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Society Position Statement

Canadian Cardiovascular Society Focused Position Statement Update on Assessment of the Cardiac Patient for Fitness to Drive: Fitness Following Left Ventricular Assist Device Implantation

Roger Baskett, MD,[a] Richard Crowell, MD,[a] Darren Freed, MD,[b] Nadia Giannetti, MD,[c] and Christopher S. Simpson, MD[d]

[a] *Dalhousie University, Halifax, Nova Scotia, Canada*

[b] *University of Manitoba, Winnipeg, Manitoba, Canada*

[c] *McGill University, Montreal, Québec, Canada*

[d] *Queen's University, Kingston, Ontario, Canada*

ABSTRACT

There have been significant advances in mechanical circulatory support during the past several years. Older pulsatile models of left ventricular assist devices (LVADs) (also known as VADs) have shown improved outcomes compared with medical therapy but have had limited durability and significant morbidity associated with their use. For this reason, Canadian Cardiovascular Society 2003 guidelines recommended permanent cessation of driving in these patients (for both private and commercial vehicle operation). However, recent advances with newer, continuous-flow devices have resulted in much lower rates of device-related complications and greater use of these devices for destination therapy. The majority of patients now are discharged home and lead active lives subsequently. Based on new evidence applied to the Society's "Risk of Harm" formula, it has been determined that patients with continuous-flow devices who are doing well 2 months post implantation are fit to hold noncommercial class drivers' licenses.

RÉSUMÉ

Au cours des dernières années, il y a eu des progrès importants dans le soutien circulatoire mécanique. Les plus vieux modèles pulsatiles de dispositifs d'assistance ventriculaire gauche (DAVG) (aussi connus sous le nom de DAV) ont démontré une amélioration des résultats thérapeutiques comparativement au traitement médical, mais ont eu une durabilité limitée et une morbidité importante associées à leur utilisation. Pour cette raison, les lignes directrices 2003 de la Société canadienne de cardiologie recommandaient de cesser de manière permanente la conduite chez ces patients (conduite d'un véhicule personnel ou commercial). Cependant, de récents développements sur les nouveaux dispositifs à débit continu ont entraîné des taux beaucoup plus faibles de complications liées aux dispositifs et une plus grande utilisation de ces dispositifs pour une implantation permanente (*destination therapy*). La majorité des patients reçoivent maintenant leur congé de l'hôpital et mènent des vies actives par la suite. Selon de nouvelles preuves obtenues par la formule d'analyse du risque de préjudice de la Société canadienne de cardiologie, il a été établi que les patients ayant des dispositifs à débit continu qui se portent bien 2 mois après l'implantation sont aptes à détenir des permis de conduire de classe non commerciale.

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Corresponding author: Dr Christopher S. Simpson, Professor and Head, Division of Cardiology, Queen's University, Program Medical Director, Cardiac Program, Kingston General Hospital, FAPC Level 3, 76 Stuart St., Kingston, Ontario K7L2V7, Canada.

E-mail: simpsonc@kgh.kari.net

The disclosure information of the authors and reviewers is available from the CCS on the following websites: www.ccs.ca and www.ccsguidelineprograms.ca.

This statement was developed following a thorough consideration of medical literature and the best available evidence and clinical experience. It represents the consensus of a Canadian panel comprised of multidisciplinary experts on this topic with a mandate to formulate disease-specific recommendations. These recommendations are aimed to provide a reasonable and practical approach to care for specialists and allied health professionals obliged with the duty of bestowing optimal care to patients and families, and can be subject to change as scientific knowledge and technology advance and as practice patterns evolve. The statement is not intended to be a substitute for physicians using their individual judgement in managing clinical care in consultation with the patient, with appropriate regard to all the individual circumstances of the patient, diagnostic and treatment options available and available resources. Adherence to these recommendations will not necessarily produce successful outcomes in every case.

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There have been significant advances in mechanical circulatory support during the past several years. Older pulsatile models of left ventricular assist devices (LVADs) (also known as VADs) have shown improved outcomes compared with medical therapy but have had limited durability and significant morbidity associated with their use.[1,2] Recent advances with newer, continuous-flow devices have resulted in much lower rates of device-related complications.[3,4] The majority of patients now are discharged home and lead active lives subsequently.[3,5] In fact, at 6 months post implant, more than 80% of patients have achieved New York Heart Association (NYHA) I or II functional class status, and this status appears to be maintained to at least 2 years.[3-5] The use of LVADs has increased dramatically, largely because of the increased safety and efficacy profile of the continuous-flow devices.[6,7] Furthermore, the Heartmate II is now approved for destination therapy in addition to the bridge-to-transplantation indication.[7] As a result of these advances, an increasing number of LVAD-supported patients are in the community, working and otherwise leading normal lives.

Previous recommendations for driving while on LVAD support were based on earlier experiences with older devices and a population of patients who were often not discharged from hospital. Recommendations and regulations regarding driving while on LVAD support are either completely prohibitive or, where more recent data are considered, inconsistent and unclear.[8-10]

The Canadian Cardiovascular Society "Risk of Harm" Formula and the 2003 Recommendation for LVAD Patients

The 2003 Canadian Cardiovascular Society (CCS) Guidelines[10] were built around calculations of risk that used the CCS Risk of Harm Formula (Appendix I; reproduced from Simpson et al.[10]). In general, it is accepted that if the risk of sudden cardiac incapacitation (SCI) is $< 22\%$ per year for a driver operating a private motor vehicle, this poses no higher risk to public safety than does a commercial driver who has a 1% annual risk of SCI. These values were set as the acceptable standard for patients with cardiovascular disease.

Both the 2003 CCS guidelines and the 2006 Canadian Medical Association guidelines[9] recommended a permanent disqualification for both private and commercial drivers who were supported with LVAD therapy. This recommendation was based on the findings from the **R**andomized **E**valuation of **M**echanical **A**ssistance for the **T**reatment of **C**ongestive **H**eart Failure (REMATCH) trial and United Network for Organ Sharing data that demonstrated that New York Heart Association IV patients on intermittent inotropes, or those on LVAD support, should not drive. In REMATCH, patients with LVADs had a 1-year mortality of 52%, and the United Network for Organ Sharing reported in 2002 that patients with LVADs or those who were receiving intermittent or home inotropes had a *weekly* mortality of 0.5% to 2%.[1,10]

Current Survival Data With LVADs

Current LVAD therapy in Canada and the United States is largely accomplished with the continuous-flow device, predominantly the Heartmate II. In the third annual report from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), overall survival for 2506 LVADs implanted from June 2006 through September 2010 was 79% at 1 year. For the 1936 continuous-flow devices implanted during that period, the survival was 83% at 1 year and 75% at 2 years.[7] Since the approval by the FDA of Heartmate II for destination therapy (in addition to the bridge-to-transplantation indication), 98% of LVADs implanted have been continuous-flow devices.[7] Survival reported in the bridge-to-transplantation trial using the Heartmate II ($n = 281$) was 79% at 18 months.[4] INTERMACS reports that survival for destination LVAD patients with the continuous-flow pumps is 74% at 1 year.[7] Overall, contemporary data for mortality in patients with continuous-flow LVADs, whether for destination therapy or as a bridge to transplantation, are remarkably consistent and reveal a considerably improved prognosis compared with that shown by the data available in 2003.

Potential for Sudden Incapacitation in LVAD-Supported Patients

Patients on long-term mechanical circulatory support with an LVAD, many of whom have an implantable cardioverter-defibrillator, do experience ventricular arrhythmias but, because of the nature of the LVAD function, are at much lower risk for sudden death, SCI, or syncope. Even with ventricular fibrillation, the LVAD is able to maintain adequate cardiac output.[11-13]

The INTERMACS registry reported, for the period 2006 through March 2009 (of which only 52% of implants were continuous-flow devices), a mortality rate of 12% (122 of 1023) beyond the first month, with, at most, a 5% incidence of deaths that may have been potentially sudden (cardiac failure, 21 of 1023; central nervous system event, 19 of 1023; and device failure, 9 of 1023).[6] In reality, the majority of these events are highly unlikely to result in sudden incapacitation in a patient with an LVAD. Cardiac failure and device failure are generally slow and progressive and not sudden in nature. Similarly, in examining the destination LVAD patients only ($n = 385$), INTERMACS reports an 18% mortality beyond 1 month. It appears that, at most, 30 of these deaths could have been sudden;, this is an 8% mortality (conditional on 1 month survival) at a mean follow-up of 6 months.[7] Again, the majority of these events are highly unlikely to have been sudden and incapacitating in nature. The hazard for death drops dramatically after 1 month of support and is fairly constant thereafter at between 0.02 and 0.03 deaths per month of follow-up.[6,7] The vast majority of these deaths are not sudden in nature.

Adverse events that could potentially result in sudden incapacitation per 100 patient-months were 2 for device malfunction, 7.7 for arrhythmia, and 2.9 for neurologic dysfunction, or 1.5 events per patient-year.[6] However, the most frequent of these, cardiac arrhythmia, rarely results in incapacitation in an LVAD patient.[11,12] Device failures are almost exclusively external drive line failures that do not result in sudden failure of the LVAD. Even abrupt loss of power to the pump does not result in sudden incapacitation, but rather heart failure. These data include the first 2 months of the year, during which time patients should be excluded from driving, so the numbers would be even lower for those beyond the 2-month mark. Based on these data, at most between 0.35 and 1.5 events that

may result in sudden incapacitation could occur per patient-year.

Based on the published trials and the INTERMACS registry data, the 1-year mortality rate for LVAD patients is approximately 20%. Deaths beyond the first month account for only one-half to two-thirds of the deaths. Of the deaths occurring during follow-up, one-third to one-half could potentially be sudden in nature. Therefore, at most, the rate of sudden incapacitation per year is likely 8% to 12%.[4,6,7] This is likely an overestimate of the real risk in these patients.

Thus, LVAD patients would appear, even in worst-case scenario calculations, to have a $< 22\%$ annual risk of SCI, making them eligible for private driving. However, they still have a rate of SCI that is above 1%, which falls short of the standard required for commercial driving. We would recommend that patients who are stable on LVAD support, discharged from hospital, and at least 2 months post implant be allowed to drive a private motor vehicle.

RECOMMENDATION

Patients with a continuous flow, NYHA class I-III, LVAD that are stable 2 months post LVAD implantation qualify for private driving only and are disqualified from commercial driving (Strong Recommendation, High-Quality Evidence). (Where more than one set of circumstances or conditions coexist, the more restrictive recommendation prevails unless stated otherwise. Please refer to the 2003 Assessment of the Cardiac Patient for Fitness to Drive and Fly at http://www.ccs.ca/guidelines/cc_library_e.aspx for a complete text of the original recommendations.)

References

1. Rose EA, Gelijns AC, Moskowitz AJ, et al. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med 2001;345:1435-43.
2. Lietz K, Long JW, Kfoury AG, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. Circulation 2007;116:497-505.
3. Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009; 361:2241-51.
4. Pagani FD, Miller LW, Russell SD, et al. Extended mechanical circulatory support with a continuous-flow rotary left ventricular assist device. J Am Coll Cardiol 2009;54:312-21.
5. Rogers JG, Aaronson KD, Boyle AJ, et al. Continuous flow left ventricular assist device improves functional capacity and quality of life of advanced heart failure patients. J Am Coll Cardiol 2010;55:1826-34.
6. Kirklin JK, Naftel DC, Stevenson LW, et al. Second INTERMACS annual report: more than 1,000 primary left ventricular assist device implants. J Heart Lung Transplant 2010;29:1-10.
7. Kirklin JK, Naftel DC, Kormos R, et al. Third INTERMACS annual report: the evolution of destination therapy in the United States. J Heart Lung Transplant 2011;30:115-23.
8. Emani S, O'Keefe CM, Wissman S, et al. Driver's education: a single center experience on the incidence and safety of driving with LVADS [abstract]. J Heart Lung Transplant 2011;30(suppl):S70.
9. Canadian Medical Association. CMA driver's guide: determining medical fitness to operate motor vehicles. 7th ed. 2006. Available at: www.cma.ca/index.cfm/ci_id/18223/la_id/1.htm. Accessed November 25, 2011.
10. Simpson C, Dorian P, Gupta A, et al. Assessment of the cardiac patient for fitness to drive: drive subgroup executive summary. Canadian Cardiovascular Society Consensus Conference. Can J Cardiol 2004;20:1314-20.
11. Slaughter MS, Pagani FD, Rogers JG, et al. Clinical management of continuous flow left ventricular assist devices in advanced heart failure. J Heart Lung Transplant 2010;29(suppl 4):S1-39.
12. Oswald H, Shultz-Wildelau C, Gardiwal A, et al. Implantable defibrillator therapy for ventricular tachyarrhythmia in left ventricular assist device patients. Eur J Heart Fail 2010;12:593-9.
13. McKelvie RS, Moe GW, Cheung A, et al. The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines update: Focus on sleep apnea, renal dysfunction, mechanical circulatory support, and palliative care. Can J Cardiol 2011;27:319-38.

Appendix I.*

Risk of harm formula derivation

The risk of harm (RH) to other road users posed by the driver with heart disease is assumed to be directly proportional to the following:

- Time spent behind the wheel or distance driven in a given time (TD);
- Type of vehicle driven (V);
- Risk of sudden cardiac incapacitation (SCI); and
- The probability that such an event will result in a fatal or injury-producing accident (Ac).

Expressing this statement as formula 1:

$$(1) \qquad RH = TD \cdot V \cdot SCI \cdot Ac$$

Fewer than 2% of reported incidents of driver sudden death or loss of consciousness have resulted in injury or death to other road users or bystanders.[1-4] In formula 1, therefore, $Ac = 0.02$ for all drivers. There is evidence that loss of control of a heavy truck or passenger-carrying vehicle results in a more devastating accident than loss of control of a private automobile.[5] Truckers are involved in only approximately 2% of all road accidents but in approximately 7.2% of all fatal accidents.[3] In formula 1, if $V = 1$ for a commercial driver, then $V = 0.28$ for a private driver.

There is no published standard or definition of what level of risk is considered to be acceptable in Canada even though this information is crucial in the formulation of guidelines based on the probability of some event occurring in a defined period. It was necessary, therefore, to develop such a standard.

For several years, the guidelines of the Canadian Cardiovascular Society, the Canadian Medical Association, and the Ca-

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nadian Council of Motor Transport Administrators have permitted the driver of a heavy truck to return to that occupation after an acute myocardial infarction provided that he or she is New York Heart Association class I with a negative exercise stress test at 7 metabolic equivalents, has no disqualifying ventricular arrhythmias, and is at least 3 months post infarct. On the basis of available data, however, such a person cannot be assigned a risk lower than 1% of cardiac death in the next year. The risk of sudden death would be lower than this but would be at least partially offset by the risk of other suddenly disabling events such as syncope or stroke. For such a person, risk of SCI is estimated to be equal to 0.01 in formula 1.

It may be assumed that the average commercial driver spends 25% of his or her time behind the wheel.[3] Thus, in formula 1, TD = 0.25. As indicated above, V may be assigned a value of 1 for commercial drivers and Ac = 0.02 for all drivers. Substituting into formula 1:

$$RH = TD \cdot V \cdot SCI \cdot Ac$$

$$= 0.25 \cdot 1 \cdot 0.01 \cdot 0.02$$

$$= 0.00005$$

Allowing such a driver on the road is associated with an annual risk of death or injury to others of approximately 1 in 20,000 (0.00005). This level of risk appears to be generally acceptable in Canada.

A similar standard may be applied to the driver of a private automobile. The average private driver spends approximately 4% of his or her time behind the wheel (TD = 0.04).[6] As indicated above, for such a driver, V = 0.28 and Ac = 0.02. The acceptable yearly risk of sudden death or cardiac incapacitation for such a person would be calculated as follows:

$$RH = TD \cdot V \cdot SCI \cdot Ac$$

$$0.00005 = 0.04 \cdot 0.28 \cdot SCI \cdot 0.02$$

$$SCI = 0.223$$

Thus, the private automobile driver with a 22% risk of sustaining an SCI in the next year poses no greater threat to public safety than the heavy truck driver with a 1% risk. Finally, for the commercial driver who drives a light vehicle, such as a taxicab or delivery truck, V = 0.28 and TD = 0.25, placing that driver at a risk between that of the private driver and that of the tractor-trailer driver.

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References

1. Ostrom M, Eriksson A. Natural death while driving. J Forensic Sci 1987; 32:988-98.
2. Hossack DW. Death at the wheel. A consideration of cardiovascular disease as a contributory factor to road accidents. Med J Aust 1974;1:164-6.
3. Parsons M. Fits and other causes of loss of consciousness while driving. Q J Med 1986;58:295-303.
4. Antecol DH, Roberts WC. Sudden death behind the wheel from natural disease in drivers of four wheeled motor vehicles. Am J Cardiol 1990;66: 1329-35.
5. Ontario Ministry of Transportation. 1987 Ontario Road Safety Annual Report. Toronto, Canada: Ontario Ministry of Transportation, 1987.
6. Fuel Consumption Survey Annual Report: October 1981 to September 1982 and October 1982 to September 1983 [Catalogue 53-226]. Ottawa, Canada: Statistics Canada, 1987.