

**ANNUAL TRANSPLANT
COORDINATORS' WORKSHOP
3rd CONSULTATIVE MEETING TO
IMPROVE ORGAN AND TISSUE
DONATION**

Organised by MOHAN Foundation

29th & 30th January 2016, The Radha Regent, Chennai

PROCEEDINGS

Edited by Dr. Sumana Navin

Supported by Sir Ratan Tata Trust and Navajbai Ratan Tata Trust

www.mohanfoundation.org

Foreword

The 3rd Consultative meeting brought out many interesting perspectives on tissue banking and the feasibility of Donation after Circulatory Death (DCD) in India.



Dr. Sanjay Deshpande & Ms. Michelle Hunter from NHS Blood and Transplant (NHSBT), UK and Dr. Vijayanand Palaniswamy from Australia shared their extensive experience in DCD in these countries. The DCD protocols followed in the UK and Australia are extremely robust. Dr. Anand K. Khakhar spoke about DCD in India. The consensus was that national guidelines are required before this kind of donation takes centre stage in India. Dr. Malvinder Singh Sahi's session on 'Ethical issues in End of life care' sparked an impassioned debate on passive euthanasia and the economic implications of ICU care. Dr. K. R. Balakrishnan spoke about the development of an affordable organ preservation system. The panel discussion on unusual case studies (DCD and DBD) had valuable take-home messages on how to handle difficult situations on the ground.

Tissue Banking is slowly coming of age in India. Dr. Sunil Keswani (skin banking), Dr. Ajoy S M (bone banking), and Dr. R. R. Sudhir (eye banking) are doing exemplary work in India. Dr. Alvin Chua spoke about the Singapore experience in setting up a multi-tissue bank facility and on the stringent requirements to ensure safety and quality in tissue banking. The participants and the experts felt that a needs assessment for tissues in India (with inputs from surgeons) needed to be done before NOTTO/ROTTTO/SOTTO ventured into this field. A visit to the NHSBT Tissue Services in Speke, Liverpool was also recommended. This sprawling facility started in 2005, is the hub for the coordination, retrieval, processing, banking and supply of human tissue grafts – bone, skin, cardiovascular, tendons and eyes. They bank and supply tissue grafts from around 400 deceased tissue donors per year and respond on a 24-hour basis to over 6,000 donor referrals.

The success story of the deceased donation programme in Kerala was shared by Dr. Thomas Mathew, Convenor and Dr. Noble Gracious, Nodal Officer, Kerala Network for Organ Sharing. The session on ‘Getting financial help for transplant surgery’ by Ms. Aneka Paul, Sir Ratan Tata Trust, Mumbai set the stage for a more detailed workshop on ‘Transplant economics’ to be held later this year. The meeting ended on a lively note with the auction of a line of jewellery inspired by the green ribbon motif symbolising ‘recycling’ oneself through organ donation. The necklaces and bracelets were designed by Mrs. Bhavna Jagwani, Convenor, MFJCF and a pioneer in the field of eye banking in Rajasthan.

The proceedings of previous meetings as well as this one are available on our website - <http://www.mohanfoundation.org/proceedings/index.asp>

It is recommended that the proceedings be read in conjunction with the resource manual that is also available on this link.

Dr. Sumana Navin
Course Director

Dr. Sunil Shroff
Managing Trustee



Programme Schedule

Friday - 29th January 2016

Time	Session	Speaker	Chair person
9.30am - 9.35am	Welcome Address	Dr. Sunil Shroff, Managing Trustee, MOHAN Foundation	
9.35am - 10.30am	DCD process	Dr. Sanjay Deshpande NHSBT, UK	Dr. Rajasekhar Perumalla
10.30am - 11.15am	Specialist Nurse in Organ Donation (SNOD) – Perspective on DCD	Michelle Hunter NHSBT, UK	Dr. Rajasekhar Perumalla
11.15am - 11.30am	Tea break		
11.30am - 12noon	Consent process video	NHSBT, UK	Mrs. Lalitha Raghuram Dr. Sumana Navin
12noon - 12.30pm	Organ Donation UK 2020	Dr. Sanjay Deshpande NHSBT, UK	Mrs. Lalitha Raghuram Dr. Sumana Navin
12. 30pm - 1.00pm	DCD in India	Dr. Anand K Khakhar, Apollo Hospitals, Chennai	Dr. Sunil Shroff Dr. Sanjay Deshpande
1.00pm - 1.30pm	Q & A	Dr. Sanjay Deshpande, Michelle Hunter & Dr. Anand Khakhar	
1.30m - 2.15pm	Lunch		
2.15pm - 3.15pm	Current scenario in skin banking in India; Challenges in establishing and running a skin bank	Dr. Sunil Keswani National Burns centre	Dr. V. B. Narayana Murthy
3.15 pm - 4.00pm	Quality management in tissue banking	Dr. Ajoy S M Department Of Orthopaedics, MSRMC & H QCO M S R Tissue Bank, Bengaluru	Dr. R. Krishnamoorthy Mr. C. E. Karunakaran
4.00pm - 4.15pm	Ex-vivo cardiac care system – an experiment into future	Dr. K. R. Balakrishnan, Fortis Malar Hospital, Chennai	Ms. Pallavi Kumar Dr. Hemal Kanvinde
4.15pm - 4.30pm	Tea		
4.30pm - 5.30pm	Panel Discussion – Unusual case studies	Dr. K.R. Balakrishnan Dr. Akila Rajakumar Dr. P. Magesh Dr. R. Radhakrishnan Dr. Arulraj Dr. R. Kanimozhi Mr. K. Prakash	Moderator – Dr. Sunil Shroff

Saturday - 30th January 2016

Time	Session	Speaker	Chair person
9.30am - 10.10am	Current trends in eye banking in India; Challenges in establishing and running an eye bank	Dr. R. R. Sudhir Sankara Nethralaya, Chennai	Dr. M. Ananda Babu Chief Cornea Surgeon, Regional Institute of Ophthalmology and Government Ophthalmic Hospital, Chennai, Chennai
10.10am - 11.00am	Towards a multi-tissue bank facility - The Singapore experience	Dr. Alvin Chua Assistant Director, Transplant Tissue Centre, Singhealth Clinical Scientist & Deputy Head, Skin Bank Unit, Department of Plastic, Reconstructive & Aesthetic Surgery, Singapore General Hospital	Dr. Sunil Shroff Mrs. Lalitha Raghuram
11.00am - 11.15am	Tea break		
11.15am - 12noon	Ethical issues in End of life care	Surgeon Captain Malvinder Singh Sahi, Senior Consultant, Critical Care & Head, Pain Management Rajiv Gandhi Cancer Institute & Research Centre, New Delhi	Dr. B. Subba Rao Dr. N. Sridhar
12.noon – 1.00pm	Procurement and sterilization of tissues	Dr. Alvin Chua	Ms. Pallavi Kumar
1.00pm - 2.00pm	Lunch		
2.00pm - 2.30pm	Australian perspective on DCD	Dr. Vijayanand Palaniswamy, Intensive care consultant, Royal Darwin Hospital, Darwin, Australia	Dr. Sunil Shroff Dr. N. Sridhar
2.30pm – 3.00pm	Kerala Network for Organ Sharing (KNOS) – Forging ahead	Dr. Noble Gracious, Nodal Officer, KNOS	Dr. Thomas Mathew Dr. N. Sridhar Dr. Vijayanand Palaniswamy
3.00pm – 3.15 pm	Getting financial help for Transplant surgery	Ms. Aneka Paul Sir Ratan Tata Trust	Dr. Georgi Abraham
3.15pm – 3.45pm	Valedictory function	Dr. Georgi Abraham Dr. J. Amalorpavanathan	

DAY 1: 29th January 2016

INAUGURATION

The inauguration started with a powerful invocation by Mrs. Lalitha Raghuram, Country Director, MOHAN Foundation followed by lighting of the lamp by the special invitees – Dr. Alvin Chua, Dr. Sanjay Deshpande and Michelle Hunter, NHSBT, UK and Ms. Aneka Paul. Dr. Sunil Shroff, Managing Trustee, MOHAN spoke on the importance of donation after circulatory death. Dr. Sanjay Deshpande released the 46th issue of the Indian Transplant Newsletter.



Release of Indian Transplant Newsletter at the inauguration

From left: Mrs. Lalitha Raghuram, Dr. Sunil Shroff, Dr. Alvin Chua, Dr. Sanjay Deshpande, Dr. Sumana Navin

DONATION AFTER CIRCULATORY DEATH (DCD)

Speaker - Dr. Sanjay Deshpande, Clinical Lead for Organ Donation, NHSBT, UK

Chairperson – Dr. Rajasekhar Perumalla



Tyne in the Northern region of UK where Dr. Deshpande comes from has a deceased organ rate of 30 per million population, which is the highest in the country. The renowned Freeman Hospital is situated in the region.

Dr. Deshpande said that three people die every day in the UK waiting for an organ. The Organ Donation Taskforce in 2008 made 14 recommendations to increase organ donation in the country. One of them was to appoint Clinical Leads for Organ Donation (CLODs) and Specialist Nurses in Organ Donation (SNODs). As a result of the implementation of the recommendations, organ donation increased by 50% in 2013. In fact in 2013-14, there were 1320 deceased organ donors compared to 809 deceased organ donors in 2007-8, which was an increase of 63.2%. Out of the 1320 deceased organ donors, 539 were DCD donors and 781

were DBD (Donation after Brain stem Death) donors. He added that evidence suggests that kidneys retrieved from DCD donors have the same outcome as those from DBD donors.

He explained that DCD is when organ donation takes place after treatment withdrawal and circulatory arrest. The advantages of DCD are that it provides further donation opportunities for people who wish to be organ donors after their death and it is also an ethically acceptable means of increasing the availability of deceased donor organs. The challenges faced are how to recognise DCD donors, how to support and maintain trust of bereaved families, and how to manage warm ischaemia time. He outlined the Modified Maastricht Classification of DCD (5 categories).

Dr. Deshpande pointed out that UK had the largest DCD programme in the world. The ethical, legal and professional framework that underpinned the deceased organ donation programme in the UK was arguably the strongest in the world. The framework was clear and unambiguous and a number of policies and documents had been put in place by the UK Donation Ethics Committee (UKDEC), an independent body, hosted by the Academy of Medical Royal Colleges. He emphasised that the decision to withdraw life sustaining treatment was made because the goals of such treatment were not achievable and was made in the patient's best interests (this includes the wishes, feelings, beliefs and values of the patient). The confirmation of death using cardio-respiratory criteria was defined (Dead donor rule - 5 minutes asystole) in the document 'A code of practice for the diagnosis and confirmation of death.' In summary, for a successful DCD, he said that the decision to withdraw treatment should be made independent of any subsequent considerations of organ donation after death, family consent needed to be obtained, and communication and teamwork between the hospital teams was critical. Organs needed to be retrieved within five hours of withdrawal and tissues within 24 hours of death. There are standard protocols and documents (Withdrawal of Treatment Plan and Critical Care Treatment Planning Document) that are followed. This eliminates consultant to consultant variation and provides robust evidence that the donation practice and non-donation practice are the same.

Rapporteur – Dr. Sumana Navin

DCD PROCESS - ROLE OF SPECIALIST NURSE

Speaker - Ms. Michelle Hunter, Specialist Nurse - Organ Donation, Northern Team, NHSBT, UK

Chairperson – Dr. Rajasekhar Perumalla



Ms. Hunter said that the Specialist Nurse - Organ Donation (SNOD) was the lynchpin in the DCD process, and that she emphasised to all units that if there was no referral there was no donor. There was 100% referral for all DBDs in 14 hospitals in the Northern region. There was 90% referral for DCDs (many of them had terminal illnesses). She took the participants through a visual timeline of the donation process (DCD) and also outlined the role and responsibilities of the SNOD. The decision on futility of treatment is made independent of organ donation. This is shared with the SNOD (referral). Two separate conversations are needed with the family– one about withdrawal of care and once that is understood, the conversation on organ donation takes place. The SNOD checks with the family about the patient’s wishes and if he is on the Organ Donor Register. Ms. Hunter

reiterated that the patient was to be treated with dignity and respect at all times. It is important to answer the concerns of the family and it may take time, but the presence of the SNOD increases the chance of consent. And it is only the SNOD who can take written consent from the family. The fact that the donation process could be lengthy should be explained to the family as well as the protocol involved in Withdrawal of Life Sustaining Treatment (WLST). The DCD process is very emotive, long and resource intense, but has immense potential to offer comfort to donor families.

After Ms. Hunter's session, an NHSBT video showing both a poor and good family approach for organ donation was screened. The audience then interacted with the faculty and gave their inputs.

Q & A with Ms. Michelle Hunter and Dr. Sanjay Deshpande

Q. Do families mistrust hospitals and doctors in the UK and do they say 'No' to organ donation because of this?

A. Ms. Hunter - One of the biggest reasons families say 'No' is because they are angry at the hospital. They feel that something was not done. This doesn't necessarily mean ICU care, but it could be something in the Emergency department, the ambulance service. Give them time to express their concern/anger and then go through the process to help them understand what the doctors have done.

Q. What has been your experience with the Black Asian Minority Ethnic (BAME) community?

A. Ms. Hunter - We give everyone the option of organ donation. We have visited all religious places. The younger generation takes leaflets, but wants to talk to their elders before making a decision.

Q. Are families offered the opportunity to observe brain stem death testing?

A. Dr. Deshpande said that a formal offer could be made to the family to observe the second set of brain stem death testing. Ms. Hunter added that very few families actually take up the offer. If the family has difficulty understanding the testing, go through the whole incident step by step. It will give the family clarity; that

everything has been done correctly. Some families need something tangible, so showing them the CT scan with a midline shift helps. It is important that consistent and clear information is provided by all members of the health care team to establish trust.

Q. Why are two sets of brain stem death tests done?

A. The second set of brain stem tests is done to confirm the results of the first testing and to avoid bias. The time of death is the set of first brain stem death tests.

Q. What kind of ongoing training do SNODs have?

A. It is imperative for SNODs to reflect on all the counselling that they have been involved in. They are asked to maintain a log - Reflections. Doing role play helps – ‘Practice makes it easier’. There is also a monthly debrief where all SNODs meet, learn and share their experiences.

Rapporteur – Dr. Sumana Navin

ORGAN DONATION UK 2020

Speaker – Dr. Sanjay Deshpande

Chairpersons – Mrs. Lalitha Raghuram and Dr. Sumana Navin



Dr. Deshpande said that based on the recommendations of the Organ Donation Task Force in 2008 changes were made that improved organ donation in the UK. There was multi-sectorial involvement and regional collaborative meetings. CLODs and SNODs were appointed and there was remuneration for CLODs. There was sharing of good practices, networking and increased positivity. The taskforce recommendations resulted in a 50% increase in deceased organ donors in five years. Most of the increase was because of DCD. A detailed strategy for Taking Organ Transplantation to 2020 is available on www.nhsbt.nhs.uk/to2020
The aims are –

1. Consent rates 80% (currently 57%)
2. 26 deceased donors per million population (currently 19.1 pmp)

3. Organ utilisation – aim to transplant 5% more organs from consented actual donors
4. Patients transplanted – deceased donor transplant rate 74 pmp (currently 49 pmp)

One of the Taskforce's recommendations is to ensure that organ donation becomes the "norm" and that one should be "proud" to donate. Best practices in donation, optimal usage and better support systems are also essential. In the Black Asian Minority Ethnic (BAME) population there are 27% recipients, but only 5% donors. There is a need to stimulate conversation and debate among families for "normalising" donation. The consent rate if on the Organ Donor Register is 93% for DBD, but only 55% if not on the register (2013/14 data). Awareness needs to be raised among the general public, religious and community leaders, members of the organ donation and transplant teams and the media.

Q & A with Dr. Sanjay Deshpande & Ms. Michelle Hunter

Q. How supportive are doctors of organ donation?

A. The majority of doctors are supportive. Some consultants are more comfortable than others with DCD. They need to be educated. It is not up to the doctor to not offer the option of organ donation. It is up to the patient/patient's family to decline the option of organ donation.

Q. Are autopsies done in all medico-legal cases of organ donation in UK?

A. No, if we can prove to the coroner that we can issue a death certificate and we are certain about cause of death, then we don't need to proceed for autopsy.

Rapporteur – Dr. Sumana Navin

DONATION AFTER CIRCULATORY DEATH (DCD) IN INDIA

Speaker – Dr. Anand K Khakhar

Chairpersons – Dr. Sunil Shroff and Dr. Sanjay Deshpande



Dr. Khakhar said that, in fact, organ transplantation started with Donation after Circulatory Death (DCD). With the legalisation of brain death in 1968, this donor pool started being utilised. But with the requirement for organs increasing there has been renewed interest in DCD/NHBD (non heart beating donors). He gave an overview of the five NHBD categories as per the Modified Maastricht classification.

He addressed the issue of Deceased Donor Liver Transplantation, i.e., DDLT: DCD/NHBD donors and machine perfusion. He said the disadvantages are that of warm ischaemia and biliary complications. However, gradually criteria have evolved and there is a set timing of warm ischaemia from the withdrawal of support to cardiac arrest and perfusion. These organs could be optimised using ECMO and machine perfusion.

In the West, the standard practice is for controlled withdrawal of support in ICU/OT. The family is present when the withdrawal of support is undertaken. They then leave. There is a gradual deterioration and arrest. If the arrest happens within 25 minutes, the liver can be used; within 45 minutes the kidneys and pancreas can be used. In India formal withdrawal of support is not done, and there is scepticism regarding DCD transplant outcomes. But Dr. Khakhar made the point that Donation after 'Death' was perfectly legal. He said in his hospital system, the family first makes a decision regarding Do Not Resuscitate (DNR) or Do Not Escalate care (DNE). Discussion about DCD takes place thereafter. Placing of lines ante-mortem/post-mortem, injecting heparin etc. require guidelines in the Indian context. A Spanish group has evolved a protocol and their transplant outcomes have been published in the American Journal of Transplantation 2007: about 60 – 70% at 24 months. This is acceptable when one sees that mortality is 50% on the liver waiting list (deceased donor) even in a large hospital. Dr. Khakhar said DCD organs are marginal organs, but can be optimised using ex-vivo perfusion pumps using Vaso-vasol machine perfusion solution. If kidneys are perfused ex-vivo for about 4-6 hours, they function quite well. He said that he was part of a group in the US that developed a liver perfusion machine, which is now commercially available. The machine was used to optimise five marginal livers with good results.

Dr. Sunil Shroff then presented three case scenarios – Can DCD be done in the following situations?

1. Cardiac arrest in a certified brain dead patient (family has already given consent) – YES (Maastricht IV)
2. First certification of brain death done, but second was not done as patient not stable. Family keen to donate – YES (Maastricht III)
3. Patient's CT shows bilateral extensive brain damage, but has extensor response to painful stimuli, and breathing spontaneously on CPAP. Family keen to donate. Intensivist refuses to consider donation as does not meet neurological criteria of death. Patient dies on 6th day. Family submits a complaint over mishandling of request. Could this patient have been shifted to OT for organ retrieval? – YES. The doctor should not have gone by brain

death criteria, but with circulatory death, especially since the family was on board.

Discussion - There was a discussion about the legal standing of a DNR/DNE order and the need for DCD national guidelines in India. There are a few hospitals in the country that are doing DCD, one of them being PGIMER Chandigarh. Dr. Sanjay Deshpande said that it might be useful to look at Bolam's principle – the law imposes a duty of care between a doctor and his patient, but the standard of that care is a matter of medical judgment.

Rapporteur – Dr. Sumana Navin

CURRENT SCENARIO IN SKIN DONATION AND SKIN BANKING

Speaker - Dr. Sunil Keswani

Chairperson – Dr. V B N Murthy



Dr. Keswani said that the first skin bank was set up at the LTMG Hospital, Sion, Mumbai about 11 years ago by Dr. Madhuri Gore. And about five years ago he set up the National Burns Centre and the Rotary Club of Bombay North (RCBN) Skin Bank. He gave an overview of the gravity of the situation of burn injuries in India – 70 lakh annually of which 1.4 lakh people die every year. 70% are in the most productive age group of 15 - 35 years. The main indication for skin homografts is burns. Burns can cause injury to a large surface area of the body leading to infection, fluid loss and death. In the early days of burns management, people used to do dressings for 2 – 3 weeks till the dead tissue sloughed off and then graft the patient. However, the dead tissue caused infection and the patient would die or if

he survived would have fibrosis and contractures. The modern treatment for burns is early excision and grafting, preferably within the first 96 hours. Therefore there is an enormous need for skin donation.

He then spoke about skin banking - the procedure and protocol involved in retrieving, serological/microbiological testing, processing, preserving and distributing skin. He emphasised that quality control and documentation are of utmost importance. Since the donation criteria for eye and skin are the same, Dr. Keswani said that he was pushing for the Eye donation helpline (1919) to also handle skin donation calls. In addition, he had offered to train the eye retrieval staff in skin retrieval as well. He felt that skin collection centres needed to be set up first, leaving the processing aside. Once the collection goes on well, the collection centre can then be upgraded in 1 – 2 years, after an audit, to a skin bank.

Dr. Keswani said that there were 250 skin donations in 2015 through National Burns Centre. Sion Hospital also collected an equal number of skin donations. In Mumbai city alone, the requirement is 2000 skin donations a year. In a survey conducted among doctors and lay people there was a lack of awareness about skin donation in both categories. He spoke about innovative methods to create awareness about skin donation - poster competitions for Art school students being one of the most effective.

Q & A with Dr. Sunil Keswani and Dr. V B N Murthy

Q. Is skin from persons with vitiligo (leucoderma) used?

A. No, it is not used as results are not good.

Q. Why is skin donation a contraindication if viral markers are positive?

A. Skin is preserved in glycerol which is bactericidal only.

Q. What is the actual requirement for skin in India?

A. It is dependent on the number of burns cases where early excision is done.

Q. Is cryopreservation of skin required?

A. No, cryopreservation is not required in India as use is fairly immediate. In the US, cryopreservation is used. The Euro Tissue Bank, which is the biggest tissue

bank in the world and has the maximum turnover, uses glycerol preservation. The bank is 50 years old and this is a time-tested technique.

Q. Can skin from two donors be used for one recipient?

A. It depends on the extent of the burns, but generally skin from two donors would be required for one patient. From a moderately built adult, about 2500 sq.cm of skin is obtained. Also a burns patient is immunocompromised and there will be no cross reaction.

Q. Why is the skin issued only after one month?

A. It takes one month to exclude fungal infection.

Dr. Alvin Chua - If there is an urgent requirement, the surgeon needs to sign an 'exceptional release' meaning that he acknowledges that the skin is not fully tested - this is the procedure in Singapore.

Q. How high is the demand for skin in Chennai?

A. Skin homografts are very useful in high body surface area burns (50% - 60%). In smaller percentage burns - opinion is divided - homografts may or may not be required. In large percentage burns, early excision and grafting needs blood and blood products, ICU care, ventilator. Not all hospitals are equipped for this, so surgeons may decide to wait for three weeks till the dead skin naturally sloughs off and then grafting is done. Half the patients die in this period. A suggestion from the audience was for National advisory guidelines from the Plastic surgeons association.

Q. What are the advantages/disadvantages of artificial skin?

A. Artificial skin like Integra is useful in degloving injuries. When used in burns, the infection rate is 22%. It is also very expensive - to cover 1% body surface area the cost is Rs.1000.

Dr. Alvin Chua - Even in Singapore it is considered expensive. If a surgeon doesn't excise well, the rate of infection increases and renders the whole effort futile. Biobrane can be used in second degree or superficial burns.

Rapporteur – Dr. Sumana Navin

QUALITY MANAGEMENT IN TISSUE BANKING

Speaker – Dr. Ajoy SM

Chairpersons – Dr. R. Krishnamoorthy and Mr. C. E. Karunakaran



Dr. Ajoy spoke about the growing need for tissue banks - there are 900,000 joint replacements done annually in the world and these will require revision in 10 to 15 years. This needs bone and the best of metal implants cannot replace it. He stressed that quality and tissue banking are synonymous and strict adherence to protocols in all aspects is required. He touched upon the Why, What, When, Where and How of tissue donation and tissue banking.

Why tissue donation? Donor site morbidity in autografts and not always available. For revision surgery allografts are required.

What is a tissue bank? Human tissues are collected, processed, stored, distributed (not for profit activity). Musculoskeletal tissue grafts – bones, tendons, menisci.

When and where is tissue donation done? - Tissues can be harvested after cessation of circulation within 15 hours. Tissues can also be retrieved in multi-organ donation (DBD). There is no disfigurement.

Who? Anybody can be a donor (after screening).

How? One of the concerns is allograft safety. This can be ensured by proper screening, careful processing, serologic testing, and attention to quality control.

Quality management starts right from the inception of the tissue bank.

- Setting up of tissue bank - separate dry and wet processing areas
- Procurement of tissues - in OT, Triple packed (Vacuum packing)
- Processing of tissues - laminar air flow and sterile environment; on a given day only one donor's tissue is processed.
- Issue of tissues - repeated cultures of tissue before issuing
- Usage of tissue – clear instructions about usage are given to the surgeon
- Do air sampling of tissue bank every three months
- Culture swabs of tissue bank surfaces
- Fumigation weekly
- HEPA filters in Laminar air flow system
- Infection control - Documentation allows you to trace donor if recipient develops infection. Records are vital.
- Sterility assurance levels

Dr. Ajoy made a strong recommendation for a uniform code for tissue banks in the country. He said an Indian Association of Tissue Banks is required and that both the government and public need to be educated regarding this.

Q & A with Dr. Ajoy S M, Dr. R. Krishnamoorthy, Mr. C. E. Karunakaran

Q. Can we have one tissue bank (for skin and bone)?

A. Yes, we can.

Q. Can amputated limbs be a source of bone?

A. Yes, amputated limbs are the major source for long bone grafts. Posttraumatic - retrieval within six hours; it needs to be a clean amputation.

Q. Wide divergence in usage of bone has been seen with one bone bank reporting that the offtake was only 1.5 bones/month, why is that?

A. Surgeons may think that allografts carry the risk of infection. In M S Ramaiah Tissue Bank, all 150 femoral heads collected in a month are utilised.

Q. What is the risk of infection?

A. Minimal. At - 80 degrees Celsius for one month, only some Clostridial species can survive, also it decreases immunogenicity. No screening for fungus.

Q. Brain dead donor - what can be retrieved?

A. All bones from upper limb and lower limb are retrieved. Reconstructed with wooden pieces. Procedure takes at least 3.5 hours.

Q. What is the cost to establish a bone bank?

A. Approximately Rs. 1.5 - 2 crores (in addition to land and building costs).

Q. Should there be an external audit agency?

A. Indian audit agency (Indian Association of Tissue Banks) can be established.

Q. How many bone banks are there in India?

A. Tata Memorial Hospital, Mumbai, Ganga Hospital, Coimbatore, M S Ramaiah Hospital, Bengaluru.

Q. Do you take consent for amputated limbs?

A. Yes, no one refuses.

Q. Does the recipient of a bone allograft need to be on immunosuppression?

A. There is no immunogenicity in a tissue allograft and therefore there is no need to give immunosuppression for recipients.

Rapporteur – Dr. Sumana Navin

EX-VIVO CARDIAC CARE SYSTEM

Speaker - Dr. K. R. Balakrishnan

Chairpersons – Ms. Pallavi Kumar and Dr. Hemal Kanvinde



Dr. Balakrishnan started by saying that the heart is exquisitely sensitive to ischaemia (4 – 6 hours) and that includes the time to implant it, which is about 30 – 45 minutes. There has been increased availability of donor organs and Fortis Malar Hospital did 41 heart transplants in 2015. Yet, many hearts are wasted. While logistics (transport) given the traffic is a major impediment, there is also the issue of the evaluation of a donor heart. An echocardiogram needs to be done and this needs to be interpreted by a cardiologist who may not be available in a small town. In brain dead individuals, cardiac function can be poor because of stress cardiomyopathy, but it may be possible to resuscitate the heart. Anaesthesiologists have been trained to do echocardiograms using a portable echo machine with an

oesophageal probe. And with the help of WhatsApp, this is shared among an expert group and decisions made regarding usability of the heart.

With regard to logistics, the 'green corridor' for speedy transport of organs started in Chennai. However, interstate organ sharing is complicated with finding suitable commercial flight timings, and Air ambulances are exorbitant. Donations are also happening in mofussil towns that are not connected by air. Transport initiatives by state governments and innovative 'courier services' may help in this regard.

A major concern overall is about increasing organ viability and an ex vivo cardiac care system can help on many fronts. This includes being able to assess the heart of a marginal donor by doing an angiogram outside the body! He also spoke about the first organ perfusion system that was described in 1892 - the Langendorff preparation. The commercial product using this principle was launched a few years ago called TransMedics, which is a blood based perfusion system. Dr. Balakrishnan said that an Indian system was on the anvil (developed by his team) and together with improved transport there would be better utilisation of hearts.

Q & A with Dr. K. R. Balakrishnan

Q. Can drones be used to transport organs?

A. Drones have a small payload of about 2 - 3 kg. The organ transport box weighs about 22 kg, so need to work on reducing the ice that is used for packing or look at a refrigerated system.

Drones for inner city use not needed, but would be useful for transport from smaller towns. Long range drones - working in collaboration with the Robotics department in Carnegie Mellon University, USA and Health Logistics department, Karolinska Institutet, Sweden - payload of 20 kg and distance of 300 miles.

Comment from audience - the issue could be clearance from Air Traffic Control given security implications.

Q. What are the heart transplant outcomes at your hospital?

A. One year survival is in excess of 96%. We give only about 15% of the immunosuppression prescribed in books. Indians do not reject as much as the black

population. In the series of 74 transplants done at our hospital, only two documented acute rejections occurred, but both survived.

Q. What is the average cost of a heart transplant?

A. Roughly Rs.20 lakhs.

Q. Why are there so few cardiothoracic surgeons doing heart transplants?

A. It is a lot of effort! Also only the sickest patients consider having a heart transplant. So we started an Assist Device programme first.

Rapporteur – Dr. Sumana Navin

PANEL DISCUSSION – UNUSUAL CASE STUDIES



Panel Members

- Dr. P. Magesh, Dept. of Neurosurgery, Rajiv Gandhi Government General Hospital, Chennai
- Dr. R. Radhakrishnan, Dept. of Anaesthesiology, Rajiv Gandhi Government General Hospital, Chennai,
- Dr. Akila Rajakumar, Intensivist, Global Hospitals, Chennai,
- Dr. R. Kanimozhi, Dept. of Anaesthesiology, Government Stanley Hospital, Chennai.
- Dr. G. P. Arulraj, Dept. of Anaesthesiology, Government Stanley Hospital, Chennai.
- Dr. K.R Balakrishnan, Fortis Mallar Hospital, Chennai
- Mr. K. Prakash, Transplant coordinator, MOHAN Foundation, Chennai

Moderated by Dr.Sunil Shroff

The last session on Day 1 was a panel discussion to discuss the unusual case studies from the programme that could provide insights to the senior transplant coordinators. In this programme in India every donation that is being done has some unique aspects and provides a great learning opportunity to the coordinators and the doctors.

Case Study1: “Patient is brain dead and only his heart is functioning”

This was what was told to the relatives of a young potential donor by the treating doctor. When the transplant coordinator counselled the relatives for organ donation, they consented for only heart donation. The coordinator was puzzled and was not sure why they were consenting for heart alone. The coordinator approached the relatives once again to consider donating the other organs as well, but they refused. Later the coordinator came to know that while communicating to the family about brain death, the treating doctor informed the following, “Patient is brain dead and only his heart is functioning due to the artificial support. If the heart stops then the body will be handed over”. The lack of clarity in explaining to the relatives about brain death made them misinterpret that not just brain, but no other organ is functioning except heart. Hence they consented to donate heart alone when they were approached for organ donation. The coordinator tried explaining to them about brain death and that organ donation could take place in such situation. Still the family refused to donate other organs and said that they would believe only what the doctor said. . The doctor had to be brought back onto the scene and once again clarify to the family members about brain death and organ donation.

Take home message

The doctors need to spend more time with the relatives and explain the concept of brain death in a language that the family can understand without much difficulty.

Communicating death to the relatives, there is no standard way how this has to be performed. Every family is unique and each family differs from one another. Understanding the family dynamics and assessing their level of understanding is very important before communicating brain death and approaching them for organ donation.

The transplant coordinator should be present when the family is informed about brain death. This helps the family to have trust on the coordinator and see him/her as a member of the team that is involved in the patient care.

Case Study 2: Hypernatremia – Medical Management

A 22-year-old male met with a road traffic accident (RTA) and was in ICU on ventilator for two days. The patient was a bit unstable and the sodium was 192 mmol/L. Triple inotropes were given and at the end of 24 hours there was an improvement in haemodynamics, but the serum sodium was still 188mmol/L. The conventional corrective measures were taken to bring the sodium level down, but there was no improvement. The family was very keen about organ donation and willing to wait as many hours as needed to proceed with organ donation.

As a last resort, Continuous Renal Replacement Therapy (CRRT) was started which was very expensive and at the end of 14 hours it was 154mmol/L.

Points discussed & Take home message

- Performing apnoea test on this patient with elevated serum sodium – The apnoea test can be performed if the cause of the irreversible coma is clearly known such as RTA. When there is a medical cause for brain stem dysfunction, then all the parameters should be taken into consideration before performing apnoea test. However this is left to the discretion of the treating doctor to decide whether the apnoea test can be performed or not.
- Using the liver with the elevated serum sodium for transplantation – There are studies which say that the severe hypernatremia in deceased liver donors does not impact early transplant outcome and the use of extended criteria livers decreases wait time for liver transplantation without adversely impacting post transplant survival.
- Meeting the expenses towards donor maintenance – Having hospital policies to meet these kind of expenses will be helpful. In this case, other measures like continuous infusion of water through nasogastric tube could have been tried to bring down the sodium level, especially if patient is unstable for dialysis. This shall be a simple measure that can be very effective without more expenses.

Similar case with elevated renal values was discussed for which the treating physician refused to perform apnoea test although the cause for the brain stem dysfunction was clearly known (RTA).

Case Study 3: Religious grounds – how does it play a role in organ donation?

A 49-year-old male of a particular religion met with an RTA and was certified as brain stem dead in a government hospital. The family was counselled for organ donation for which they refused. This was in the year 2009.

In 2011 in the same hospital, a 30-year-old male of the same religion was admitted followed by an RTA and was certified as brain stem dead. The relatives especially the wife immediately consented for organ donation. But later their religious leaders opposed the organ donation; hence the family took back their consent.

Take home message

The awareness has widely reached the public and this has been evidenced by the change in the public's attitude. However it is very important to sensitise the people who can influence the public in making a positive decision such as religious leaders, celebrities, etc. Also there should be an ongoing effort in creating awareness and engaging the public with adequate knowledge on organ donation.

A few other case studies/points discussed at the forum were -

Breaking the social stigma: A 48-year-old man with extradural haematoma was certified as brain stem dead. His daughter was the only legal heir who was a transgender. She consented to donate her father's organs.

Referral cases - More cautious: A 32-year-old male with a history of RTA was identified as a brain stem dead patient in the hospital where he was admitted and later referred to a government hospital for organ donation. While examining the patient, he was found to have spontaneous breathing and responded to painful stimuli. **Take home message:** Physicians should be more cautious when the patients are referred from different hospitals.

Certifying Brain Death in Paediatric Patients: A 3-year-old child had a traumatic brain injury. Surgery was done, but child became brain stem dead. All the necessary testing was done, but this could not be communicated to the parents

as they were extremely emotional. So the medical team allowed the parents to stay with the child in the ICU. They explained in detail, but in simple language about the condition of the child. The parents finally understood and gave consent for organ donation.

Ancillary tests as confirmatory tests: According to the Transplantation of Human Organs Act of India, apnoea test is the only confirmatory test. Ancillary tests can support the diagnosis of brain stem death, but should not be a standalone confirmatory test.

Time delay in deceased organ donation: Many a times, families refused to donate their loved ones' organs due to the long waiting hours especially in medico-legal cases where the police and forensic personnel are also involved. Early identification and effective medical management is another challenge because of which there may be a delay. **Take home message:** Explaining to the families about the time required to complete the organ donation process is very important. It has been evidenced that families are usually cooperative if they are constantly updated and informed about the expected time delay.

Rapporteurs – Dr. Sunil Shroff and Ms. Sujatha Suriyamoorthi

DAY 2: 30th January 2016

CURRENT TRENDS IN EYE BANKING IN INDIA AND CHALLENGES IN ESTABLISHING AND RUNNING AN EYE BANK

Speaker – Dr. R. R. Sudhir

Chairperson – Dr. M. Anand Babu



Dr. Sudhir spoke about the enormity of the problem of corneal blindness in India – 14% of the total blindness in the country. The number of corneal transplantations done is 15 per million population (pmp), while the number of cataract surgeries is 4000 pmp. The volume of cataract surgery blindness control is a good indicator of the readiness of a country to perform corneal transplantations. In this regard, India

is well prepared to undertake this procedure. The major causes of corneal blindness in India are infectious keratitis (corneal ulcer) and pseudophakic bullous keratopathy (a complication of cataract surgery). The different types of corneal transplantation are full thickness or Penetrating Keratoplasty (PKP), Therapeutic PKP (done in infections), Lamellar Keratoplasty or DSEK (done in bullous keratopathy).

He said that an eye bank is a not-for-profit institution for collecting, processing, evaluating, preserving donor corneas, and for distributing them to trained corneal graft surgeons. Rigorous quality control is essential. It is also involved in research and public awareness. Dr. Sudhir also spoke about the infrastructure (eye donation centres, eye bank, eye bank training centre) and manpower that is needed. He touched briefly on donor screening and tissue harvesting - mostly donor corneal rim excision is done, enucleation (removal of entire eyeball) is done sometimes when scleral tissue is required for other surgeries and research. The storage medium that is now being used by many eye banks is Cornisol. The results are good and it is affordable. It was developed by Arvind Eye Care System (Aurolabs) at a cost of Rs.975/vial. The corneal tissue can be stored for 14 days. Before the cornea is used it is evaluated. The most important deciding factor is the endothelium. A specular microscopic evaluation (cell count, type and quality of cells) is done and the results of the corneal transplantation depend on this.

According to the Eye Bank Association of India (EBAI) corneal tissue utilization improved from 34% to 48% (2003 to 2013). As per Vision 2020, we need to perform 100,000 corneal transplantations by 2020. Only 15 eye banks collect more than 1000 eyes per year. In 2013 - 2014, there were 10.2 million deaths in India, but eyes were collected from only 0.5% of deaths. If eyes are collected from 1% of deaths, vision 2020 could be achieved. The focus needs to be on utilisation of corneas with collection of good quality tissues. This is possible through a Hospital Cornea Retrieval Programme (HCRP) using the services of a professionally trained counselor. It can also be a part of the organ donation programme. The challenges are capacity building, uniform quality of tissues, accreditation and licensing of eye banks, building good training centres in each zone and networking.

Comments by Dr. Anand Babu & Dr. R. R. Sudhir

- The eyes from burns patients yield high grade corneas, not from other causes of death. That is because burns deaths are in the age group of 15 – 35 years.
- Even children less than one year can donate corneas.
- Brain dead patients are on the ventilator for a long time and there is exposure keratitis many a time, so therefore can't be used. ICU consultants need to be made aware of care of the cornea.
- Longer duration preservation media not required in government setup since corneas are used almost immediately. So MK media is used which costs Rs.250.
- EBAI does not have a centralised distribution system. At present, SightLife is working to standardize protocols and network.
- Dr. Chua wanted to know if the eye banks collaborated with skin banks since it was the same pool of donors. Dr. Sudhir said that when there are multi-organ donations, corneas are also retrieved many a time.

Rapporteur – Dr. Sumana Navin

TOWARDS A MULTI-TISSUE BANK FACILITY - THE SINGAPORE EXPERIENCE

Speaker – Dr. Alvin Chua

Chairpersons – Mrs. Lalitha Raghuram and Dr. Sunil Shroff



Dr. Alvin Chua said that the Singapore multi-tissue bank facility followed American Tissue Bank standards, but it wants to come up with its own standards that would work in the local context. In 1998, a skin bank was set up under the Singapore General Hospital, Burns Centre and the National Cardiovascular Homograft Bank was started in 2008. In 2015, in an effort to pool resources, reduce wastage, and achieve synergy both the banks were merged to form a multi-tissue bank facility – Transplant Tissue Centre, SingHealth.

The legal framework in Singapore is the Human Organ Transplant Act of 1987. This was for kidneys only initially (now other organs are also included) and works

through an opt-out system. This is applicable to Singaporeans and Permanent Residents only. The Medical Therapy, Education, and Research Act (MTERA), 1972 allows for anyone >18 years and of any nationality to pledge and donate organs (opt-in). There are very tissue donors in Singapore.

Dr. Chua discussed the entire tissue donation process starting with medical suitability evaluation based on information available at time of referral to the transplant coordinator. If eligible, the transplant coordinator approaches the family for tissue donation. Once consent is obtained, a more thorough donor suitability assessment is done and only then tissue recovery. Tissue recovery is within 15 hours (if not refrigerated) and 24 hours (if refrigerated within 12 hours). Donor screening/selection is done using Donor Risk Assessment Interview (DRAI) questionnaire. Stringent norms have to be followed as per American standards, but it is difficult, for example, given the culture in Asia to ask about sexual history. So instead of just a 'yes' or 'no', a 'don't know' option has also been included. A lot of documentation is called for to comply with quality assurance requirements. Both skin and cardiovascular homografts are cryopreserved using 10 – 15% DMSO as a cryoprotectant at -196 degrees Celsius (5 years shelf life). Retrospective clinical studies are done to review results of skin allograft and cardiovascular homograft usage. It was found that the usage of skin homografts after early massive excision in severe burns reduced the mortality rate from 45% to 16%. Also a study was done to compare clinical outcomes of glycerol preserved and cryopreserved skin homografts. The mortality was lower in the cryopreserved group, but it was not significant. This is just a trend, so waiting for more data to decide whether to switch to 85% glycerol preservation since it is cheaper than cryopreservation.

Q & A with Dr. Alvin Chua

Q. In Singapore, do you retrieve skin at home?

A. No. The body is taken to hospital for tissue (skin) recovery.

Q. Are there any issues with skin taken from refrigerated bodies in Singapore?

A. No. (In India, skin is not taken after 6 hours even if refrigerated).

Rapporteur – Dr. Sumana Navin

ETHICAL ISSUES IN END-OF-LIFE CARE

Speaker – Dr. Malvinder Singh Sahi

Chairpersons – Dr. B. Subba Rao and Dr. N. Sridhar



Dr. Subba Rao set the tone for the speaker by saying that advances in ICU care have helped people recover from life-threatening illnesses on the one hand, but on the other hand have also prolonged suffering. In addition, these interventions can also be expensive. The moral and ethical issues in this regard need to be discussed.

Dr. Malvinder Singh Sahi said that ethics in end of life care (EOLC) was not existent in India per se. There was no formal education in this field and the terminal part of a patient's life is glossed over. If a patient has a good death, then care has been ethical. He elaborated on the principles of a good death. It starts with the questions –

- Has the patient / family understood the situation?
- What does the patient want when he is dying?

A patient has the right to a dignified death and to have loved ones present. 80% of patients want to die at home. The patient needs to be able to retain control of what happens, especially with regard to pain management and other symptoms. He needs to be able to issue advance directives to ensure compliance to one's wishes. He has the right to refuse treatment. Dr. Sahi said that once the family accepted that their loved one was dying, the EOLC pathway can be initiated. It is important that the primary team and the ICU team are on the same page. The principles of medical ethics need to be adhered to in EOLC– autonomy, beneficence, non-maleficence, truth, confidentiality and justice in allocation of resources. The needs of the patient to be addressed are adequate pain management, avoid prolonging the dying process, bond with loved ones, relief from emotional burden, and some control over the decision making process. The needs of the family include wanting to be with the dying person, to be assured of 'comfort' of the dying person, be kept informed of the patient's condition and feel accepted, supported and comforted by the health professionals. However, there are legal pitfalls in providing EOLC – "EOLC is not involuntary passive euthanasia." The matter is subjudice.

The actual scenario today is that precious resources are often wasted in palliative/supportive care, instead of real ICU care because patients cannot be looked after at home. Hospice care is almost non-existent in India and the concept of Advance directives is not there either. Patients are, in fact, paranoid about intrusive medical technology, but medical futility of treatment is not being discussed. DNR – Do Not Resuscitate / AND - Allowing Natural Death are not permitted in our country. DNI – Do Not Intubate & ventilate and DOR – Discharge on Request or LAMA – Leave Against Medical Advice are allowed.

Palliative care and Critical care have to come together for those critically ill or dying. The patient and the family have to be approached holistically and there has to be clear communication between the hospital team and the family.

Editor's note - The Indian Society of Critical Care Medicine and the Indian Association of Palliative Care have issued a Joint Position Statement on End-of-life care policy: An integrated care plan for the dying.

Q & A with Dr. Malvinder Singh Sahi, Dr. B. Subba Rao, Dr. N. Sridhar

Q. Why are families not engaged in decision making?

A. Financial implications drive end-of-life care in India.

Q. Can DNR be written on the case sheet?

A. No, it cannot.

Q. What if family cannot afford care in the ICU?

A. Best supportive care is provided under the circumstances (legal advice needs to be taken). Hospital responsibility lies only with emergency care. It does not have a responsibility with prolonging care if family cannot afford treatment.

Discussion – An impassioned debate ensued on the financial implications of ICU care in a private setup and whether care can be withdrawn or the ventilator switched off? One of the suggestions was that the patient could be shifted to a government hospital if there was a possible good outcome, but it should not be seen as ‘dumping’ the patient. Maintaining a good relationship with government hospitals could enable that, it was felt. Dr. Sahi said that the practice was to take signatures from the family members if they did not want to put the patient on the ventilator or if they did not want expensive interventions.

Another much debated point was with regard to the certification of brain stem death being linked to organ donation. The question was that if brain stem death was certified and the family declined organ donation, could the ventilator be switched off? One section of the audience felt that it could not be switched off in such situations since brain stem death is mentioned only in the Transplantation of Human Organs Act. Another section felt that it could be done with the hospital management on board. The point was raised that in Tamil Nadu declaration of brain stem death was mandatory and not linked as such to organ donation, but it was unclear as to whether it was actually being done.

Rapporteur – Dr. Sumana Navin

PROCUREMENT AND STERILIZATION OF TISSUES

Speaker – Dr. Alvin Chua

Chairperson – Ms. Pallavi Kumar



Dr. Chua focused on the National Cardiovascular Homograft Bank in Singapore. It was the first tissue bank in Asia to obtain accreditation from the American Association of Tissue Banks (AATB). Human heart valves have the advantage of not requiring blood thinners and are beneficial for specific groups of patients with little risk. But their availability is limited due to a small donor pool unlike mechanical valves that are readily available. He said that heart valves, arteries and veins were retrieved based on exclusion criteria of the AATB. Block recovery of aortic and pulmonary valves was done and the donor's chest cavity closed just like in any operation. Every donor is treated with respect and dignity. After tissue dissection, the valve is sized and incubated in antibiotics for disinfection – vancomycin and amikacin – for 24 to 32 hours at 2 to 8 degrees Celsius. Post incubation rinsing is done, individually packaged using the cryoprotectant DMSO

and cryopreserved. Artery or vein grafts (Iliac vessel allografts) are frequently used for vascular reconstruction in liver transplantation.

Dr. Chua said that all the transplant programmes and tissue banks came together as Tissue Transplant Centre, SingHealth in 2015. This kind of synergy optimizes manpower and allows efficient use of resources, and there also has been an increase in the number of donors for both skin and heart valves. It promotes growth expansion.

Tissue sterilization is also done as per AATB standards. The process involves disinfection, sterilization, terminal sterilization and bioburden. The different methods of sterilization need to be validated. Irradiation of skin is done in Argentina only.

Q & A with Dr. Alvin Chua

Q. Why do you use Amikacin –Vancomycin for antibiotic decontamination of cardiovascular homografts when they are the last line of antibiotics?

A. When Penicillin-Streptomycin was used, the discard rate was higher at 11% as compared to 5.1% with Amikacin-Vancomycin. The tissue is kept at 4 degrees Celsius for 24 hours.

(In skin donors, when Penicillin-Streptomycin was used, the discard rate of tissue was 20%, while it was 8.82% with Amikacin-Vancomycin)

Q. What is a suitable anti-fungal media formulation for skin homografts?

A. An antibiotic cocktail of Amphotericin B (in different concentrations) with Amikacin and Vancomycin is being studied in Singapore for effectiveness against three species of candida. Amphotericin B is cytotoxic towards fibroblasts and keratinocytes, so one has to check for cell viability at different concentrations. These studies are important to validate methods of disinfection that can be used locally.

Q. How important is it for all tissue banks to come under one roof?

A. There can be different collection centres, but one processing centre – this is most cost effective and resource efficient. An integrative approach for all tissue banks should be looked at. In Canada, they have a comprehensive tissue bank for heart valves, skin, bones, tendons, cartilage. It can be a challenge to integrate staff from different tissue banks who may be used to different working styles!

Rapporteur – Dr. Sumana Navin

DONATION AFTER CIRCULATORY DEATH (DCD) IN AUSTRALIA

Speaker – Dr. Vijayanand Palaniswamy

Chairpersons – Dr. J. Amalorpavanathan and Dr. Ravi Wankhede



Dr. Vijayanand Palaniswamy started the session by saying that he worked in a remote part of Australia (the Northern Territory) in a hospital that had no neurosurgeon, no cardiothoracic surgeon and that if a person was brought with a head injury he would need to be transported 2500 km for expert care. The hospital had 18 ICU beds. However, the organ donation rate (ODR) in the Northern Territory was 28.3 per million population (pmp) compared to the national ODR of 16.1 pmp in 2014. Even though the government had invested quite a lot in the programme, the ODR dropped from 16.9 pmp in 2013 to 16.1 pmp in 2014. Interestingly, the number of organs transplanted went up from 1177 in 2013 to 1193 in 2014. There were 378 deceased donors (271 DBD and 107 DCD) in 2014. The consent rate for organ donation was 58% only, while the target was 75%. To

address this, the government made it mandatory for all ICU doctors to attend a three day family conversation workshop to train them in counselling families about organ donation.

Dr. Palaniswamy gave an overview of DCD, the criteria, warm ischaemia time (starts when systolic blood pressure drops to < 50 mmHg after extubation) and the process of DCD. There is a national protocol for DCD that came out in 2010 (free download available from Donate Life Australia website). To determine circulatory death the following criteria need to be met -

- Immobility
- Apnoea
- Absent skin perfusion
- Absence of circulation as evidenced by absent arterial pulsatility for at least 2 minutes duration (not more than 5 minutes)

Dr. Palaniswamy said that Maastricht III (withdrawal of life support in ICU – controlled) and IV (cardiac arrest following formal determination of brain death – controlled) categories are done in Australia. There have to be separate discussions about withdrawal and donation. The family needs to be informed that if heart does not stop within 90 minutes after withdrawal, there can be no organ donation, only tissue donation. He said that DCD required seamless team work, communication and coordination.

Discussion – The chairperson said that there was no legal framework in India to undertake Maastricht III DCD. Only Maastricht IV could be done here, but in fact a well-maintained ICU should not have donors from this category; it should be prevented from happening and one should ensure that DBD takes place once family consent has been obtained.

Rapporteur – Dr. Sumana Navin

KERALA NETWORK OF ORGAN SHARING – FORGING AHEAD

Speaker – Dr. Noble Gracious

Chairpersons – Dr. Vijayanand Palaniswamy, Dr. N. Sridhar , Dr. Thomas Mathew



Dr. Noble Gracious gave an overview of the Government of Kerala's Deceased Donor Organ Transplantation programme, Mrithasanjeevani – Kerala Network for Organ Sharing. He said that the programme started in August 2012 with nine donations and moved up to 63 donations in 2015. In January 2016 there have already been 12 donations. Dr. Noble said the target for the year was 100 donations. He said the programme has been doing well because of manifold reasons – government initiative, public-private hospital partnership, participation of non transplant organ retrieval centres, support of the media (print and visual), support of the church especially in central Kerala, and other NGOs, and a high literacy rate with 60% of the population being graduates. The organ donation rate in Kerala was 1.8 per million population in 2015 while the organ donation rate for

India was 0.5 per million population. It was the first state in India to do hand transplant and larynx transplant. A matter of pride was that 50% of deceased donor kidney transplants were done in government hospitals. While challenges remain, future plans include outcome registry for deceased organ transplantation and skill training programmes.

Discussion - Dr. Thomas Mathew, State Convenor, Deceased Donor Organ Transplantation programme, KNOS said that political will paved the way for the programme and that the government continued to support it wholeheartedly. He urged stakeholders in the hospitals to also come forward to do the same. From a public health activist's point of view, he said that the organ donation scenario in Kerala had gone through the four stages of social mobilisation drive - awareness creation, demand generation, community participation, and social mobilisation. The focus now is on doing a liver transplant in the government sector.

To a query about air transport of organs, Dr. Noble said that the government was considering using a single air carrier for this. There was a suggestion from the audience that requesting famous jewellers in Kerala who have private planes to help in transporting organs could be considered.

Rapporteur – Dr. Sumana Navin

GETTING FINANCIAL HELP FOR TRANSPLANT SURGERY

Speaker - Ms. Aneka Paul

Chairperson - Dr. Georgi Abraham



Ms. Aneka Paul started by saying that the Tata Trusts motto was 'Making a sustainable difference' in the country. The Trusts were established almost 100 years ago.

Transplant surgeries are expensive. She gave some indicative transplantation costs:

Kidney: 2.5 – 3.5 lakhs

Liver: 20 – 25 lakhs

Heart: 18 – 20 lakhs

Lung: 18 – 20 lakhs

Immunosuppressants: Post transplant – Rs.6000 to Rs.10,000 per month; Lifelong – Rs.3000 to Rs.5000 per month.

Funding for transplant surgeries comes from different sources -

- Insurance – Could work on creating and developing specific products/packages and negotiating with the insurance companies
- Government funding – for continued funding good transplant outcomes need to be documented and validated
- Corporate Social Responsibility and Philanthropy – individuals and agencies like the Tata Trusts. These at best do a ‘Band-aid job’

She suggested various methods that could be explored to bring down costs –

- Get immunosuppressants included in the essential drug list (negotiate with ICMR)
- Research on QoL, life expectancy, generic medicines for immunosuppression, low cost perfusion fluids, adult stem cells, drones (Tata Trusts has given MIT and IIT, Bombay grants to develop drones for chemical spraying and could be adapted for organ transport)

She also gave an outline of the application process for a financial assistance grant for organ transplant from the Tata Trusts. She said one could write to igpmed@tatatrusts.org for more information. The same patient could be supported on a cyclical basis every three years. It could be for dialysis, transplant surgery or medicines.

Dr. Georgi Abraham said that in Kerala the Panchayat appeals to the whole community when a person needs a transplant, collects and deposits the money in the recipient’s account or in a joint account. Father Davis Chiramel started this initiative.

Rapporteur – Dr. Sumana Navin

VALEDICTORY FUNCTION



At the valedictory function, Mrs. Lalitha Raghuram summarised the proceedings over the two days. She introduced a line of jewellery inspired by the green ribbon motif symbolising ‘recycling’ oneself through organ donation. All the pieces – necklaces and bracelets were designed by Mrs. Bhavna Jagwani, Convenor MFJCF and a pioneer in the field of eye banking in Rajasthan.

Dr. Georgi Abraham recalled the first multi-organ donation that took place in 1995 at the Madras Medical Mission (located at the Vijaya Hospital). It was a medico-legal case and after a lot of difficulties, the heart and kidneys were retrieved. He said that he was confident that by 2025 India would be carrying out the largest number of deceased donor organ transplantations. He added that with everyone working together as a team, this could definitely be achieved from ‘Kashmir to Kanyakumari’ and from ‘Gujarat to Manipur’.

Dr. J. Amalorpavanathan said that it was the transplant coordinators who burnt the midnight oil to ensure that government policy on deceased organ donation and transplantation was carried out. He expressed his gratitude to all the coordinators. He suggested that they make presentations and externalise their exemplary work.

Dr. Sunil Shroff proposed the Vote of Thanks.

