OUTCOME OF CADAVERIC RENAL TRANSPLANTATION-
SINGLE CENTRE EXPERIENCE

Dissertation Submitted to

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In Partial fulfilment of the regulations for the award of the degree of

D.M DEGREE EXAMINATION
BRANCH III - NEPHROLOGY

GOVERNMENT STANLEY MEDICAL COLLEGE
AND HOSPITAL

CHENNAI – 600001

AUGUST – 2014
CERTIFICATE

This is to certify that the dissertation entitled “OUTCOME OF CADAVERIC RENAL TRANSPLANTATION: SINGLE CENTRE EXPERIENCE” is the bonafide original work of Dr. Senthil Kumar R P in partial fulfilment of the requirements for D.M NEPHROLOGY BRANCH – III Examination of the Tamil Nadu Dr. M.G.R. Medical University to be held in August 2014. The period of postgraduate study and training was from August 2011 to July 2014.

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DECLARATION

I, Dr. SENTHIL KUMAR R.P, solemnly declare that the dissertation titled, “Outcome of cadaveric renal transplantation- single centre experience” is a bonafide work done by me at Govt. Stanley Medical College & Hospital during 2011-2014 under the guidance of and supervision of PROF. DR. M. EDWIN FERNANDO, M.D., D.M., Professor and Head, Department of Nephrology, Government Stanley Medical College, Chennai-600 001.

The dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, towards partial fulfilment of requirement for the award of D.M NEPHROLOGY (BRANCH – III) in NEPHROLOGY.

Place: Chennai.

Date: 26-03-2014.

(Dr. SENTHIL KUMAR R P)
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OUTCOME OF CADAVERIC RENAL TRANSPLANTATION- SINGLE CENTRE EXPERIENCE
INTRODUCTION

The biggest medical breakthroughs of this century are transplantation of human organs. The escalating End stage Renal Disease population and the lack of suitable donors – this discrepancy is well known. The first deceased donor renal transplantation in our hospital was performed in the year 1996 with 73 deceased donor transplantations performed thereafter.

Though deceased donor transplantation was started in the year 1996, it started gathering momentum only after the year 2008, when a doctor couple donated their brain-dead son’s organ, which gained widespread public attention.

The rate of deceased donors per million in India is far behind the world average rate. When compared with other countries like United States, Portugal and Spain the renal transplantation rate in India with a population of about 1.3 billion is only 3.2 per million population.

The major cause of End Stage Renal Disease are Diabetes and Hypertension which is on the increase. The age-adjusted incidence of end stage renal disease is estimated to be 232 per million population.
The only hope for patients with ESRD is renal transplantation, as the dialysis centres are limited to certain regions especially they are concentrated in the urban cities and is also expensive in the long run. The importance of this scenario is exemplified by this.

The only way to combat the commercial organ transplantation is to increase the deceased donor transplantation. It also reduces the burden on the live related renal transplantation.

Until a decade ago there was a lack of knowledge among the general public about deceased organ donation. But the crucial role played by the non governmental organization and media in support by the government implemented the deceased donor programme in the state of Tamilnadu successfully.
AIMS

1. TO ANALYSE THE VARIOUS DONOR AND RECIPIENT CHARACTERISTICS.

2. TO ANALYSE THE POST TRANSPLANT INFECTIONS AND POST OPERATIVE COMPLICATIONS

3. TO ANALYSE THE INFECTION RATES AND ACUTE REJECTION RATES WITH THE USE OF INDUCTION IMMUNOSUPPRESSION.

4. TO ANALYSE THE PATIENT SURVIVAL RATES.

5. TO ANALYSE THE GRAFT SURVIVAL RATES.
MATERIALS AND METHODS

This was a prospective and a partly retrospective study conducted from October 2008 to March 2014.

INCLUSION CRITERIA

All patients who underwent deceased donor renal transplantation in our centre were included in the study.

EXCLUSION CRITERIA

All patients who underwent live renal transplantations were excluded from the study.

STATISTICAL METHODS

- The various donor and recipient characteristics, cold ischemic time (CIT), tacrolimus levels, post transplant infections were analysed using multivariable Cox regression model, Pearson chi square test, Fisher’s exact test.
- Kaplan-Meier analysis to evaluate survival rates of patient & graft at 1 year & 4 years
The renal replacement therapy options available for patients with End Stage Renal Disease are dialysis or transplantation. Dialysis could be either peritoneal or haemodialysis. Despite achieving the targets for adequate haemodialysis / Peritoneal Dialysis and better management of anaemia with erythropoietin, the quality of life is poor when compared to transplantation. Patients on dialysis tend to have progressive, peripheral and autonomic neuropathy, bone disease and progressive Cardio Vascular Disease.¹,²

The cumulative costs of Dialysis either Haemodialysis or Peritoneal Dialysis is much more than that of a transplantation over a period of five years.³ The life-expectancy in dialysis is far lower than patients who had received a transplant. The long term survival rates for renal transplant recipients were better who received either an ideal or marginal donor. Though there is increased mortality rates associated with the surgical procedure and immunosuppressive drugs the survival benefit can be recognized within the one year of transplantation.⁴

The extent of the survival benefit varies depending upon the quality of the transplanted kidney and the patient profile at the time the patient is enrolled on the waiting list. It is very high for both young and diabetic patients. A high quality donor kidney has the capacity to about double the anticipated life span of a waitlisted dialysis patient.⁵
Hence, undoubtedly renal transplantation has the highest potential for restoring a healthy, productive life in most patients with End stage renal disease. The donor options available are living related, living unrelated (emotionally related) and deceased donors. The disparity between the escalating End Stage Renal Disease population and availability of living donors is well known. The only other option available for these populations is Deceased donor renal transplantation.\textsuperscript{6,7}

**INDIAN SCENARIO**

As per the Chronic Kidney Disease Registry of India, the crude and age-adjusted incidence rates of End Stage Renal Disease (ESRD) is estimated to be 151 – 232 per million population per year, respectively in our country. The renal transplantation rates are only 3.20 per million populations per year. Renal transplantation offers better survival,\textsuperscript{8} Quality of life\textsuperscript{9} and is cost effective.\textsuperscript{10}

The availability of live related donor and costs are major barrier to transplantation in India. The renal transplantation rate in India with a population of 1.2 billion is only 3.25 per million population which is far below when compared to other counties like Spain and United States.\textsuperscript{11} The mismatch between the escalating ESRD patients and availability of organs for transplantation is significantly reduced by deceased donor transplantation.\textsuperscript{12,13}
In the year of 2012 due to Road traffic accidents, 3,94,982 people have died and more than three-fourths among them are brain dead.\textsuperscript{14} There are several important steps in Deceased donor transplantation which involves brain death declaration, getting consent from the relatives, harvesting and storage of organs and taking it to the hospital for transplantation. More difficulty is encountered in the initial two stages.

**SPANISH MODEL**

Large numbers of brain death donors arise from critical care wards and hence therefore they are the place where organ donations have to be more concentrated for. Huge numbers are lost only due to not identifying them at the correct time. Hence the critical care ward doctor in charge should be vigilant regarding the same and as a part of end of life care promote the idea of organ donation. Spain's legal framework of presumed consent is frequently attributed to its success. There was no impact on donation rates with the introduction of opting out of deceased donation in 1979. The donation rates have increased further in Spain with the implementation of separate organization for transplant at the national level and persons to coordinate the donors.\textsuperscript{15}

**THE NEED FOR A MODEL**
Commercialisation of organ transplants increased in various regions India increased only due to the mismatch between the supply and demand.

Accordingly the government of Tamil Nadu decided to curb the commercialisation of renal transplantation by promoting deceased donor transplantation.16

The transplantation of Human Organs Act was promulgated by the Indian government in 1994 and thereafter deceased donor transplantation Program was initiated. Then to maintain the demand and supply of organs in a particular part a protocol was needed. The supply was grossly outnumbered by the demand of deceased donor organs.

When there was an illicit organ transplant scam arose in the year 2007, the Tamil Nadu Government made policies to encourage deceased donor transplantations. Workshops were organized between the public and private to encourage partnership in which medical personnel, NGOs and officials participated in large numbers.

To make DDT program more popular among general public many NGOs joined with the Government. A model of transplantation was needed which maintain all the current activities of organ transplantation and help to escalate the DDT.17
DDT is a goal that is easily achievable and is the right way of doing things. There are approximately two lakh people. According to National Crime Records Bureau (NCRB) there is about 1,35,000 road traffic mortalities in 2010.

As per the Indian Journal of Neurotrauma in 2008, about 69% have brain death. If most of the families consent to donate then there will be 90,000 potential organ donors. Only a small percentage of these donors are sufficient to meet the ends for various organ donations. Hence all these facts suggest the model with transparent activities there will be an end to illicit organ transplantation by meeting the organ requirement of the patients.

To supplement the Tamil Nadu Human Organs Transplantations ACT 1994, the government set guidelines and promulgated orders to lay down a set of norms.  

THE TAMILNADU EXPERIENCE

Deceased donor transplantation is very much eligible to be the main source of organ transplantation requirements and there are various reasons for it. Several lives could be saved and commercialisation of transplantation can be eliminated. There is also decreased need for near relatives to donate their organs and they are without any moral
compulsion. The wealthy and economically downtrodden will benefit from it. If only the relatives of the deceased donors are made aware most of they would be willing to do so. The infrastructure and other logistics are available for this to happen.\textsuperscript{19}

When compared to other countries, India is far behind in the rates of human organ transplantation. The four cardinal States that intensely practice deceased donor transplantation are, Maharashtra, Andhra Pradhes, Gujarat and Tamil Nadu.

There were studies done in deceased donor survival rates in Tamil Nadu and Gujarat. The study done in Gujarat with 160 deceased donor transplantation, which was a single centre experience showed a mean follow up of 2.35± 1.24 years with patient and graft survival rates of 77.5 % and 89.5 %. The study from Tamil Nadu which was also a single centre experience showed patient survival rates of 79.8 % and 74.8 % at 1 and 3 years respectively. The same study showed the graft survival rates which was censored for death as 92.4 % and 87.9 % at 1 and 3 years respectively.\textsuperscript{20}

From October 2008 to March 2014, the Tamil Nadu Deceased donor transplant programme facilitated the retrieval of 2508 organs from 454 deceased donors. The average rate of generation of deceased donors in the state of Tamil Nadu is seven per month at present. When compared
head on with International Standards it far behind, but when compared head on with other states in India it is more than ten times more.

THE ROLE OF NON GOVERNMENTAL ORGANIZATIONS (NGOs)

The Deceased donor transplantation programme was made successful in our State because it was the ensuing collaborative effort involving the NGOs, private sectors and the State Government. The team work of them starts early with the identification of deceased donor, maintenance in the dedicated intensive care unit, counselling given to the donor families who have lost their dear ones and timely organ retrieval, which is coordinated by the transplant coordinator and involves the joint effort of NGOs and the hospital in which the transplant is done.  

NGOs also played a crucial role in the success of this program in the state of Tamil Nadu. The cardinal work done by, MOHAN (Multi organ Harvest Aid Network) an NGO for the past fifteen years and has coordinated organ transplantation very well.

The effective implementation and its success have attracted many other states and also the defence personnel. Indian defence forces through their hospital network implemented successfully this program and more
than forty thousand army personnel have pledged their organs in case accidental death.

The Rajiv Gandhi Government General Hospital alone have played a crucial role in the success of this programme and have counselled several families with a conversion rate of 66%. More than 300 organ and tissues were harvested and transplanted from 62 deceased donors in this hospital. The important stakeholders include media which played a crucial role in the total framework of deceased donor transplantation programme. Their motto is ‘deceased donor organ transplantation saves lives; it can eliminate illegal organ trade’.

THE TAMIL NADU MODEL

The deceased donor transplantation program is effectively functioning through a framework that promotes organ allocation which is fair and transparent manner only to support the recipient.

The structure of this model is comprised of an anchor; he is also called the Convener in this programme. His role is to maintain the list of recipients who are waiting for transplantation and allocate organs, collect data on transplantation and maintaining the statistics, to arrange for periodic meetings and creating programs on awareness.
His effort is supported by the advisory committee that has been formed to establish formats and procedures, to supervise the compliance with the same procedure, to adequately ensure the stability of functioning of the program and to streamline the program by recommending a coordination body.

Certain sub-committees have also been set up by the advisory committee to provide inputs for the same and are available for help and consultation and aiding in the decision making. There are various sub-committees for renal, heart, liver and lung transplantation. This framework functions as per the orders of the state government and the advisory committee guidelines.

The Tamil Nadu model involves the allocation of one kidney, liver and heart automatically to the same hospital where there is declaration of brain death and they are called local organs. The second kidney, the heart and liver if not used by the local hospital will become shared organs and is given to others hospital on priority basis and guidelines.23

**IMPORTANT GOVERNMENT ORDERS**

1. Declaration of brain death has been made compulsory IN Government Medical College Hospitals in Chennai – Orders issued. G.O (Ms) No.6 dated: 08.01.2008.
2. Procedure for declaration of brain death in Government Medical college hospital.


THE ROLE OF TRANSPLANT COORDINATOR

The transplant coordinator should be available round the clock and should in touch with the convener with two other medical officers in the hospital. He also makes sure that the hospital creates a waiting list of patients who are awaiting transplantation. And it is also frequently updated. The full details of the recipient with the emergency contact phone numbers should be available in the hospital.

He should also be in constant touch with the intensive care doctor in case there is any brain death is suspected and make
arrangements for certification of brain death and offer grief counselling to
the relatives. He should also inform the convener immediately once the
family is willing to donate. He should also give the full details of the
donor to the convener.

All the allocation and prioritisation of the organs is done under the
norms of the government to maintain the transparency.

The shared kidney if it is from a government hospital will be given
in the following priority,

- Combined government hospital list
- Combined private hospitals list
- Government hospital outside the state
- Private hospitals outside the state
- Foreign national in/out of state.

The shared kidney from a private hospital is allocated as follows,

- Combined government and private hospitals list
- Government / private hospital outside the state
- Foreign national in or out of state.
ENHANCEMENT OF PUBLIC AWARENESS

The Tamil Nadu model not only framed vital rules and regulation for the allocation of organs but also played an important role in creating awareness about the programme. Public awareness is useful in building a conducive environment for governments and the hospitals to work in. By ensuring that influential persons in society sign up as organ donors we can create awareness. There is also a concept of donor card created by this program. Having this card sensitises the relatives to donate organs during the right situation. The whole exercise is coordinated by the convener. Highest record of transplants was recorded following successful implementation of this program and five hospital in the state contributed the vast majority.

The state of Tamil Nadu has the highest deceased donor transplantation rate in India only through public-private partnership. The current rate in our state is 1.3 million which more than 15 times of the national average.

BRAIN DEATH AND OTHER MEDICO LEGAL ISSUES

The stage at which all functions of the brain-stem have permanently and irreversibly ceased is considered as brain death. The Human organs transplantation act also makes it legal death, provided the
certification is carried out as per norms. The declaration of brain death is made mandatory in all the government medical college hospitals in Chennai and issued procedures for the same.

For the certification of brain death, four doctors should sign the legal documents which include medical practitioner who is in charge of the hospital, a medical practitioner and neurologist nominated by the hospital and the doctor who is treating the patient.

**Maastricht Categories for Non-Heart –Beating Donors**

Category I : dead on arrival

Category II : unsuccessful resuscitation

Category III : awaiting cardiac death

Category IV : cardiac death in a brain-dead donor

Category I and II DCD donors are also referred to as uncontrolled donors, are asystolic and pulseless after adequate but failed attempts at resuscitation. Uncontrolled DCD is the most common form in Spain and Japan. Category III or controlled donors is the most common form in United States. Category IV donors are referred as crashing donors, who become hemodynamically unstable enroute to organ retrieval after a diagnosis of brain death.
Donation after cardiac death is associated with high rate of delayed graft function, but long-term graft survival is similar when compared to that of brain-dead donors.

DECEASED DONOR MAINTENANCE IN ICU

Deceased donors are maintained by a team of dedicated Anaesthetists who perform the apnoea test twice in a six hour interval. The same is confirmed by Neurologist. To ensure adequate tissue perfusion for oxygenation by maintaining the mean arterial pressure of the organs is the overall goal. The most common problems encountered during cadaver maintenance are hypotension, hypoxia, pulmonary oedema, cardiac arrest and renal shut down.

The following tests are done after the first apnoea test is performed:

- Blood grouping and typing
- Hepatitis B surface antigen
- Human immunodeficiency virus I & II
- Hepatitis C virus
- Renal function tests
- Liver function tests
- Complete hemogram including coagulation profile
ROLE OF TRANSPLANT COORDINATOR

Once it is confirmed that there are no contraindications for donation the transplant coordinator is required to:

- Counsel the family for organ donation and seek their consent
- Inform all other transplant team personnel
- Complete all legal formalities except for filling the Brain Death form (Form 8)
- Obtain drugs and fluids necessary for the donor

ORGANS RETRIEVAL

The removal of kidneys is part of multi-organ procurement and frequently includes harvesting of liver, heart and sometimes lungs and pancreas. Corneal retrieval can take place at the end of solid organs removal. The principles of organ removal include wide exposure and in situ perfusion with cold intracellular-based fluids to preserve the organs. The organs after cross-clamping are removed in the following order – heart, lungs, liver, pancreas and kidneys.

The organs should be removed with utmost care to avoid any anatomic damage and to preserve their vasculature. After all the efforts have been taken to identify, certify, obtain consent and ensure maintenance of a potential donor it would be very frustrating to lose an
organ due to technical errors. The relatively high incidence of multiple vessels in kidneys necessitates careful dissection. It is best that the team that is going to perform transplant should also retrieve it.²⁵

**PERFUSION FLUID**

The Celsior-solution, UW (University of Wisconsin) and HTK (histidine-tryptophan-ketoglutarate) solution all are equally effective and are standard for multi-organ and single kidney harvesting procedure.²⁶ Perfusion with crystalloid solution is sufficient for living donors, in whom a long cold ischemia time is not expected.

**Aims of modern kidney storage solutions**²⁷

- Reduce the cell-swelling during ischemia
- Maintaining the intra- and extra-cellular electrolyte gradient
- Acidosis buffering
- Giving energy reserve
- Decreasing reperfusion and oxidative injury

The two methods of kidney preservation are:

- Cold perfusion initially followed by ice storage.
- Continuous machine-perfusion
(The latter is preferred for non heart-beating donors and marginal donors).

Duration of organ preservation:

The cold ischemic time should be kept as minimum as possible. Elderly donors more than fifty-five years and marginal donors are much more sensitive to ischemia when compared to young donors. Hypothermic organ preservation lowers the metabolic rate, preserves stores of adenosine tri phosphate, and prevents formation of oxygen-free radicals during the reperfusion phase.

PACKING OF KIDNEYS FOR STORAGE AND TRANSPORTATION

The packing of kidney is done by three bag technique, it is found to be safe and keeps the kidney sterile, especially if plastic bags are used for packing.

Only cold preservation should be used in the inside bag with kidney fully immersed in it. It must be ensured there should be no leaks in the bag before making an air-tight closure of the bag.
RECIPIENT PREPARATION

The three senior most patients in the waiting list of the concerned blood-group are called for and Complement Dependent Cytotoxicity Crossmatch is performed. The patient with the least percentage of negative cross-match ($<20\%$) is selected as the recipient.

INDUCTION AGENTS

The Kidney Disease : Improving Global Outcomes (KDIGO) Guidelines recommends to use induction therapy with a biologic agent to be used as part of the initial immunosuppressive regimen. It also recommends Interleukin 2-receptor antagonist (Basiliximab) as the first-line induction therapy. In renal transplant recipients with high immunologic risk lymphocyte-depleting agent, rather than an Interleukin 2-receptor antagonist is preferred.

We have used Anti-Thymocyte Globulin- rabbit origin (r ATG), in a dose of 1-1.5mg/kg body weight single dose in the peri-operative period. In the absence of rATG, we have used Basiliximab. In Government Hospitals Induction agents are given free of cost and is only available to the patient recently. Cytomegalovirus prophylaxis is given for three months to all patients who had received lymphocyte depleting agents as induction therapy.
IMMUNOSUPPRESSIVE DRUGS

KDIGO recommends starting immunosuppressive medications prior to or at the time of kidney transplantation. We start immunosuppressive drugs one day prior to transplant. We start C.Tacrolimus in a dosage of 0.1 mg/kg, T. Mycophenolate mofetil 500 mg twice daily and T. Prednisolone in a dosage of 0.5 mg/kg and tapered to 10 mg per day at the end of four months.

IMMUNE SURVEILLANCE

When a tissue from a donor who is genetically different is transplanted, the recipient mounts an immune response which ultimately results in the destruction of the graft. Continuous immune monitoring and surveillance have significantly reduced the rates of acute rejection. However the same has not translated into improved graft survival and long-term graft loss continues to be a problem.

Based on the time of occurrence of infections, rejection is traditionally classified as hyper acute, early acute, late acute or chronic. The Banff criteria of renal allograft rejection classifies it into T cell mediated (acute or chronic), or antibody mediated (acute or chronic) based on the pathological features. It has updated the C4d staining characteristics and the presence of Donor Specific Antibodies.
Graft failure could be due to various immune and non-immune factors and identification of risk-factors both before and after transplant also enhances the success rate. The three important factors that influence the risk stratification are clinical factors, HLA typing and alloantibody screening. Hence both before and after transplantation immune surveillance is very important.\textsuperscript{28}

**IMMUNOLOGICAL RISK**

This was well stratified by Gebel et al into three broad risk categories for a given combination of the donor and the recipient. This was adapted by the British society for histocompatibility and British Transplantation Society which are as follows,

1. High immunological risk: This is characterized by high titre of circulating antibodies at the time of transplant, which directed against the donor HLA antigens.

2. Intermediate risk: which is characterised by historically documented donor reactive sensitisation but not documented at the time of transplant?

3. Low risk: is characterised by lack of sensitisation or sensitisation with non donor specific antibodies.

Hence it is clear that HLA typing and matching of the donor and recipient and alloantibody testing for Donor
Specific Antibodies are critical for immunological risk stratification.

FACTORS AFFECTING GRAFT SURVIVAL

Though there is a significant reduction in acute rejection rates with the introduction of Tacrolimus, Mycophenolate mofetil and Interleukin-2 Receptor Antagonist induction, the results of long-term graft survival in renal transplantation have been mixed. The data from Collaborative study done at Europe show substantial improvement in graft survival half-life. But another study from United States show only modest improvement with graft survival half-life increase from 6.7 years in 1990 to 8.7 years in 2006 for Deceased Donor Renal Transplantation.

RISK FACTORS FOR GRAFT FAILURE

They could be classified as,

Donor factors : age > 60 years, Female gender, Vascular disease, prolonged cold ischemia times as in Donation after cardiac death and Deceased donation and delayed graft function.

Recipient : obesity, Hypertension, hyperlipidemia and Diabetes Mellitus, smoking and non-adherence to immunosuppressive drugs and mismatch in the size and female gender.
Immunologic factors: Poor HLA matching, prior sensitisation, inadequate immunosuppression.

CAUSES FOR GRAFT FAILURE\textsuperscript{30}

The major causes for graft failure are

\textbf{Immunological}: Rejection both cellular and antibody mediated, non-adherence to immunosuppressant.

\textbf{Non-immunological}: recurrent or denovo glomerular disease, Graft pyelonephritis, BK virus nephropathy, CNI toxicity, obstruction, vascular causes.

ANALYSIS OF PATIENT AND GRAFT SURVIVAL\textsuperscript{31}

The results of the transplant unit have to be followed closely for future improvement.

Kaplan–Meier probability estimate of patient and graft survival is the most widely accepted descriptor of outcome. Survival estimates is calculated at periods of time after transplantation and should be expressed with their 95\% confidence intervals.

Kaplan–Meier survival estimates are calculated in three ways.

- ‘Patient survival’ is calculated from the date of transplantation to the date of death or the date of the last follow-up.
- Non-censored for death graft survival is calculated from the date of transplantation to the date of irreversible graft failure - return to long-term dialysis or retransplantation or the date of the last follow-up during the period when the transplant was still functioning or up to the date of death. Here, death with graft function is treated as graft failure.

- Death-censored graft survival is calculated from the date of transplantation to the date of irreversible graft failure - return to long-term dialysis (or retransplantation) or the date of last follow-up during the period when the transplant was still functioning. If the patient dies with a functioning graft, the follow-up period is censored up to the date of death. 30
OBSERVATION AND RESULTS
• Total no of Deceased donor transplantations : 73

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**BLOOD GROUP WISE DISTRIBUTION**

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**CAUSES OF BRAIN DEATH**

- ROAD TRAFFIC ACCIDENT : 56
- FALL FROM HEIGHT : 13
- ANEURYSMAL BLEED : 2
- SUB-ARACHNOID HEMORRAGE : 1
- TRAUMATIC ASPHYXIA :

![CAUSES OF BRAIN DEATH](image)

**NATIVE KIDNEY DISEASE:**

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<td>FSGS</td>
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<td>IgAN</td>
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<td>1.4</td>
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<tr>
<td>NK</td>
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<td>SLE</td>
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<td>73</td>
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### DESCRIPTIVE STATISTICS

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<tr>
<th>Variable</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
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<tr>
<td>Age (years)</td>
<td>73</td>
<td>18</td>
<td>57</td>
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<td>.80</td>
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<td>on HD-months</td>
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<tr>
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<tr>
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<td>2</td>
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<td>Age of donor (years)</td>
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<td>12</td>
<td>68</td>
<td>33.51</td>
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<td>CIT (hours)</td>
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<td>0</td>
<td>1891</td>
<td>733.14</td>
<td>593.439</td>
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</table>
• The mean duration of Haemodialysis prior to transplant was 20.14 (± 13) months.

• The overall mean age of the recipient was 34 (± 7.8) years.

• The overall mean age of the donor was 33.51 (± 13.3) years.

• HTK ( Custodiol ) was the organ perfusion solution used in all patients.

• The mean cold ischemic time was 8.01 (± 2.73) hours.

• Total recipients who had received induction immunosuppression were 13 patients.

• Anti-Thymocyte Globulin, rabbit origin (rATG) was used in 6 patients.

• Interleukin-2 receptor antagonists (Basiliximab) were used in 7 patients.

• Significant intra-operative events encountered in 10 patients such as
  
  - Bleeding : 2
  - Mottling : 1
  - Hypotension : 4
  - Impending graft rupture : 1
  - Accessory artery to External iliac artery : 2
INTRA OP

**INTRA OP EVENTS**

<table>
<thead>
<tr>
<th>Absent</th>
<th>Frequency</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>63</td>
<td>86.3</td>
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</tr>
<tr>
<td>Present</td>
<td>10</td>
<td>13.7</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>100.0</td>
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</table>

- Significant post-operative complications were encountered in 30 patients.

POST OPERATIVE EVENTS

<table>
<thead>
<tr>
<th>POST OPERATIVE</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>43</td>
<td>58.9</td>
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<tr>
<td>Present</td>
<td>30</td>
<td>41.1</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>100.0</td>
</tr>
</tbody>
</table>

- Sepsis : 7
- Delayed graft function : 6
- Graft nephrectomy : 4
- Persistent drain (lymphocele) : 9
- Pancreatitis : 3
- Right lower limb ischemia : 1
INFECTIONS DURING FOLLOW UP

- Pneumonitis : 7
- Sepsis : 10
- Recurrent UTI and BK virus : 1
- HCV Related DCLD : 1
- Mycobacterial tuberculosis – 3 (Joint TB in 1, Pulmonary in 2)

- Accessory renal arteries were found in 22(30.1%) patients, triple in 4 and double in 18.

**GRAFT BIOPSY**

<table>
<thead>
<tr>
<th>Valid Need for Biopsy</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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</thead>
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<td>80.8</td>
<td>80.8</td>
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<td>Total</td>
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</table>

**GRAFT FUNCTION**

<table>
<thead>
<tr>
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<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>45</td>
<td>61.6</td>
<td>61.6</td>
<td>61.6</td>
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<tr>
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<td>23</td>
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<td>31.5</td>
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<td>5</td>
<td>6.8</td>
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<td>100.0</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td></td>
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</table>
- Mean tacrolimus levels on fourth postoperative day were: 6.75 (±4.05) ng/ml
- Acute cellular rejections were encountered in 7 (9.58%) patients.
- Acute antibody mediated rejection was encountered in 2 (2.74%) patients.
- Acute tubular necrosis (ATN) – biopsy proven – was observed in 6 (8.21%) patients.
- Mean follow up period was 4 years.
- Recent mean serum creatinine is 1.45 (±0.42) mg/dl.
- New onset of Diabetes after renal transplant (NODAT) was observed in 10 (13.69%) patients.
- Post transplant Erythrocytosis was observed in 8 (10.96%) patients.

**GRAFT SIDE**

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
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<td>43</td>
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<td>Left</td>
<td>30</td>
<td>41.1</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>100.0</td>
</tr>
</tbody>
</table>
SEROLOGY STATUS

- One patient was HBsAg positive prior to transplant
- One patient was HCV positive prior to transplant
- One patient who was HCV negative prior to transplant turned out to be HCV positive post transplant.

<table>
<thead>
<tr>
<th>HCV</th>
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</thead>
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<tr>
<td>Negative</td>
<td>70</td>
<td>95.9</td>
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<tr>
<td>Total</td>
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</table>

GENDER OF DONOR

<table>
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<th>Percent</th>
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</thead>
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<tr>
<td>Total</td>
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</table>

PATIENT SURVIVAL USING KAPLAN-MEIER

Number of Cases: 73  Censored: 28 (38.36%)  Events: 45
<table>
<thead>
<tr>
<th>Survival Time</th>
<th>Standard Error</th>
<th>95 % Confidence Interval</th>
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</thead>
<tbody>
<tr>
<td>Mean</td>
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<td>71</td>
</tr>
<tr>
<td>Median</td>
<td>1168</td>
<td>144</td>
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</tbody>
</table>

- Patient survival at the end of 1 year is 89.33 %
- Patient survival at the end of 3 years is 50.40 %
# GRAFT SURVIVAL (CENSORED FOR DEATH)

Number of Cases: 73  Censored: 14  (19.18%)  Events: 59

<table>
<thead>
<tr>
<th>Survival Time</th>
<th>Standard Error</th>
<th>95 % Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
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<td>869</td>
<td>73</td>
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<tr>
<td>Median</td>
<td>752</td>
<td>206</td>
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</table>

**Survival Function**

![Survival Function](image_url)

**No of days graft functioned**

**Cum Survival**

- Survival Function
- Censored
<table>
<thead>
<tr>
<th>Valid</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dead</td>
<td>28</td>
<td>38.4</td>
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<tr>
<td>Survive</td>
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<td>61.6</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>100.0</td>
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</table>

- OUT OF 73 PATIENTS 28(38.4%) DIED.
DISCUSSION
Total number of deceased donor transplantations was 73 up to March 2014.

Though the deceased donor programme began in the year, it started gathering momentum only after 2008, when a doctor couple donated their son’s organs who sustained RTA which drew widespread public attention.

In Tamil Nadu the total number of deceased donor transplantations was 425, and the total number of organs shared was 2315 including 825 kidneys.

GENDER DIFFERENCE

The number of male recipients was 74 % (n=54) outnumbering female recipients which the usual scenario even in live renal transplantation. The number of female recipients was only 26 % (n=19).

SOURCE OF THE ALLOGRAFT

Rajiv Gandhi Government General Hospital (RGGGH) tops the list by contributing to 46 deceased donations out of 73 deceased donor transplantations in our hospital, which is a staggering 63 %. Being the biggest government hospital in the state, it is the top most referral
institute and sought after hospital in Chennai. In this hospital brain death certification is made mandatory.

Our institution tops the list next by contributing to 14 donors which comes to 19.1%. The other private hospital from the city and the state contributed to the rest of organs donations.

**BLOOD GROUP WISE DISTRIBUTION**

As is the prevalence of blood group so is the transplantation. O blood group being more common tops the list of transplantations, it accounts for 39.7% (n=29). B blood group tops the list next with 34.2% (n=25) and A has 16.4% (n=12) and AB blood group is the least prevalent blood group accounting for only 9.6% (n=7) of the total deceased donor transplantation.

**CAUSES OF BRAIN DEATH**

Road Traffic Accidents (RTA) tops the list accounting for the majority of donations. As is already evident from the gender of the donors the majority are males who sustain RTA without wearing an helmet. The next most common cause of death is fall from height, who are usually construction site labourers without adequate safety precautions. The other causes of brain death are berry aneurysmal bleed, Sub-arachnoid hemorrhage among hypertensives and alcoholics and
traumatic asphyxia in a factory worker due to fall of heavy object over his chest.

NATIVE KIDNEY DISEASE

The prevalence of Native kidney disease among recipients is as follows, the cause is not known in the majority of patients, which is the usual scenario as they are asymptomatic in the earlier stages of the disease; they are on poor follow up after detection of renal failure and refusal for renal biopsy in the earlier stages of the disease. They usually present with overt uremic symptoms when they have small contracted kidneys and renal biopsy could not be performed. Hence the cause is presumed to be CGN/CIN in 37 (50.7 %) patients.

1. Biopsy proven Chronic Glomerular Disease was demonstrated in only 27 (37 %) patients.

2. Alport’s syndrome was the cause of renal failure in 2 (2.7 %) patients.

3. Autosomal Dominant Polycystic kidney disease (ADPKD) was the cause of renal failure in 2 (2.7 %) patients,
4. Focal Segmental Glomerulo sclerosis was the cause in another 3(4.1 %) patients and

5. Systemic Lupus Erythematosus was found in 1 patient (1.4 %).

WAITING PERIOD PRIOR TO TRANSPLANT

The mean duration of Haemodialysis prior to transplant was 20.14 (±13) months. The median waiting period for transplantation is 1.5 years in our centre. The number of patients on each blood group is 15 except for AB blood group and the number deceased donor transplants per year are 10 on an average. Hence there is a long waiting period prior to transplant.

MEAN AGE OF THE DONOR AND RECIPIENT

The overall mean of the donor and recipient was 34 (± 7.8) years and 33.51 (± 13.3) years, since most of the donors were male who sustain RTA, they are relatively young. The recipients also have to come for follow up every month and have withstand dialysis for at least two years, the average waiting period. Hence the recipients are also young.
ORGAN PERFUSION AND PRESERVATION

HTK (Histidine-Trptophan-Alfa Ketoglutarate) – CUSTODIOL was used in all the deceased donor transplantations. The sterile three bag technique is used for packing and transportation is done in sterile ice.

COLD-ISCHEMIC TIMES

The mean Cold Ischemic times was 8.01 (± 2.73) hours. It varied between a minimum of 3 hours when the organ harvest takes place in our centre and is up to 15 hours when the organ harvest takes place in other centres.

Delayed graft function (DGF) and Slow graft function (SGF) was observed whenever the cold ischemic time is more than 10 hours. Out of the 28 patients who had DGF and SGF, nearly twenty of them had cold ischemic time of more than 8 hours.

INDUCTION AGENTS

Only induction agents are available very recently and it is being given totally free of cost in government hospitals. Only 13 patients had received induction agents out of 73 deceased donor transplantations.

Anti-Thymocyte Globulin – rabbit origin (rATG) was used in 6(8.21 %) patients. A single dose of 1.5 mg/kg was given as intravenous infusion
in the preoperative and intraoperative period. T. Valganciclovir 450 mg twice daily is given for three months for Cytomegalovirus prophylaxis for all patients who had received ATG as induction agent.

Among the rATG group, 3 patients died, pneumonitis was the cause of death in all the three patients. One patient had knee joint tuberculosis and tuberculous laryngitis.

Interleukin-2 receptor blockers (Basiliximab) was used in 7(9.58 %) patients. Two doses of 20 mg each is given at 4 days interval.

Among the Basiliximab group one patient died due to pneumonitis of tubercular etiology.

INTRAOPERATIVE EVENTS

The significant intra operative events that were encountered in 10 patients are as follows,

Bleeding following clamp release necessitating two re-suturing of the graft artery anastomosis occurred in 2 patients, mottling of graft occurred in one patient, hypotension in 4 patients, impending graft rupture necessitating graft nephrectomy in one patient, accessory artery anastomosis to External Iliac Artery in two patients.
POST OPERATIVE EVENTS

The significant postoperative events encountered are as follows,

- Sepsis in 7 patients
- Delayed Graft Function in 6 patients
- Graft Nephrectomy in 4 patients – 2 patients had impending graft rupture and 2 patients had graft artery thrombosis
- Persistent drain due to lymphocele in 9 patients
- Pancreatitis in 3 patients
- Right lower limb ischemia following external iliac artery thrombosis in one patient

INFECTIONS

- About 7 patients had Pneumonitis – mostly bacterial, one patient had Pneumocystis carinii pneumonitis
- Mycobacterial tuberculous infections were seen in 7 patients – 4 patients had lymphnodal involvement, 2 patients had pulmonary tuberculosis, one had Knee joint & laryngeal involvement.
- One patient had recurrent Urinary Tract Infection and Graft dysfunction and was found to have BK Virus nephropathy.
- Sepsis occurred in 10 patients, mostly within first 6 months of transplantation, when they are exposed to peak immunosuppression.

- Hepatitis C Virus related decompensated liver disease occurred in one patient.

**GRAFT BIOPSY**

Graft Biopsy was performed in 14 patients,

- Acute cellular rejections were seen in 7 (9.58 %) patients. Out of 7, 4 was early acute rejections and 3 was late acute rejections. All of them responded to steroids.

- Acute Antibody Mediated rejections was seen in 2 (2.74 %), both improved with plamapheresis.

- Acute Tubular Necrosis was seen in 6 (8.21 %) patients.

**FOLLOW-UP**

- **THE MEAN FOLLOW UP PERIOD WAS 4 YEARS.**

- The recent mean serum creatinine is 1.45 mg/dl.

- New onset of Diabetes after transplantation (NODAT) was seen in 10 (13.69 %) patients.

- Post transplant Erythrocytosis was observed in 8 (10.96 %) patients.
The mean tacrolimus was 6.75 (±4.05) ng/ml as measured by Chemiluminiscent Microparticle Immunoassay.

VIRAL SEROLOGY

- One patient was HCV positive prior to transplant.
- One patient was HBsAg positive prior to transplant, he died due to pneumonitis.
- One patient who was HCV negative prior to transplant became HCV positive, had Decompensated liver disease and hepatic encephalopathy and died.

PATIENT STATUS

- Out of 73 renal transplantations 28(38.4 %) patients died.
- Patient survival at the end of 1 year is 89.33 % and at the end of 4 years is 56.40 %. (KAPLAN-MEIER ESTIMATES)

GRAFT SURVIVAL (Censored for death)

- Graft survival at the end of 1 year is 73 % and at the end of 3 years is 44%.

The patient and graft survival rates are very much comparable to that of live related renal transplantation.
### GSH – CADAVER Tx - SURVIVAL RATE – comparison with other centers

<table>
<thead>
<tr>
<th>CENTER / YEAR</th>
<th>n</th>
<th>PATIENT SURVIVAL</th>
<th>GRAFT SURVIVAL</th>
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<tr>
<td></td>
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<td>2ND YR</td>
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<tr>
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<td>80%</td>
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<td>89.33%</td>
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<tr>
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<td>54</td>
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<td>SRMC, CHENNAI2</td>
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<td>--</td>
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<td>IKRDC, GUJRAT3</td>
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<td>USRDS DATA4</td>
<td>13,780</td>
<td>92.6%</td>
<td>88.4%</td>
</tr>
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</table>

2. Transplant Proc. 2008 May;40(4):1104-7
4. USRDS DATA 2012
CONCLUSIONS
CONCLUSIONS

- The survival rates for both patient and graft of deceased donor transplantation is equal to that of live related renal transplantation.

- Out of 73 deceased donor transplantations, 28 (38.4 %) patients died.

- The causes of death were Sepsis and Delayed Graft Function - 20, Pneumonitis – 7, HCV related Decompensated liver disease -1.

- Only way to combat the illicit organ trading (commercial renal transplantation) is deceased donor transplantation.

- Cadaver organs should be considered as nation’s resource and organs wasted should be treated as lives lost.

- Our deceased donor program demonstrates that it can be implemented successfully as long as the framework of the program maintains transparency and adheres to established protocols.

- Hence deceased donor transplantation is the need of the hour, which can be promoted by positive public attitude, identification of early brain death and certification, getting prompt consent for organ donation and adequate hospital
infrastructure are essential prerequisites for successful organ transplantation.

- The state of TamilNadu would definitely be a good role model in this regard.
BIBLIOGRAPHY


26. Agarwal A, Murdock P, Fridell JA. Comparison of histidine-


28.Collaborative Transplant Study. CTS Outcome Graphs.

2011; Graph K-14103E-0711. Available at:


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<th>Height</th>
<th>Weight</th>
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<th>Tx - I/II :</th>
<th>PTE :</th>
<th>CIT :</th>
<th>LVH :</th>
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