P24

CERTIFICATE

I, Dr. BALJIT. K. SHARMA ..... hereby declare that I have actually performed ~~all the procedures listed~~/carried out the project under report.

Signature.... Bsh .....

Place: TVM

Name in.. BALJIT. K. SHARMA .....

Date: 18th Aug '86 capital letters

FORWARDED

HOD CVTS

~~LIST OF PROCEDURES DONE~~

PROJECT REPORT

TITLE OF THE PROJECT:

EX-VIVO EVALUATION OF CHITRA VARIFLOW OXYGENATOR ADULT/PAED WITH INTEGRAL CARDIOTOMY RESERVOIR

NAME DR. BALJIT K. SHARMA

PROGRAMME: M.Ch (C.V.T.S.)

MONTH & YEAR OF SUBMISSION: August 1986.

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**

Date	Name of the patient	Age	Sex	Patient No.

(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

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D) IN MITRAL VALVE POSITION.	7.
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CHITRA VARIFLOW HARD SHELL OXYGENATOR ADULT/PAED WITH INTEGRAL CARDIOTOMY RESERVOIR.

CHITRA VARIFLOW HARD SHELL OXYGENATOR ADULT/PAED WITH INTEGRAL CARDIOTOMY RESERVOIR.

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

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INTRODUCTION

Oxygenators are the devices which provide artificial gas exchange during temporary suspension or cessation of respiratory function of lungs. Originally introduced in cardiac surgery by Gibbon in 1953, the oxygenator technology has advanced rapidly over the years owing mainly to a better understanding of gas liquid mass transfer and the biocompatibility of materials.

While the oxygenators cannot equal the performance of normal lung, they are expected to fulfil stringent functional criteria, which include gas transfer, damage to blood constituents, non toxicity of component materials, durability of function and test animal survival.

There are three basic types of oxygenators in clinical use. The film oxygenators, the bubble oxygenators and the membrane oxygenators. In the film oxygenator the gas exchange takes place on the surface of the exposed blood film – minimizing trauma to the blood. However, a large surface area is usually necessary for proper gas exchange and thus they require a higher priming volume. In a bubble oxygenator, the gas is dispersed in blood. This is one of the most effective and simple oxygenator. However, trauma to blood by mechanical introduction of gas is maximum. In the membrane oxygenator the gas exchange takes place across a permeable membrane between the blood and gas. This causes least trauma to the blood.

Essentially the bubble oxygenator consists of chambers of bubbling, defoaming and settling

arranged sequentially or in a concentric fashion. The sequential bubblers have largely been replaced by the concentric models because of their efficiency, disposability, relatively low cost, low priming volume and ready integration of heat exchanger in their design.

Chitra hard shell oxygenator is a bubble oxygenator designed and fabricated at the biomedical technology wing of our institute. It consists of the usual three chambers of a bubbler arranged in a concentric manner with an integral heat-exchanger and a cardiotomy reservoir. This new device has the advantage in that the blood flow ratio can be changed from an adult to paediatric circuit and it obviates the need for an additional cardiotomy reservoir in the circuit.

AIM

The present study was undertaken to evaluate the following functions of the oxygenator - by using sheep as the experimental model.

Gas exchange efficiency.

Trauma to blood components.

Comparative evaluation with an imported unit

Long term perfusion studies to determine the organ damage.

MATERIAL AND METHODS

A total of 13 experiments were done, which were divided into three categories.

1 hour CardioPulmonary bypass with Chitra-Oxygenator 10

1 hour Cardiopulmonary bypass with Bentely oxygenator 1

Acute Long term perfusion of 6 hours using Chitra oxygenators. 2

PREOPERATIVE PREPARATION

All the animals were weighed and pre-conditioned before surgery. A complete haemogram, coagulation profile, Renal and Liver function studies were done to determine the basal values. The animals in the weight range of 26 kg to 34.5 kg (m = 30 kg) were fasted for 24 hrs with restriction of fluids 12 hours before operation. 1 gm of neomycin sulphate was administered orally 12-14 hours prior to operation. Blood samples were taken for analysis and cross-matching.

PREMEDICATION

All animals were pre-medicated with atropine [0.1 mg/kg body wt] I/M - 1 hour before the operation.

ANAESTHESIA

The G.A was induced with 2.5% I/V thiopentone sodium. The animal was intubated in the Left Lateral position. The G.A was maintained with repeated small doses of thiopentone and scoline.

INTRA-OPERATIVE MONITORING.

Continuous arterial B.P and CVP were monitored by cannulating the Left common carotid and Left external jugular vein respectively. A prepucial catheter was placed to monitor urine output. E.C.G was monitored continuously during the operation.

OPERATION

With the animal in right lateral position, a Left Lateral thoracotomy was made through the 4th Intercostal space. Systemic heparinisation was carried out by giving heparin [3mg/kg body weight] I/V. The descending thoracic aorta and the right ventricle thro' the main pulmonary artery were cannulated for arterial and venous return respectively. The CPB was established.

EXTRA CORPOREAL CIRCUIT [E.C.C]

The E.C.C consisted of a "CHITRA" variflow oxygenator with integral cardiotomy reservoir, blood pump, venous, arterial, cardiotomy suction and vent lines. After initial washing of the E.C.C with saline — the oxygenator was primed with the following

Ringer's Lactate	———	1000 ml
Blood	———	500 ml
Mannitol	———	80 ml
Sodabicarb	———	40 ml
Heparin	———	75 mg

The animals were put on CPB for a period of 1 hr in 11 cases [group A+B] and for 6 hrs in 2 cases [group C].

CPB DATA

The total priming volume was 1620 ml with average circulating haemoglobin of 6.0 gm%. The blood flow was maintained around 40 ml/kg body weight keeping the perfusion pressure between 60 mm to 100 mm of Hg.

All the animals were cooled to 30 – 32°C & then rewarmed before terminating the CPB. The blood to gas flow ratio was maintained at 1:1.

After the required time on CPB, the animals were gradually weaned of CPB and decannulated. Heparin was reversed with I/v Protamine [6mg/kg body wt]. The haemostasis was secured and the chest was closed in layers after placing a single left pleural drainage tube. The animal was nursed in a prone position on the operation table and ventilated electively for a few hours till it recovered fully. After the animal became fully conscious it was weaned of the ventilator and extubated. The monitoring lines, the chest tube and the urinary catheter were removed. The animal was brought down on to the floor. Only I/v fluids were given to the animal on the day of operation and oral feeds were started from the 1st post-op day. Systemic antibiotics [streptomycin – 500 mg I/m B.D and procaine penicillin 4 Lac I/m B.D] were administered on the day of operation and continued till the 5th P.O.D.

PARAMETERS MONITORED DURING EX-VIVO EXPERIMENT.

CLINICAL

Heart rate, B.P, C.V.P, hourly urine output, respiratory rate and temperature.

LAB

Arterial blood gases, haematological and biochemical - parameters.

IN IMMEDIATE POST-OP PERIOD

The Corneal reflex, pain reflex, head lifting, tail movements and swallowing reflex were tested to check the level of consciousness.

Haematological parameters monitored were -

Haemoglobin, plasma free haemoglobin, platelets, RBC, WBC, clotting time, P.T & P.T.T.

Biochemical Parameters monitored were -

BUN, Creatinine, Electrolytes, Total proteins, albumin, globulin and bilirubin.

OBSERVATIONS & RESULTS.

In Group A consisting of 10 animals which underwent 1 hour CPB using 'Chitra-Oxygenator' there were two early deaths. [Mortality - 20%].

The first animal died 36 hours after operation due to pulmonary insufficiency.

AUTOPSY - revealed grass particles lining all the major and minor bronchi.

CAUSE OF DEATH - ASPIRATION PNEUMONIA.

The second animal developed severe reaction to blood transfusion immediately after termination of CPB. The plasma free hemoglobin was found to be 300 mg %.

The animal was sacrificed.

CAUSE OF DEATH - MISMATCHED BLOOD TRANSFUSION.

The remaining eight animals survived and had uneventful post-operative recovery. They were alive and well after 6 months of operation.

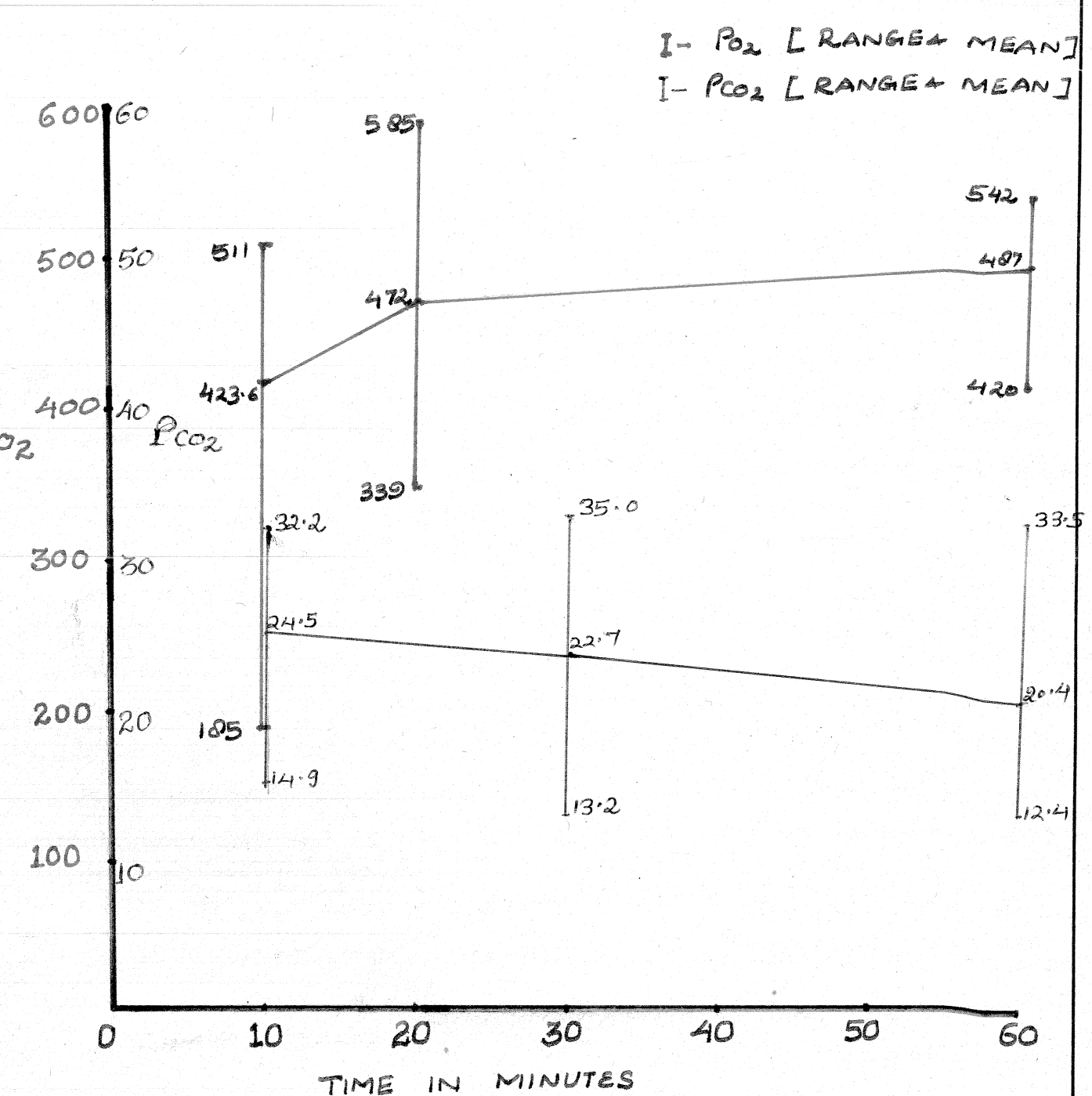
HAEMATOLOGICAL PARAMETERS

PARAMETER	PRE-OPERATIVE	1st P.O.D	8th P.O.D
HAEMOGLOBIN (gm %)	(m = 11.87) 8.2 —— 13.6	(m = 8.1) 6.4 —— 10.6	(m = 6.78) 3.8 —— 9.5
HAEMATOCRIT (%)	(37.01) 25 —— 43	(22.17) 19 —— 33	(22) 16 —— 30
TLC	(7,957) 4,925 —— 13,550	(9,575) 3,800 —— 18,275	(12,500) 10,950 —— 13,500
PLATELETS	(374,000) 137,000 —— 510,000	(230,000) 144,000 —— 290,000	(414,000) 201,000 —— 540,000
PROTHROMBIN T. (SECS)	(16.6) 10 —— 22	(28.75) 19 —— 60	(18.0) 14 —— 25
P.T.T (SECS)	(45.4) 31 —— 65	(61.33) 46 —— 82	(40) 32 —— 48
C.T (MIN'-SEC")	(5'-0") 3'-21" —— 6'-17"	(6'-28") 3'-27" —— 7'-52"	(3'-58") 3'-14" —— 5'-17"

BIOCHEMICAL PARAMETERS

PARAMETER	PRE-OPERATIVE	1st P.O.D	8th P.O.D
BUN (mg%)	(m = 25.23) 14 —— 37.8	(m = 24.9) 14.2 —— 36	(m = 27.5) 20 —— 31.4
CREATININE (mg%)	(1.73) 1.0 —— 2.5	(1.82) 1.0 —— 3.0	(1.4) 1.1 —— 1.8
BILIRUBIN (mg%)	(0.7) 0.4 —— 1.0	(0.88) 0.8 —— 1.2	(0.8) 0.6 —— 1.0
TOTAL PROTEIN (g%)	(10.02) 9.12 —— 11.6	(6.9) 5.32 —— 8.5	(8.5) 7.82 —— 8.8
ALBUMIN (g%)	(5.23) 4 —— 6.3	(3.84) 2.5 —— 5.3	(5.07) 4.5 —— 5.8
GLOBULIN (g%)	(4.69) 3.8 —— 5.3	(3.49) 1.92 —— 3.6	(3.62) 2.82 —— 4.3

BLOOD GAS VALUES ON C.P.B. [CHITRA] OXYGENATOR



Group B – consisted of one animal which underwent 60 min CPB using a Bentely's oxygenator. The same haematological and biochemical parameters were studied and no appreciable difference was found in the two groups.

Group C – consisted of two animals which underwent 6 hrs CPB using the 'Chitra-oxygenator'. After successfully terminating the CPB – both the animals were sacrificed. The brain, kidneys, Liver, Lung, heart & spleen were examined grossly & under the microscope.

Macroscopic Examination – showed focal areas of haemorrhage in the Lungs with evidence of fresh haemorrhage involving the endocardium, myocardium and epicardium of the left ventricle. All the other organs appeared to be normal.

Histological sections – from Lungs showed focal fresh interstitial & intra-alveolar haemorrhages in both cases. Focal atelectasis was noted in one animal. There were fresh haemorrhages involving the endocardium, myocardium, epicardium and Left ventricle of the heart. Mild congestion of Liver was seen in one case. All the other organs were normal. There was no evidence of infarcts.

Examinations of these sections with polarized Light revealed no silicone particles in any section.

CONCLUSIONS

'CHITRA HARD SHELL OXYGENATOR' was found to have excellent gas transfer efficiency as evidenced by maintenance of average P_{O_2} of over 400 m·m with mean blood to gas flow ratio of 1:1 Lit/min and mean P_{CO_2} of 22 mm.

Damage to the blood elements by this device was within acceptable normal limits.

It compared extremely well with the performance of an imported unit [Bentely's Oxygenator].

In acute perfusion studies of 6 hrs CPB in two animals no gross or microscopic evidence of damage to any organ could be demonstrated.

There was no demonstrable organ dysfunction related to the oxygenator in long term follow up of more than six months in all the surviving animals.

EX-VIVO EVALUATION OF CHITRA TILTING DISC VALVE

EXP 4.

IMPLANTATION OF A VALVED CONDUIT IN MPA

Standard CPB was established in sheep as described previously. The arterial return was through a cannula in the descending aorta and the venous return was with a cannula placed in the right atrium. On CPB the animal was cooled to 30°C. The MPA was clamped proximally and distally just before its bifurcation. About cm of the MPA was excised. A dacron graft with a No. 23 chitra tilting disc valve sewed into it was used to reconstruct the defect. The patient was weaned of CPB and the chest was closed as described earlier.

PROBLEMS

The dacron valve conduit was longer than the defect in MPA could accomodate inspite of excising the MPA.

The presence of a competent proximal pulmonary valve did not allow proper functioning of the chitra-valve.

The valved conduit did not function well.

RESULTS - All animals died on the operation table.

IMPLANTATION IN PULMONARY VALVE POSITION

2

Using the same CPB circuit as described in the previous operation, the MPA was incised and the pulmonary valve was replaced with a No. 23 'Chitra - Valve'. Since the pulmonary annulus was narrow and inadequate for 23 size valve, the right ventricle outflowtract was enlarged using a plasma preclotted dacron gusset.

PROBLEMS:—

Inadequate size of pulmonary annulus - which necessitated widening of the RVOFT.

RESULTS— All animals died in the early post-operative period.

IMPLANTATION IN TRICUSPID POSITION

1

A right Lateral thoracotomy was made thro the 4th I.C.S. CPB was established by cannulating the right carotid artery, SVC & IVC. The animal was cooled on CPB to 30°C. on total CPB - the tricuspid valve was excised. An aortic cross clamp could not be placed, which led to excessive flooding of the operating field making it virtually impossible to replace the valve.

The operation was abandoned.

EXP 7

IMPLANTATION IN MITRAL POSITION

A left thoracotomy was made thro the 4th I.C.S. CPB was established by cannulating the descending thoracic aorta and M.P.A. The animal was cooled to 28°c. The aorta was not clamped and no cardioplegia was given. Using fibrillator - the heart was fibrillated and the left atrium was opened by making an oblique incision. The mitral valve was excised and replaced with a no. 23 Chitra Valve using interrupted 2 '0' ethibond sutures. The L.A. was sutured in two layers. The animal was rewarmed and could be easily weaned of CPB and decannulated. The haemostasis was secured and the chest was closed in layers after placing a pleural tube.

The intra-operative and immediate post-operative management as described earlier.

Short duration of anaesthesia, minimum dosage of anesthetic drugs, standardisation of CPB and no blood transfusions led to increased number of animal survivals.

RESULTS - of the 7 animals - there were 4 early deaths.

ANIMAL NO - 2, 5 and 6 survived and did well.

All the surviving animals were kept on oral antiplatelet drugs.

EXPT	DEATHS	DURATION	CAUSE
1.	DIED	6 Hrs Post op.	?
3.	DIED	DAY OF OPERATION	BLEEDING FROM L.A (SUTURE LINE)
4.	DIED	DAY OF OPERATION	BLEEDING FROM L.A. (SUTURE LINE)
7.	DIED	4th P.O.D	CHEST INFECTION

INTERPOSITION GRAFT IN THORACIC AORTA OF DOGS

EXPT 3

OPERATION

A Left Lateral thoracotomy was made through the 4th I.C.S. The thoracic aorta was dissected and looped both proximally & distally. A 1cm piece of aorta was excised and replaced with a no. 10 mm dacron graft.

RESULTS

ANIMAL - [1] — The animal dereloped paraplegia as the aortic cross clamp was applied for 30 minutes. It was sacrificed.

[2] — Due to bleeding from a tear in the arch of aorta - the animal died.

[3] — The animal dereloped hypovolemic shock - due to blood loss. It was sacrificed.

MONITORING OF INTRA-CRANIAL PRESSURE IN DOGS

OPERATION

Under G.A, with the dog placed in a prone position two Burr-holes were made over the parietal regions. Through one a catheter was passed in the ventricle to monitor the intra-vent pressure and the second one was used to monitor the epidural pressure. After the study – the dogs were sacrificed.

EXPERIMENTAL PRODUCTION OF A-V FISTULA

OPERATION

An experimental study was undertaken to create arterio-venous aneurysm so that these could be occluded with catheter embolisation at a later date. The femoral artery and vein were isolated, looped proximally + distally. A 3 mm anastomosis was constructed using a 6 '0' continuous prolene sutures. The anastomosis functioned well and the distal end of the femoral vein was kept patent and the distal end of the femoral vein was kept patent and the proximal end was ligated. An aneurysmal dilatation occured after a few days.

RIGHT UPPER LOBECTOMY

OPERATION

1

A right- Lateral thoracotomy was made through the 4th Ics. The branches of P. artery to the right- upper lobe were dissected and divided between ligatures. The right- upper lobe bronchus was dissected. The branches of superior pulmonary vein were identified. These tributaries were divided between ligatures. The bronchus was divided and the proximal stump was closed with a continuous suture of 3 '0' ethibond. The haemostasis was secured and the chest was closed in layers.

Post-operatively - the animal did very well.

OESOPHAGECTOMY WITH OESOPHAGO-GASTROSTOMY

OPERATION

1

In a dog - where esophageal monitoring of EKG changes was being done and the animal was to be sacrificed later - a transthoracic esophagectomy was done. The stomach was pulled up through the hiatus and an esophago-gastrostomy was performed. The anastomosis was functioning well. Later the animal was sacrificed.