The Development, Practices, Certification Process and Challenges of Cardiovascular Perfusion in India

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Dear Colleagues, ladies and gentlemen. I would like to thank the Academy for inviting me as the Charles C. Reed Memorial lecturer for this year and giving me the opportunity to address this august gathering. I have no financial disclosures to make. Actually one disclosure: I like to be deeply involved in the conduct, teaching and training of perfusion science, especially as it pertains to the patients in the pediatric age group. Therefore I am likely to lean more and more towards a discussion on pediatric perfusion in the course of this talk.

Contrary to the popular belief, the job of a cardiac surgeon is not that romantic. It needs the hands of a maiden, the vision of an eagle, the supreme confidence of a prima donna, the compassion and care of the almighty, and above all a great team! Cardiac surgery is a divine specialty, which essentially involves teamwork where the role of each member is of equal importance and concern. Needless to say a skilled perfusionist is one of the biggest assets to this team because he or she is responsible for maintaining the functioning of all the vital organs of the patient when the surgeon goes about the task of repairing cardiac defects. The conduct of perfusion has important implications not only in terms of early survival, but also on the entire hospital course and long-term outcomes. Therefore it is essential that this science develop and flourish in a scientific manner. In various parts of the world, this specialty has evolved in a different manner with different practices and India is no exception. In the course of this talk, I will briefly touch upon (a) the origin and progress of open-heart surgery and perfusion technology in India (b) the certification process (c) challenges and their possible solutions and finally (d) cost containment.

The origin and progress of open heart surgery and perfusion technology

Between 1948 and 1960, the practice of cardiothoracic surgery was evolving in India, and there were no dedicated programs for imparting training to the medical and paramedical staff. Although there were four metropolitan cities: Delhi, Bombay (now called Mumbai), Calcutta (now called Kolkata) and Madras (now called Chennai), only few selected centers in India used to practice cardiac surgery, and these were centered in Mumbai and Vellore. These two centers played a pivotal role in the further progress of the specialty as well as in training the budding surgeons and perfusionists throughout the country.

Dr. G. B. Parulkar (King Edwards Memorial Hospital-Mumbai) was one of the pioneer cardiac surgeons, and he began his studies in hypothermia in the animal laboratory as early as 1955 even when he was a junior resident in surgery. These experiments enabled his group to begin clinical open-heart surgery in 1956 when he closed an atrial septal defect by lowering the patient's body temperature to 30^{o}C and had a total circulatory arrest time of four minutes. Experimental work on the possibilities on extracorporeal circulation began in 1958. These efforts enabled this group to test the vertical screen and the rotating disc oxygenators as well as plan the development of a disposable helical bubble oxygenator. Although it was possible to achieve good initial results, the majority of the animals succumbed after extracorporeal circulation due to uncontrolled hemorrhage.[1]

The work of Dr. Profulla Kumar Sen at Mumbai was a source of inspiration to the next generation cardiac surgeons throughout India.[2] His team started animal experiments in cardiac transplantation as early as 1954. His constant efforts gave him the credit of performing the first human heart transplant in India in 1968, which was also the sixth heart transplant in the world. Based on his "snake heart concept", he developed the technique of transmyocardial laser revascularization in 1964, which gained world-wide popularity shortly thereafter.

Dr. Kersi N. Dastur, at the Nair Hospital, Mumbai was another pioneer surgeon.[3,4] (See Figure 1) Starting with experimental dog surgeries at the Nair Hospital, he meticulously developed a totally indigenous heart-lung machine as well as an oxygenator system. (See Figure 2) He could perform various open-heart surgeries using his heart-lung machine very safely which opened a new era of cardiac surgery in the entire country. He went on to establish departments of cardiovascular surgery at various hospitals in Mumbai including the Nair Hospital, Nanavati Hospital, Jaslok and Breach Candy Hospital, all of which later became centers of repute. He also helped to start and encourage the specialty in Delhi, Chandigarh and Srinagar.

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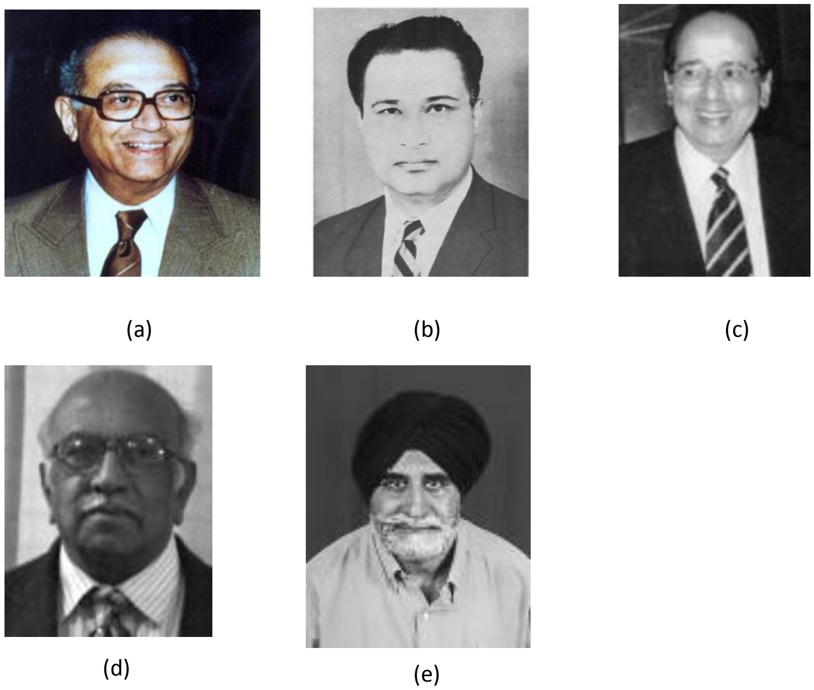

Figure 1. Some of the pioneers contributing to open-heart surgery and perfusion in India. (a) Dr. Kersi N. Dastur (b) Dr. P. K. Sen (c) Dr. G. B. Parulkar (d) D. N. Gopinath (e) Mr. Virender Singh who was instrumental in developing perfusion services at the All India Institute of Medical Sciences, New Delhi. *Photographs with permission from (a) Kalke BR, Magotra RA. Tribute to Kersi Dastur, a pioneer in open heart surgery in India. Indian J Thorac Cardiovasc Surg 2010; 26:228–232 and (b-e) from: Indian J Thorac Cardiovasc Surg (suppl.) 2004S:16-24.*

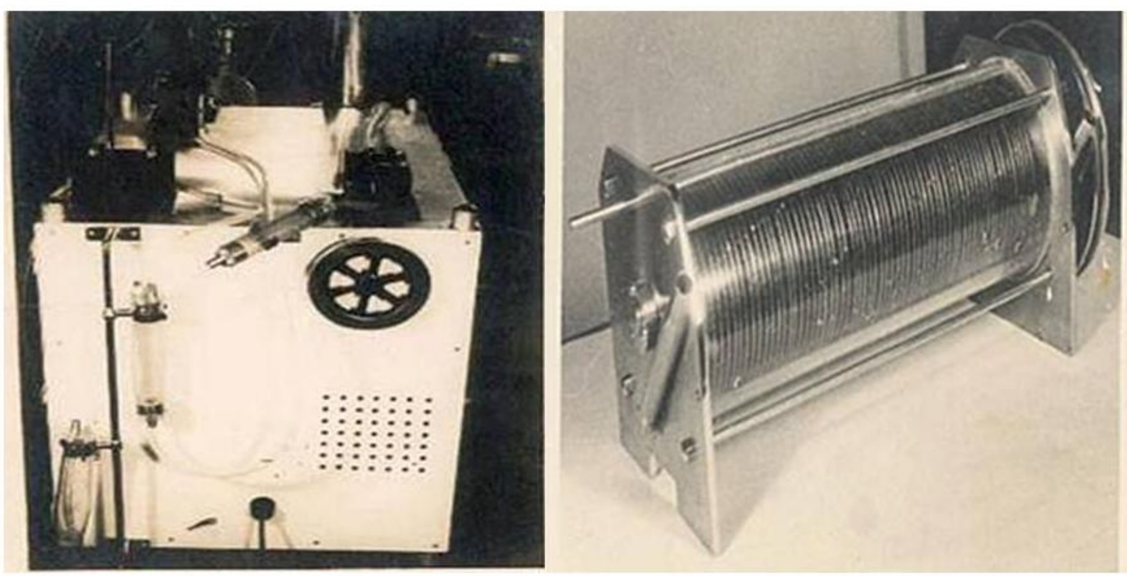

Figure 2. Dr. Dastur's heart-lung machine and disc oxygenator.
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At the same time, important developments were taking place in Vellore, a small town in the South Indian state of Tamil Nadu. Dr. Reeve Hawkins Betts established the first accredited cardiovascular and thoracic surgery unit at the Christian Medical College, Vellore in 1948. The unit initially performed thoracic and closed heart surgeries. The first patent ductus arteriosus ligation was performed in 1950 followed by the first Potts shunt in 1951 and the first Blalock-Taussig shunt in 1953. Dr. Nagarur Gopinath joined as a resident in the department for training under Dr. Betts. After training with Dr. C. Walton Lillehei from 1957 to 1958 in the United States, Dr. Gopinath performed the first successful closure of an atrial and a ventricular septal defect in 1961. He is credited with the establishment of the Department of Cardiothoracic and Vascular Surgery at All India Institute of Medical Sciences (AIIMS), New Delhi in 1968 even though cardiac surgeries were being performed in the institute since 1956. This institute has now progressed to a high volume center engaged in patient care, teaching, research and manpower training from all over India.

Development of perfusion technology at AIIMS

Perfusion technology started at AIIMS in 1968 with a helix oxygenator and a Pemco heart-lung machine. Sincere constant efforts from the whole team improved surgical outcomes and increased the number of surgeries day by day. The combination of helix oxygenator and the Pemco heart-lung machine was very ideal to work with. The heart-lung machine was completely manual and reliable. However, assembling the circuit along with the helix oxygenator was time-consuming. With the development of the disc oxygenator, the performance was better and hence the team switched over to the disc oxygenator with silica gel coating. The glass chamber made it possible to ensure all was fine but the major problem was that the glass chamber was fragile, to prepare the circuit required a lot of labor, one had to wash it, then coat the discs with silica gel then pack it in a safe manner, and finally get it sterilized. The tubing had to be washed, and then the inner part was cleaned with a pull through (a rod with a cloth bunch at one end). In 1976, with the development of the bubble oxygenator and the heart-lung machine with safety limits and alarm capabilities, perfusion techniques became quicker and safer. Bubble oxygenators had the risk of air embolism and required huge priming volumes. This led to the introduction of the membrane oxygenator in 1989, which required less priming volume as well and had an arterial filter to eliminate the risk of air embolism. However, until 1999- 2000, membrane oxygenators were used only for cases with longer anticipated cardiopulmonary bypass (CPB) times.

Cardiovascular perfusion was then performed by a variety of persons with varying qualifications and experience. During the initial period of the history of cardiac surgery in India the assistant surgeon used to run the pump. This was then taken over by theater assistants, who had been assisting the "perfusionist" surgeon in setting up the extensive heart-lung machine system comprised of the reusable disc oxygenator, stainless steel discs, end plates, connectors and other components that had to be thoroughly cleaned and sterilized before and after use.

The year 1983 saw the establishment of the Indian Society of Extra Corporeal Technology (ISECT) with a symbol of its own. The society started with three founding members, with Mr. V. M. Joshi as the founding president and Mr. S. Kuppuswamy as the founding general secretary. The society has grown so much that it has over 500 members at present throughout India. The Ministry of Human Resources Development, Government of India, recognized this society only after their continued perspiring efforts, and a three-day strike at AIIMS. The society attained a rapid pace of growth so that they could begin a journal of their own: The Indian Journal of Extra Corporeal Technology. Initially the annual conference of the society was held in combination with the Indian Association of Thoracic and Cardiovascular Surgery, but from the year 2001 onwards, ISECT has started having their own separate annual conference.

Perfusion training/ education in India

The efforts to provide scientific education and training in perfusion technology were initially made by the Christian Medical College, Vellore in the early 1980s by starting a postgraduate diploma course in perfusion technology. Later on in 1986, the same was extended to King Edwards Memorial Hospital at Mumbai. In 1990, the Indian Association of Thoracic and Cardiovascular Surgeons and Medtronic, Inc. started a one-year course which included an initial six months of training in basic medical sciences theory and six months practical training in perfusion at any reputed institute. Annually, 11 students were admitted for the course and the basic qualification was Bachelor of Sciences (BSc). However, these numbers were grossly inadequate in addressing the growing demand for more trained personnel. Presently, there are more than ten institutions which offer various courses in perfusion technology. (See Figure 3) These institutes are located at Delhi, Chandigarh, Baroda, Bhopal, Bangalore, Hyderabad, Chennai, Mumbai, Vellore and Cochin. A wide variety of courses are offered that include (a) Postgraduate diploma in perfusion technology (PGDPT): the eligibility criteria for this course is a bachelor's degree in science and the course is of one year duration (b) Bachelor's degree in perfusion: the eligibility criteria for this course are a basic school education after grade 12 in a science stream and this course is of four years duration (c)

Master's degree in Perfusion: the eligibility criteria for this course is a Bachelor's Degree in Science and the duration of this course is two years. Overall 80-100 perfusionists are trained annually at these centers.

Figure 3. Institutions that offer various courses in perfusion technology in India.

The department of Cardiothoracic and Vascular Surgery and the Department of Cardiac Anesthesiology at AIIMS conduct a Master's (MSc) course in perfusion technology, which is of two years duration and admits four students per year. The training program includes weekly theory classes for two years and daily operating room training with exposure to approximately 400-600 on pump cases per year of all types. The students are supervised to conduct approximately 75-100 pumps annually. In addition students are given adequate exposure to the set up and conduct of extracorporeal membrane oxygenation (ECMO) duties in the intensive care unit. It is mandatory for the students to submit a thesis/research project prior to the final examination to get qualified for the Master's degree. The entire course is offered free of cost by the institute.

Board of Cardiovascular Perfusion- India (BCP-I)

The BCP-I was founded by Dr. R. R. Rau and its headquarters are located at Ahmadabad. The duties assigned to the Cardiovascular Perfusion Board in India are: certification, recertification, maintaining a registry of certified members course for perfusionists, accreditation of perfusion schools and courses, and awarding continuing education units (CEUs) to all educational activities in India such as participating in national or regional conferences, paper presentations, or publications. The requisite criteria for certification are (a) Diploma in Perfusion Technology awarded by Indian Association of Cardio-vascular and Thoracic Surgeons (b) Diploma given by any other Perfusion School (c) Degree in Perfusion given by any recognized college/university (d) practicing perfusionists with 10 years experience having done a minimum of 50 pump cases a year.

BCP-I conducts the annual exam for certification. The Board certifies those who pass for a period of five years with annual review. Every year certified perfusionists are required to submit to the Board the number of cases done by them and the continuing medical education (CME) activities attended. All CME and conferences, publication of papers, and presentation of papers in conferences are awarded points and each perfusionist must accumulate required points for annual review and for recertification at the end of five years. It is also envisaged to establish a Perfusion Council by the ISECT. This is proposed to be the sole controlling authority in respect of the perfusion profession and serves to regulate the perfusion profession in India. The council shall hold the key for formulating the responsibilities, professional conduct, and duties of perfusionists. It shall also maintain a central registry of perfusionists in the entire country. Once the council comes into existence the standards will be fixed, and it will enter into international association for mutual recognition of perfusion bodies around the world.

Perfusionists in India: Dark realities

In spite of being attracted towards the fascinating world of cardiac surgery and perfusion technology, the young perfusionists in India have to face hard realities once they complete their training and have to move out of the training institute. Since cardiac surgery is a fast growing specialty in India, simply finding a job may not be difficult for a perfusionist, but finding a right job at the right place to provide enough professional and personal satisfaction is really challenging. After completion of training, they may get placement in any of the government/public hospitals or private hospitals. But presently no teaching/faculty jobs are offered anywhere in India. A major problem they face is the low salary offered: at public hospitals: 400-500 USD/month and in private hospitals: 1000-1200 USD/month. In a majority of the private hospitals, the perfusionist's job is just to stand by for off-pump coronary artery bypass grafting (CABG) (95%) or intra-aortic balloon pump (IABP). In many centers, the surgeons and anesthesiologists exercise strict control over the whole team leaving no important role for the perfusionist in prime decision-making.

Differences in perfusion practices and challenges of perfusion in India

A perfusionist in India is faced with many practical problems while conducting a pump case.The cost and availability of hardware is an important issue. The limited availability of modern monitoring facilities such as online hematocrit and arterial blood gases monitoring, NIRS, etc. introduces the need to be extra vigilant and makes the conduct of perfusion difficult. The anesthesiologist controls the decision-making on the use of various drugs and anesthesia gases and a constant dialogue between the two is essential. Moreover undue stress and overwork has the potential to limit the efficiency of patient management.

Table 1. Existing leading public institutions in India for cardiovascular surgery.

Institution	Total open heart surgeries (in the year 2004)
AIIMS, New Delhi	3200
Sri Satyasai Institute, Whitefield,Bangalore	1500
Sree Chitra Tirunal Institue, Trivendrum	1400
Sri Satyasai Institute, Puttaparthi	1200
Nizam's Institute, Hyderabad	930
Govind Ballabh Pant Hospital, New Delhi	903
Sri Jayadeva Institute of Cardiology, Bangalore	811
King Edwards Memorial Hospital, Mumbai	799
Southern Railway Hospital, Tamil Nadui	774
Civil Hospital, Ahmedabad	678
Sawai Masingh Hospital, Jaipur	615
Christian Medical College, Vellore	579
Lokmanya Tilak Municipal General Hospital, Mumbai	504

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In India and in other developing countries, differences in disease patterns exist. Tables 1 and 2 show the pattern of cardiovascular disease in India. Many patients present quite late with congenital heart disease and a significant number is accounted for by patients with adult congenital heart disease, which requires special consideration and care at the time and after surgery. A simple lesion is Tetralogy of Fallot (TOF). In the Western world, a vast majority of these patients are operated below one year of age. In India, this is exceptional. The usual age-range is still 3-5 years and more than one-third of these patients are adults and are severely hypoxemic and polycythemic which adds to the difficulties of subjecting them to extracorporeal circulation and results in a higher risk of bleeding and multi-organ dysfunction.

Table 2: Spectrum of cardiac surgeries performed at AIIMS, New Delhi in 2006

Procedure	**Number**
Coronary artery bypass surgery	574
Valvular Heart surgery	
Aortic valve replacement (AVR)	129
Mitral valve replacement (MVR)	246
AVR + MVR	107
AVR + MVR + Tricuspid repair	7
Aortic valve repair	14
Mitral valve repair	83
Closed mitral valvotomy	42
Surgery for Congenital heart diseases	
Atrial Septal defect (ASD) closure	218
Repair of Tetralogy of Fallot	288
Ventricular septal defect (VSD) closure	156
Systemic to pulmonary artery shunts	171
Patent duct arteriosus	108
Coarctation of aorta	27
Atrial switch operation	14
Arterial switch operation	54
Atrioventricular septal defects	18
Conduit repairs	11
Bidirectional Glenn shunts	63

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Besides this, there is an evident mismatch prevailing between the requirement and availability of the health care facilities in India at present.[5] This fact is depicted in Figure 4.

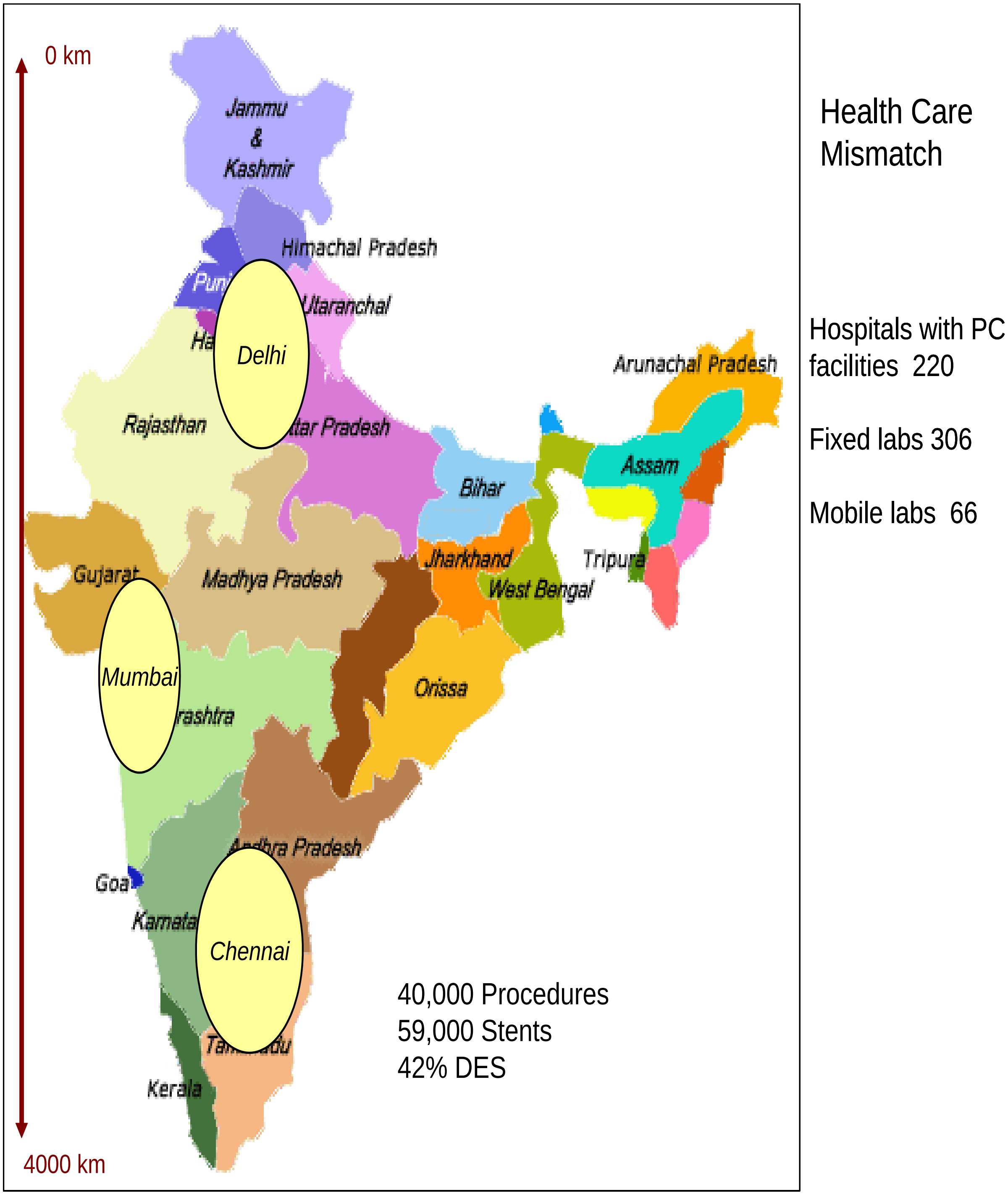

Figure 4. Facilities for cardiac catheterization in India.
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Issues of cost containment

The approximate costs for a patient undergoing surgery for congenital heart disease are listed in Table 3.

Approximate costs of surgery for common surgical procedures for congenital heart disease

Diagnosis	AIIMS (Rs)	SGPGI (Rs)	SCTIMST (Rs)				US * (Dollars)
			B1	B	C	D	
ASD	45000	50000	21000	56000	63000	70000	13,418 ± 4,955
VSD	55000	60000	23000	60000	65000	75000	28,285 ± 27,535
TOF	55000	60000	24000	64000	70000	80000	71,736 ± 78,847
AVCD	55000	NA	NA				44,415 ± 42,433
Fontan	60000	NA	24000	64000	70000	80000	NA
ASO	65000	NA	27000	72000	81000	90000	NA
PDA	6000	NA	6000	15000	17000	18000	NA
COA	20000	NA	7000	18000	20000	22000	NA
BT Shunt	20000	NA	6000	14000	16000	17000	NA
TAPVC	+65000	NA	NA				NA

ASD = atrial septal defect, VSD = ventricular septal defect, TOF = tetralogy of Fallot, AVCD = atrioventricular canal defect, ASO=arterial switch operation, PDA = patent ductus arteriosus, CoA = Co-arctation of aorta, BT = Blalock-Taussig, TAPVC = Total anomalous pulmonary venous connection. AIIMS = All India Institute of Medical Sciences, New Delhi, India. SGPGI=Sanjay Gandhi Post-graduate Institute of Medical Sciences, Lucknow, India. SCTIMST = Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram, Kerala, India
* Data from Duke's University Medical center, Durham, North Carolina, US.
NA = Data not available.
At SCTIMST, patients are categorized depending on their monthly income (Rs) as A=Less than 400, B1=400 to 700, B=701 to 1300, C=1301 to 2000 & D=above 2000.No charges for category A, but only 20% such procedures are allowed annually.

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Needless to say, these are beyond the reach of the common man in India, and in consideration of these issues, we have adopted a series of measures that are listed in Table 4.[6]

Table 4. Summary of recommendations for containment of costs in surgery for congenital cardiac disease

Pre-operative recommendations
Creating awareness among the primary health providers for early diagnosis and referral
Echocardiographic diagnosis (encourage training programs for screening echocardiograms at peripheral centers
Avoid cardiac catheterization
Risk stratification and counseling of parents with complex congenital heart disease
Single-stage procedures avoiding multiple stages unless necessary
Same day admission
Intra-operative recommendations
Product procurement and utilization
Active participation by clinicians and surgeons in decision making and procurement
Import technology, not products
Avoid intermediaries in supply line
Promote use of autologous tissues, avoid prosthetic material
Promote use of homografts by locally established homograft tissue banks
Promote use of indigenously produced material
Surgical innovation and modification of procedures to suit local condition
Intra-operative transesophageal echocardiography
Blood conservation by minimizing loss, pharmacologic strategies and modified ultrafiltration
Post-operative recommendations
Invest in building a team of trained intensivist, nurses and respiratory therapist
Avoid irrational use of antibiotics, inotropes, steroids and blood products
Early extubation
Avoid unnecessary and repeated laboratory testing
Substitute pulse oximetry for repeated arterial blood gases
Avoid repeated radiographs
Minimize stay in the intensive care unit and in hospital
Miscellaneous
Training of manpower and collaboration with established centers
Develop protocols to suit local needs
Develop products locally
Surgical audit

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At the AIIMS, we have made several indigenous modifications in the perfusion practices to keep them safe, simple, reliable and reproducible and extremely inexpensive. Some of these are: (a) Use of homograft saphenous vein for facilitating arterial cannulation in neonates.[7] (See Figure 5) This facilitates cannulating the diminutive aorta in neonates, avoids the use of a prosthetic graft and lessens the chance of intraoperative and postoperative bleeding from the tube graft. Whenever required selective brain perfusion can be accomplished easily through the cannula placed in the vein. (b) A simplified circuit of modified ultrafiltration [8] (See Figure 6). (c)The "integrated ECMO circuit"[9] which is specifically designed for "retraining of the left ventricle" in delayed presenters (>3 months) of transposition of great arteries undergoing the arterial switch operation and in complex procedures in neonates/infants where postoperative ECMO is anticipated. By integration of the ECMO circuit in the CPB circuit (See Figure 7), extra costs of the separate circuits are avoided. Moreover, after the surgery is completed, the patient can be transferred to the intensive care unit along with the circuit and ECMO can be established rapidly avoiding prolonged cardiopulmonary resuscitation. (d) Bidirectional superior cavo-pulmonary anastomosis without cardiopulmonary bypass.[10] (See Figure 8) (e) Techniques of selective antegrade cerebral perfusion in adult patients undergoing aortic surgery using simple endotracheal tubes.[11] (See Figure 9) There is still scope for doing more and more considering the rising costs and the case volumes.

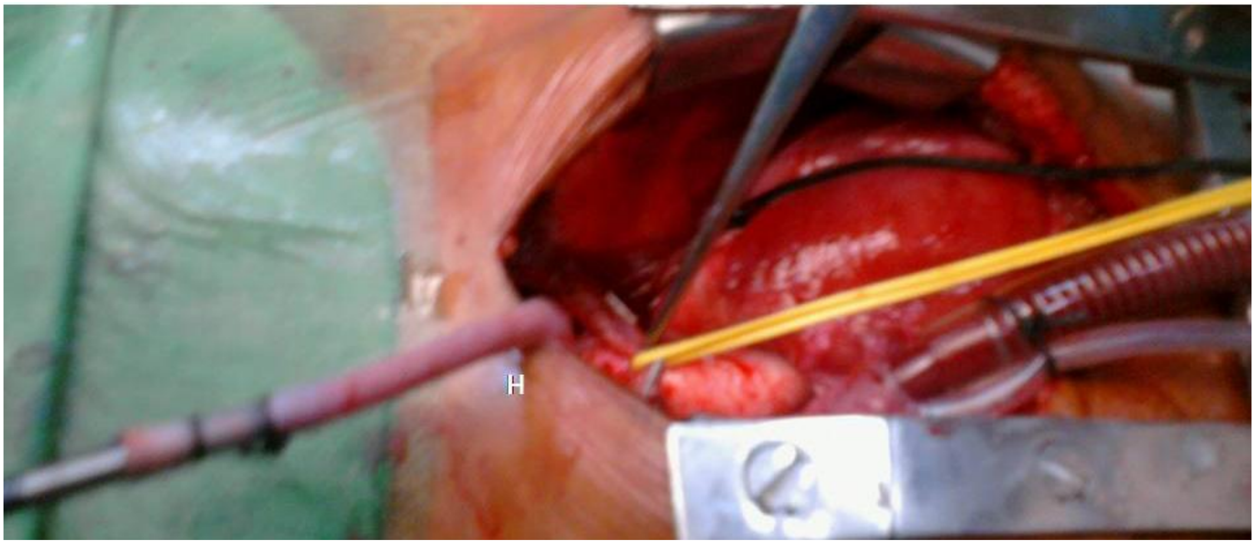

Figure 5. Homograft saphenous vein has been sutured to the innominate artery to facilitate arterial canulation in a neonate.

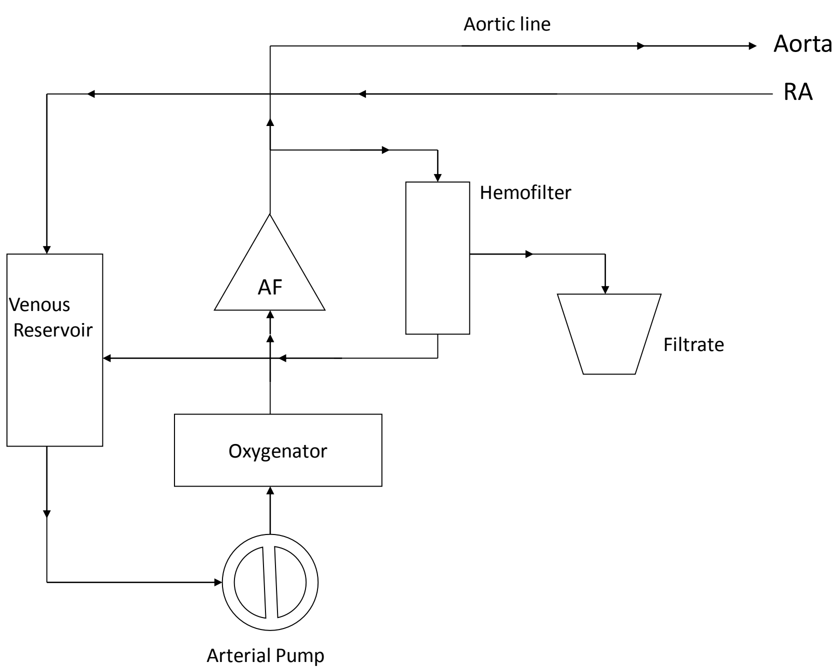

Figure 6. (A) The circuit for conventional ultrafiltration during the rewarming phase of cardiopulmonary bypass. AF = arterial filter, RA = right atrium
Reproduced with permission from Choudhary SK, Talwar S, Airan B, Yadav S, Venugopal P. A simplified circuit of modified ultrafiltration. Heart, Lung, Circulation 2007;16:113-5.

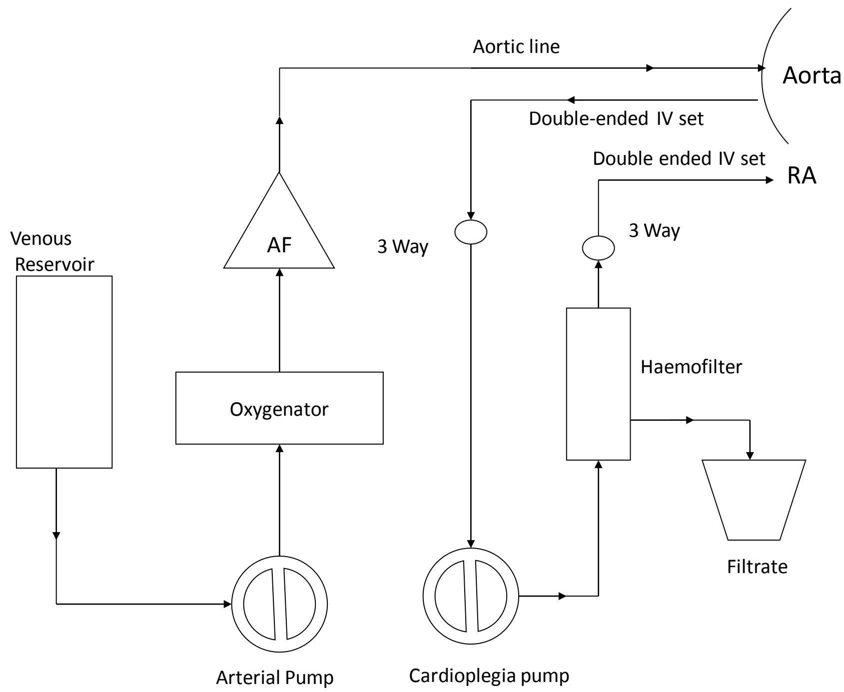

Figure 6 (B) The circuit for modified ultrafiltration after termination of cardiopulmonary bypass. AF = arterial filter, RA = right atrium, IV = intravenous.

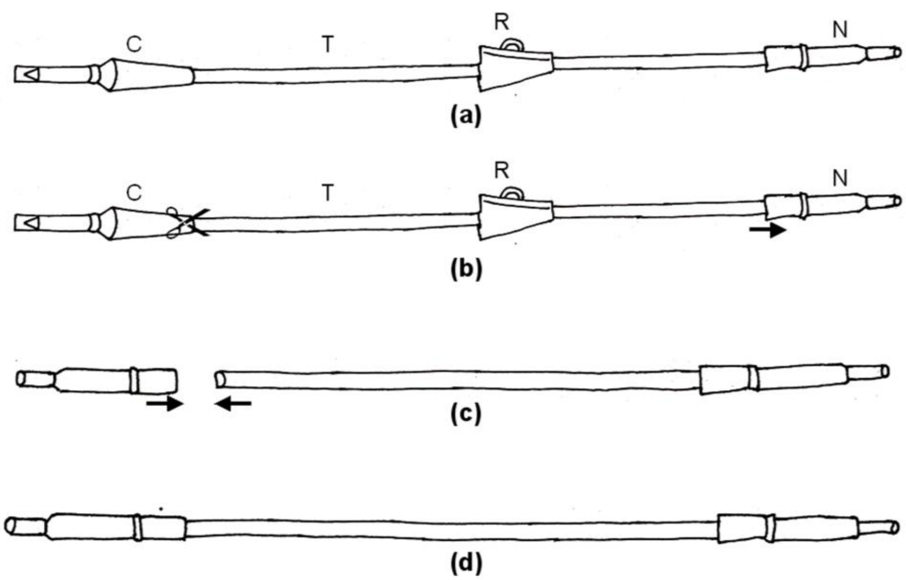

Figure 6 (C) Preparation of a double-ended intravenous (IV) set.

(a) A normal IV set. Two such IV sets are required.

(b) The Chamber (C) of the IV set is cut, the regulator (R) is removed by pulling out. The soft rubber connector nozzle (N) of the other IV set is simply pulled out of the tubing (T).

(c) The rubber connector nozzle is connected to the other cut end of the tubing of the first IV set by simply inserting the tubing into it.

(d) Prepared double ended IV set.

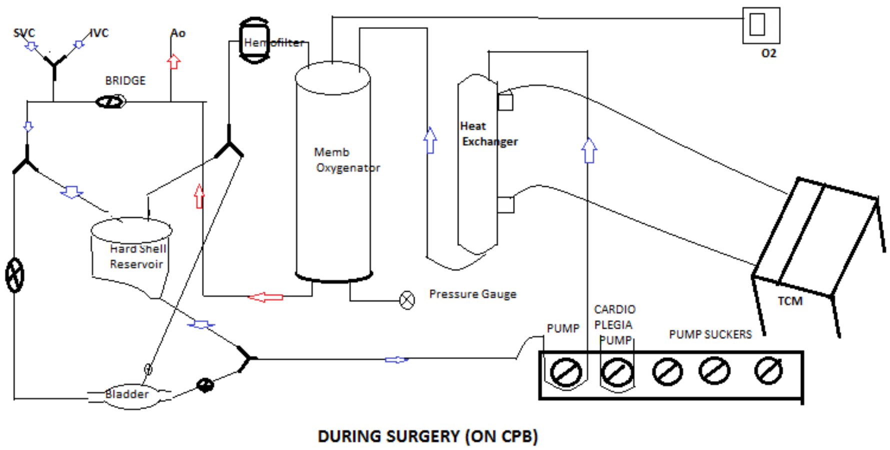

Figure 7(A). Integrated ECMO circuit in the operating room.
Reproduced with permission from: Chauhan S, Malik M, Malik V, Chauhan Y, Kiran U, Bisoi AK. Extracorporeal membrane oxygenation after pediatric cardiac surgey: a 10 year experience. Ann Card Anaesth 2011;14:19-24.

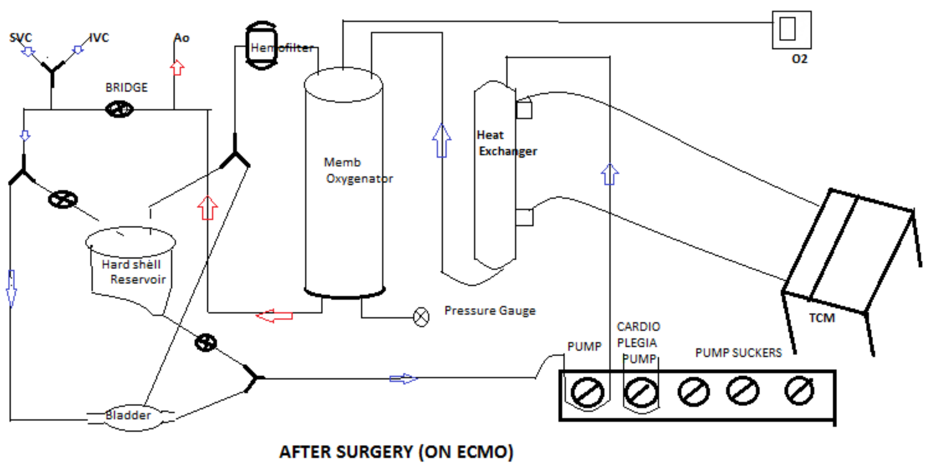

Figure 7(B). Intergrated ECMO circuit in the intensive care unit.
Reproduced with permission from: Chauhan S, Malik M, Malik V, Chauhan Y, Kiran U, Bisoi AK. Extracorporeal membrane oxygenation after pediatric cardiac surgey: a 10 year experience. Ann Card Anaesth 2011;14:19-24.

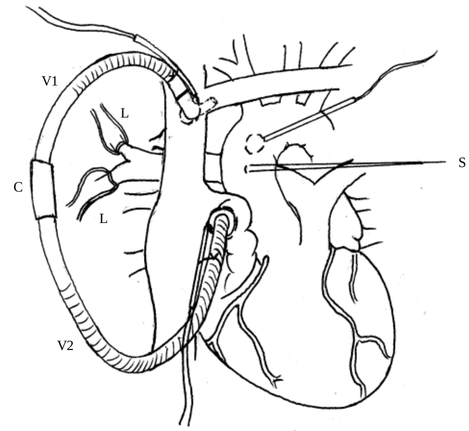

Figure 8. Basic set-up for a safe off-pump bidirectional Glenn. The cannula in the SVC-innominate junction (V1) is connected to a cannula (V2) in the right atrial appendage using a connector (C). A stay suture (S) has been placed on the aorta to retract it to the left and improve exposure. Vessel loops (L) have been placed around the hilar branches of the right pulmonary artery.

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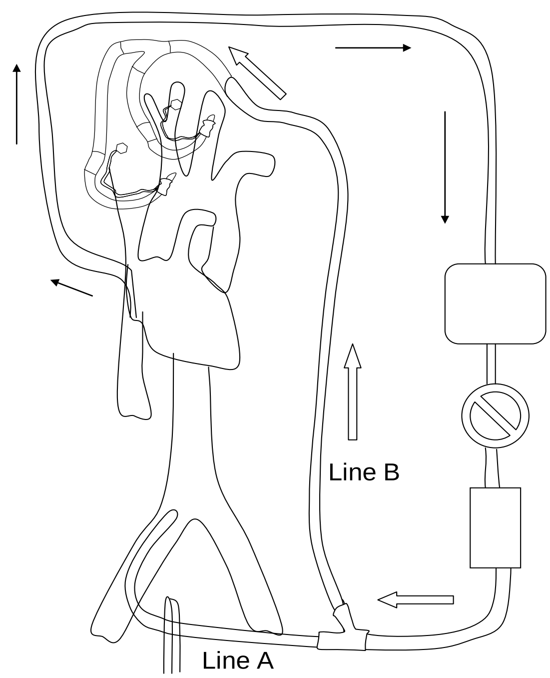

Figure 9. Technique of selective antegrade cerebral perfusion. (a)The 3/8 inch tubing of the arterial line is bifurcated by using a 3/8 inch 'Y' connector and 3/8 inch extra tubing. The line A is used either for ascending aortic or femoral arterial cannulation. Line B is bifurcated again in the similar fashion.

Reproduced with permission from Malankar D, Talwar S, Makhija N, Choudhary SK. An inexpensive technique of selective antegrade cerebral perfusion. Interact CardiovascThorac Surg. 2009 ;8:577-8.

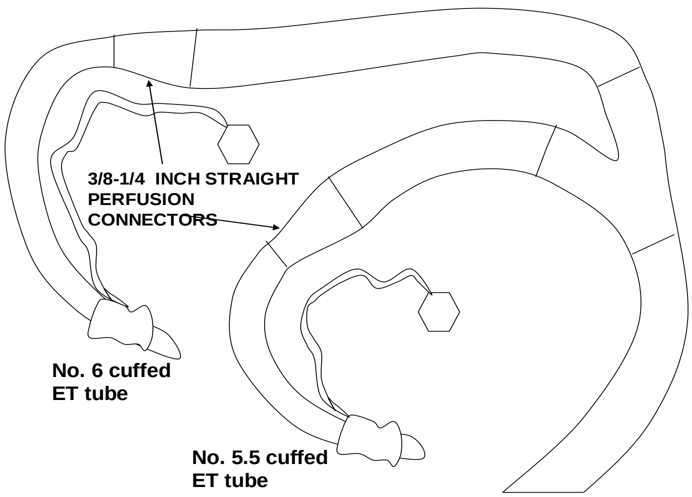

Figure 9 (b) Line B is bifurcated again in a similar fashion. Two cuffed endotracheal tubes, one No. 6 and another No: 5.5 are connected to both the divisions of line B using two 3/8-1/4 inch straight perfusion connectors.

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The present Indian scenario

In conclusion, the number of patients with congenital and acquired heart disease in India is so alarming that the whole team comprising surgeons, anesthesiologists, and perfusionists is subjected to increasing work-load and stress every day. The certification process for the perfusion courses is still evolving. The stressed and overworked Indian perfusionists are provided with little background support in terms of limited personnel and technology.We have to go a long way forward along the road of hardships to provide the best care for our patients and at the same time ensure a well-trained, cohesive and happy team. Sir Winston Churchill had once said, “Success is not final, failure is not fatal: it is the courage to continue that counts.” And that is what we firmly believe in. After all, “If it were not for hope… the heart would break.” Together we all share a partnership, which we have to carry forward for our patients and advancement of the specialty.

Thank you all for your kind attention.

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