Direct Mechanical Ventricular Actuation for Cardiac Arrest in Humans*
A Clinical Feasibility Trial

Direct mechanical ventricular actuation (DMVA) is a non-blood-contacting method of biventricular cardiac massage which may be applied expeditiously for total circulatory support. The purpose of this study was to assess the feasibility of DMVA application for patients suffering refractory cardiac arrest. Following informed consent, DMVA was applied to 22 patients. Vascular access for hemodynamic monitoring was possible in only 12 patients, whose outcomes serve as the basis for this report. The mean age of the patients was 48.2 ± 4.2 years (seven men; five women). The average time from witnessed cardiac arrest to DMVA application was 81 ± 9 minutes. Application took less than two minutes from the time of skin incision and resulted in immediate hemodynamic improvement. Systolic and diastolic blood pressures averaged 75 ± 4 and 41 ± 4 mm Hg, respectively, with a mean cardiac output of 3.14 ± 0.18 L/min during a mean of 228 ± 64 minutes of circulatory support (range, 25 minutes to 18 hours). In selected cases the device was temporarily removed for 2 to 3 minutes and open-chest cardiac massage (OCCM) performed at similar compression rates. DMVA increased arterial pressures 65 percent and cardiac output 190 percent compared to OCCM. Initial arterial pH (7.12 ± 0.04) improved by the time the device was removed (7.24 ± 0.05). Serum lactate levels decreased from 18.0 ± 2.3 μmol/L to 14.9 ± 2.9 μmol/L. Four patients were successfully defibrillated: two had inadequate cardiac function and died within 1 h, and two were successfully resuscitated, but later died from cardiac failure and respiratory insufficiency. Another patient regained normal neurologic function during DMVA and was successfully bridged to cardiopulmonary bypass for emergent coronary artery bypass grafting, but died later from myocardial infarction. There were only two complications: (1) a cardiac laceration during pericardiotomy (1/22 patients); and (2) a ventricular rupture during OCCM (1/22).

No complication resulted from the device. We found DMVA to be a feasible method for acute cardiovascular stabilization in victims suffering refractory cardiac arrest. Human clinical trials employing earlier DMVA application are required to determine its resuscitative potential.

(Chest 1991; 100:86-92)

ACLs = advanced cardiac life support; CCC = closed-chest compression; DMVA = direct mechanical ventricular actuation; OCCM = open-chest cardiac massage

Conventional CPR using CCCs, along with standard types of therapy, termed ACLS, has become accepted as the first line of treatment for cardiac arrest; however, many investigators emphasize that CCC and ACLS have limited resuscitative potential. These limitations are primarily related to low-flow states generated by CCC, which deteriorate as the duration of cardiac arrest progresses. Furthermore, cerebral blood flow is particularly low if CPR is not begun immediately following cardiac arrest. While CPR may result in successful resuscitation, even under optimal circumstances, survival has been discouragingly low. Therefore, interest has focused on using other interventions in selected cases of cardiac arrest when standard therapies are not effective. Circulatory assist devices are one such intervention. Various devices have been used for the purpose of resuscitation in patients suffering cardiac failure. The role of circulatory support devices for cardiac arrest is not yet clearly defined.

Direct mechanical ventricular actuation is a unique biventricular circulatory support device which has several advantages for patients requiring urgent cardiovascular stabilization. The device can be rapidly applied with relative technical simplicity and avoids blood contact. DMVA may be best understood as an improved method of internal cardiac massage. The device employs a contoured cup (Fig 1), which is pneumatically driven to actuate the ventricular myocardium. The drive system regulates the cup's actuation (cycle rate, systolic duration, actuating forces, and rate of force delivery) and supplies a continuous vacuum to maintain the cup's attachment. This vacuum creates a constant seal between the ventricular myo-
cardium and the actuating diaphragm of the cup. During actuation the ventricular myocardium is "pushed" into systolic and "pulled" into diastolic configurations, creating an action with remarkable effectiveness compared to other modalities using similar concepts.15-18

MATERIALS AND METHODS

Following the institutional review board's approval, DMVA was available at two institutions for patients suffering witnessed cardiac arrest. During a two-year period, all patients less than 60 years old who suffered witnessed cardiac arrest not responsive to 30 or more minutes of in-house ACLS were considered candidates for the device. The study protocol was explained to available family members by a member of the investigational team.

Only following informed consent from a family member was the device applied. An assistant cup of appropriate size was chosen and placed over the ventricles through a left anterior thoracotomy (Fig 2). Circulatory support was provided with the following drive settings: rate of 80/min to 100/min; systolic force of +110 to +130 mm Hg; diastolic force of -90 to -110 mm Hg; and a systolic duration of 50 percent. These drive parameters were tailored to maximize arterial pressures. The DMVA assistant cups were changed only when gross size discrepancies between the cup and heart were evident.

Hemodynamic Data

The placement of arterial, venous, and Swan-Ganz pulmonary catheters was attempted in patients eligible for DMVA application. Percutaneous and cutdown techniques were used during CPR and subsequent to DMVA application. Hemodynamic data were recorded every 15 minutes during the resuscitative protocol.

Resuscitative Protocol

Defibrillation was attempted at 15-minute to 30-minute intervals following DMVA application by temporary removal of the device. Pharmacologic agents were administered only in cases of severe hypotension or persistent unimproving acidosis. Those who did not revert to a perfusing rhythm were maintained on DMVA for variable periods of time. Duration of DMVA application in these circumstances was dependent on hemodynamic and clinical responses to the device. The DMVA was discontinued after 30 minutes if resuscitation was not successful or no signs of neurologic function were observed. Patients who were hemodynamically stabilized (maintenance of mean arterial pressure greater than or equal to 50 mm Hg) or who demonstrated signs of neurologic recovery were maintained on the device until their status deteriorated or family members requested removal of the device. Successfully resuscitated patients had their chests closed in the operating room. They were then transferred to the intensive care unit.

In selected patients (with absence of cardiac and neurologic function and in whom hemodynamics were stabilized with DMVA), the device was temporarily removed and OCCM performed using a two-hand technique. In these cases, DMVA cycle rates were decreased to rates achievable with OCCM (60/min and 80/min). The OCCM was then performed for brief durations at similar rates. DMVA and OCCM were alternated while hemodynamic data were recorded.

Serum Lactate Level and Arterial Blood Gas Analyses

Samples of arterial blood were collected prior to DMVA and at 15-minute intervals during DMVA application. Samples of serum were also collected for determination of lactate levels.

Data Analysis

Due to the emergent setting of this clinical trial, blood samples and hemodynamic measurements were not obtained in all patients. The relatively small studied group and the absence of a control group for comparison make statistical analysis of limited value. Instead, the data are presented as mean values (±SE), which are illustrated graphically. Results were interpreted by analyzing the apparent trends.

RESULTS

Twenty-two patients had application of DMVA following informed consent. The time from skin incision
Anstadt and Penland (1979) reported that the application of the device took two minutes or less. Due to technical difficulties, the placement of arterial and venous catheters for hemodynamic monitoring was possible in only 12 patients. Ten of these 12 patients presented to the emergency room in cardiac arrest. The other two patients suffered refractory cardiac arrest during admission to the hospital: (1) a 47-year-old white man who suffered arrest during elective cardiac catheterization; and (2) a 25-year-old white woman who suffered arrest during anesthesia for elective eye surgery. The mean age of the patients was 48.2 ± 4.2 years (range, 25 to 77 years), with a M:F ratio of 7:5. The average time from witnessed cardiac arrest until application of DMVA was 81 ± 9 minutes (range, 40 to 114 minutes). Circulatory support was provided by DMVA for 228 ± 84 minutes (range, 25 minutes to 18 hours).

Mean arterial pressures averaged 54 ± 4 mm Hg (n = 12) during circulatory support, with systolic and diastolic blood pressures averaging 78 ± 4 mm Hg and 41 ± 4 mm Hg, respectively (Fig 3). Pulmonary artery catheters were successfully placed in seven patients. Cardiac outputs measured by thermodilution techniques averaged 3.14 ± 0.18 L/min (Fig 4). Pulmonary artery diastolic and wedge pressures were obtained in six patients, averaging 15 ± 3 and 18 ± 1 mm Hg, respectively. Central venous pressures were recorded in five patients, averaging 15 ± 4 mm Hg. A series of hemodynamic recordings taken from a representative patient are illustrated in Figure 5.

Arterial blood gas levels were obtained in 14 patients. Initial arterial pH values averaged 7.12 ± 0.04. Subsequent arterial pH values demonstrated a relative increase during circulatory support, averaging 7.24 ± 0.05 prior to removal of the device. Serum lactate levels were obtained in five patients. Initial mean serum lactate levels (18.0 ± 2.3 mmol/L) decreased when compared to samples obtained prior to removal of the device (14.9 ± 2.9 mmol/L).

![Figure 2. Application of DMVA is made via left anterior thoracotomy. Assistor cup self-attaches when positioned over apex of heart (top). Appropriate fit is obtained when base of assistor cup lies near atrioventricular groove without incorporating atria (bottom). (From Anstadt MP, et al. Resuscitation 1991; 21:7-23)](image)

![Figure 3. Mean systolic (upper line) and diastolic (lower line) arterial pressures generated by DMVA during circulatory support (mean ± SE). Patients received CPR for a mean time of 81 ± 9 minutes (range, 40 to 114 minutes) prior to DMVA.](image)
**DMVA vs OCCM**

Hemodynamic data recorded during OCCM were compared to those during DMVA at similar rates of compression. Average cardiac outputs generated by DMVA (3.62 ± 0.77 L/min) were 190 percent greater than those generated by OCCM (1.25 ± 0.42 L/min) (Fig 6). DMVA also increased systolic (59 percent) and diastolic (68 percent) blood pressures when compared to OCCM (72 ± 10 vs 45 ± 7 mm Hg and 34 ± 9 vs 20 ± 7 mm Hg, respectively) (Fig 7).

**Outcome of Resuscitation**

All 22 patients had serial attempts at defibrillation following varying periods of circulatory support. Of the 20 patients presenting to the emergency department, four were successfully defibrillated to a perfusing rhythm (20 percent). Two of these patients died within 1 h: (1) one patient developed an arterial pressure of 31/19 mm Hg with a cardiac output of 0.4...
L/min; and (2) another patient developed an arterial pressure of 60/20 mm Hg with average cardiac outputs of 1.36 L/min. The other two patients were successfully resuscitated: (1) one patient had initial arterial pressures of 92/54 mm Hg with a cardiac output of 3.03 L/min; and (2) another patient’s initial arterial pressure was 140/100 mm Hg with cardiac outputs of 2.5 to 3 L/min. Both of these patients were taken to the operating room for thoracotomy closure and then transferred to the intensive care unit. One patient survived for 14 hours, after which he died of cardiac failure. The second patient survived for 24 hours and then died from respiratory failure secondary to aspiration.

The first in-house patient to receive DMVA suffered cardiac arrest during induction of anesthesia, which did not respond to over 90 minutes of ACLS. DMVA resulted in immediate hemodynamic stabilization and provided circulatory support for over 18 hours of VF; however, cardiac and neurologic function did not return, and the device was removed. Another patient suffered arrest in the cardiac catheterization laboratory and was unresponsive to over 40 minutes of ACLS efforts, with fixed and dilated pupils. This patient regained normal neurologic function within minutes of DMVA application. He was then successfully transferred to the operating room and placed on CPB. A three-vessel coronary artery bypass grafting procedure was performed. Since the patient was unable to be weaned from CPB, DMVA was reapplied for 30 minutes. DMVA had no adverse effects on the saphenous vein grafts, which remained intact and appeared to function well during DMVA application; however, due to a massive myocardial infarction, cardiac function could not be restored, and the patient was allowed to die.

Complications

Two complications occurred in this study (2/22 or 9 percent). One patient received an inadvertent epicardial laceration during pericardiotomy. Another patient’s ventricle tore during OCCM prior to DMVA application. Neither complication was related to the device itself.

Discussion

DMVA was initially described in the mid-1960s. Subsequent laboratory and clinical investigations over the following six years demonstrated a number of potential applications. More recent studies have found DMVA to be superior to CCC and OCCM. DMVA has also been shown to improve salvage of the ischemically injured myocardium. Human application has been encouraging, but is limited to case reports and is thereby anecdotal.

The investigators of this study believed that the advantages of DMVA (technical simplicity, ease of application, and no blood contact) warranted further human investigation. Therefore, the feasibility of using DMVA for emergent cardiovascular stabilization in patients suffering refractory cardiac arrest was evaluated. Only patients with witnessed cardiac arrest were eligible, so the duration of cardiac arrest and resuscitative efforts prior to DMVA could be documented. Such restrictions were expected to allow a reasonable chance of successful resuscitation by eliminating long “downtimes.” Unfortunately, the acquisition of informed consent led to an excessively long period of CCC before DMVA application (averaging nearly 1½ hours). The discouraging outcome in these cases is likely related to the prolonged period of CCC prior to DMVA; however, a number of important observations were made.

DMVA was found to be technically simple to apply and provided reliable circulatory support. Either surgeons or emergency medicine physicians could easily and expediently apply the device. Once the decision to apply DMVA was made, circulatory support was
possible in less than 2 min. Even with such rapid application, only two complications occurred. These low complication rates appear acceptable under the urgent setting of this study.

The findings of reliable, expedient application and an associated low complication rate support the feasibility of using DMVA for refractory cardiac arrest. Resuscitation and survival outcome following interventions such as DMVA are yet to be determined. It is difficult to assess the hemodynamic results of this study, since the earliest application of DMVA followed 40 minutes of CCC (range, 40 to 114 minutes). One might expect little potential for hemodynamic stabilization when circulatory support is instituted after such prolonged periods of profound hypotension. Interestingly, the average cardiac outputs generated by DMVA appear adequate for resuscitation; however, resulting arterial pressures are more difficult to interpret. Persistence of relative hypotensive states was either secondary to appropriate vasodilatation during reperfusion of ischemic tissues or to the inability of a damaged vascular system to regain vascular tone. The observed changes in serum lactate levels and arterial pH suggested a general improvement in tissue perfusion during circulatory support.

Other observations made in this study are easily interpreted. It seems clear that even when DMVA is slowed to less efficient rates, the device generates improved hemodynamics compared to OCCM. Any comparison between DMVA and OCCM should also point out the following relative limitations of OCCM: the risk of myocardial trauma (one of the complications reported in this study); the provider's experience; and the provider's fatigue. DMVA overcomes these limitations and, therefore, seems to be a favorable alternative.

Open-chest cardiac massage has been suggested by many investigators to improve the likelihood of resuscitation during cardiac arrest.\(^1\) Clinical studies using OCCM for resuscitation have been discouraging,\(^20\) however, such results may be related to the limitations of OCCM previously discussed. The improved hemodynamics generated by DMVA may lead to better resuscitation rates if the device is applied early enough. While the out-of-hospital arrests successfully resuscitated following DMVA in this study seemed low (2/20 or 10 percent), they were encouraging when compared to those reported (13 percent) in which similar resuscitative criteria were used.\(^2\) It is emphasized that “successful resuscitation” in the present study occurred following much longer durations of CCM, making such an outcome far less likely.\(^3-4\)

DMVA has other important advantages when considering the field of circulatory support. DMVA can be maintained for prolonged periods, whereas operation fatigue limits OCCM. Furthermore, DMVA has been used for up to three days of total circulatory support with long-term survival in animals.\(^30\) This advantage makes the device a potential bridge to other forms of circulatory support that otherwise cannot be expediently applied (i.e., left ventricular assist devices). These technically entailed methods of circulatory support have demonstrated their resuscitative potential in treating cardiogenic shock\(^7,21\) but require CPB as a necessary step prior to their institution; however, vascular access required to institute CPB can be difficult. It is interesting that the relatively small catheters used for hemodynamic monitoring in the present study could be placed in only 10 of the 20 patients (50 percent). This may represent a limitation for urgent institution of CPB during cardiac arrest, as the cannulation techniques can be time-intensive or even impossible. In this study, one patient was smoothly bridged to CPB. Therefore, DMVA may serve as an interim method of circulatory support that may allow bridging to CPB and related assist devices when appropriate.

Cardiopulmonary bypass is currently advocated for treating patients in refractory cardiac arrest.\(^32\) A number of studies have recently assessed CPB for this purpose.\(^9,11\) It is difficult to compare such studies with this report, as nearly all of the published series used CPB following relatively brief in-house cardiac arrests; however, the fact that CPB has been successful for such therapy indicates that DMVA might be more efficacious when used following similar arrest periods. DMVA avoids technical problems inherent in CPB (difficult cannulations, the need for a perfusionist, and time-consuming pump-priming procedures) and can be rapidly applied without blood contact. Recent studies have documented that the fibrillating heart better tolerates DMVA, compared to CPB,\(^33\) while both methods generate similar end-organ perfusion.\(^34\) Ongoing studies are comparing survival and neurologic outcome between DMVA and CPB when used for resuscitation from cardiac arrest.

In conclusion, we found DMVA to be a feasible method for emergency cardiovascular stabilization during cardiac arrest. The device can be rapidly applied with few associated complications. Results indicate that DMVA can greatly improve hemodynamics, compared to OCCM, even when DMVA cycle rates are decreased to those rates achievable by OCCM. While resuscitation rates in this study were low, outcome was probably in part related to the prolonged periods of closed-chest massage. However, the results were encouraging when compared to overall resuscitation rates reported following witnessed cardiac arrest. Furthermore, DMVA may allow bridging to more technically difficult circulatory support interventions and has the advantage of rapid application without any blood contact.
Human clinical trials employing earlier institution of DMVA will determine its resuscitative potential. The delay imposed by obtaining consent in the present study can be overcome by using "deferred" consent protocols. Thereby, any benefit which DMVA offers will have a reasonable chance of improving a patient's outcome.

REFERENCES
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