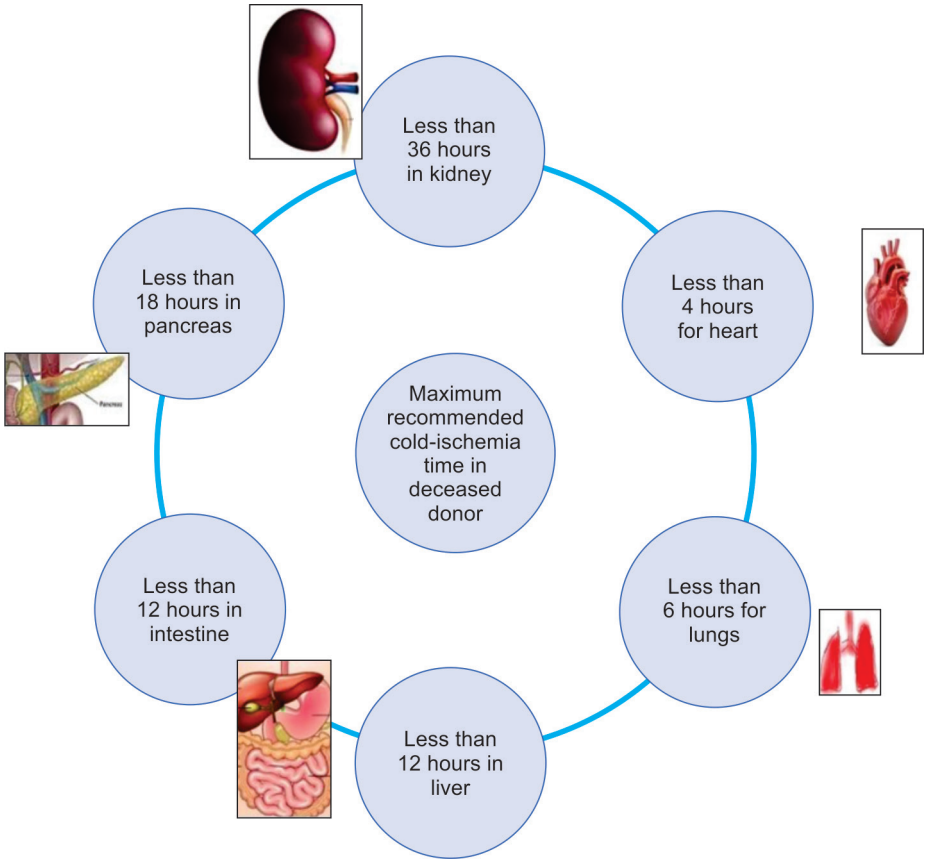

Fig. 4: Cold ischemia time limits in deceased donor

The approval criteria for organs are still varied, limiting the potential to standardize recommendations, good results have been widely reported with careful selection and short cold ischemia times. Cold ischemic time affects outcome of ECD.

Special Situations

Deceased Donor with Vaccine-induced Thrombosis and Thrombocytopenia (VITT)

VITT is reported in few patients, typically occurs between 4 and 28 days after vaccination with the ChAdOx1 nCoV-19 vaccine.[51] This rare disorder resembles heparin-induced thrombocytopenia (HIT) with the production of autoantibody against platelet factor 4 (PF4).[52] VITT can be debilitating or even fatal if left untreated.[53] Safety of organ donation from deceased donor with VITT is limited. High risk of thrombosis and bleeding in allograft has been reported in recipients who have received transplants from deceased donor with VITT.[54]

Recommendation 26: *ISCCM recommends against organ transplantation from deceased donors with VITT at present in view of lack of substantial evidence (Grade C).*

Conclusion

Recommendations for deceased donor organ evaluation are not discussed in most intensive care guidelines. Statements given in this document highlight the key role of intensivist in all phases of deceased donor transplantation, from the detection of potential brain-dead donor to organ procurement. Excellent communication and coordination between the intensivist-led critical care staff, family of deceased donor, and the transplant team is essential to ensure the optimization of both the number and quality of organs transplanted. Extending the standard donation criterion is certainly important to address the scarcity of organs for transplantation. The growing gap between supply and demand for transplants necessitates the use of organs from ECD.

Orcid

Kapil G Zirpe https://orcid.org/0000-0002-8140-727X
Anand M Tiwari https://orcid.org/0000-0002-9791-8365
Rahul A Pandit https://orcid.org/0000-0002-5846-3708
Deepak Govil https://orcid.org/0000-0002-4624-1614
Rajesh C Mishra https://orcid.org/0000-0001-6305-5998
Srinivas Samavedam https://orcid.org/0000-0001-6737-8663
Palepu B Gopal https://orcid.org/0000-0002-5261-1730
Atul P Kulkarni https://orcid.org/0000-0002-5172-7619
Subramanian Swaminathan https://orcid.org/0000-0001-7971-6842
Subhal B Dixit https://orcid.org/0000-0002-1441-0807
Arindam Kar https://orcid.org/0000-0002-0979-2927
Rajesh K Pande https://orcid.org/0000-0002-0149-727X
Dhruva Chaudhry https://orcid.org/0000-0001-5138-2908

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