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~~LIST OF PROCEDURES DONE~~

PROJECT REPORT

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

NAME: DR. H.L. SUBBA RAO.

PROGRAMME: M.Ch. CVTS

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

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Date	

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

CONTENTS

Postings at 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.

ⓐ Mitral valve Replacement in sheep using Chitra tilting disc valve (i) Implantation in mitral Annulus
(ii) Desending thoracic Aorta
(iii) Pulmonary annulus.

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

ⓒ Intra cranial pressure monitoring with an Extra dural device.

EX. VIVO EVALUATION OF CHITRA VARIFLOW OXYGENATOR ADULT / PAEDIATRIC WITH INTEGRAL CARDIOTOMY RESERVOIR

INTRODUCTION

Oxygenators are the devices which poovide artificial gas exchange during the suspension or absense of Lung function. Originally introduced by Gibbon for open heart surgery in 1953, oxygenator technology greed rapidly in subsequent years coith 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 fulfil 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 type 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, defoaming and settling which are either arranged sequentially or concentrically

Eventhough 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 - Bio-medical technology wing. It consists of a central column through which venous blood mixed with oxygen climbs and a surrounding chamber of antifoam coated substrate through which oxygenated blood descends to the bottom of the unit. It also contains a integral metal coil for circulation for cold or warm water 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 oxygenator using sheep as the experimental animal.

Aim of the study was to evaluate the following functions of oxygenator.

① oxygenation efficiency.
② CO_2 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 33.5kg (Mean 31.3kg)
. 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 upto one week

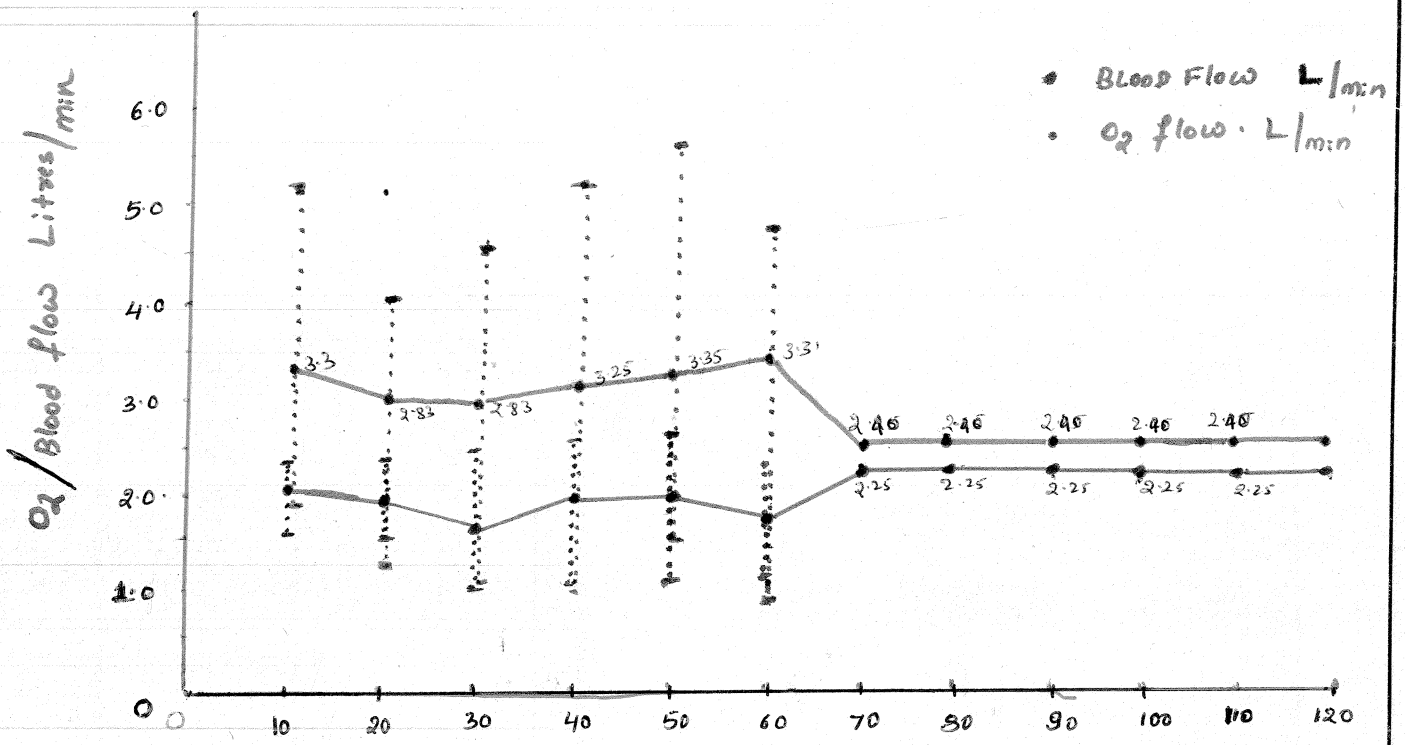
After pre operative preparation with 24 hour fasting, 12 hour water restriction and systemic antibiotic prophylaxis animals were pre medicated with atropine and diazepam. Under General anaesthesia Left lateral thoracotomy was done. After systemic heparinisation Cardio-pulmonary bypass was established 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-dilutent prime . i.e. 1500ml of Ringer's lactate, 500mL of Blood, mannitol-80ml. $NaHCO_3$ 75ml $CaCl_2$ 20ml. and heparin 75mg.

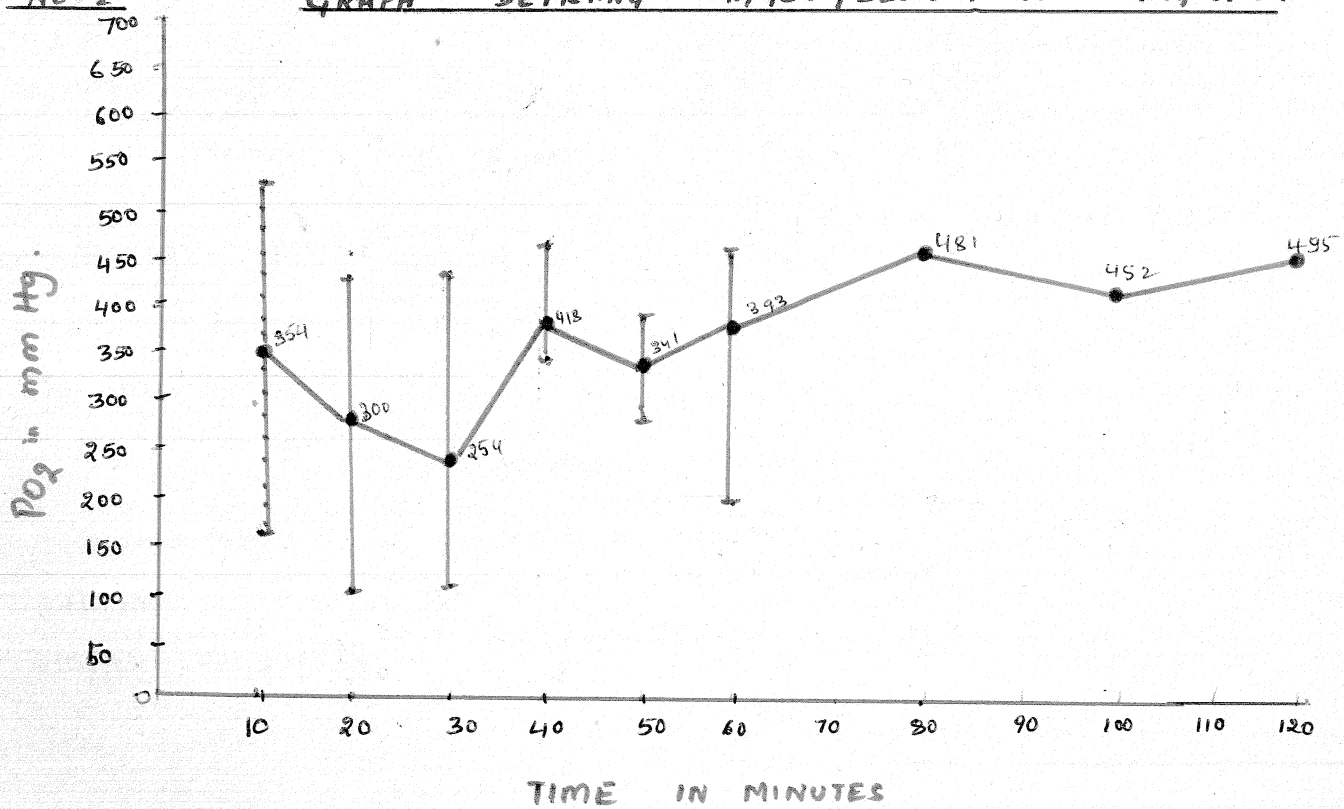
- Total priming volume was 2200ml. Average circulating Haemoglobin was 6.4 gm%.
- Blood flow rate was maintained around 70ml / kg Body wt.
- During the procedure, Heart rate, Blood pressure, Central Venous pressure, Urine output; rectal temperature were monitored. Cardio pulmonary bypass was maintained for one hour except one animal where it was continued for 2 hours.
- Active cooling and rewarming were done in three experiments to assess efficiency of heat exchanger.
- Additional crystalloid / Blood was added to cardiotomy reservoir during the procedure to assess on 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 gradually it was reduced to 1:1 flow ratio.
- Cardio pulmonary bypass was terminated at the End of one hour except in one experiment where 2 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 upto one week in the surviving animals / or ~~until~~ until death of animal.

Results and Observations.

- pre operative haematocrit of animals ranged between 10.8 to 12.0 gm (mean 11.6 gm%)
- Circulating haemoglobin during CP bypass maintained between 6.0 to 7.0 gm% (mean 6.49 gm%)
- Total perfusion period in all experiments 60 minutes Except one where it was two hours.
- perfusion pressure during CPB was maintained between 39 to 92 mm Hg (Average 72.0 mm Hg)
- Blood flow ranged between 1.2 to 2.67 L/min - Mean Blood flow 2.03.
- Oxygen flow during CP bypass ranged between 1.35 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 1:1.9 L/min
- PO_2 during perfusion Varied between 104 to 506 mm Hg (Mean 345 mm)
- Mean PCO_2 in all experiments was 22.37 mm Hg
- 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.
- Cardiotomy reservoir worked efficiently in all the Experiments without any clogging of filters.



NO 1 GRAPH DEPICTING OXYGEN / BLOOD FLOW DURING CPB.



NO 2. GRAPH SHOWING THE PO2 VALUE DURING CPB.

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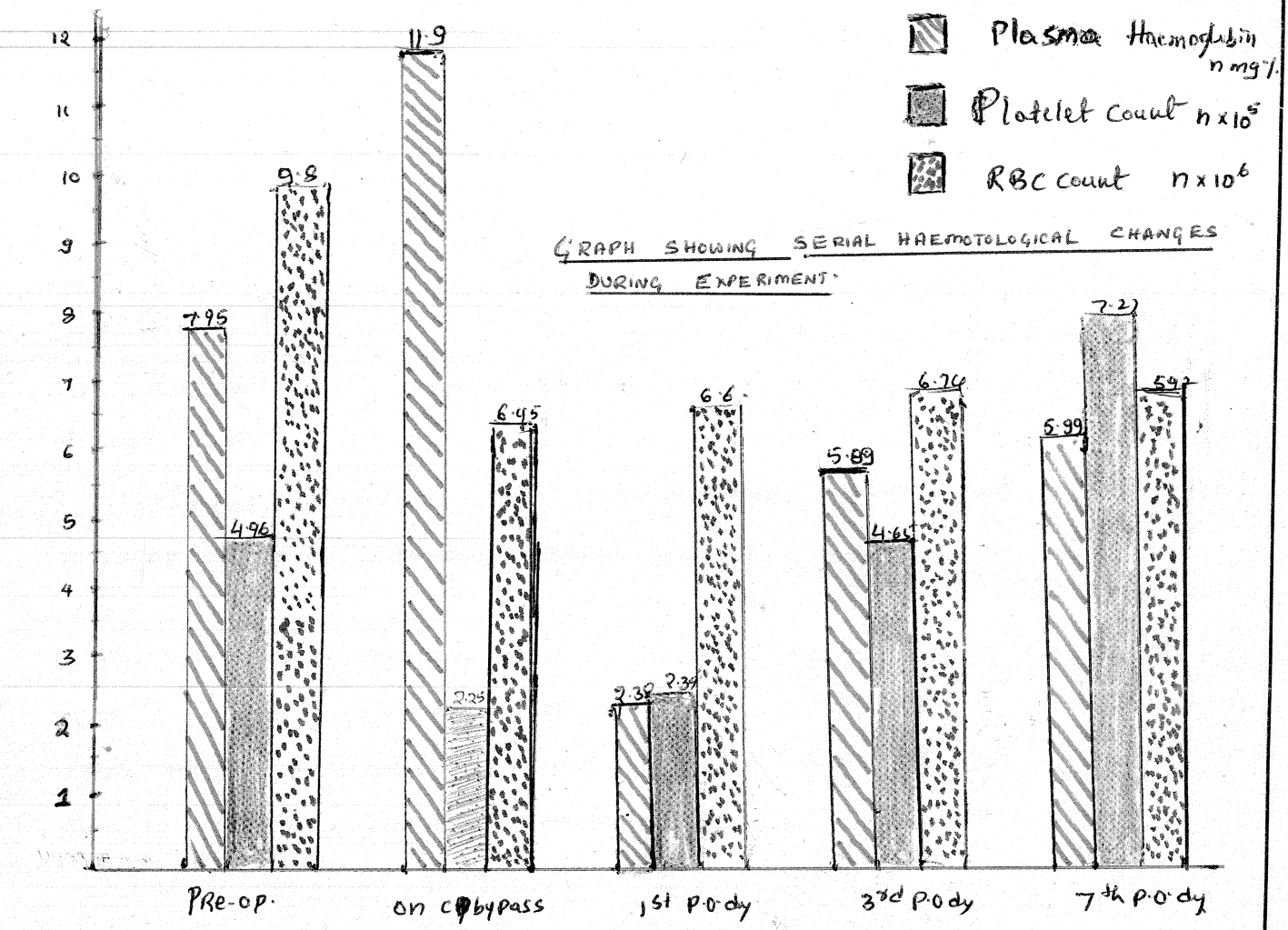

Average pre operative plasma haemoglobin was 7.95gm%. during CP Bypass it increased to 11.9gm%. and returned to pre operative level on 3rd Post operative day.

In all the six animals CP bypass was successfully weaned off

Animal regained conciousness on an average 2 - 2½ 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 immediat 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 DAY	11.6 gm%	8.7 gm.	23.0	0.7
1st P.O DAY	7.3 gm%	7.7 gm	49.6	0.8
3rd P.O DAY	7.1 gm%	7.0 gm	33	0.7
7th P.O DAY	6.5 gm%	8.239m	33.5	0.7

Conclusions.

- This new oxygenator device was found to have Excellant gas transfer efficiency as evidenced by maintainance of average PO_2 345 mmHg. with mean Blood to gas flow ratio 1:1·8 L/min and mean PCO_2 22·37 mm
- Damage to the blood elements by this device was minimal and acceptable.
- Heat Exchanger and Cardiotomy reservoir function was Excellant.
- There was no demonstrable organ dysfunction related to the oxygenator except for mild renal dysfunction related to non-pulsatile cardio pulmonary bypass.

Mitral valve Replacement with Chitra tilting disc prosthesis.

(1) Implantation of mitral valve in mitral annulus.

No of experiments. 3.

Under general anaesthesia, Left thoracotomy was done through the 4th Intercostal space. Pericardium was opened and marsupialised. Cardio-pulmonary 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 upto 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 repaired. Seperate ~~Cardiopul~~ LA Vent was put and Aortic Clamp was released Cardiopulmonary bypass was weaned off ~~Art~~ 34°c and Decannulation was done (Venous decannulation) immediatly as most often cannula was obstructive to RV. After Systemic ~~heparin~~ Protamine Aortic decannulation 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.

Thragh Left thoracotomy, part of descending thoracic aorta was Looped with two tapes between origin of neck vessels and intercostal vessels. In View of small size of Aorta, Valve without the 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 prosthesis was fixed to the gussel- anteriorly. Aortotomy was prepaired with gussel- 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. CARDIO PULMONARY BYPASS WAS not used

(3) Implantation in Pulmonary annulus.

No of Experimat - 1

In these experiment CP bypass was used. Right atrium was cannulated with difficulty for Venous drainage. and arterial return to ascending aorta - Pulmonary arteriotomy was done and Pulmonary valve was excised. As the annules was narrow, incision extended across RV outflow and after seating the valve in the Posterior portion of pulmonary annulus, Dacron Patch was used to accomodate the over- Sized valve and to reconstruct the RV outflow. Anteriorly valve was fixed to RV outflow Patch.

Creation of aneyrysms in Experimental animals.

No of Experiment [redacted] 4

Dogs were choosen as the Experimental model. This experimet was done for the purpose of Evaluation of new intra Luminal ballon Occlusive device to obliterate the aneurysm sac.

Under General anaesthesia Vertical incision was made anterior to sternomastoid musle. Both Carotid artery and jugular veins were looped. Bull dog Vascular clamps were used to occlude both artery and vein together on either side of proposed site of anastamosis. After clearing the adventitial Layer, 3 mm anastamosis was done between artery and vein using 6-0 prolene Continuos sutures with a single Knot. Total carotid occlusion time ranged between 15 to 25 minutes. At the end of the procedure good continuos thrill was felt over the Vein in all animals. In first experiment, after occlusion of vein above and below the anastamosis with snuggers there was rapid ballooning of segment near the anastamosis 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 seperate stab incision above an below the

Site of anastamosis (close to anastamosis) on the jugular vein with a polythene tube covering over it to prevent [redacted] adhesions. Delayed Ligation was done 2 weeks later.

(5) INTRA-CRANIAL PRESSURE MONITORING WITH EXTRA-DURAL DEVICE.

No of Procedures. 3.

- In this project, frontal burr hole was created and the device was fixed into the burr hole of 2.5 mm diameter and pressure changes were monitored.