LIST OF PROCEDURES DONE
PROJECT REPORT

TITLE OF THE PROJECT: **EX-VIVO EVALUATION OF CHITRA VARIFLOW OXYGENATOR ADULT/PAEDIATRIC WITH INTEGRAL CARDIOTOMY RESERVOIR**

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**PROGRAMME:** M.Ch. C.V.T.S.

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**Forwarded & Recommended**

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM 695011
Note:

(i) In the case compilation of procedures done, the contents and the subsequent pages should be made into different sections (a) Procedures done (b) Procedures assisted (c) Procedures participated (d) Procedures attended/participated etc in Other Centres. Each section should be preceded by a leaf carrying the name of the section that is succeeding.

(ii) The Contents page will carry into, as per model given under

PROCEDURES DONE

Closed Mitral valvotomy........................................124 (say)
Patent ductus arteriosus-ligation.................................10
Atrial septal defects.............................................20

PROCEDURES ASSISTED

Closed Mitral valvotomy.................................100 (say)

(iii) In the subsequent pages details of each procedure done/assisted should be given in the format given below:

Heading: **Closed mitral valvotomy**

<table>
<thead>
<tr>
<th>Date</th>
<th>Name of the patient</th>
<th>Age</th>
<th>Sex</th>
<th>Patient No.</th>
</tr>
</thead>
</table>

(iv) In the case of Project Report in the page immediately following the Certificate page the under-mentioned details should be given:

(a) Title
(b) Duration
(c) Aim and scope
(d) 50 word summary of work done
CONTENTS

1. PROJECT REPORT OF EX-VIVO EVALUATION OF OXYGENATOR.

2. SURGICAL TECHNICQUE OF MITRAL VALVE REPLACEMENT IN ANIMALS

3. CAROTID ARTERY - JUGULAR VEIN ANASTOMOSIS WITH DELAYED LIGATION TO CREATE ANEURYSMS IN ANIMALS.
Postings of Biomedical technology wing accounted for two activities.

1. Taking part in on going project of Ex-vivo evaluation of Chitra hard shell oxygenator.

2. Taking part in other on-going research projects which involve the surgical procedures to improve surgical skill.

(a) Mitral valve replacement in sheep using Chitra tilting disc valve
   (i) Implantation in mitral annulus
   (ii) Descending thoracic aorta
   (iii) Pulmonary annulus

(b) Carotid artery - Internal jugular vein anastomosis followed by delayed ligation of vein to create aneurysm in experimental animals (dog) - 1

(c) Intra cranial pressure monitoring with an extra dural device.
EX VIVO EVALUATION OF CHITRA VARIFLOW OXYGENATOR
ADULT/PAEDIATRIC WITH INTEGRAL CARDIOMGY RESERVOIR

INTRODUCTION

Oxygenators are the devices which provide artificial
gas exchange during the suspension or absence of
lung function. Originally introduced by Gibbon for
open heart surgery in 1953, oxygenator technology grew
rapidly in subsequent years with advancement in knowledge
regarding biology of respiration, biocompatibility of the materials
and gas-liquid mass transfer.

Although oxygenators cannot equal the performance
of normal lung, they are expected to fulfill stringent
functional criteria which cover gas transfer, damage to
the blood elements, non-toxicity of component materials,
durability of function and test animal survival.

Three basic types of oxygenators are:
1. Film oxygenators
2. Bubble oxygenators
3. Membrane oxygenators.

In bubble oxygenators, oxygen is dispersed into venous blood
through small holes in the distributing manifold located at the
bottom of the bubble chimney. Bubble oxygenators consists of
chambers of bubbling, deoiling and settling which
are either arranged sequentially or concentrically.
Even though sequential bubble oxygenators continue to be in current use because of their efficiency, disposability, low cost, concentric bubble oxygenators have currently claimed wider acceptance despite high cost due to their compactness, low priming volume, and ready integration of heat exchangers.

Chitra hard shell oxygenator is a new bubble oxygenator of concentric design manufactured at our institute Biomedical Technology wing. It consists of a central column through which venous blood mixed with oxygen climbs and a surrounding chamber of anti-foam coated substrate through which oxygenated blood descends to the bottom of the unit. It also contains an integral metal coil for circulation for cold or warm cooler for cooling or warming of blood. A cardiotomy reservoir has been incorporated in this new design. This new model has facility to change the blood gas flow ratio from adult to paediatric circuit.

**EXPERIMENTAL PROTOCOL**

This study was undertaken to evaluate the new oxygenators using sheep as the experimental animal.
Aim of the study was to evaluate the following functions of oxygenator:

1. Oxygenation efficiency.
2. CO2 removal efficiency.
3. Damage to blood components.
4. Efficiency of heat exchanger device.
5. Function of cardiotomy reservoir.
6. Organ dysfunction if any.

Total of six experiments were done in sheep.

Weight of the animals ranged between 29.5 kg to 33.5 kg (mean 31.3 kg).

In all animals pre-operative haemogram, coagulation parameters including plasma Haemoglobin, Liver and Renal functional parameters were done to know the basal value and in the surviving animals these parameters were monitored post-operatively up to one week.

After pre-operative preparation with 24 hour fasting, 12 hour water restriction and systemic antibiotic prophylaxis animals were pre-medicated with atropine and diazepam.

Under General anaesthesia Left lateral thoracotomy was done. After systemic heparinisation Cardio-pulmonary bypass was established with arterial return to descending thoracic aorta and venous drainage from RV outflow through Pulmonary artery into the oxygenator.

Oxygenator and bypass circuit were primed with haemo-diluent prime i.e. 1500 ml of Ringer's lactate, 500 ml of blood, mannitol 50 ml, NaHCO3 75 ml, CaCl2 20 ml and heparin 75 mg.
Total priming volume was 2800ml. Average circulating Haemoglobin was 6.4 g/dl.

- Blood flow rate was maintained around 70 ml/kg/min.
- During the procedure, Heart rate, blood pressure, central venous pressure, urine output, rectal temperature were monitored. Cardiopulmonary bypass was maintained for one hour except one animal where it was continued for 8 hours.

- Active cooling and rewarming were done in three experiments to assess efficiency of heat exchanger.

- Additional crystalloid-blood was added to cardioplegic reservoir during the procedure to assess its function.

- Blood gas analysis was done every 10 minutes on bypass.

- At the initiation of bypass Blood to Gas flow ratio was maintained at 2:1 Later on gradually it was reduced to 1:1 flow ratio.

- Cardiopulmonary bypass was terminated at the end of one hour except in one experiment where 8 hour CP bypass was conducted. Once the animal was awake and has regained spontaneous breathing effort animal was weaned from the ventilator. Time of awakening was also noted.

- Post-operatively Haematocrit, plasma Hb, RBC, WBC, platelet count, Serum bilirubin, BUN, creatinine total proteins were serially estimated up to one week in the surviving animals or until death of animal.

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Results and Observations:

- Pre-operative haematocrit of animals ranged between 10.8 to 12.0 g/dL (mean 11.6 g/dL).
- Circulating haemoglobin during CPB bypass maintained between 6.0 to 7.0 g/dL (mean 6.49 g/dL).
- Total perfusion period in all experiments 6 minutes except one where it was two hours.
- Perfusion pressure during CPB was maintained between 80 to 92 mmHg (average 72.0 mmHg).
- Blood flow ranged between 1.2 to 2.67 L/min. Mean blood flow 2.03.
- Oxygen flow during CPB bypass ranged between 1.25 L/min to 5.0 L/min. Mean flow 3.69 L/min.
- Blood to gas ratio varied between 1:0.75 and 1:2.5. Average blood to gas flow ratio 1:1.8 L/min.
- PO₂ during perfusion varied between 104 to 506 mmHg (mean 345 mmHg).
- Mean PCO₂ in all experiments was 88.37 mmHg.
- Average pH measurement was 7.6.
- Rate of drop of temperature during cooling was 0.493°C/min with water bath temperature not exceeding 10° difference from body temperature.
- Rate of rewarming was 0.194°C/min.
- Cardiomyotomy reservoir worked efficiently in all the experiments without any clogging of filters.
Graph depicting oxygen/blood flow during CPB.

Graph showing the PO2 value during CPB.

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Average pre operative plasma haemoglobin was 7.95 gm/l.

During CP bypass it increased to 11.9 gm/l. and returned to pre operative level on 3rd post operative day.

In all the six animals CP bypass was successfully weaned off.

Animal regained consciousness on an average 2-2.5 hours after completion of the procedure.
Of the six animals two died on the day of operation. First animal died due to acute pulmonary edema suspected to be related formalin sterilisation of the oxygenator. Later gamma irradiation was used for sterilisation. Other animal died of hyperkalaemia. One animal died on the second post-operative day due to infection. Other three animals are surviving and doing well.

Serial estimation of haemogram, biochemical parameters post-operatively demonstrated mild reduction in the haemoglobin, RBC count, platelet count, total proteins in the immediate post-operative period which gradually improved over a week period. Mild increase in Blood urea nitrogen was noted in all experiments probably related to non-pulsatile cardiopulmonary bypass.

| TABLE Showing Biochemical Parameters and Haemoglobin – Serial Values |
|-----------------|-----------------|-----------------|-----------------|-----------------|
|                | Hb.             | Total Proteins  | BUN             | Bilirubin       |
| Pre-op        | 11.6 gm%        | 8.7 gm%         | 23.0            | 0.7             |
| 1st post-op   | 7.3 gm%         | 7.7 gm%         | 49.6            | 0.8             |
| 3rd post-op   | 7.1 gm%         | 7.0 gm%         | 33.0            | 0.7             |
| 7th post-op   | 6.5 gm%         | 8.23 gm%        | 33.5            | 0.7             |
Conclusions:

- This new oxygenator device was found to have excellent gas transfer efficiency as evidenced by maintenance of average PO₂ 845 mmHg with mean blood to gas flow ratio 1:1.8 L/min and mean PO₂ 283 mmHg.

- Damage to the blood elements by the device was minimal and acceptable.

- Heat exchanger and cardiomyocyte reservoir function was excellent.

- There was no demonstrable organ dysfunction related to the oxygenator except for mild renal dysfunction related to non-pulsatile cardio-pulmonary bypass.
Mitrval valve Replacement with Chitra tilting disk prosthesis.

1. Implantation of mitral valve in mitral annulus.

Under general anaesthesia, left thoracotomy was done through the 4th Intercostal space. Pericardium was opened and marsupialised. Cardiopulmonary bypass was established with arterial return to descending thoracic aorta and venous drainage from RV outflow through the pulmonary artery into the oxygenator. Core cooling was done up to 30°C. On view of the non-accessibility of root of aorta, myocardial protection using cardioplegia was not possible. Hence in few experiments only ischaemic arrest with topical cooling was used. In two animals intermittent aortic cross clamping i.e. ischaemic arrest for 10 minutes followed by reperfusion for 3 minutes was used as a method of myocardial protection. Mitral valve was approached through the LA appendage. Mitral valve was excised leaving 3 mm rim of native leaflet tissue. Chitra tilting disc prosthesis was inserted using all interrupted 2-0 ethibond sutures.
Left atrial incision was reopened. Separate
crossclamps LA and Ao was put and aortic
clamp was released. Cardio pulmonary bypass
was weaned off at 34°C and Decannulation
cwas done (Venous de cannulation) immediately
as most of the cannula was obstructive to RV.
After systemic heparin Protamine aortic de cannulation
was done and chest was closed in layers
with a basal pleural drain in situ.

2. Implantation of valve in descending thoracic
Aorta.

No. of Experiments: 2.

As in the previous experiment, post operative
lung function was rapidly compromised by prosthetic
valve resulting in mortality, descending thoracic
aortic implantation was done to obviate the above
problem.

Through left thoracotomy, part of descending
thoracic aorta was looped with two tapes between
origin of neck vessels and intercostal vessels. On
view of small size of Aorta, Valve coated with teflon
sewing ring was used for implantation. After
clamping the Aorta above and below vertical
Aortotomy was done. Four stay sutures were
taken from posterior aortic wall to fix the
Prosthesis. Anteriorly a prosthetic gusset was used to cover the protruding portion of valve and the prosthesis was **fixed** to the gusset anteriorly. Aortotomy was prepared with gusset. Total cross clamp time was 35-40 minutes. Due to gross mismatch of size between aorta and valve, lot of tension was present over the suture line. Both the animals died because of bleeding. CARDIOPULMONARY BYPASS WAS NOT USED.

(3) Implantation in pulmonary annulus.

In these experiment, CP bypass was used. Right atrium was cannulated with difficulty for venous drainage, and arterial return to ascending aorta. Pulmonary arteriectomy was done and pulmonary valve was excised. As the annulus was narrow, incision extended across RV outflow and after seating the valve in the posterior portion of pulmonary annulus, Dacron patch was used to accommodate the oversized valve and to reconstruct the RV outflow. Anteriorly valve was fixed to RV outflow patch.
Creation of aneurysms in experimental animals.

Dogs were chosen as the experimental model. This experiment was done for the purpose of evaluating a new intra luminal balloon occlusive device to obliterate the aneurysm sac.

Under general anaesthesia, a vertical incision was made anterior to sternomastoid muscle. Both carotid artery and jugular veins were looped. Bulldog vascular clamps were used to occlude both artery and vein together on either side of the proposed site of anastomosis. After clearing the adventitia layer, a 3 mm anastomosis was done between artery and vein using 6-0 prolene continuous sutures with a single knot. Total carotid occlusion time ranged between 15 to 25 minutes.

At the end of the procedure, good continuance thrill was felt over the vein in all animals. In the first experiment, after occlusion of vein above and below the anastomosis with snugger's clamps, there was rapid ballooning of segment near the anastomosis with a thin wall. Hence it was decided that ligation of the vein to be done at a later date without re-opening the wound. For this purpose, two prolene suture loops were brought outside through separate stab incision above and below the...
Site of anastomosis (close to anastomosis) on the jugular vein with a polythene tube covering over it to prevent adhesions. Delayed ligation was done 2 weeks later.

6) INTRA-CRANIAL PRESSURE MONITORING
EXTRA-DURAL DEVICE
No of Procedures: 3.
In this project, a frontal burr hole was created and the device was fixed into the burr hole of 9.5 mm diameter and pressure changes were monitored.