Artificial Organs
28(3):278–286, Blackwell Publishing, Inc.

Under-Utilization of Mechanical Circulatory Support in Canada: Why and What Can Be Done?

*Tofy Mussivand, †Michel Carrier, ‡Ray C.J. Chiu, *Ross A. Davies, §Diego H. Delgado, ¶Mario C. Deng, *Haissam Haddad, *Paul J. Hendry, *Wilbert J. Keon, **Arvind Koshal, *Roy G. Masters, *Thierry Mesana, and §Vivek Rao

**University of Ottawa Heart Institute, Ottawa; †Montreal Heart Institute; ‡McGill University Health Center, Montreal; §Toronto General Hospital, Toronto, Canada; ¶New York Presbyterian Hospital, New York, USA; and **University of Alberta Hospital, Edmonton, Canada*

Abstract: In October of 2002, a workshop was held as part of the Canadian Cardiovascular Congress in Edmonton, Canada, entitled "Under-Utilization of Mechanical Circulatory Support in Canada. Why and What Can Be Done?" The workshop examined various issues related to the use of mechanical circulatory support devices in the Canadian context. Representatives from all Canadian centers with active mechanical circulatory support programs were invited to participate and participants included surgeons and cardiologists, as well as other affiliated health professionals. Opinions were solicited from the workshop participants and a series of recommendations were formulated. **Key Words:** Heart-assist device—Extracorporeal circulation—Congestive heart failure—Transplantation—Registries—Health economics.

Mechanical circulatory support has evolved as a vital tool in the clinical armamentarium for the treatment of advanced heart failure. While cardiac transplantation is clearly the gold standard in the treatment for end-stage heart failure, the number of heart failure patients far outweighs the supply of donor organs. This shortfall in donor availability led to an increased use of mechanical circulatory support as an interim measure for patients who deteriorated hemodynamically while awaiting transplantation. Initial clinical results have led to broadening the potential indications for mechanical circulatory support to include the following three major categories (1):

1. *Acute support*: Typically with support less than a month, in patients with a potential likelihood for recovery. These patients would be those with cardiac failure postcardiotomy, shock postmyocardial infarction, and acute cardiomyopathies such as myocarditis.
2. *Prolonged support*: Typically with support from one month to one year, in patients who are suitable for transplantation, but who deteriorate while awaiting transplant.
3. *Permanent support*: Typically as an alternative to transplant for patients who do not meet current transplantation criteria. This application is also called destination therapy.

While utilization of mechanical circulatory support has rapidly expanded over the last decade in the US and Europe, similar adoption patterns have not been seen in Canada. To begin to understand the reasons behind this difference, this workshop was convened. Representatives from all Canadian centers with circulatory support programs were invited to participate. The workshop utilized audience participation via electronic polling to solicit the participant's views on mechanical circulatory support.

Received November 2003.
Address correspondence and reprint requests to Dr. Tofy Mussivand, FRSC, Chair, Medical Devices Centre, University of Ottawa Heart Institute, 40 Ruskin Street, Room H560, Ottawa, Ontario, Canada K1Y4W7. E-mail: tmussivand@ottawaheart.ca
From a Workshop held October 29, 2002, at the 2002 Canadian Cardiovascular Congress, Edmonton, Alberta, Canada. The recommendations set forth in this report are those of the workshop participants and do not necessarily reflect the official position of the sponsoring organizations.

Dr. Wilbert J. Keon (University of Ottawa Heart Institute, Ottawa, Canada) opened the workshop by reminding the participants of the importance of mechanical circulatory support (MCS) in the treatment of end-stage heart failure. While Canada has experienced a somewhat lower rate of heart transplantation as compared to the United States (5.5 vs. 8.0 transplants per year per 1 million population, respectively), the rate of mechanical circulatory support device use in Canada is significantly lower than that of our colleagues both in the US and Europe (2,3). Examining the data for a single device (Novacor LVAS, World Heart Corp., Ottawa, Canada) between 1998 and 2001 found rates of utilization per population were 3.8 times higher in the US and an astounding 6.3 times higher in Germany, when compared to Canada. This under-utilization is a very serious problem, driven in part by the lack of funding programs for these devices, with many programs paid for from research funds and other private sources. In addition, improvements in heart failure medical therapy, delays in the introduction of second-generation of devices, and lack of clinical research with these devices in Canada, have also negatively impacted the adoption of the technology in Canada. This situation is beginning to change through educational efforts; however, strong clinical leadership is required that is willing to takes chances in this field, rather than maintain a strictly conservative approach. Mechanical circulatory support (MCS) devices give great promise to end-stage heart failure patients and accordingly it is important for Canadian centers to establish strong clinical research programs to ensure that this emerging technology is available to their patients both today and in the future.

ELECTRONIC POLLING

Dr. Diego Delgado (Toronto General Hospital, Toronto, Canada) led the participants through a series of 10 questions designed to assess their current opinions of mechanical circulatory support. Workshop participants responded to each of questions using electronic keypads. The questions were asked at the beginning of the workshop (baseline) and repeated at the end of the workshop (after didactic segments) to assess changing views. The questions and results of polling are contained in Appendix A.

Following the baseline polling, faculty presentations were presented on the following topics: (1) Mechanical Circulatory Support—International Perspective, (2) Mechanical Circulatory Support—Canadian Utilization/Database, and (3) Mechanical Circulatory Support—Establishing Funding and New Programs. Then the questions were repeated to assess changing views.

Summary results from the polling showed:

1. Little variation from baseline, which is not surprising given that the majority of the participants (~80%) were from centers with existing circulatory support programs, and thus have well-established opinions.
2. There were however, two notable changes in opinion after the workshop: (a) an increase in the number of participants that felt circulatory support should be available at all cardiac transplant centers (changed from 52% to 69%), and (b) an increase in the number of centers willing to contribute to a national data registry (changed from 81% to 96%).
3. In addition, at the workshop close, 96% of the participants supported a national initiative to establish a comprehensive report aimed at supporting funding applications for provincial health ministries.
4. The commitments of the participants to undertake national initiatives such as database participation and a comprehensive report for funding, reflects an important "meeting of the minds" and will play a central role in the workshop recommendations.

INTERNATIONAL PERSPECTIVE

Dr. Mario Deng (New York Presbyterian Hospital, New York, NY, U.S.A.), who serves as the Medical Director for the International Society for Heart and Lung Transplantation (ISHLT) Mechanical Circulatory Support Devices (MCSD) Database (4), provided the participants an overview of the international database efforts and the driving principles behind this approach. To increase societal support for clinical utilization of circulatory support, a reasonable level of data on the efficacy and safety of the technology is required. Increasingly, the principles of evidence-based medicine are being applied. By examining mechanical circulatory support with the Oxford Center for Evidence-based Medicine—Levels of Evidence criteria (http://www.cebm.net/levels_of_evidence.asp), we find only a single randomized controlled trial, and several observational cohort studies. This level of evidence of the benefits of circulatory support may not be sufficient to convince cardiologists who are typically trained in an area that conducts multiple large-scale randomized trials. Furthermore, without this type of information, widespread adoption of this technology maybe severely hindered. The ongoing international effort to develop a MCSD database is designed in part to

increase the availability of high quality data in the field to specifically address this issue.

Over 15 years ago, Pae and Pierce proposed the creation of voluntary registry for the clinical use of mechanical ventricular assist pumps and total artificial hearts (5). This database operated for over 10 years releasing six major reports in the *Journal of Heart and Lung Transplantation*, but was discontinued due to a lack of sustained funding. Many in the field supported reinstatement of the database; however, for a variety of reasons it was not until the early 2000s that sufficient interest by all of the major players was achieved. One major turning point was the American College of Cardiology Consensus report developed at the 2000 Mechanical Cardiac Support Conference, wherein Stevenson et al. recommended the "establishment and maintenance of a mandatory registry that includes all implantable devices, both before and after approval" (1). This eventually led to the development of the current MCSD database initiative that is being overseen by the International Society of Heart & Lung Transplantation.

The value of a strong database effort can be seen in the example of the Novacor LVAS European Registry that was active for all consecutive implants of the device after market introduction. This database subsequently gave clinicians important insight into important risk factors for survival with a mechanical circulatory system (6). This type of information is an invaluable input to allow advancement of the field and to modify and optimize patient management. This registry also provided a blueprint for the current MCSD database development.

The purpose of the ISHLT MCSD Database is: (1) to characterize overall practice worldwide, (2) assess MCSD safety & efficacy (using uniform event and risk factor definitions), and (3) generate data for government-funded studies. As of January 1, 2002, the database is up and running, utilizing a web based system. Centers worldwide collect data, and input the data into a central system at the UNOS/Transplantation Informatics Institute (UNOS/TII) in Richmond, VA, U.S.A., which was awarded the contract to operate the database.

Currently the system accepts Tier 1 data, including patient demographics, as well as data on implant admission, implantation (device type, etc.), postimplant recovery, postimplant discharge, explant, transplant, and death. Additional plans call for monitoring postimplant events through Tier 2 data (patient-related events) and Tier 3 (device-related events). Tier 2 and Tier 3 data details are currently being finalized.

Within the framework of the ISHLT MCSD database it was envisioned that specific groups could initiate different projects within the overall structure of the database. For instance, one of the first projects considered was utilizing the international database as the home for a Canadian database, with Canadian centers entering data into the database and the system allowing access to the combined Canadian subsets of data on a periodic basis (quarterly, annually, etc.). In addition, the observational databases on recovery after circulatory support which currently run independently in both the US and Europe, could also utilize this system. There are also a number of additional projects underway or in discussions including conversion of the existing Novacor LVAS European Registry (58 centers), and a pilot project tracking what type of alternative therapies are being considered at time of referral of advanced heart failure patients to a designated transplantation and MCSD center.

The ISHLT MCSD database has many diverse partners who have provided important input to the development of the system. For example both regulatory agencies and industry are looking to the system for potential postmarket surveillance of devices, in addition third party payers also have a keen interest in the type of information that can be derived from this type of database. There is also increasing interest from both the US Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) in establishing standards for centers for "destination therapy" to address potential quality issues. A white paper was developed (7) on behalf of the Board of Directors of the ISHLT for this purpose. The paper proposed certain center criteria for destination therapy, which would include: (a) existing program for advanced heart failure, (b) low-ejection fraction cardiac surgery program, (c) bridge to transplant program or a transplant-associated hospital, (d) mandatory MCSD database participation, (e) advanced heart failure research and teaching infrastructure, and (f) quality assurance program.

Further information on the ISHLT MCSD Database is available at http://www.ishlt.org/registries/mcsdDatabase.asp. In addition, a demonstration of the database entry system is available at http://www.demo.ishlt.org/mcsd (Login: UNOS, Password: UNOS). Most recently the first annual report from the ISHLT database has been released (8).

CANADIAN UTILIZATION/DATABASE

Dr. Paul Hendry (University of Ottawa Heart Institute, Ottawa, Canada) reviewed the general

indications and implant criteria for use of mechanical circulatory support (ventricular assist devices and total artificial hearts) in Canada. The implant criteria typically include: end-stage congestive heart failure patients with NYHA Class IV symptoms on inotropic support with or without intra-aortic balloon pump, with compromised hemodynamics: cardiac index (CI) < 2/L/min/m^2 and pulmonary capillary wedge pressure (PCWP) > 20 mm Hg. Patients can be triaged into three major groups: (1) patients who are eligible for heart transplantation (i.e., dilated cardiomyopathy [DCM] and acute myocardial infarction [AMI] in cardiogenic shock), (2) patients who can potentially be weaned from circulatory support (i.e., early DCM, acute myocarditis, and postcardiotomy), and (3) destination therapy for those patients who are either not transplant candidates, or for whom there is a reduced likelihood of receiving a donor organ due to factors such as body size, blood group, or the chronic shortage of available donors.

The first use of advanced mechanical circulatory support began in 1986 at the University of Ottawa Heart Institute, and there are now six active centers in Canada with advanced circulatory support programs (Ottawa, Montreal (2), Sainte-Foy, Toronto, Vancouver), along with a number of other centers currently establishing new programs. Based on information received from various ventricular assist devices (VAD) manufacturers (WorldHeart, Thoratec), VAD use in Canada to date is summarized in Table 1, including device type, indication of use, support duration, and clinical outcomes. The majority of implants have been for bridge to transplant use, however, three patients received the Novacor LVAS as destination therapy a part of the ongoing INTrEPID Trial (Investigation of Non-Transplant-Eligible Patient who are Inotrope Dependent).

From an international perspective, Stevenson and Kormos reviewed worldwide data for over 3000 MCS patients and found 60–70% of supported patients were transplanted with 85–90% survival at discharge, and approximately 5% of the patients were able to weaned from the device (1). Furthermore, recently approximately 50% of patients with implantable devices have been able to be discharged while on device support, vastly improving the recipient's quality of life. These clinical benefits are however, not without a substantial cost. In 2000, McGregor estimated the direct cost to the health care system of ventricular assist device installation at $138 000 (CDN) and calculated the cost effectiveness at $91 000 to $126 000 (CDN) per life-year saved when utilized as a bridge to transplantation (9). Dr. Hendry, however, noted that these levels are relatively comparable to other interventions such as the use of implantable cardiac defibrillators ($44 000–$140 000 [US] per life/year saved) or brain surgery ($169 000 [US] per life/year saved). It was also noted that Moskowitz et al. reported the first year cost of mechanical circulatory support devices was roughly comparable to the first year cost of cardiac transplantation ($192 154 vs. $176 605 [US]) (10).

In terms of improving accessibility of this technology for all Canadians, there are a number of issues that need to be addressed: (1) lack of communication between the various centers, including between centers with and without heart failure clinics, since many heart failure patients are cared for by general practitioners and internists, (2) lack of familiarity in

TABLE 1. *Indication of use, support duration, and clinical outcomes of mechanical circulatory support in Canada as of October 2002**

	Thoratec	HeartMate	Novacor
Patients implanted	55	5	16
Median age (years)	47.5 (12–63)	46 (29–58)	49 (16–71)
Median duration (days)	15	129	113
Longest duration (days)	175	234	305
Total VAD support (days)	1119	756	1711
Bridge to transplant	48	5	13
Bridge to recovery	2	—	—
Destination therapy	—	—	3
Other (postcardiotomy, AMI)	5	—	—
Patients ongoing	4	3	2
Transplanted*	30/51 (59%)	1/2	10/14 (71%)
Weaned/explanted*	2/51 (4%)	1/2	—
Unknown outcome*	6/51 (12%)	—	—

*Based on the number of patients with an established outcome, i.e., total number of patients minus those ongoing.

Source company reports: Thoratec VAD and HeartMate VAD—Thoratec Corporation (Pleasanton, CA, U.S.A.), Novacor LVAS—World Heart Corporation (Ottawa, Canada).

clinical circles of the technology, its accessibility, and its capabilities, (3) lack of stable funding, especially from health funding agencies, and (4) lack of a clear understanding of the potential risks and benefits. Moreover, available devices have various shortcomings that need to be clearly understood by those utilizing the technology as well as the potential recipients. For instance the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) results showed relatively poor device reliability results for the HeartMate device (11), although the manufacturer has indicated some of these issues are being addressed with various design changes. In the case of the Thoratec VAD, which has been an effective a paracorporeal device, clinical research is underway to assess an implantable version (IVAD) with a titanium shell, and this approach may result in a reasonable and cost effective option. In the case of the Novacor LVAS, the early patient experience demonstrated a high rate of thromboembolic events, however, with the introduction of a new expanded polytetrafluoroethylene (ePTFE) inflow conduit (12), the rate has been significantly reduced to around 7% or lower. All of these improvements to devices, as well as the next generation devices being developed, will make the technology better suited to more wide scale application. Potential solutions to help increase VAD accessibility in Canada include improving data collection on both an institutional and national basis. This data collection and analysis using institutional databases, the ISHLT database and the McGill registry in Quebec, will help to provide important information on clinical outcomes and cost effectiveness to build a strong case for increased and stable funding in Canada. In addition, we need to increase our educational efforts such as this workshop to educate our colleagues on the efficacy of this modality, as well as streamline communications between centers in order to facilitate patient assessment.

In regard to the database issue, currently there are a number of different approaches including institutional, multicenter, and international databases. These databases are being utilized to address different issues, for example the multisite McGill database is looking at outcomes and cost effectiveness, whereas on a National level the ISHLT database would allow a Canadian subset of data within the existing international structure. While each approach has both limitations and advantages, increasingly we are looking towards linked databases to allow for greater accessibility. Regardless of the politics and issues related to the different approaches, each will undoubtedly add to the availability of information, which can prove useful in improving our practices and supporting funding applications.

ESTABLISHING FUNDING AND NEW PROGRAMS

Dr. Vivek Rao (Toronto General Hospital, Toronto, Canada) provided an overview of the recently established circulatory support program at the Toronto General Hospital. The program was established in 2001 in part to address a 19% mortality on the transplantation waiting list, as well as an increased number of listings (21%) without a similar increase in donors (just 6%). Therefore, it became important to risk stratify the patients on the waiting list to: (1) identify those with greatest need, (2) identify those who will derive the greatest benefit, and (3) provide maximum support including mechanical circulatory support. The program would also play an important role in the ability to perform high-risk surgeries, using mechanical circulatory support as an emergency backup.

From July 2001 to July 2002, 33 patients were referred to the program, with 40% of referrals from outside of the Toronto General Hospital. Of the 33 referrals, 21 patients (64%) were considered acceptable for the mechanical support program. The clinical outcomes for all referred patients are listed in Table 2. Of the 21 patients accepted for mechanical assistance, 2 improved with bi-ventricular pacing and were discharged home, 3 high-risk cardiac surgeries were performed with Abiomed VAD as back-up, and 3 heart transplants were done with Abiomed back-up. The program selected the Abiomed BVS-5000 as a short-term device for two main reasons: (1) right-sided ventricular support capabilities, and (2) low-cost alternative for emergency assessment of potential patients.

Three patients who were deemed acceptable for mechanical circulatory support required the paracor-

TABLE 2. *Clinical outcomes of patients (n = 21) accepted at the Toronto General Hospital Left Ventricular Assist Device Program and outcomes of those patients (n = 12) not accepted into the program*

Outcome	Accepted (n = 21)	Not accepted (n = 12)*
Home	7 (33%)	6 (50%)
Transplant	6 (28%)	1 (8%)
VAD	6 (28%)	0
Death	2 (10%)	5 (42%)

*1 patient lost for follow-up.

poreal Thoratec VAD due to body size limitations. Unfortunately, this device was not available at our institution. Two of these patients died awaiting transplant while the third was successfully transplanted. However, for longer-term support, the implantable HeartMate LVAS, which allows patients to be discharged home, was selected for use. To date, 5 HeartMate implantations were conducted with a mean support duration of 114 days. Of these 5 patients, 2 were transplanted, 1 patient was explanted and is awaiting transplant, 1 patient was discharged home and one is currently in hospital. Mean hospital stay for these patients was 3.4 days in ICU and 56 days total length of hospital stay.

Selecting the most appropriate patients is always important, but even more so when establishing a new VAD program. To facilitate the selection of the patients, Rao et al. (13) previously developed a LVAD screening score to quantify risk (Table 3). In comparing the early results in this program using this scoring system, 86% of all patients screened who had a LVAD score of greater than 6 died, whereas there were no deaths in the accepted patients who had a score of less 6 (Table 4). The ideal first patients have chronic decompensated heart failure, had a prior "elective" transplant evaluation performed, are hemodynamically stable in CCU, and have good psychosocial support. Most importantly you need to establish those patients that meet those criteria and also have a high risk for mortality on the waiting list, namely due the factors including blood type O, large body weight, pulmonary hypertension which is reversible, or renal insufficiency.

Funding is of course a critical issue, and to establish a program there are really three sources of funding: (1) private benefactor(s), (2) global hospital budget, (3) provincial Ministry of Health. In terms of this program, the funding for the disposable costs are being supported by a private benefactor, the hospital is picking up the ICU care, the nursing care and the ward care, and a submission has been made for support from the Ministry of Health. Establishing a program can be an expensive undertaking including the costs of training the substantial team required, reusable hardware, disposable hardware, and the ongoing patient care costs. These types of programs also require a dedicated team including members from surgery, cardiology, anesthesia, perfusion and allied health personnel (nursing, physiotherapy, etc.), and perhaps most importantly a strong LVAD coordinator to oversee the various activities.

TABLE 3. *LVAD screening score developed to risk stratify patients for mechanical circulatory support*

Variable	Score
Ventilated	4
Postcardiotomy	2
LVAD in situ	2
Central venous pressure > 16 mm Hg	1
Prothrombin time > 16 s	1

TABLE 4. *LVAD screening score results for both those accepted and not accepted into the Left Ventricular Assist Device Program*

	LVAD score < 6	LVAD score > 6
Accepted (n = 21)	n = 17	n = 4
Home	7 (33%)	0
Transplant	6 (28%)	0
VAD	4 (19%)	2 (9%)
Death	0	2 (9%)
Rejected (n = 12)	n = 9	n = 3
Home	5 (42%)	1 (8%)
Transplant	1 (8%)—later died	0
VAD	0	0
Death	3 (25%)	2 (16%)

As this program moves forward a major goal is to decrease the overall hospital length of stay, during the early experience there was natural reluctance to send the first few patients home, but as the program evolves it is expected that most of patients could go home at about 3 weeks postimplant. In addition, to ensure the viability of the program, long-term funding both from the Ministry and other sources will be required to be located. Finally, the program is interested in adding an additional device for long-term use (destination therapy), such as the Novacor LVAS, which is well suited for this type of extended support.

Dr. Arvind Koshal (University of Alberta Hospital, Edmonton, Canada) provided comments on mechanical circulatory support in relation to transplant programs. Dr. Koshal was previously involved in circulatory support utilization at the University of Ottawa Heart Institute with both the Jarvik Total Artificial Heart and the Thoratec VAD. Therefore when he moved to the University of Alberta Hospital, he requested a VAD program be established. While the group has acquired a VAD (HeartMate LVAS), it has not yet been utilized clinically. Since the human donor heart is still the best device available, their program has instead focused on activities to increase the number of transplants performed, and have thus expended more resources in this area, including going to the US for organs. Currently they are performing approximately 40 heart transplants per year with a population base of 3 million, which is

substantially higher than some other centers with much larger population bases. Dr. Koshal also raised questions in regard to the current status of circulatory support technology as a bridge to transplantation including device size, cost, and rate of complications (bleeding, infection, etc.).

In regard to funding these programs, it is important to combine the transplant and circulatory support programs under a single funding umbrella with emphasis on both aspects of the program. For a new center starting out the best approach may be to obtain private funding to purchase the initial systems, and to publicize the success of the technology for individual patients, which should help in future efforts to establish public funding for this technology. Dr. Koshal also indicated that he does not believe that funding will be a major limiting factor going forward, and believes that devices will play an important role as the technology evolves, especially for destination therapy.

DISCUSSION

Dr. Ray Chu-Jeng Chiu (McGill University Health Center, Montreal, Canada) and **Dr. Michel Carrier** (Montreal Heart Institute, Montreal, Canada) chaired a discussion and summary of the workshop. It was concluded that due to the size of the country the most logical approach was to contribute to International Registries, such as the ISHLT database, since this would ensure common criteria and data collection, thus allowing appropriate clinical comparisons on a national level. It was noted that educational efforts will also be important in two areas: (1) public education which will be vital to support both public and private funding efforts, and (2) education of physicians outside of the transplant centers to the benefits of the technology, to ensure all of the patients that could potentially benefit are given access to the life-saving technology. There was also significant discussion regarding the transplant status system on a national basis, and the potential for inequality between centers with and without mechanical circulatory support programs.

While the current Canadian healthcare environment is especially difficult for funding new technology, it was generally concluded that this is an important and essential life-saving technology for transplant centers. It was further suggested that increased efforts to work together are needed to explain the impact of this technology, in the Canadian context to health care administrators, and government funding agencies. Finally, it was agreed that the workshop provided a basis for establishing a Canadian forum for mechanical circulatory support not only in terms of improving the funding situation, but also to enhance communications between involved centers, establish national consensus on key issues, to discuss best practices and techniques, as well as to provide a vital resource for new centers interested in the technology and for clinical education efforts.

CONSENSUS RECOMMENDATIONS

The following recommendations were developed based on the polling results, and the discussions held during the question and answer session.

#1: A workshop on mechanical circulatory support in Canada should be held on an annual basis to increase communication between the centers utilizing mechanical circulatory support or for those interested in either establishing programs or referring patients.

#2: Future workshops should be expanded to include the affiliated health care professionals (Nursing, Perfusion, Clinical Engineering, Rehabilitation, etc.) who play a vital role in the delivery of a quality mechanical circulatory support program.

#3: All centers in Canada utilizing mechanical circulatory support should be encouraged to participate fully in the International Society for Heart and Lung Transplantation Mechanical Circulatory Support Devices (MCSD) Database. This will allow comparison of Canadian results on the International stage and contribute to furthering clinical knowledge of mechanical circulatory support thus leading to improved patient selection and better understanding of the risks and benefits of the modality.

#4: A comprehensive position paper on the use mechanical circulatory in Canada should be developed cooperatively by involved Canadian centers and supporting professional societies. The paper would outline the international supporting evidence, current status in Canada, funding issues, and provide recommendations on a national level. This could provide important material for educational purposes, as well as supporting documentation for individual provincial funding applications.

Sponsoring organizations and acknowledgments: The workshop was conducted with financial and other support from the following organizations: the Canadian Cardiovascular Society, the Medical Devices Center at the University of Ottawa Heart Institute, and World Heart Corporation.

The authors would like to acknowledge the staff of the Cardiovascular Devices Division, University of

Ottawa Heart Institute, for their efforts in both organizing the Workshop and in compiling the Consensus Report.

REFERENCES

1. Stevenson LW, Kormos RL, Barr ML, et al. Mechanical cardiac support 2000: Current applications and future trial design. *Circulation* 2001;103:337–42.
2. Canadian Institute for Health Information. 2002 Canadian Organ Replacement Registry Preliminary Report: Preliminary Statistics on Organ Donation, Transplantation and Waiting List (2000 data). March 1, 2002. Ottawa, Ontario.
3. HHS/HRSA/OSP/DOT and UNOS. 2000 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network: Transplant Data 1989–98. February 16, 2002. Rockville, MD, and Richmond, VA.
4. Deng MC. The Mechanical Circulatory Support Device Database of the International Society for Heart and Lung Transplantation. *Curr Opin Cardiol* 2003;18:147–52.
5. Pae WE, Pierce WS. Combined registry for the clinical use of mechanical ventricular assist pumps and the total artificial heart. *J Heart Transplant* 1986;5:6–7.
6. Deng MC, Loebe M, El-Banayosy A, et al. Mechanical circulatory support for advanced heart failure: Effect of patient selection on outcome. *Circulation* 2001;103:231–7.
7. Deng MC, Young JB, Stevenson LW, et al. Destination mechanical circulatory support: proposal for clinical standards. *J Heart Lung Transplant* 2003;22:365–9.
8. Deng MC, Edwards LB, Hertz MI, Rowe AW, Kormos RL. Mechanical Circulatory Support Database of the International Society for Heart and Lung Transplantation: First annual report—2003. *J Heart Lung Transplant* 2003;22:653–62.
9. McGregor M. Implantable ventricular assist devices: Is it time to introduce them in Canada? *Can J Cardiol* 2000;16:629–40.
10. Moskowitz AJ, Rose EA, Gelijns AC. The cost of long-term LVAD implantation. *Ann Thorac Surg* 2001;71:S195–8.
11. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med* 2001;345:1435–43.
12. Mussivand T, Portner PM. Improved clinical results with the Novacor LVAS through ongoing refinements of the inflow conduit. *Int J Artif Organs* 2002;25:682 (Abstract).
13. Rao V, Oz MC, Flannery MA, et al. Revised screening scale to predict survival after insertion of a left ventricular assist device. *J Thorac Cardiovasc Surg* 2003;125:855–62.

APPENDIX A

Questions and Results (percent of respondents at baseline and after didactic segments, the number of respondents was between 23 and 31 for each question) from the Electronic Polling of Participants

General Questions

1. Would you consider Mechanical Circulatory Support:
   a. Clinically Proven Modality (96%/84%)
   b. Experimental Procedure (0%/16%)
   c. Other (4%/0%)
2. What do you consider to be the major barrier to adoption of Mechanical Circulatory Support in Canada:
   a. Devices Too Expensive/No Established Funding (75%/81%)
   b. Unproven Technology (7%/8%)
   c. Other (18%/11%)

Mechanical Circulatory Support—International Perspective

3. Mechanical Circulatory Support Utilization Rates in Canada:
   a. Are Comparable to USA/Europe (4%/0%)
   b. Are Lower than USA/Europe (33%/36%)
   c. Are Much Lower than USA/Europe (63%/64%)
4. Based on the Global Experience Circulatory Support should be:
   a. Available at all Cardiac Surgery Centers (22%/8%)
   b. Available at all Cardiac Transplant Centers (52%/69%)
   c. Available at only Selected Centers (26%/23%)

Mechanical Circulatory Support—Canadian Utilization/Registry

5. Would your Center be Willing to Contribute to a National Registry:
   a. Yes (81%/96%)
   b. No(4%/0%)
   b. Not Sure (15%/4%)
6. What is the Major Concern in Participating in a National Registry:
   a. Added Cost/Effort (77%/72%)
   b. Release of Center Results (19%/24%)
   c. Need for Additional Patient Consent (4%/4%)

Mechanical Circulatory Support—Establishing Funding

7. Would you Support a National Initiative to Establish a Comprehensive Report aimed at Supporting Funding Applications for Provincial Health Ministries:
   a. Yes (88%/96%)
   b. No (0%/0%)
   c. Not Sure (12%/4%)
8. What do You Believe to be the Most Important Factor to Achieve Provincial Funding for Circulatory Support:
   a. Cost-Effectiveness Data (50%/64%)
   b. Increased Clinical Adoption (29%/20%)
   c. National Lobby of Experts (21%/16%)

Mechanical Circulatory Support – Establishing a New Program

9. Status at your Center:

a. Currently has a Mechanical Circulatory Support Program (77%/83%)
b. Actively Considering Establishing A Program (10%/4%)
c. Not Sure (13%/13%)

10. What is the Most Important Requirement to Establishing a New Program:
    a. Previous Clinical Experience (19%/8%)
    b. Key Individual for Leadership (45%/54%)
    c. Team Work (36%/38%)