A Report on the Use of Both Extracorporeal Circulation and Hypothermia for Open Heart Surgery *

WILL C. SEALY, M.D., IVAN W. BROWN, JR., M.D., W. GLENN YOUNG, JR., M.D.

From the Department of Surgery, Duke University School of Medicine, Durham, North Carolina

SATISFACTORY open heart surgery can be done only when the method for cardiopulmonary bypass allows sufficient time for deliberate and accurate intracardiac repair. Any method that does not permit this must have only limited application. Since hypothermia alone allows only limited operating time and low flow extracorporeal circulation has this same pitfall, it has been advocated that the extracorporeal system should mimic normal cardiac output.[1] These latter devices, however, are complicated to run, expensive to acquire and maintain, and difficult to clean and sterilize. Because of these objections, they have certain dangerous potentialities as well as limited general utility. Since the diminished oxygen need in hypothermia is the basis upon which the body will tolerate circulatory occlusion it has occurred to us,[2] as well as others,[3,4] that the low oxygen requirements of the body in hypothermia might be supplied by a simple low-flow extracorporeal pump oxygenator to achieve deliberate and time consuming intracardiac surgery. The laboratory studies of Gollan, Pierce, and our group have provided a sound laboratory basis for the clinical application of this combination of technics to open heart surgery.

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The purpose of this report is to record our clinical experience with the combination of extracorporeal circulation and hypothermia for open heart surgery. Data will be presented to emphasize the advantages of this method and to show how its disadvantages have been overcome.

Forty-nine patients have been operated upon using this combination of technics. In addition to the 46 patients who are the subject of this discussion, there were three others operated on in the first three weeks of life. None of these patients survived, for all had complicated neonatal deformities.

Methods

Extracorporeal oxygenation and perfusion was obtained in the first 22 cases by special plastic bag oxygenator [5] and an occlusive finger pump. This method was satisfactory when rates of below 1000 cc. per minute were required. In the last 27 cases a modified DeWall oxygenator [6] was employed (Fig. 1). This is essentially the same device described by DeWall except for the use of both a leveling chamber and a helix. This device achieved from 97 per cent to 100 per cent saturation in every instance save one where the mixing chamber was made too short. Connection of the patients to the extracorporeal system was done in a variety of ways. In the first 22 patients the left subclavian artery, right subclavian vein, and right saphenous vein were used. In the last 25 patients the femoral artery, saphenous vein, and auricular appendage were employed (Fig. 2). This technic permitted us to approach auricu-

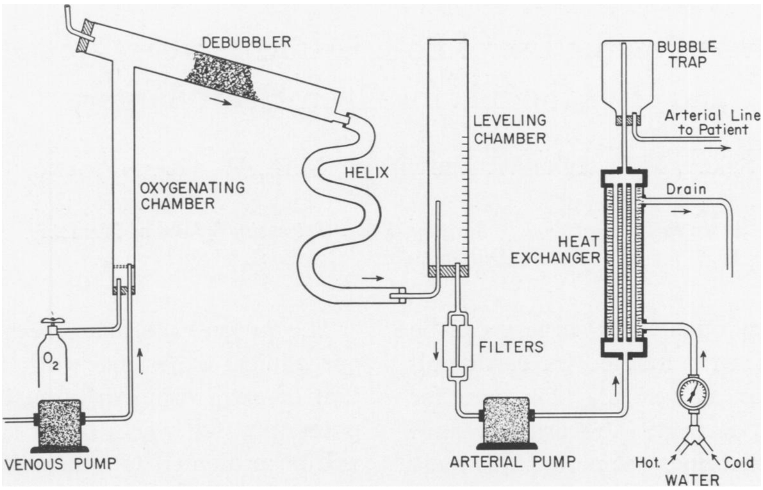

FIG. 1. A diagrammatic sketch of the modified DeWall oxygenator with the Brown-Emmons heat exchanger added for body temperature control.

lar defects through a unilateral incision and allowed us to assist the circulation after closure of the heart. This also made it possible to lower and raise the temperature by perfusion without encumbering the auricle with catheters. The measurement of the rate of flow when the plastic bags were used was by weighing the inflow and outflow. In the bubble oxygenator calibration was made before perfusion.

Hypothermia in the first 40 cases was induced with external body cooling either with a refrigerated blanket or an ice pack. When a rectal temperature of 33.5° C. to 34.5° C. was obtained, the patient was removed from the cold. Drift down to below 32° C. always occurred. In two instances it was necessary to use warm water in the thorax to prevent drift below 28.5° C. The perfusion from the blood used to prime the pump-oxygenator also tended to lower the temperature. The range of 30° to 31° C. was sought in all patients.

In the last nine patients hypothermia has been obtained by a heat exchanger [7] incorporated into the extracorporeal circuit. This was designed so that cooling could be obtained in three to ten minutes. The refrigerant fluid was hot and cold tap water. The entire exchanger was constructed of stainless steel, and the conduits for blood are straight and easily cleaned.

Where the ventricle was opened, a cardioplegic solution of potassium 0.81 per cent, magnesium sulphate 2.47 per cent, and neostigmine 0.001 per cent was employed.[8, 9] This was injected into the coronary arteries through the base of the aorta after the latter had been occluded.

During all the operative procedures the electroencephalogram and electrocardiogram were monitored.

Arterial pH, pCO_2, and O_2 were obtained from samples from an arterial needle in the wrist. Mixed venous oxygen determinations were obtained from samples taken from the outflow tubes just before they entered the venous pump. Simultaneous arterial samples were drawn from the leveling chamber on the pump oxygenator. The oxygen determinations for A-V differences were done by the method of Hickam and Frayzer.[10] The arterial pH was corrected to the patient's body temperature at the time of sampling. The carbon dioxide tension was determined from the arterial pH, and carbon dioxide content using the Henderson-Hesselback equation.

Blood lactic acid levels before, during, and after the extracorporeal perfusion were obtained in 17 of the patients using a colorimetric method.[11]

During perfusion the repeated blood pressure measurements were obtained by an arterial needle in the wrist in all the patients.

Heparin 1 mg. per Kg. of weight was used for anticoagulation. This was neutralized at the end of operation by protamine sulphate given in amounts equal to the injected heparin.

Results

The clinical results are summarized in Tables 1 and 2. A division of patients has been made into ones with a right ventriculotomy and the ones with atrial or valvular defects. In the latter group there was one death 14 days after operation from causes not related to perfusion. In the ventriculotomy group there were nine deaths in 21 cases with one dying 12 days after surgery from over-digitalization. There were three deaths on the operating table, one in a patient who had been in failure two weeks before operation with a pulmonary arterial pressure of 90 mm. of mercury. The second had an unrecognized aortic stenosis, and the third was a patient with tetralogy of Fallot in whom the aortic obstruction followed the closure of the septum and displacement of it toward the left. In all a heart beat was restored for 20 to 45 minutes. There were three deaths in the first 12 hours from what was thought to be the underlying pulmonary vascular disease. The fourth death followed the repair of a large atrial defect, ventricular defect, and pulmonic stenosis. The patient died 40 hours after operation from heart failure.

In none of the survivors has there been any central nervous system damage, and all of them awakened following surgery. In some of the patients there would occur a transient deterioration in the pattern of the electroencephalogram in the first minute of perfusion. This, however, soon returned to normal and was thought to follow transitory superior vena caval obstruction. In five of the patients perfused with the plastic bag oxygenator, the arterial infusion was started two minutes after vena caval occlusion. The ECG tracing disappeared immediately but returned to normal after the perfusion was started.

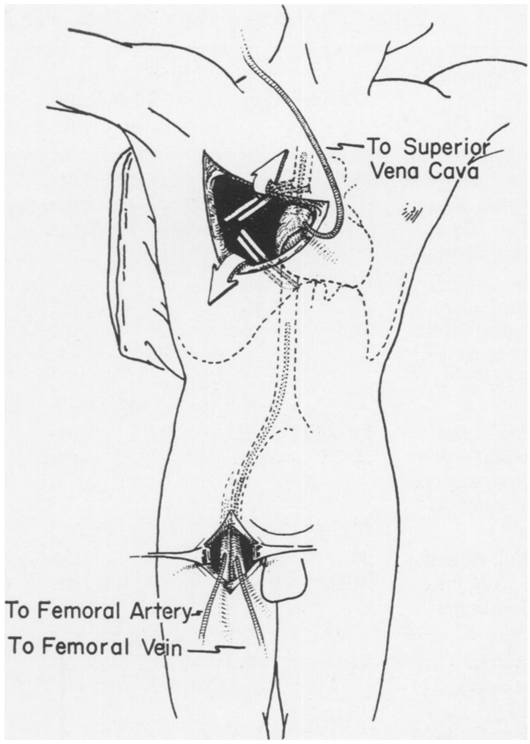

FIG. 2. This figure illustrates the method of cannula insertion used for atrial, semilunar valvular, and ventricular defects. This allows perfusion to begin early and to continue after intracardiac surgery without encumbering the auricle with large catheters. A unilateral incision is used for auricular defects.

Flow rates have varied and are summarized in Table 1 and 2. In some very low rates have been used. The repair of a septum primum auricular defect in an adult was achieved using a flow rate of 12 cc. per Kg. per minute. In a case of a tetralogy of Fallot in a 16-year-old patient of 60 Kg., flows of 28 cc. per Kg. per minute were employed with vena caval occlusion time of

TABLE 1. *Summary of Perfusion Data on 25 Patients with Atrial Defects and Valvular Stenosis*

Diagnosis Age No. Pts.	Temperature ° C.		Flow Rate cc./Kg./min.		Minutes Caval Occlusion Low–High–Mean	Minutes Perfusion Low–High–Mean	Comments
Auricular septal defect 5 to 10 yrs., 10 patients	28.5–30 30.5–32	6 pts. 4 pts.	17–30 31–40 40–50	3 pts. 2 pts. 5 pts.	6–25–15	8–28–20	1 Septum primum 2 Anomalous right pulmonary veins All survived
Auricular septal defect 10 to 20 yrs., 3 patients	29 31.5	1 pt. 2 pts.	15 25 40	1 pt. 1 pt. 1 pt.	6–13–10	8–18–11	All survived
Auricular septal defect 20 to 45 yrs., 6 patients	29 30–32	3 pts. 3 pts.	15 30–35	2 pts. 4 pts.	7–19–13	9–22–18	1 Septum primum 1 Anomalous right pulmonary vein All survived
Pul. stenosis 5 to 26 yrs., 4 patients	29 31.5	3 pts. 1 pt.	20 50	3 pts. 1 pt.	4.5–12–8	4.5–13–7	All survived
Aortic stenosis 14 yrs., 1 patient	29	1 pt.	20		5	7.3	Survived
Mit. stenosis 31 yrs., 1 patient	28.5	1 pt.	29		18	33	*Died 15th day P.O.

* Death occurred suddenly from cardiac arrhythmia after apparent satisfactory recovery.

32 minutes. This patient recovered. In some of the patients long perfusion times have been used. In the latter part of this series this was for temperature control, but it has also given prolonged support to the heart and has resulted in much better recovery where cardioplegia has been used.

During perfusion the blood pressures varied from 40 to 100 mm. of mercury. In the majority this averaged 60 mm. of mercury. There has been very little correlation between the perfusion rate and blood pressure level. In one instance an adult of 60 Kg. maintained a pressure over 100 on a flow rate of 28 cc. per Kg. per minute at a temperature of 30° C. A graph of blood pressure variation during operation on two patients is shown in Figure 3 and 4. In this study there has been no blood pressure fall that could be attributed to hypothermia.

Table 3 shows the arterial and venous oxygen saturation during perfusion. Figure 3 and 4 show this finding in relationship to the blood pressure and temperature. The high level of venous oxygen in two adults perfused at 29 cc. and 40 cc. per Kg. per minute is notable. There was another patient in whom the venous saturation was never below 81 per cent.

Metabolic changes were surprisingly small as measured by the arterial pH, carbon dioxide tension, and lactic acid. Before perfusion hyperventilation was purposefully introduced. During perfusion the pH was usually at normal levels. In only one patient did the pH fall below 7.30 and that

TABLE 2. *Summary of Perfusion Data on 21 Patients with Ventriculotomies*

Defect Age No. Pts.	Temperature ° C.		Flow Rate cc./Kg./min.		Minutes Caval Occlusion Low–High–Mean	Minutes Perfusion Low–High–Mean	Comments
I. V. Pul. pressure 85% of aortic pressure, age 4–8 yrs., 9 patients	29 30	3 pts. 6 pts.	20–35 50	5 pts. 4 pts.	8–27–15	21–81–23	3 Survived. 2 Died in O.R. 4 Died in 12 hrs. P.O.
I. V. Pul. pressure less than 85% of aortic pressure, age 4–8 yrs., 6 patients	30–31	6 pts.	50 20	4 pts. 2 pts.	8–19–13	20–40–23	5 Survived *1 Died 14 days P.O.
Tetralogy of Fallot, age 8–33 yrs., 6 patients	28.5–30 31.8	5 pts. 1 pt.	20–30 40–50	3 pts. 3 pts.	19–33–25	22–67–40	4 Survived **1 Died in O.R. ***1 Died 40 hours P.O.

* Died from arrhythmia associated with overdosage of digitalis.
** I. V. septum shifted during repair and partially occluded aorta.
*** Had large atrial defect. Died of heart failure.

was to 7.21. There was no remarkable change in the carbon dioxide tension. The lactic acid levels were measured in 17 patients. The variations were not remarkable in any of the patients. There was an increase of less than 5 mg. per cent in 11 patients during perfusion and the same increase in nine after perfusion. An increase of more than 10 mg. per cent was present in only three patients during and five after perfusion. In only one instance was there a rise of more than double the pre-perfusion level and this occurred at the very end of operation in a patient who died on the operating table. The pre-perfusion variations of blood lactic acid ranged from 15 to 51 mg. per cent. After perfusion it was from 12 to 77 mg. per cent.

Temperatures were if possible kept below 31° C. during perfusion. In the first 40 cases using surface cooling from one to two hours was required to reduce the rectal temperature to the desired level. With the heat exchanger and extracorporeal circulation the esophageal temperature of 29° C. to 31° C. was obtained in from five to 12 minutes. Esophageal temperatures have been found to approach heart temperatures in our experimental studies. In children of 20 to 30 Kg. the utilization of the femoral artery for inflow had little effect on the differences in temperature in the rectum and esophagus. In the adult there was some lag between the two depending upon which regional vessel was used (Fig. 5). This was not unexpected since perfusion for cooling was made without caval occlusion. In all patients where the heat exchanger was used esophageal temperatures above 34° C. were attained before perfusion was stopped. More complete details of the temperature in various parts of the body as well as the technical aspects of the apparatus will be reported elsewhere.[7]

The problem of ventricular irritability has not presented any difficulties, nor has it contributed to any of the bad results. In two cases spontaneous fibrillation occurred,

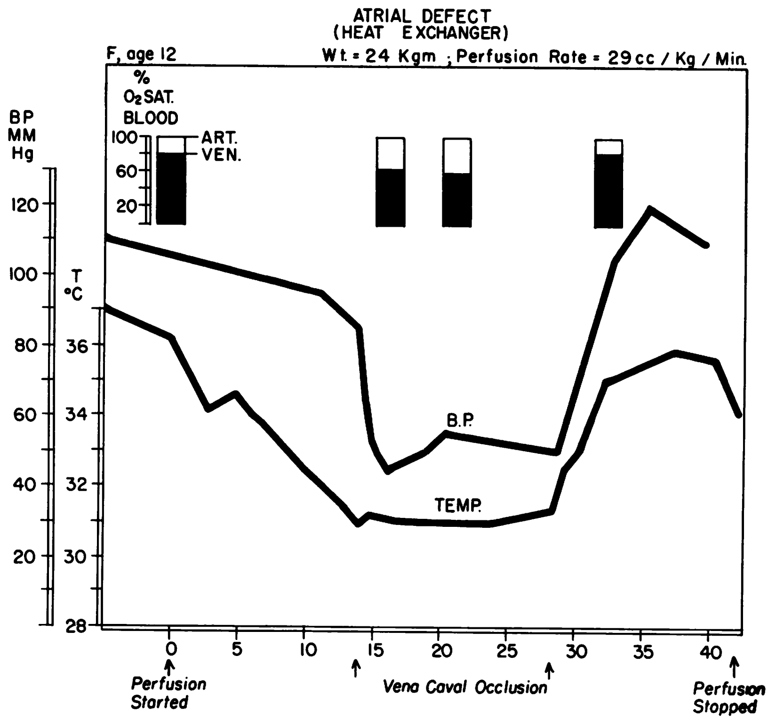

FIG. 3. A graph showing the esophageal temperature and systolic blood pressure in a patient who had a repair of an atrial septal defect. The bar graph represents the arterial and venous oxygen levels. The first sample is the control.

both due to air emboli. In the first instance this occurred from air introduced by mistake through the venous catheter in a patient with tetralogy of Fallot. The heart was stopped with the cardioplegic solution. In reopening the aorta, fibrillation recurred and electrical stimulation reverted the rhythm to normal even with temperature of 28.5° C. In the other patient a mitral valvulotomy was being performed from the right side and air entered the left ventricle via the mitral valve. The temperature was raised by our heat exchanger from 28.5° to 34° C., and defibrillation was easily accomplished (Table 3). In 50 per cent of ventriculotomies fibrillation has followed washout of the cardioplegic solution due, we believe, to its uneven removal. Electrical defibrillation has always followed without difficulty. The three patients who died on the table both had regular rhythm re-established following cardioplegia, though both eventually died of cardiac standstill. The factors of preceding failure, irreversible vascular damage to lung, and associated defects all played a role in these deaths.

During the course of operating upon these 46 patients certain technical hazards have occurred that have proven the combination of hypothermia and extracorporeal circulation to be life saving. In one instance of pulmonary valvular stenosis, a pulmonary artery was torn and repair required 13 minutes, which of course is longer than the safe period of hypothermia. In the first adult patient in whom the DeWall oxygenator was used, arterial oxygen saturation of only 60 per cent was obtained. In spite of this, we were allowed 17 minutes of operating time for closure of an atrial

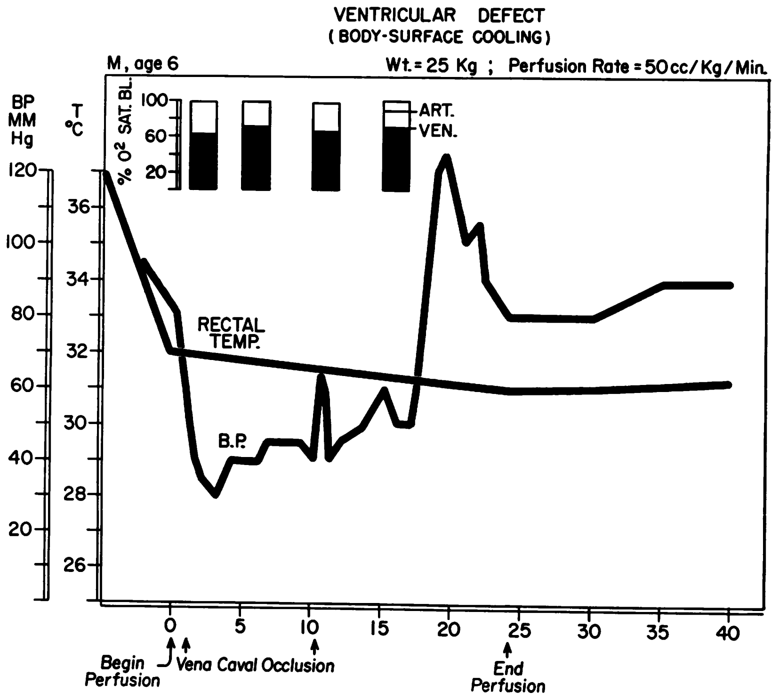

FIG. 4. A graph of the rectal temperature and blood pressure variations in a patient who had a ventricular septal defect repaired. The bar graph represents the arterial and venous oxygen levels obtained during perfusion. The first sample is the control. Body surface cooling was used.

defect. In another patient the superior vena cava line became obstructed, and the closure of the interatrial defect was still completed in spite of serious though temporary changes on the electroencephalogram.

Discussion

This clinical experience has confirmed our previous laboratory studies that hypothermia and extracorporeal circulation were complementary. We have been able to use low perfusion rates and at the same time maintain acceptable level of oxygenation and metabolic balance. The DeWall apparatus has been found to be a satisfactory pump-oxygenator. This is assembled and heat sterilized by our central supply room just as any other item of sterile equipment. We have experienced instances of equipment failure and technical accidents that might have been fatal, and the few minutes of extra time allowed by the hypothermia have been life saving. Moreover the two technics together have removed the time limit to intracardiac surgery afforded by hypothermia alone.

In clinical application the principal objections to using both technics has been the time necessary to induce cooling, the inability to control the temperature level, and the slow rewarming period. The heat exchanger we now employ has removed these objections. With an additional ten to 15 minutes of perfusion following release of caval occlusion, we have been able to raise the temperature to 34° C. or above. The problem of increased solubility of oxygen at the lower temperatures has not thus far added any demonstrable risk to the procedure.

Cardiac irritability during hypothermia is simple to control when one has an extra-

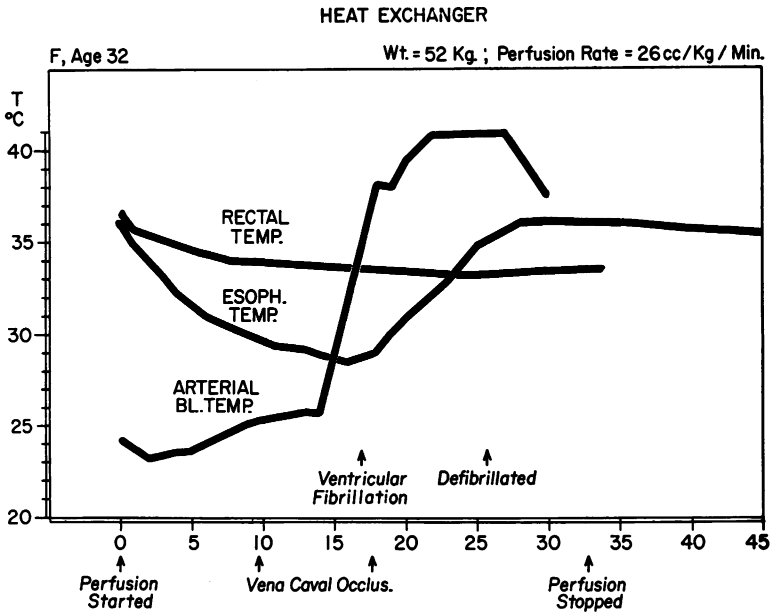

FIG. 5. A graph showing the temperature changes in the rectum, esophagus, and arterial blood as the latter enters the patient through the right subclavian artery. This demonstrates the time needed for cooling and rewarming the patient. Ventricular fibrillation developed from air introduced into the left ventricle, but its reversal was easily accomplished. The difference in the rectal and esophageal temperature is explained by the site of the arterial cannula insertion. This patient had the third recurrence of mitral stenosis.

corporeal system. Where we have used induced cardiac standstill with magnesium sulphate, potassium citrate, and neostigmine regular rhythm has always been re-established even at temperature below 29° C. There has been only one instance of fibrillation in the non-ventriculotomy group. This was a patient with mitral exploration and was due to emboli from air entering the left ventricle. In this patient cardiac action was easily restored. In fact, our experimental studies [12] as well as those of Gollan [13] suggest that the cold heart will tolerate ischemia much better than the heart at normal temperature. With an adequate heat exchanger as well as the assistance of the extracorporeal system, one has a reliable means of correcting the ventricular fibrillation that occurs at any degree of hypothermia.

It is not within the scope of this paper to discuss the advantages of high flow over low flow extracorporeal systems. If, however, one wishes to employ a device as economical and simple as the DeWall oxygenator, it is our opinion that total perfusion rates should not exceed 2,000 cc. per minute. At normal temperatures this would permit only dangerously low flow rates in larger patients. The adequate venous oxygen saturations shown by our patients at rates of flow one-third to one-half those recommended by Kirklin [14] indicates that adequate oxygen is being delivered to the patient. DeWall [15] and Cross [16] have reported venous oxygen saturations of one-half the levels recorded here when perfusion was done at normal temperatures using slightly higher rates of perfusion. The lack of significant alterations in the arterial pH, CO_2 tension, and lactic acid is a further demonstration that flows of

TABLE 3. *A Summary of the Arterial and Venous Oxygen Saturations, the Blood Pressure, the Caval Occlusion Time, the Temperature, and Flow Rates on 14 Patients*

Diagnosis	Age	Temp. °C.	Flow Rate cc./Kg./min.	Perfusion O_2 Art./Ven. % Saturation				Systolic B. P. During Perfusion	Minutes Caval Occlusion
				1	2	3	4		
Mitral stenosis	31	28.5	29	98.2 / 79.8	99 / 76	98 / 70	99** / 80	70	10
I. V.	7	30	50	100 / 73.8	100 / 96		103 / 72	50	13
Tetralogy of Fallot	8	29.6	40	100 / 56	100 / 71	100 / 76	100 / 74	65	26
I. V.	8	29	50	100 / 77	100 / 76	100 / 84	100 / 67	40	22
I. V.	5	29	35	100 / 58	100 / 59	100 / 57	100 / 57	40	27
I. A.	5	29	33		100 / 64	100 / 68.9	100 / 88	50	8
I. V.	5	30	40		100 / 78.9	100 / 79.4		50	10
I. V.	7	29	35	100 / 89.7	100 / 62	100 / 69.6	100 / 62.8	40	8
I. V.	8	31	25–50	99.8 / 98.7		99.3 / 91.3	98.9** / 96.6	70	20
I. A.	10	28.5	50	98.4 / 92.1	100 / 61	99.8 / 61.5	99.8** / 93	50	17
I. V.	7	31	50	99 / 62.6	98 / 72.9	99 / 66	99** / 70	50	11
I. V.	13	28.7	50	99.5 / 97	100 / 81	100 / 63.5	100 / 65	50	14
I. A.	47	31	40	99 / 86	97 / 91.4	98 / 75	98 / 84	90	10
I. V.	5	30	50	97 / 85	100 / 75	100 / 75	99 / 70	80	20

* 1 is the first mixed venous sample returning to pump after caval occlusion, 2, 3, 4 obtained during caval occlusion except as noted below.

** Samples after caval occlusion but with perfusion.

this low level are adequate if combined with hypothermia.

The application of any method of open heart surgery to seriously ill patients makes the appraisal of the method difficult. We believe this is the principal source of confusion concerning the disadvantages of various pump-oxygenator systems. Atrial septal defects and valvular deformities where the ventricle is not opened and the heart is not stopped offer the best method of evaluation. In this group in our series, there was only one death two weeks after surgery, and this could not be attributed to a perfusion failure.

Though the combination of hypothermia and extracorporeal circulation is unquestionably safe, is it really necessary? Others [16, 17, 18] have attained good results without the deliberate addition of hypothermia. The elimination of cumbersome and expensive equipment for oxygenation is, in itself, adequate justification for the use of the two technics. There are other potential safety factors that are realized, such as the increased tolerance of the cold heart to ischemia and the maintenance of a satisfactory metabolic balance. With an efficient method of temperature control that is a part of the extracorporeal pump-oxygenator, it is not unlikely that it will be practical to utilize to a greater extent the favorable metabolic effects of cold by employing still lower levels of temperature.

Conclusion

Low flow extracorporeal circulation and hypothermia have proven to be complementary for open heart surgery. This is supported by the high venous oxygen saturation and the minor alteration in the lactic acid levels in the blood during perfusion. The problem of temperature control has been solved by utilization of a heat exchanger in the extracorporeal system.

A right ventricular incision and exploration with cardioplegia has been easily achieved. Cardiac irritability has not been a serious problem.

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Discussion

Dr. Edward F. Parker: In closing, I would like to say that the senior author of the paper presented by me was Dr. Darby. Secondly, I would like to congratulate Dr. Sealy on his excellent work. I am sorry to say that we have not had in the laboratory such good results with the combination of hypothermia and bypass. In general our results were poorer with the combination of intentional hypothermia and bypass, than with bypass without intentional hypothermia. However, it should be said that for us it has been difficult in the dog to prevent a little hypothermia during bypass experiments. In our human cases, we have had unintentional hypothermia, down as low as 34° C., with bypass, because of the difficulty in maintaining the temperature of the blood circulating through the extracorporeal system. At present we are concerned with trying to maintain normothermia during operation.

Dr. Will C. Sealy: (closing) I would like to thank Dr. Parker for his discussion. His observations on the heart during controlled standstill are most interesting. Many people have used extracorporeal circulation and hypothermia unintentionally. This may explain some of their good results.

I would like to show an additional slide: This shows the pH, lactic acid and CO_2 level on arterial blood of a patient who has a repair of the tetralogy of Fallot. You can see the perfusion period was of 30 minutes duration. These findings were all within the limits of normal.