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Initial Application of Ventricular Assist Devices (VAD)

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Introduction

Left or right monoventricular and biventricular circulatory assist devices have been realized to be the popular standard methods[9,17] for postoperative low cardiac output syndrome (LOS) following various heart surgeries. 32 patients have been applied monoventricular and/or biventricular assist devices in Japan especially during the last three years and the number of patient is now suddenly increasing. There are three types of ventricular assist device made in Japan, including the Tokyo University type[12] (Nippon Zeon, Co., Ltd.), the National Cardiovascular Center type[19] (Toyobo, Co., Ltd.) and the Tomasu type of artificial heart[6] (Kyoto University and Tomasu Laboratory), which have been initiated successful human experiments of use. And also the Thoratec Pierce-Donachy VAD[14], one of the assist devices developed in the United States has been used in two cases up to date in Japan. Five out of the 32 patients, however, have successfully achieved long-term survival and discharged from hospital, and over 85 percents of the patients could be weaned from the VADs applied for the LOS, although multiple organ failure was the main cause of death following the LOS and severe septic infections, but not from thromboembolism.

In order to meet the so called Starling-like response of heart[3], a multilayer diaphragm of thin soft polyurethane have been developed in the Utah types of air driven heart, and according to the Dr. *Kolff*'s philosophy that the simpler is the better, the Utah types of the heart have been controlled with a preset fixed heart rate. The Tomasu heart which is one of the Utah types of heart has been made in Japan and implanted in 34 sheep achieving 226 days of long-term survival[8], in 20 goats with a longest survival of 8 days and 44 calves with of 67 days as the total artificial replacement. The same structures of the Tomasu total artificial heart[4] has been duplicated in the Tomasu assist device with the transcutaneous inflow and outflow cannula.

Key words : Clinical application of VAD, Ventricular assist device, Non synchronizing pumping, Low cardiac output syndrome, Actificial heart.
索引語：補助心臓臨床応用，補助人工心臓，非同期駆動，低心拍出症候群，人工心臓
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which has been utilized in four patients in our institutes, obtaining two long-term survivors, a weaned highly effective patient and an effective two-week survivor. Those experience have been carefully examined retrospectively and compared with the data from our two own cases with the Pierce-Donachy VADs applied in our institutes.

Materials and Method

Soft Multilayer Diaphragm Types of VAD:

Prior to the human applications, the Tomasu assist heart and the Thoratec Pierce-Donachy VAD have been tested hydrodynamic functions in a single mock circulatory system and in chronic experimental animals, comparing with other types of artificial heart. The Tomasu assist devices are connected to an atrial chamber through a 12 mm in diameter 15 cm in length inflow cannulae which has a stainless steel cage on the tip and to an aortic chamber through the same size of outflow cannulae with 5 cm long vascular graft on the tip (Fig. 1). A full stroke volume of the Tomasu heart are measured approximately 60 cc excluding regurgitation through two mechanical valves used. The Fig. 2 reprints the hydrodynamic functional characteristics of the Tomasu assist heart comparing with the sac type of VAD heart with a 0.7 mm thick layer of blood sac. The minimum necessary driving positive pressures applied during systolic phase and negative pressures applied during diastole are measured as shown in the Fig. 3 under the conditions with 80 mmHg or 100 mmHg of a mean aortic pressure to meet the full stroke volume of VAD. These minimum necessary driving pressures were almost the same as the pressures

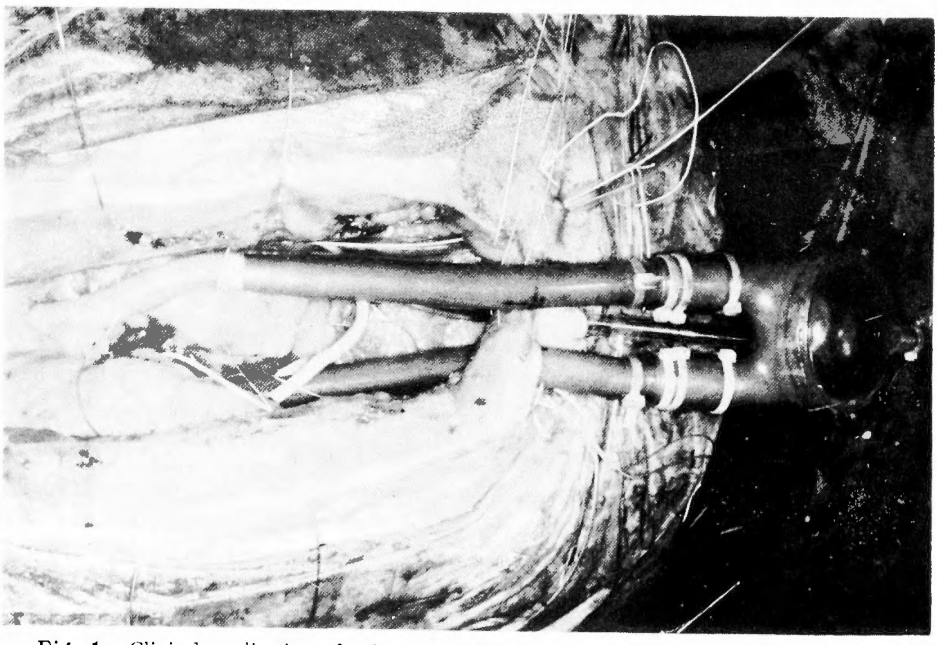

Fig. 1. Clinical application of a Tomasu VAD as a LVAD. The withdrawal cannulae was inserted into the left atrium through the right side free wall of left atrium and the return cannulae was anastomozed to the ascending aorta in this case.

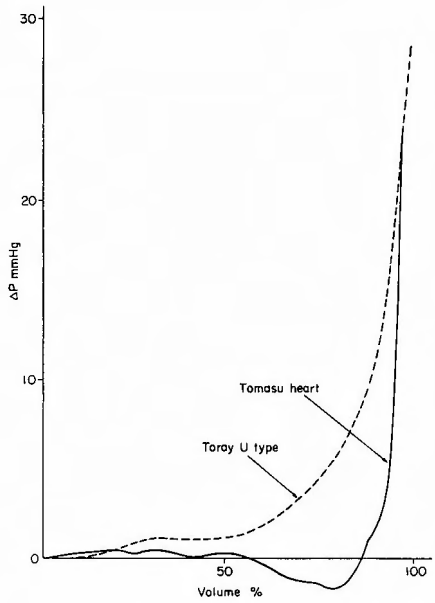

Fig. 2. Hydrodynamic characteristics of the Tomasu VAD with soft thin multilayers of polyurethane diaphragm. Comparison studies were investigated in a mock circulatory system to define hydrodynamic characteristics of the Tomasu VAD and the Toray U type (a sac type) of VAD heart with a 0.7 mm thick layer of blood sac. The much higher negative pressure was requested to pump 100% full stroke volume of the sac type VAD than the Tomasu VAD heart. $\triangle$P; differential pressures to move the blood membranes, Volume %; % volumes out of a full stroke volume.

required with the Thoratec Pierce-Donachy VAD but were remarkably lower than the other types of artificial heart which have a thicker lay of polyurethane diaphragm or a thicker blood sac in its'. The animal experiments[7] investigated prior to the human applications had successfully proved no evidences of thrombus formation in the Tomasu assist heart without use of any anticoagulants and of thromboemolism in the multiple organs even at the autopsies, as well as with the Thoratec Pierce-Donachy VAD.

Patients Selection:

The most difficult part of clinical application with the VADs was the final decision for selection of *Pierce's*. The Pierce's criteria described in his papers[15] may be the best ones but are not always practical especially at the time of application. Therefore, we finally decided to indicate them when the patients could not be weaned or were expected not to be weand from the Heart-Lung (H-L) machine within the first postoperative 6 hours even with use of conventional medical treatments and effective IABP supports.

The Table 1 summarizes all of the cases which have received the Tomasu heart or the Pierce-Donachy heart in our institutes. The first two patients received a Pierce-Donachy heart, one as the right ventricular assist device and another as the left VAD. The other four patients received the Tomasu hearts. Three of the four received the left VADs (LVAD) including a LVAD with a transapical left ventricular withdrawal cannulae and two with a transatrial with-

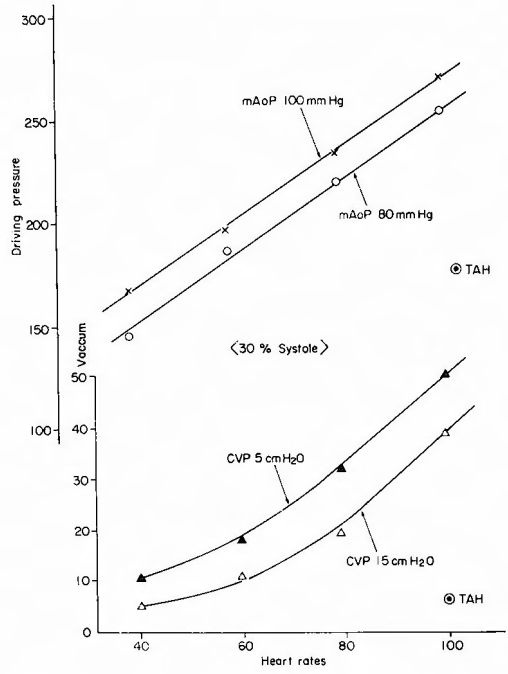

Fig. 3. The minimum necessary driving pressures for the Tomasu VAD heart with two 12 mm in diameter 15 cm in length inflow and outflow cannula. mAoP; mean aortic pressure, CVP; central venous pressure, TAH; in cases of total artificial heart. Driving pressure means the positive driving pressures applied during the systolic phase. Vacuum means the negative driving pressures applied during the diastolic phase.

drawal cannulae, and another received a right VAD (RVAD) with a transatrial right atrial withdrawal cannulae. In all of the six cases, the Thoratec pneumatic assist heart driver was used as the driver for both Tomasu and Thoratec VADs.

Table 1. Summaries of the clinical cases applied the VADs in our institutes.

Clinical Application of VAD

No.	Name	Sex	Age	Date	Op Procedures	VAD	Duration	Heart	Results
1.	K. N.	F	70	'85. 8. 2.	A-C bypass	RVAD & IABP	3 hrs	Thoratec	Death on Table
2.	A. I.	M	52	'85.11.15.	AVR+MVR+TAP	LVAD	4 days 12 hrs	Thoratec	Weaned 36 days
3.	M. K.	F	28	'85.12.27.	Bentall	LVAD Transapical	11 days 16 hrs	Tomasu	Weaned 19 days
4.	Y. O.	M	69	'86. 1.31.	A-C bypass	LVAD	14 days	Tomasu	Effective
5.	J. A.	M	69	'86. 3.17.	A-C bypass LVane-tomy	RVAD & IABP	5 days	Tomasu	long-term
6.	K. M.	M	60	'86. 3. 7.	VSP closure	LVAD	2 days	Tomasu	long-term

F; female, M; male, A-C bypass; aorto-coronary bypass surgery, Bentall; Bentall's precedure, LVane-tomy; Left ventricular aneurysmectomy for LV aneurysm due to acute myocardial infarction, VSP closure; a patch closure of ventricular septal perforation due to acute myocardial infarction, Thoratec ; Thoratec Pierce-Donachy VAD heart, Tomasu; Tomasu VAD heart.

VAD Performance:

The Thoratec assist heart driver has three functional VAD driving modes, including a synchronized pumping with the QRS on ECG, a volume-depend pumping with various heart rates and a constant full stroke volume according to the venous blood return to atria, and a non synchronized pumping with a preset mannually fixed heart rate. Regarding to the results of our animal experiments[7] which demonstrated no evidences of significant deference among with these modes, we used a non synchronizing mode only in all cases.

In order to minimize the afterload from aortic pressures to the injuried natural ventricle[5], the bypass blood flow rates through a left VAD were always slightly limited just after weaning from the prolonged extracorporeal circulation, especially if the withdrawal cannulae was inserted into the left atrium. The limited blood flow rates were approximately 2.1 litters/min/m^2 of cardiac index (C.I.) and were alternated up to 2.5 litters/min/m^2 when the functions of natural left ventricle recovered as well as seeing the ejection peaks from the natural ventricle on the aortic pressure waveforms created by the VAD, which usually occured within 2 days. The 2.5 litters/min/m^2 of cardiac index flow rates were kept until the functions of injuried ventricle recovered enough well to maintain its own cardiac outputs at the level of 2.5 litters/min/m^2 or more of cardiac index without any supports of VAD for 30 seconds.

The mean left atrial pressure was monitored to be kept always below 15 mmHg, or 10 mmHg if possible, by controlling the best balance of right and left ventricles. The pulmonary arterial pressures were not monitored but were calculated[3] from analysis of the right VAD driving pressure forms when the RVAD was adapted. The RVAD was always accomplished with an intra-aortic balloon pumping (IABP) and the assist bypass blood flow rates through a RVAD was controlled as minimum as the RVAD keeps the cardiac output through a natural left ventricle and a RVAD at the level of 2.5 litters/min/m^2 of cardiac index.

The removal of VAD was performed surgically through a reopening medsternal incision when the functions of injuried natural ventricles recovered completely or near completely. The recovery of disturbed ventricular functions occurred rather suddenly at the time of postoperative 4th or 5th day, and if the ventricular functions recovered remarkably at this moment, a removal of VAD was performed uneventfully within 2 or 3 days following the sudden ventricular recovery.

Postoperative Evaluation:

Thrombus formations in the VADs were examined macroscopically and microscopically at the end of clinical applications. Thromboembolisms were examined at the autopsy in only a case of the No. 4 patient who died of the suddenly onset bronchial massive bleeding into the left lung 2 days after successful weaning of a LVAD. Multiple organs failure was determined only by the clinical signs and syndromes. Infected organs was defined by the blood and tissue cultures, although the antibiotics given were selected according to the results of antibiotic sensitivity tests. Pulmonary edema suspected to be created by the RVAD was defined with the definitely increased volume of bronchial secretion and pleural effusion sucked through the chest drainage tubes out.

Results

Three out of the four patients with the Tomasu assist heart and one of the two patients with the Thoratec Pierce-Donachy VAD have been successfully weaned from the VADs. Two of them, one with a Tomasu RVAD and another with a Tomasu LVAD have been able to recover completely from the postoperative LOSs and discharged from hospital. Only a patient could not benefit any valuable supports by the VAD, which was the first case of our clinical VAD applications and received a RVAD just before she went out. All of the rest five patients could have remarkable efforts of significant assist bypass effects for functional recovery of the ventricular myocardium, although one of the five could not be weaned from the LVAD and died on the postoperative 15th day.

Case No. 1.

The patient with three vessel diseases of coronary artery underwent A–C bypass surgeries and developed biventricular failures, especially right ventricular failure after the prolonged 3 hours of total and 6 hours of partial extracorporeal circulation (ECC). The mechanical left ventricular support of intra-aortic balloon pumping was initiated at the end of ECC and the patient was attempted to wean from the ECC several times. When the patient had almost gone, the decision was made for the first human application of VADs in our institutes, and only a RVAD could be successfully inserted before the patient went out. A half minute of RVAD pumping developed severe pulmonary edema due to the severely failed functions of left ventricle even under the use of IABP.

Case No. 2.

When the patient could not be weaned from the ECC after the prolonged 6 hours of partial assist ECC, the decision was made for a LVAD following the two valve replacements and tricuspid valve annular plasty under the 3 hours of total ECC. A withdrawal cannulae of LVAD was placed into the left atrium through the incision made at the center of two pursestring sutures near the left atrial appendage, and a return cannulae was connected to the ascending aorta with end to side anastomosis. Non synchronized assist pumping of LVAD was initiated following the removal of IABP and the patient could be weaned from the ECC within 10 minutes with the minimum supports of conventional medical treatments. On the postoperative 2nd day, ejection type of pressure peaks from the natural ventricle was initially seen above the aortic pressure waveforms created by the non synchronized VAD, and then the bypass blood flow was increased up to 2.5 litters/min/m^2 of C.I.. On the postoperative (PO) 4th day, the ventricular functions recovered remarkably and the LVAD was successfully removed on the P.O. 5th day, although the patient developed gradually and finally severe renal failure around the P.O. 9th day and septicemia during the following days. The use of hemodialysis was able to support the patient until the 52 years old male died of respiratory insufficiency with severe infections on the P.O. 36th day.

Case No. 3.

She was a 21 year old female of the Murfan's complexes with an aortic annulo ectasia and underwent the Bentall's method of surgical repair with a Björk-Shiley (Bj-Sh) valve and a Cooley vascular graft. The patient received a LVAD with a transapical withdrawal cannulae and a return cannulae to the ascending aorta on the part of vascular graft. The initial pumping of LVAD was started with 2.1 litters/min/m² of C.I., because the aortic Bj-Sh valve did not open if the mean aortic pressure was maintained over 85 mmHg with 2.5 litters/min/m² (C.I.) of the assist bypass flow. Ejection type of flow peaks from the natural heart was realized above the aortic pressure wave forms on the P.O. 4th day (Fig. 4). This patient developed silent syndromes of cardiac tamponade on the following day, and when the chest was reopened at the P.O. 6th day, remarkable recovery of the injuried ventricular functions was seen immediately but acute renal failure could not be avoid. The LVAD could be removed on the P.O. 10th day without using assistance of IABP. The patient looked so healthy until she suddenly developed massive intrabronchial bleeding into the left lung and died on the P.O. 12th day. In this case, the transapical blood removal of the VAD out of the severely failed natural left ventricle was realized to be very useful to prevent the ventricular myocardium especially subendocardiac myocardium from the acute infarction suspected with the distended left ventricle due to the regurgitated blood from the aorta through a Bj-Sh valve. In the fact, when the assist bypass blood flow through a LVAD was reduced down to below a half, the left ventricle was severely distended and 40 mmHg or more of the left ventricular endodiastolic pressures were monitored.

Case No. 4.

The patient was a 69 year old male and underwent emargency pericutaneous transluminal coronary recannalization (PTCR) and angioplasty (PTCA) within 8 hours following the initial attack of acute myocardial infarction (AMI). An emergency surgery was performed with the methods of aorto-coronary (A.C.) bypass for three vessel diseases resulting in successful reperfusion of the left anterior descending (LAD) and the circumflex coronary arteries (CX) which were main arteries for the AMI. Prior to the surgery, IABP was initiated at the end of the catheterization. A attack of hypotension, however, suffered during the introduction of total anesthesia until the chest was quickly opened and the patient was connected to ECC

Following the complete repair of coronary arteries subendocardial bleeding was found forming multiple miliary hematoms in the posterior wall of LV and the postoperative LOS required a quick application of LVAD in 30 minutes after the ECC was removed. Without any supports of ECC insertion of a LV withdrawal cannulae could be successfully performed through the right free wall of LA, but the aortic pressures (AoPs) gradually dropped and high left atrial pressures (LAPs) led us to malmanagements of complete removal of air out of the assist device, although the AoPs and LAPs quickly returned to the of levels within the normal limits immediately after the LVAD was started pumping.

The cardiac outputs through a LVAD were maintained at the level of 2.1 litters/min/m² of cardiac index during the following several days. However, the remarkable recovery of left

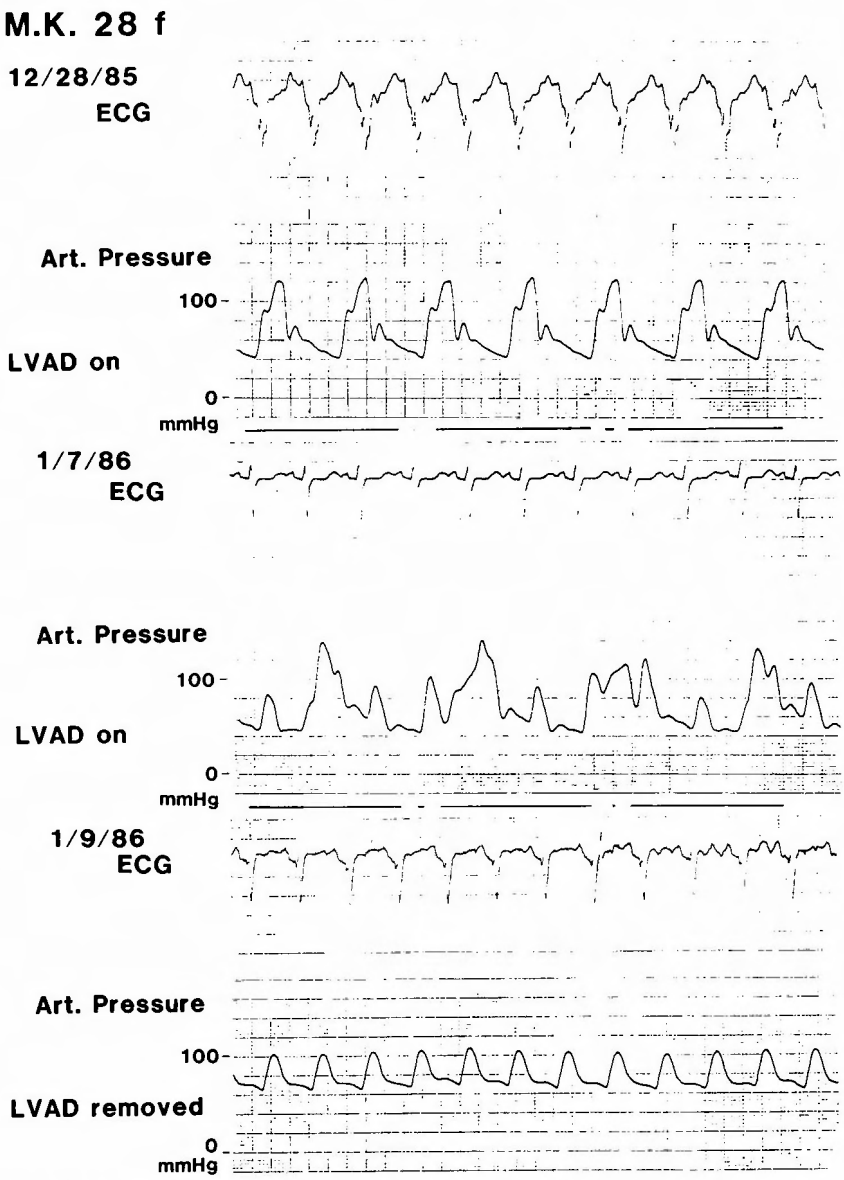

Fig. 4. A postoperative course of hemodynamics with a left ventricular assist device pumping and ECG. A female patient named M. K. received a LVAD on December 27, 1985 and was removed the LVAD on Jannuary 8, 1986. The aortic pressures listed on the top demonstrated only the aortic pressures created by the VAD. The aortic pressure wave forms listed on the middle have a the additional ejection type of peak wave form created the remarkably recovered natural left ventricle with a LVAD. The normal aortic pressures were realized after the LVAD removed.

ventricular myocardial functions could not be realized, which is usually seen at the 4th to 6th days, and clear consciousness did never come back. The raising cardiac outputs near to 2.5 litters/min/m^2 of C.I. could be observed only on the P.O. 9th and 10th days, but failed to avoid developing pulmonaly edema, septicemia and other multiple organ failures, especially the renal

failure required hemodialysis several times before the patients died on the P.O. 15th day.

Case No. 5.

A 67 year old male patient underwent left ventricular aneurysmectomy and double CX and right coronary A-C bypasses of surgery under a prolonged period of ECC, resulting in slightly failed both ventricular functions. The vein vascular graft anastomosed to the RCA was a little too short and was occuluded when the right ventricle was slightly extended following the successfully weaned ECC. Sinus tachycardia and ventricular fibrillation repeated several times. Although the IABP applied was very useful for the left ventricular failure to keep left atrial pressures to be sufficiently low, the right ventricular failure required a RVAD.

The RVAD bypass flow was attempted to keep as low as possible and maintain 1.8 litters/min/m² of C.I. keeping the mean loft atrial pressure below 10 mmHg at the initial stage of postoperative course. On the next day of surgery, however, the cardiac output was able to increase up to 2.0 litters/min/m² of C.I., and his general conditions were very good including pulmonary functions until the right ventricular functions gradually recovered on the P.O. 3rd day remarkably, resulting in the secondary respiratory failures (Fig. 5) accompanied with increase of chest dranage fluid (perhaps pulmonary edema). Thus the driving conditions were changed to decrease the cardiac outputs through a RVAD down to approximately 1.5 litter/min/m² of C.I., although the thrombus formation in the VAD were strongly afraid, and the respiratory failure recovered immediately after the RVAD were successfully removed on the P.O. 5th day. Acute renal failure could be treated well by hemodialysis and recovered completely at the end of P.O. first month.

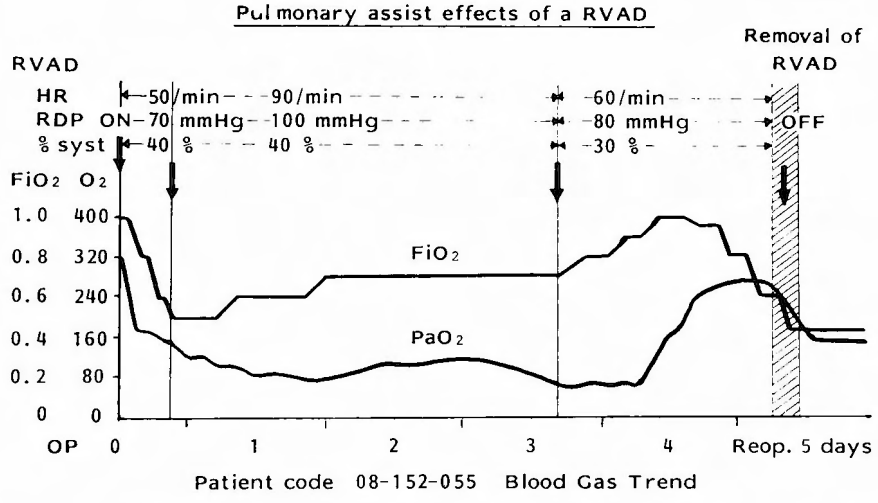

Fig. 5. A postoperative course of respiratory functions in the patient of No. 5. This patient developed respiratory failures probably caused by overdriving of a RVAD on the postoperative 3rd to 4th day and the respiratory failures recovered spontaneously after the overdriving of RVAD was corrected. The left atrial pressure was alway kept carefully below 15 mmHg.

Case No. 6,

The 60 year old male with an acute myocardial infarction was accompanied with a large ventricular septal perforation and was continuously treated with IABP for a month prior to the surgery with a patch closure for VSP and the prescheduled postoperative LVAD bypass assistance. His postoperative course was completely uneventrul with intermittent use of heparin keeping the activating clotting time around 200 seconds. The bypass flow rates with approximate 2.5 litters/min/m^2 of C.I. were maintained for 24 hours and were reduced down to 1.5 litters/min/m^2 on the P.O. 2nd day. The LVAD could be removed on the P.O. 3rd day successfully. He is now very healthy and successfully discharged hospital.

None of anticoagulants has been given in all of the cases except the No. 6 patient, although the LOS due to cardiac tamponade was seen in a case which received a transapical ventricular withdrawal cannulae for LVAD. None of the other cases had the postoperative bleeding problems and clinical signs of thromboembolism. However, the minimum thrombus formation was found around the metal rings of mechanical valves in the VAD in all of the cases (Fig. 6), and one of the thrombuses formed around the inflow valve grew up to be long enough to connect to the thrombus around the outflow valve (Fig. 7) in a case of No. 5 which received a RVAD and the low bypass flow of 1.5 litter/min through the RVAD for a whole day. No cases have had troubles with the mechanical failures of devices.

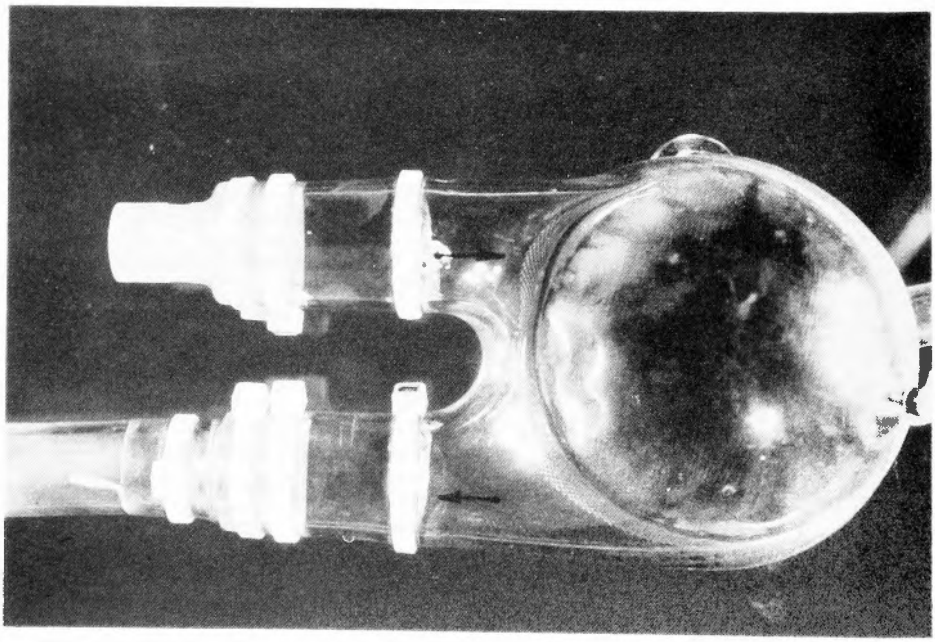

Fig. 6. The clinically used Tomasu VAD heart. No thrombus formations were found in the artificial ventricles except a small mount of thrombus formed only around the metal ring of Björk-Shiley valve fixed in the inflow tract. This heart had been implanted in a patient for 15 days without anyone of anticoagulants.

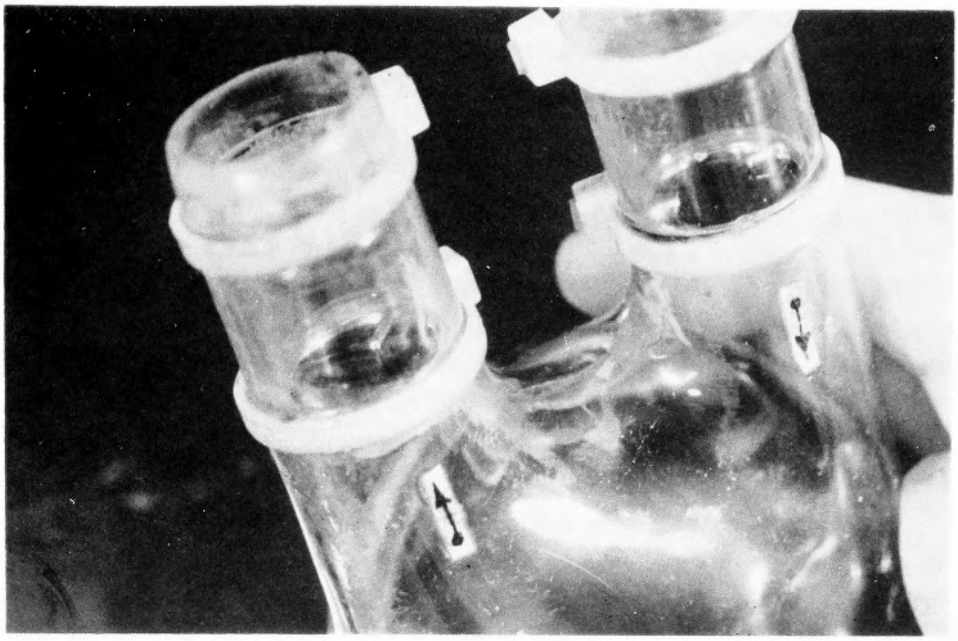

Fig. 7. Thrombus formation in a RVAD. Only one of the Tomasu VAD hearts formed a relatively large thrombus in the inflow tract, which grew up and connected to the thrombus formed in the outflow tract during when the bypass blood flow was reduced down to below 1.5 litter/min for over 12 hours without administration of any anticoagulants in a patient.

Discussion

Human application of VAD was initiated in 1974. Since then over 200 patients[17] have received a left or right monoventricular assist device or biventricular assist devices throughout the world and among the last 100 cases[1] 65 percents or more of the patients have been successfully cured from the severe postoperative LOSs which usually kill the patients immediately after the surgeries, although only 10 to 15 percents of the patients could be saved among the first approximate 100 patients with VAD. On the contrary, 32 patients have received a left or/and right VAD in Japan since 1984, and five patients out of the 32 have successfully achieved long-term survival and could discharge from hospitals, including two out of the 12 patients who received the Tokyo University type of sac heart[10,11], one of the 13 patients who received the National Cardiovascular Center type of thick diaphragm heart[18] and two out of the 6 patients who received the Tomasu type or the Thoratec type of thin soft multilayer diaphragm heart up to date.

Multiple organ failure (MOF)[2] was one of the main causes of death and the cardiac failure usually recovered remarkably on the P.O. 4th or 5th day in almost all of the patients even if they died of the MOFs later. The multiple organ failure must be due to the insufficient blood circulation to the peripheral organs during the phase of LOS before, during and after heart surgeries, although the initial cardiac outputs through our LVADs was maintained around the 2.1 litters/min/m^2 of C.I. which might be too low to maintain the sufficient blood circulation to all of the peripheral important organs, in order to protect the severely injured ventricular myocardium

from the over after-loads with high aortic pressures created by the LVADs.

More recently, *D.G. Pennington* and his associates[13] recommended to use the transapical ventricular withdrawal cannulae for a LVAD instead of a transatrial atrial withdrawal cannulae. *J. Peter* and his associates[16] used to recommend that in order to reduce oxygen consumption of the left ventricle 80 percents or more of ventricular blood flow must be bypassed through the transapical withdrawal cannulae. In two of our cases, the left ventricle could not pump any blood out of the ventricle when the mean AoP rose up above 85 mmHg, and the LV gradually distended, but the left ventricle returned to be smaller when the mean AoP was lowered to below 80 mmHg or the ventricular blood was bypassed through the transapical cannulae to a LVAD.

Remarkable recovery of the injuried ventricular myocardial functions occured on the P.O. 4th to 5th day in three cases of the six. In one who recovered quickly, the remarkable recovery of myocardium was realized before the P.O. 4th day, and the patient who could not be weaned from a LVAD, did not have such kinds of remarkable recovery on the postoperative hemodynamics. Thus, the remarkable recovery of injuried myocardium seen on the P.O. 4th or 5th day might be a very important sign as the turning point. It takes 4 to 5 days for the high energy components of the TCA cycle to be restored enough creating a sufficient volume of ATP.

Anticoagulant therapy is highly recommended to be a standard method for the use of artificial heart. However, no anticoagulants were used in the five of our 6 cases and there were no evidences of thromboemolism and the minimum thrombus formation was found only around the metal rings of mechanical valves placed in the inflow and outflow tracts of VAD. Bleeding problem has been reported as another main causes of death in 10 to 25 percents of the past cases. However, no bleeding troubles were realized in all of our cases except one who received a transapical ventricular withdrawal cannulae and developed a cardiac tamponade just after the natural ventricular functions recovered remarkably.

Infection must be carefully avoided from the whole body especially around the chest cavity. All of our cases were able to close the midsternal incisions even after the VADs were connected, and the Dacron felts covered on the transcutaneous part of withdrawal and return cannula helped very well to avoid infiltration of bacterias along the cannula, although the severe infection once occured in the mediastinal cavity caused septicemia at the end stage of the No. 2 patient who were successfully weaned from the LVAD and died on the 36th day after surgery.

Conclusion

Four out of six patients could not be cured unfortunately with the VADs, although four of the six patients could be successfully weaned from the mechanical supports of LVAD or RVAD and two of them recovered completely from the severe postoperative low cardiac syndromes which usually kill the patients immediately after surgeries failing to wean from the ECC. No use of anticoagulant therapy caused the minimum thrombus formations around the metal rings of mechanical valves placed in the inflow and outflow tracts of the Tomasu assist hearts and the Thoratec Pierce-Donachy VADs. There were no bleeding troubles except in a case who received a transapical cannulae of LVAD and developed a cardiac tamponade on the postoperative 5th

day. Multiple organ failure was one of the main causes of death, and infection occured in the mediastinal cavity developed septicemia at the end stage. Acute renal failure following the LOS could be treated completely with a method of hemodialysis in a case.

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和文抄録

補助人工心臓の初期臨床応用

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欧米では近年，術後重症低心拍出症候群の標準的治療法として補助人工心臓が使われることが多くなってきた．すでに200例を超える症例が報告された．そして，最近100例の成績では67%の救命率が得られたと報告されている．それに対して，本邦では1984年以来わずか32例に適応されたと報告しているにすぎない．そのうち5例のみが長期生存で，救命率も15.6%とあまり良いとはいえない．しかし，本邦症例でも，特に救命された症例が最近の症例に集中しており，救命率は急速に上昇しつつある．

我々の施設でも，現在までに国産トーマス型補助人工心臓症例4例と，米国産ソラテック社製ピアス・ドナヒー型補助人工心臓症例2例の計6例，補助人工心臓臨床例を経験した．うち4例にECC（体外循環）および補助人工心臓よりの離脱に成功し，うち2例に長期生存を得た．6例中4例は左心補助として単独使用し，2例は右心補助として使用，左心補助のためのIABPと併用した．

トーマス型人工心臓は，ユタ型人工心臓と同様薄膜多層型人工心臓で，実質60 ccの一回拍出量を確保でき，機能的には米国産ピアス・ドナヒー型補助人工心臓と同等の機能が期待された．駆動法としては，非同期的駆動法を採用，初期駆動は体外循環中に重症のダメージを受けた肺と心室心筋の前負荷・後負荷を最少限にするために，左心では2.1 $l/m^2/min$，右心では左心房圧が15 mmHgを超えない最少の補助とした．その後補助維持流量は左心で2.5 $l/m^2/min$，右心では左心の拍出量2.5 $l/m^2/min$を保つに必要な最少補助とした．左心補助4例中1例では術後2日目，2例では術後4～5日目に著明な左心室機能の回復，右心補助では2例中1例に，術後2～3日目に右心室の著明な機能回復を認めた．

補助人工心臓の適用基準は必ずしも容易なものではないが，トーマス型とピアス・ドナヒー型の間で差はなかった．