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Progress in Cardiology

末期的拡大心に対する新しい手術：左室形成術 (Batista Procedure)

New Surgical Procedure for Patients With Dilated Heart and End-Stage Cardiac Failure (Batista Procedure)

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Abstract

A 53-year-old man with dilated cardiomyopathy underwent left ventriculoplasty (Batista procedure), a new surgical procedure, which reduces ventricular volume to improve left ventricular function. Left ventricular ejection fraction increased from 19.7% to 43.7%. Unfortunately, he died of pneumonia 12 days after surgery. This is the first such procedure in a human in Japan.

Key Words
Left ventriculoplasty (Batista operation), Cardiomyopathies (dilated), Heart failure

左室形成術の現況

拡張型心筋症を含む心腔の拡大を伴った心筋症の予後は不良である．欧米の心臓移植対象患者のリストに載る，New York Heart Association (NYHA) 分類IV度の心不全状態に陥った患者の大半が，数ヵ月の生存しか望めないのが現状である．この疾患群に対する治療は，薬剤による保存的療法か心臓移植が現在までの選択肢であった．

薬剤治療では長期予後の改善は望みえず，心不全の軽減ないしは一時的な改善が得られるのみである．一方，心臓移植治療は，正常心を移植した直後から良好な心機能が得られるが，免疫機能との戦いは一生続き，頻回に心筋生検を施行し，免疫抑制剤による綿密なコントロールが必要である．我が国では脳死の問題が解決されていないために心臓移植は再開されていないが，欧米でもまた深刻なドナー不足に悩まされている．この心臓移植術の代案として人工心臓の開発が急がれているが，現在，埋め込み型の心室補助装置が漸く実用化された段階であり，しかも血栓の問題は解決されておらず，経費の点でも心臓移植術より高価なもので，心臓移植へのbridge treatmentとして位置付けされているにとどまっている．

この両極端の治療に対して，新しい外科的治療法として世界中で注目されているのが，左室形成術 (left ventriculoplasty) である (**Fig. 1**)．本法はブラジルのRandas J.V. Batistaが約10年前に開始したもので，心不全末期の拡大心に対し，現在までに300例以上の臨床経験を有し，その成績は1996年度の日本胸部外科学会総会において報告された[1]．

手術は拡大した左室の自由壁の一部を切除し，左室容量を減少させるもので，Batistaは心腔の拡大による

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Selected abbreviations and acronyms

EF＝ejection fraction
LVAD＝left ventricular assist device
MR＝mitral regurgitation
NYHA＝New York Heart Association
TEE＝transesophageal echocardiography

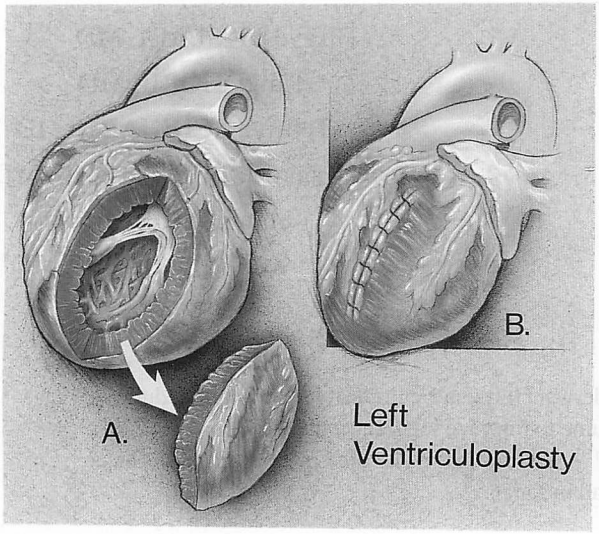

Fig. 1　Schema of the Batista procedure

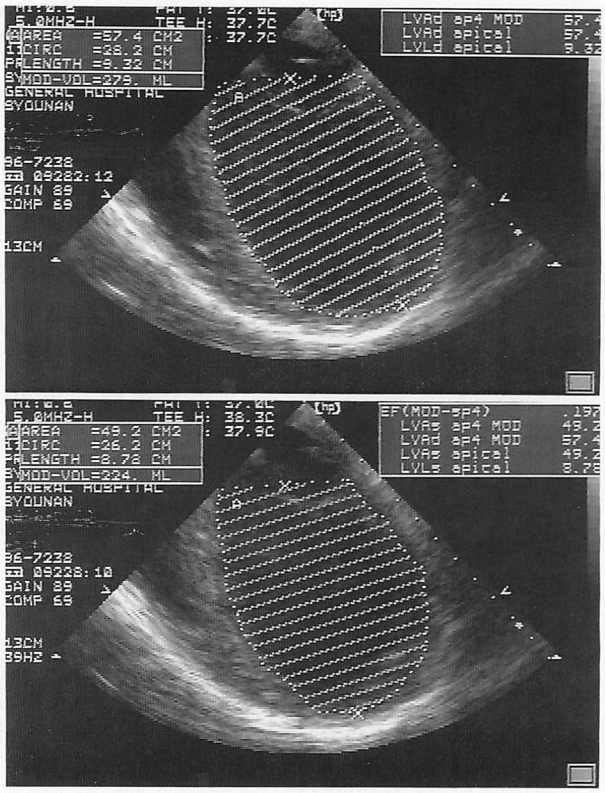

Fig. 2　Preoperative echocardiograms
Upper: diastole.　*Lower*: systole.
Left ventricular ejection fraction is 19.7%.

著しい容量負荷が心機能悪化の主因であると考え，左室内径の縮小を目的に左室自由壁の一部を切除した．手術方法自体は従来行われている心室瘤切除術で用いられる手技に類似しているが，瘢痕化した心筋である瘤壁を切除するのではなく，比較的正常な心筋を大量に切除して，心室形態を整える (remodeling) という発想が斬新である[2]．

対象が末期的心臓病患者でもあり，多くの外科医はその臨床応用を躊躇していたが，1994 年頃から欧米で注目されるようになった．Batista の施行した 305 例の手術成績では，手術死亡は 32 例 (10.5%) で，心不全症状の改善を 70% で認め，1 年生存率は 60% であった[1]．現在，欧米の最先端心臓センターの外科医および末期心臓病に対する専門内科医らが直接ブラジルへ出かけ，自ら手術を見学してその効果に興味をいだき，それによって本法が徐々に広まりつつあるというのが実状である．

1996 年度の米国心臓病学会においても，Cleveland Clinic の P. M. McCarthy が自らの経験を発表し，ABC 放送を通じて全米に報道された．1996 年 6–12 月までの 7 ヵ月間に 41 例 (年齢 15 ヵ月–72 歳) にこの手術が行われ，そのうち 1/3 が catecholamine 投与下に入院中の症例であった．術後死亡は 3 例で，脳血管障害 (術後 1 ヵ月)，突然死 (術後 3 ヵ月)，補助心臓装着後の肝腎不全 (時期不明) がそれぞれ 1 例ずつであるが，生存例の 70–80% に NYHA 分類 I–II 度への改善が得られたとしている．Cleveland Clinic においては，現在適応を特発性拡張型心筋症に限っている．

本手術は，Batista 自身が現在までに約 350 例に施行し，その他に約 100 例が米国を中心として世界各国で行われている．1997 年 2 月の米国胸部外科学会 (The Society of Thoracic Surgeons) では Batista 自身が最近の成績を発表し，McCarthy も手術手技の講演をすることが話題になっている．Batista ら[3]によれば，1994–1996 年の 2 年間に 120 例 (年齢 9 ヵ月–95 歳) に本法を施行した．心拡大の病因は特発性心筋症，虚血性心疾患，弁膜症，Chagas 病，その他がそれぞれ 20% を占め，術前の駆出率 (ejection fraction: EF) は 5–20% で，95% の症例が NYHA 分類 IV 度であった．左室部分切除と同時に弁形成または弁置換を 90% の症例に，また冠

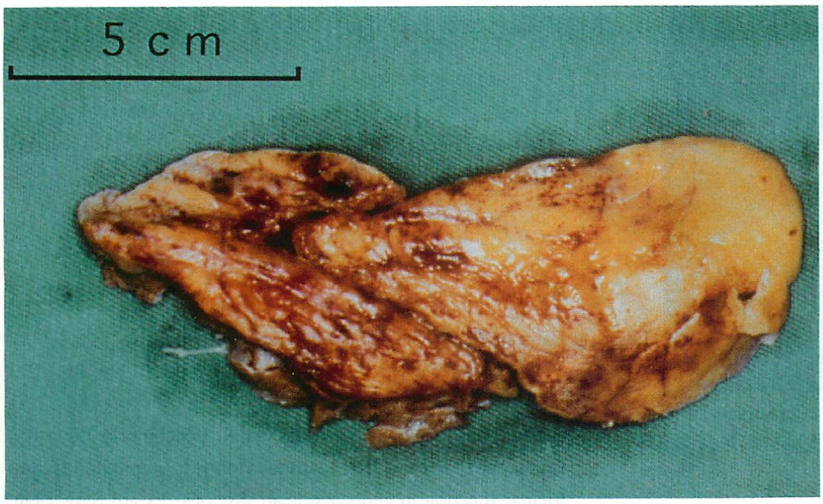

Fig. 3　Excised left ventricular wall (13×5 cm, 63 g)

動脈バイパス手術を20% の症例に施行した．周術期生存率は95%，院内生存率は70%，1年生存率は60%で，平均9ヵ月の follow-up において95% の症例がNYHA分類I–II度に改善し，EFは平均30% (20–65%) に増加した．

自　験　例

症　例　53歳，男

164 cm，57 kg．1年前に比べて体重が5 kg減少．

1995年8月から心不全にて入退院を繰り返し，1996年7月，心不全増強のため他院入院．同年11月にはdopamine 5 μg/kg/min，dobutamine 7 μg/kg/min の持続点滴にても収縮期血圧100 mmHg 以下となり，アシドーシス進行(BE–5)．1996年4月に施行した左室造影ではEF 16%，左室拡張末期容積364 m*l*，左室収縮末期容積305 m*l* と心拡大の増強を認め，拡張型心筋症と診断した．

また，この頃から僧帽弁逆流 (mitral regurgitation : MR) が出現し，11月の心エコー図で左室径(拡張期/収縮期) は80/75 mm, EF 19.7%，高度の僧帽弁逆流，中等度の三尖弁逆流を認めた (**Fig. 2**).

1996年12月2日手術施行．胸骨正中切開にて心嚢を開く．心臓は著しく大きく(通常の約2倍位)，経食道心エコー図 (transesophageal echocardiography : TEE) にて三尖弁逆流がないのを確認し，右房1本脱血とした．上行大動脈送血．大動脈基部に potassium 注入用の root cannula を挿入した．

体外循環開始．大動脈遮断せず．Cardioplegia 使用せず (Batista 原法に従う)．左心耳より vent tube 挿入．Root cannula より potassium を2–3 m*l* 注入し，心拍動を低下させた．心尖部から左室側壁に向けて切開し，左心内を観察 (拡大著明，前後の乳頭筋の間隔は広い)．前後の乳頭筋の間を長軸に沿って切除(13×5 cm) した後 (**Fig. 3**)，Alfieri 法[4] による僧帽弁形成を試みたが効果がないため，左室側からø29 mm bioprosthesis にて僧帽弁置換術 (mitral valve replacement : MVR) 施行．左室切開部を二重縫合し，心尖部より air vent を行い，閉鎖した．心拍動下に TEE にて MR 消失を確認．体外循環を離脱し，止血を終えた後，GRF グルー (接着のり) をウシ心膜に塗布して左室縫合部に貼り，後出血を予防した．ペースメーカーワイヤーを縫着し，心嚢内にドレーンを2本入れて胸骨を閉じ，手術を完了した．TEE にてEFは術直前の19% から30% に増加，肺動脈収縮期圧は術前60 mmHg から術後30–40 mmHg へと低下し，心拍出量は5 *l*/min へと増加した．体外循環時間73分，手術時間4時間20分であった．

術後は大動脈内バルーンパンピング (intraaortic balloon pumping : IABP) を必要とせず，心拍出量は4–6 *l*/minを保ち，心エコー図にて左室収縮の改善を認めた (**Fig. 4**; EF 30–40%) が，第5病日から肺炎出現し，種々の集中治療を行ったが，第12病日に死亡した．肺炎発症後も左心機能は良好に保たれていた．剖検にて左室縫合部ならびに僧帽弁置換部に問題なく，左室内腔の縮小を確認した．

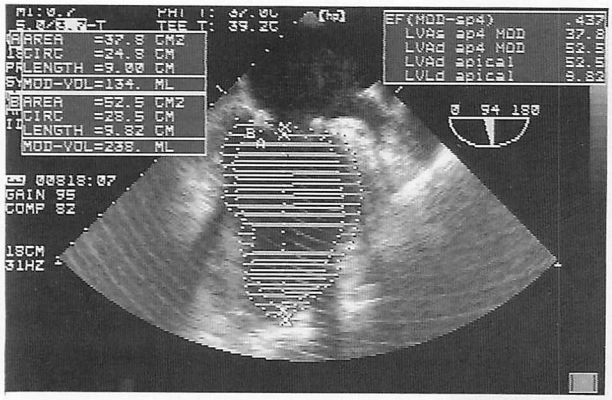

Fig. 4　Postoperative echocardiogram (3 days after surgery)
Left ventricular ejection fraction is 43.7%.

結　　語

現在，末期的拡大心に対する有効な治療法として確立されているのは，心移植のみである．しかし，脳死の認定，ドナー不足，術後の拒絶反応との戦いなど多くの問題が今なお残されており，新しい治療法が諸分野で探究されている．

左室形成術は最近ようやく注目されるようになった新しい手術法であるが，大きな期待のもとに，その安全性の確立と効果の判定に集学的な研究がなされつつある．

今回の手術に際し，来日し貴重な助言を賜ったTomas Salerno, Gerald Buckberg, Antonio Calafiore の3教授に深甚の謝意を表する．

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INVITED COMMENTARY

Dear Dr. Suma

Thank you for your letter inquiring about our experience with the Batista procedure. In short, we are cautiously optimistic about the results of this operation. I stress, however, that we are still very cautious about this.

So far we have done 41 operations at the Cleveland Clinic; the patients ranging in age from 15 months to 72 years. The 15-month-old child was done by one of my partners in desperation, and she died one month following surgery with seizures (possibly embolic). One patient had sudden death at three months; and one other patient eventually failed and went on to a HeartMate left ventricular assist device (LVAD) only to die of hepatorenal failure after the Batista procedure. In general, 70 to 80% of patients have clinically obvious significant improvement. Clinically class III and IV heart failure patients return to class I to II symptoms.

We are trying to do only patients with idiopathic dilated cardiomyopathy (occasionally we have had a misdiagnosis and found scar from ischemic cardiomyopathy). I have done one patient with familial cardiomyopathy, at least one patient with alcoholic cardiomyopathy, and one patient with valvular cardiomyopathy. I do not think that most patients with ischemic cardiomyopathy will benefit from this operation because if you have scar in all three vessel distributions then the heart won't function better simply because it is smaller. Most patients have been in class IV heart failure and approximately one-third have been in-hospital on inotropic medications (usually heart transplant candidates). Twice I have encountered patients that I thought were "too sick", one is currently being aggressively medically managed, and the other was placed on a HeartMate LVAD as a "bridge-to-recovery", or for Batista procedure with LVAD removal.

The perioperative care is sometimes difficult even though 70 to 80% of the patients will improve. In total, six patients now have received HeartMate LVADs in the early perioperative period. Most of the time this is as a bridge-to-transplant, but in one patient the HeartMate was weaned and

successfully removed after three months of support. Typically the diuretic requirements are increased in the perioperative period. Sometimes inotropes are required, I have only placed a balloon pump in one patient.

In concept I do the operation the way Dr. Batista does. The details of how I do the operation though are quite different. I now routinely use cardioplegia (Buckberg solution, antegrade and retrograde). I think that the mitral valve repair is a very important component of the operation. I have replaced the valve only twice and in all others have done a posterior valvuloplasty with Alfieri repair (suturing the anterior and posterior leaflets together in the mid-portion of the mitral valve!). Sometimes I resect one or both papillary muscles to increase the extent of resection, and then re-implant the transected papillary muscle. Usually I start the operation through the left atrium and place the Cosgrove-Edwards posterior valvuloplasty ring, close the left atrium, and then proceed with resection. I always close the ventriculotomy with some type of reinforcement, because there are many anecdotal reports of exsanguinating hemorrhage within 24-hour of surgery. Usually I have used soft felt for this closure (three layers) but more recently I am using strips of bovine pericardium.

Some patients already have implantable defibrillators before the operation because so many patients with idiopathic dilated cardiomyopathy have ventricular arrhythmias. We have only had one sudden death episode related to ventricular arrhythmias, and all patients are maintained on amiodarone postoperatively. One patient required a new automatic implantable cardioverter defibrillator after surgery. In general, ventricular arrhythmias have not been as much a problem as we had been warned about.

In general, I think the Batista procedure is a much more effective operation than cardiomyoplasty, and much less expensive than permanent LVAD insertion. We still have much to learn about this operation however. Our longest follow-up is now only seven months, and Dr. Batista's is approximately two-and-a-half years. I have told several visitors from Japan, however, that I think that this is a very appropriate and exciting operation for your country. I would suggest cautious applications in patients who are not near-terminal, and who have well-documented idiopathic cardiomyopathy. If your program can begin successfully it will go a long way to continued success.

Best of luck and please feel free to contact me if you have any further questions.

Sincerely yours,

December 16, 1996

Patrick M. McCarthy, M.D.
Director, Cardiac Assist Device Program
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A New Operation to Treat End-Stage (Dilated) Cardiomyopathy

Tomas A. Salerno, M.D.*

Patients with end-stage dilated cardiomyopathy and severe congestive heart failure pose a great challenge in management. Mortality is in the range of 40% annually[1]. In countries where cardiac transplantation is available, these patients are offered transplantation when appropriate, *i.e.,* young patients, patients without multiorgan failure or pulmonary hypertension, and from social economical and education status that allow for careful follow-up. Alternatives include some form of mechanical assistance, including LVAD or cardiomyoplasty. The latter, is usually not indicated in patients with severe valvular diseases which usually accompany end-stage cardiac diseases due to annular dilatation. Batista recently introduced a new procedure to treat these patients[2]. The principle underlying the Batista operation is related to LaPlace's law, *i.e.,* in order to reduce wall tension, the diameter of the left ventricle must be reduced. This is accomplished by removal of a large wedge of left ventricular myocardium extending from the apex to include the papillary muscles and mitral valve apparatus. In some patients in whom the distance between the papillary muscles is large, mitral valve repair is possible.

The Batista operation is new and the longest follow-up period is approximately two years. The procedure was first introduced worldwide outside Brazil at the Buffalo General Hospital, and other hospitals in Texas, Cleveland, Boston,

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Tampa, Bristol (England) and Chieti (Italy) have already performed the procedure. The indications for Batista operation are evolving and it would appear that patients with very dilated cardiomyopathy of any etiology, with or without valvular diseases, are the best candidates. Ischemic patients with dilated cardiomyopathy have been similarly treated by Rinaldi *et al.*[3] in Puerto Rico, although long-term results are not available. At the Buffalo General Hospital, we have performed 21 such procedures. There were nine deaths [one sudden 10 months postoperatively; two at three months postoperatively; three from low volume resection of the ventricle (initial experience); and the remainder three were not candidates and were in extreme conditions (salvage operations)]. Of the 12 patients alive the following is their condition : preoperatively all were class IV. Postoperatively two are class I; six are class II; four are class III. One patient (class III) has been placed on the transplantation list as he is not happy with his life style.

Batista reported 410 patients[4] with an intraoperative mortality of 5%, hospital mortality of 15% and one year survival of 65%. The ejection fraction in these patients increased from 100 to 300%. Stolf *et al.*[5] reported actuarial survival of 62.3±11.3% at 12 months following the Batista operation in 21 patients with congestive heart failure and dilated cardiomyopathy. Bombanato *et al.*[6] reported no mortality in 10 patients undergoing the Batista operation with improvement in New York class in most patients.

In summary, the Batista operation is a new experimental procedure to treat patients with end-stage dilated cardiomyopathy of varying etiologies. It is very promising as a new operation for patient who due to religious, social economic, or legal reasons cannot receive cardiac transplantation. The procedure can be performed in the simplest of the centers, such as in Brazil, or in any other modern centers such as in Buffalo. As an experimental procedure, informed Institutional Review Board (IRB) approval and informed consent are needed. Long-term follow-up of these patients is not available and it remains to be seen whether or not this procedure will stand the rest of time. The case in Japan exemplifies the importance of this procedure for patients with dilated cardiomyopathy who otherwise would not be candidates for surgery.

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