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Technology Assessment Unit of the McGill University Health Centre

The Impella® Percutaneous Ventricular Assist Device

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Report prepared for the Technology Assessment Unit (TAU)

of the McGill University Health Centre (MUHC)

By

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Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it has influenced policy decisions in any way.

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GLOSSARY OF TERMS

BiVADs	**Bilateral Ventricular Assist Devices**
CABG	**Coronary Artery Bypass Graft**
CADTH	**Canadian Agency for Drugs and Technologies in Health**
CI	**Confidence Interval**
CRD	**Centre for Reviews and Dissemination**
ECMO	**Extracorporeal Membrane Oxygenation**
FA	**Femoral Artery**
IABP	**Intra-Aortic Balloon Pump**
ICU	**Intensive Care Unit**
INAHTA	**International Network of Agencies for Health Technology Assessment**
LV	**Left Ventricle**
LVAD	**Left Ventricular Assist Device**
MUHC	**McGill University Health Centre**
NICE	**National Institute for Health and Clinical Excellence**
OR	**Operating Room**
PCI	**Percutaneous Coronary Intervention**
RCT	**Randomized Controlled Trials**
RV	**Right Ventricle**
RVAD	**Right Ventricular Assist Device**
STEMI	**ST-Segment Elevation Myocardial Infarction**
VAD	**Ventricular Assist Device**

EXECUTIVE SUMMARY

Background

In early 2008 the Department of Cardiovascular Surgery received authority to use the Impella® percutaneous ventricular assist device for the temporary support of up to 10 cases of actual or threatened left ventricular failure after which there should be a complete evaluation of the use of this device based on the available literature and on this experience. On February 3, 2009 the TAU was requested by Mr Gary Stoopler to undertake such an evaluation.

Systematic Review

Reported experience of this device is still limited. Of 45 publications, 21 are small case series, and 24 are single case reports. In general the device is being used in two ways.

Prophylactic use. Impella® has been used *"prophylactically"* to provide vascular support during elective procedures such as PCI in dangerously compromised patients for a total of 143 cases. All of these patients were successfully weaned from the device and the estimated survival rate was 0.951(95% CI, 0.89-1.00).

Rescue use. Impella® has been used as a *"rescue" intervention* in 131 cases of otherwise uncorrectable acute vascular collapse . Of these the rate of successful weaning from the pump was 0.82 (95%CI: 0.70- 0.94), and the survival rate 0.71 (95%CI: 0.52-0.89) .Significant complications were rare. Haemolysis, when reported, was mild.

MUHC experience

Clinical outcome. The records of the 8 cases in which Impella® has been used were reviewed with the surgeon concerned. The outcomes were compared to the most likely outcome of the management that would have been used in the absence of Impella. In summary, Impella® use compared to alternate treatment resulted in; one life saved, substantial reduction of risk in 3, and no influence on outcome in 4. There were no significant adverse events.

Costs. The two Impella® models used at the MUHC, Impella® 2.5 and Impella® 5.0 cost $7,500 and $ 15,000 respectively. It was estimated that compared to the cost of the most likely alternative management, Impella® use in these 8 cases resulted in a net cost saving of approximately $216,000.

Conclusions

- The Impella® device is clearly more clinically effective than IABP or ECMO. It is also less traumatic and less expensive than other available ventricular assist devices.
- In the context of an institution in which the decision has already been made to provide mechanical support of acute vascular collapse, the use of Impella® can be cost saving.

- However, case selection is critical. Used too early, when patients could have survived without its use , Impella® use is unproductive and expensive. Used too late, when pump failure, end-organ failure or brain death are irreversible its use is wasteful.
- Review of current use of this technology at the MUHC indicates that utilisation is restrained and appropriate.

Recommendations

- This technology should be supported by the MUHC**.** However it is an expensive technology and its use should be monitored.
- Should the annual use of Impella® exceed the currently estimated 10 units per year, the appropriateness of selection of cases, should be reviewed.

RÉSUMÉ

Introduction

Au début de l'année 2008, le Département de Chirurgie cardiovasculaire a reçu l'autorité pour utiliser Impella® ® d'assistance ventriculaire percutanée pour le soutien temporaire d'un maximum de 10 cas de menace réelle ou défaillance ventriculaire gauche après quoi il devrait y avoir une évaluation complète de l'utilisation de cet appareil basé sur la littérature disponible et sur cette expérience. Le 3 Février 2009, le TAU a été demandé par M. Gary Stoopler à entreprendre telle évaluation.

Revus systématiques

Expérience rapporté de cet appareil est encore limitée. De 45 publications, 21 sont de petites séries de cas, et 24 sont des rapports de cas. En général, les appareils sont utilisés de deux façons.

L'utilisation prophylactique :Impella® a été utilisé «prophylactiquement» pour fournir un soutien vasculaire électif au cours de procédures telles que PCI chez les patients gravement compromis, pour un total de 143 cas. Tous ces patients ont été sevrés de l'appareil et avec un taux de survie de 0.951(95%IC 0.89-1.0).

L'utilisation sauvetage: Il a été utilisé comme une intervention «sauvetage», dans 188 cas autrement incorrigibles de collapse vasculaire aiguë. Parmi eux, 78% des patients ont été sevrés avec succès avec un taux de survie de 0.71 (95%IC 0.52-0.89. Des complications étaient rares et l'hémolyse, lorsque mentionné, était doux.

L'expérience à MUHC

Les dossiers des 8 cas dans lesquels Impella® a été utilisé ont été examinés avec le chirurgien concerné. Les résultats ont été comparés à l'issue la plus probable de

la gestion qui aurait été utilisées en l'absence d'Impella. En résumé, l'utilisation d'Impella® par rapport à un autre traitement a abouti à l'une vie sauvée, une réduction importante des risques dans 3 cas, et aucune influence sur le résultat chez les 4 cas restants Il n'y avait pas d'effets indésirables significatifs.
Les deux modèles utilisés d'Impella® à MUHC, Impella® 2.5 et Impella® 5.0 coûte $ 7,500 et $ 15.000, respectivement. Par rapport au coût le plus probable de la gestion alternative, l'utilisation d'Impella® de ces 8 cas ont donné lieu à une nette réduction des coûts d'environ $ 216.000.

Conclusions

•Impella® est nettement plus efficace que IABP ou ECMO. Il est aussi moins traumatisant et moins coûteux que d'autres appareils d'assistance ventriculaire.

• Dans le contexte d'une institution dans laquelle la décision a déjà été fait pour fournir un soutien mécanique de l'effondrement vasculaire aiguë, l'utilisation d'Impella® peut être une économie de coût.

• Toutefois, la sélection des cas est critique. Utilisé trop tôt, lorsque les patients ont pu survivre sans son utilisation, Impella® est improductif et coûteux. Utilisé trop tard, lorsque l'insuffiance cardiaque,, la défaillance hépatique ou renale, ou la mort cérébrale est irréversible, son utilisation est gaspillé.

• Analyse de l'utilisation de cette technologie au MUHC indique que l'utilisation actuelle est restreinte et approprié.

Recommandations

Cette technologie devrait être soutenue par le MUHC. Toutefois, il est une technologie coûteuse et son utilisation doit être contrôlée. Si l'utilisation annuelle d'Impella® dépasse actuellement environ 10 unités par an, la pertinence de sélection des cas, devrait être revue.

The Impella® Percutaneous Ventricular Assist Device

Introduction

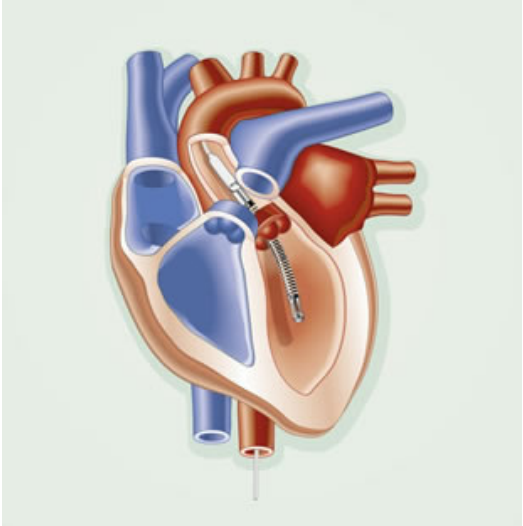
CONTEXT

In early 2008 the Department of Cardiovascular Surgery received authority to use the Impella® percutaneous ventricular assist device for the temporary support of up to 10 cases of actual or threatened left ventricular failure, after which there should be a complete evaluation of the use of this device based on the available literature and on this experience. On February 3, 2009 the TAU was requested by Mr. Gary Stoopler to undertake such an evaluation.

IMPELLA® TECHNOLOGY

The Impella® LP device is a small rotary pump attached to the end of a catheter which is passed retrograde through the aortic valve into the left ventricle from which it aspirates blood which it delivers immediately above the aortic valve (See Figure 1). There are two models:

- Impella® LP2.5 (pump diameter 12 F) is usually inserted via the femoral artery.(maximal flow 2.5 L/min).
- Impella® LP 5.0 (pump diameter 21 F) can be inserted in the operating room through the aortic root, or via the femoral artery when surgical incision is necessary. (maximum flow 5.0 L/m).



Source: www.Abiomed.com

Both devices are now licensed in Canada, and in the US. The Impella® LP 2.5 is principally used as a prophylactic measure in patients undergoing high-risk percutaneous coronary interventions (PCI). The Impella® LP 5.0 is principally used in the management of acute life-threatening left ventricular failure, either as a bridge to recovery, or as a bridge to an LVAD or to heart transplantation. Because the LP 5.0 was not available in the US until June 2009, the use of the LP 2.5 is often documented in such "rescue" situations in that country.

Alternative treatments

Several forms of mechanical support are available for the temporary management of acute left ventricular failure:

- The Intraaortic balloon pump (IABP) is the most widely used mechanical support for the failing left ventricle. However, for this device, which improves ventricular function by lowering ventricular filling pressure, some cardiac function is necessary, and it can only modestly improve hemodynamic parameters(1) When IABP is inadequate to maintain circulation one of the following forms of support becomes necessary.

- ECMO. Until the IMPELLA® became available the commonest approach to the management of severe cardiogenic shock was the Extracorporeal Membrane Oxygenator (ECMO). This instrument can temporarily replace the function of both heart and lungs but takes time to install (mobilization of a team, including surgeon and perfusionist, priming an ECMO circuit and cannulating the patient). Further, it cannot be used for more than a few hours. Until IMPELLA® became available ECMO was used approximately five times each year in the MUHC in this context [Dr P Beaudry, MUHC, personal communication].

Another alternative is to use Left Ventricular Assist Devices (LVADs), or biventricular assist devices (BIVADS) which provide partial or total support to the failing heart. Two of these are external pumps (Thoratec PVad, and Abiomed AB5,000), while a third device (the Heartmate 2) functionally replaces both ventricles and is implanted in the thorax.

By contrast with all of the above, the Impella® can be rapidly installed through a peripheral artery, and can be maintained in operation for several days. During this time the reversibility of shock and the potential for recovery of the nervous system can be evaluated, thus potentially avoiding the need to use more cumbersome, traumatic, and expensive cardiac assist devices.

METHODS

Meta-analysis. A systematic search of the medical literature, including the Cochrane library, Pubmed, Embase and health technology databases (INAHTA, CADTH, NICE, CRD, AETMIS) under the search term [Impella] was performed up to March 27, 2009. Additional searches were also conducted on the Internet with Google and Scirus. References of relevant articles were manually searched to identify additional publications. The manufacturer was also contacted for a list of relevant publications. Because of the small number of available publications, results in abstract form were also included. We extracted information on the device used, the clinical context of each use, the haemodynamic response, the complication rate the number with sufficient haemodynamic recovery to be successfully weaned from

Impella® and the number of survivals (thirty-day survival or survival to discharge from hospital as reported in different studies) For meta-analysis we used a random effects generalised linear mixed model (5)

Clinical Experience . The clinical records of the first 8 patients managed with the Impella® device at the MUHC over the past year were reviewed to determine the role that Impella® had played in their outcome, and the costs incurred.

RESULTS

Literature Review

A total of 45 publications on the use of Impella® were identified. The device has been used for two fairly distinct purposes. First, for the prophylactic support of circulation while performing high risk Percutaneous Coronary Interventions (PCI) in highly compromised hearts, invariably using the Impella® LP 2.5, and second for "rescue procedures" in the presence of irreversible cardiogenic shock due to several causes. Outside the USA the Impella® 5.0 has usually been used for this purpose.

Use of Impella® during high risk PCI.
There were 18 reports of prophylactic use of Impella® during high risk PCI (16 in Table 1 and two in Table 2), of which 11 were reports of small case series, and 9 were single case reports . In the reports summarized in Table 1 it can be seen that the Impella® was used in the management of 139 patients during high risk PCI. All were successfully weaned from the device and all but three survived.(Survival rate, 0.951. 95% CI, 0.89-1.00) "Survival" in the following report means either thirty-day survival or survival to discharge from hospital.

What the outcome would have been in these cases in the absence of Impella® use is obviously unknown, but for this instrument to be used there was probably a fairly high probability of vascular collapse and death. Regardless of the therapeutic benefit that may have occurred it is clear from these reports that the device caused no significant morbidity, and was relatively simple to use with out any prolonged learning curve (many of these reports were of first usage). Complications will be discussed below.

Use of Impella® as a "rescue" device.
A total of 23 reports (22 in Table 2 and one in Table 1) describe other uses of Impella®, mostly as a rescue procedure, and mostly in cases of irreversible cardiogenic shock. There are only two small randomised studies in which cases in ischaemic cardiogenic shock were randomly assigned to IABP or Impella® 2.5(2;3). In both these studies the authors report a better haemodynamic response with Impella® than with IABP, and in both slightly more Impella® patients were weaned and survived (see Table 2). However, it should be noted that the smaller pump with an output limited to 2.5 l/min would not be used for this purpose at the MUHC.

In another RCT, not a rescue procedure, the use of Impella® was compared to medical support without any pump during coronary revascularisation of the beating heart(4). The outcome of interest was that in the absence of Impella® use 8/23 (35%) patients required conventional pump support while this was required in only 1/15 (7%) patients when Impella® was used.

There were 11 small case series (One in Table 1, and 10 in Table 2) and 12 individual case reports, all of which described rescue procedures carried out in acute failure situations in which all medical approaches had failed and in many of which IABP was also used (See Table 2) . Of the 131 patients treated with Impella® reported in Table 2, the estimated rate of successful weaning from the pump was 0.82 (95%CI: 0.70- 0.94), and the survival rate 0.71 (95%CI: 0.52-0.89)

What the survival rate would have been without the use of Impella® in these cases can only be surmised, but reported survival rates for in-hospital shock resulting from ischaemic left ventricular failure are usually lower [eg 32%(6), 56%(7)]. Impella® support was frequently maintained for up to a week, and in one report was maintained for 18 days. No upper limit has yet been identified.

Complications

Access was almost always via the femoral artery but twice when this was not possible the axillary (8)and subclavian (9) approaches were used. Considering that most of these reports describe early experience with the Impella® the frequency of complications may be considered low. In one early report of 33 cases there were "access related complications" in five, and pump malfunctions in three. In one case the device was dislocated and pressure of the shaft on the mitral valve caused "mitral stenosis" which was rapidly relieved when the instrument was withdrawn (10). However, such incidents appear to be rare. Surprisingly there are no reports of aortic regurgitation which was looked for using ultrasound by several authors.

In one early report haemolysis was encountered fairly frequently until the pump was modified. Thereafter, there was no haemolysis in which free haemoglobin levels exceeded 80 mg /dl (11). Haemolysis was documented in several other reports (11-15), but was never severe. In one study it was reported to occur only within the first 24 hours (14).

In summary, this review of the literature suggests that use of this device is a relatively simple procedure that can be rapidly carried out, with a complication rate even with inexperienced operators that is relatively low. When used for prophylactic support of patients undergoing high risk PCI, successful weaning and survival can be anticipated. When used as a rescue procedure for acute irreversible left ventricular failure most patients (82%) can be weaned and either successfully bridged to other forms of support or to survival (71%). These outcomes are, of course, very dependent on the selection of cases

MUHC Experience

Of the eight cases in which Impella® was used at the MUHC during the past year, two were prophylactic (support of severely compromised circulations during performance of a PCI and a cholecystectomy, respectively) and 6 were used in a rescue situation. These cases are summarised below and in Table 3.

Case notes.

Below, we summarise each case and compare the outcome and cost of Impella® use to an estimate of what the outcome and cost would have been in the absence of Impella® use.

Case 1(16) Cardiac transplant for ischaemic cardiomyopathy six years previously. Now undergoing acute rejection.
Management. Circulation supported for seven days with Impella® during intensive anti-rejection medication. Successful. Full recovery.
Cost. of Impella® 5.0 = $15,000
Alternate Management. Without Impella® the only alternate would have been ECMO. Use of conventional VADs would have been excessively risky due to previous surgery and immunosuppression. Survival probability with ECMO was estimated at 25%.
Cost. of alternate Management. ECMO disposable items= $800. Perfusionist full-time for 72hr X $49.92/hr = $3,594 . Total = $4,394
Net Cost of Impella® management. $15,000 -$ 4,394 = $10,606
Summary. Impella® use probably saved one life at an ***increased cost of $10,006***.

Case 2
Acute viral myocarditis presenting in shock.
Management. Impella® management for 172 hours with full haemodynamic recovery. Brain death.
Cost of Impella® 5.0 =……. $15,000
Alternate Management. In the absence of Impella® this patient would have been treated with a conventional paracorporeal (Bi)VAD for the same period of time (until it became evident that there would be no brain recovery). The outcome, haemodynamic recovery with brain death, would probably have been identical, (However, mortality and morbidity of (Bi)VAD insertion would have been greater).
Cost of alternate Management. Pump disposables= $104,000. OR, 6 hours X$824/hr = $4,944. ICU, 4 days X $1,217/day = $4,868. Blood 10 Units, Platelets 10 Units. 20 X $400 = $8,000.
Total =…$121,812.
Net Cost of Impella® Management. $121,812 – $15000 = $106,812 (savings)
Summary. Impella® use resulted in the same outcome with ***a saving of $99,512***.

Case 3 (17) Four year history of dilated cardiomyopathy with acute severe deterioration, heart failure, and multi-end organ failure.
Management . Supported five days on Impella® 5.0 awaiting a heart transplant. Heart not available so bridged to an Abiomed AB 5,000 LVAD. With survival and eventual discharge from hospital.
Cost of Impella® 5.0 = $15,000
Alternate Management. Initial BiVAD support would have been necessary. In the context of severe end organ failure this would have carried an increased risk of mortality of possibly 60%. Impella® use allowed recovery of the right ventricle and reversal of end organ failure, greatly improving the probability of survival with BiVAD
Cost of alternate Management. If, as was anticipated, a heart had been available, Impella® use could have avoided VAD use with major cost saving. In effect, the need for initial BiVAD management was avoided with a saving of $52,000.
Net cost of Impella® management. $52,000 - $15,000 = $- 37,000 (saving).
Summary. Impella® increased probability of survival with a ***net saving of $37,000***

Case 4
End-stage ischaemic cardiomyopathy urgently requiring PCI.
Management. Prophylactic use of Impella® 2.5 during PCI. Uneventful recovery.
Cost of Impella® $7500.
Alternate Management. In absence of Impella® PCI would probably have been undertaken in spite of high risk. Possible vascular collapse would have demanded use of IABP with prolonged ICU stay.
Cost of alternate Management too hypothetical to merit estimation .
Summary. There was possibly a significant cost saving . In effect the risk of intervention was greatly reduced by Impella® use at an ***increased cost of $7,500***.

Case 5(18) End-stage ischaemic cardiomyopathy. While awaiting cardiac transplantation developed refractory biliary colic.
Management. Prophylactic use of Impella® 2.5 as a support during laparoscopic cholecystectomy. Uneventful recovery.
Cost of Impella® 2.5= $7500.
Alternate Management. To proceed with open cholecystectomy with IABP support, at greatly increased risk.
Cost of alternate Management. Cost of IABP disposables =$543. Two days in ICU X $1.217/day = $2,434. Total = 2,977.
Net cost of Impella® use. $7500 - $2,977 = $4,523.
Summary. In Reduction of risk. Avoidance of IABP. ***/increased cost of $4,523.***

Case 6
17-year-old male found on the sidewalk in cardiac arrest. Fulminating acute myocarditis with severe pump failure.
Management. Successful management of vascular collapse with reversal of end organ failure. Impella® explanted day 5.. No recovery of brain function. Death day 10. *Cost*. Impella® 5.0 = $15,000. ICU 5 days X $1217/day = $6085. Total = $21,085.
Alternate Management. BiVad would have been implanted and maintained until it was established there was no brain function (+/- 14 days). The outcome would have been the same. Haemodynamic recovery with brain death.
Cost of alternate Management. Abiomed BiVADs = $104,000. ICU at $1217/day X 14 days = $17,038. Total = $121,038
Net cost of Impella® $121,038 - $21,085 = $99,953 (saving)
Summary. Impella® did not influence the outcome but resulted in ***$99,953 savings***

Case 7
An acute viral myocarditis and pericarditis with pump failure.
Management. Impella® 5 did not produce sufficient haemodynamic support and was replaced after 36 hours by a BiVad, AB 5,000. Survival with eventual discharge.
Alternate Management. This would have been to use the BiVad from the beginning. Outcome would have been unaltered.
Summary. Use of Impella® did not influence outcome***. Increased cost of $15,000.***

Case 8 (19) Emergency CABG with mitral valve repair. Surgery completed on IABP. First post-op day developed ischemia left leg at site of IAEP implantation. Haemodynamic support became necessary.
Management. Since femoral artery could not be used Impella® 2.5 was inserted via axillary artery. Full haemodynamic recovery with explantation at 48 hours. However, left leg became necrotic, surgery refused, leading to death.
Cost. Impella® 2.5 = $7,500.
Alternate Management. In the absence of Impella® an LVAD would have been implanted. The outcome would have been the same .
Cost of alternate Management . AB5,000 LVAD = $52,000. ICU 3 days X $1.217 / day = $3,651. Total = $55,651
Cost of Impella. $55,651 - $7500 = $ 28,151 (saving).
Summary. Impella® did not influence outcome but resulted in a ***saving of $28,151***.

Summary of outcomes in 8 cases managed by Impella® at the MUHC
If the assumptions on which the above summaries are based are correct, Impella® experience at the MUHC can be summarised as follows

- Impella® use almost certainly saved one life and greatly reduced the risk of mortality in three others. In four cases it had no influence on the outcome.
- Assuming that the alternate treatments would have been carried out in the absence of Impella® the net result of use of Impella® would be approximately **$194,337 savings**.

DISCUSSION

Literature evidence. There is sufficient evidence to indicate that use of this device is a relatively simple procedure that can be rapidly carried out, with relatively low complication rates even by inexperienced operators. Its use can clearly allow interventions such as PCI or cholecystectomy to be undertaken when the risk would otherwise be too great. The literature also indicates that when used as a rescue procedure for acute irreversible left ventricular failure, most patients (82%) can be weaned and successfully bridged to other forms of support or to survival (71%). These outcomes are, of course, very dependent on the selection of cases

Local experience . The limited local experience is consistent with the above findings. The Impella® instrument has been used without complications in eight cases, resulting in almost certain clinical benefit in 4. In an institution, such as the MUHC, that is already committed to the use of mechanical means of cardiovascular support, with careful case selection the use of Impella® can clearly also result in substantial savings. More generous use of the instrument could clearly increase costs with limited or no clinical benefit.

Future use of Impella.

The selection of cases is vitally important. When Impella® is installed too early in cases that would have recovered , its use becomes wasteful. On the other hand, when it is installed too late, heart failure, end organ failure, and brain death will be increasingly common and irreversible. Review of local experience suggests that this critical judgement has been made successfully. Assuming the same decision-making is maintained it is estimated that the need for Impella® pumps at the MUHC in the coming year will be approximately ten, six of these for use in rescue cases, and four for the support of high-risk procedures in critically ill patients.

CONCLUSIONS

- The Impella® device is clearly more clinically effective than IABP or ECMO. It is also less traumatic and less expensive than other available ventricular assist devices.
- In the context of an institution in which the decision has already been made to provide mechanical support of acute vascular collapse, the use of Impella® can be cost saving. For example, when support is essential while determining whether brain function will recover, support by this device is less traumatic and less costly than the available alternatives.
- However, case selection is critical. Used too early, when patients could have survived without its use , Impella® use is unproductive and expensive. Used

too late, when pump failure, end-organ failure or brain death are irreversible its use is wasteful.

- Review of current use of this technology indicates that use is restrained and appropriate.

RECOMMENDATIONS

This technology should be supported by the MUHC**.** However it is an expensive technology and its use should be monitored. Should the annual use of Impella® exceed the currently estimated 10 units per year, the appropriateness of the selection of cases, should be reviewed.

Table I: Publications on Use of Impella® in high risk PCI.

Author year (country)	N	Device used	Type of patients	Comments	% Weaned	% Survival
Benali(20) 2007 abstract (Europe)	50	Impella® 2.5	high-risk PCI	Mean age 71 yrs .Mean EF25%. Complications: limb ischaemia 2%, bleeding 4%, infection 2%, "a vascular complications" 8%.	50/50	47/50
Dixon(12) 2009(US)	20	Impella® 2.5	high risk PCI	Hemolysis 10%. No other complications	20/20	18/20
Burzotta(21) 2008 (Italy)	10	Impella® Recovery LP 2.5	high-risk PCI	One patient died after removal due to acute stent thrombosis	10/10	9/10
Bautista-Hernandez(22) 2007(Spain)	6	Impella® Recovery LP 2.5	high-risk PCI	All survived uneventfully.	6/6	6/6
Remmelink (23) 2007 abstract (Netherlands)	11	Impella® Recovery LP 2.5	high-risk PCI	Increased aortic and intracoronary pressure. Decreased cor. resistance,& cor flow reserve, hyperemic flow velocity and cor flow reserve.	11/11	11/11
Vecchio(24) 2008 (Italy)	11	Impella® Recovery LP 2.5	5 high-risk PCI (6 cardiogenic Shock)	5 patients with PCI and 6 with cardiogenic sock Impella® proved successful in only 2 patient with shock whereas all PCI patients were safely discharged	5/5 (4/6)*	5/5 (4/6)*
Henriques(13) 2006 (Netherlands)	19	Impella® Recovery LP 2.5	high-risk PCI	Procedural success in all 19 patients No aortic valve regurgitation. Minor fall in Hb No important device-related adverse events	19/19	19/19
Thomopoulo (15) 2008 (Greece)	3	Impella® Recovery LP 2.5	high-risk PCI	Impella® use,2-24(mean 9.3) hrs. No aortic regurgitation reported. Hb fall Mean 1.7 g/dl	3/3	3/3
Pereira(25) 2007 abstract (Spain)	6	Impella® Recovery LP 2.5	4 high-risk PCI (2 cardiogenic shock)	No significant bleeding complications. Intermittent claudication in one case.	4/4 (2/2)*	4/4 (2/2)*

Table 1 continued . Case reports						
Author year (country)	**N**	**Device used**	**Type of patients**	**Comments**	**% Weaned**	**% Survival**
Minden(26) 2006 (Germany)	1	Impella® Recovery LP 2.5	high-risk PCI	Procedure successful without complications	1/1	1/1
Eichhofer(27) 2008 Abs (Canada)	1	Impella® Recovery LP 2.5	high-risk PCI	Successful prophylactic use.	1/1	1/1
Farhat(9) 2008 (France)	1	Impella® Recovery LP 5.0	end stage CCF support during aneurysm surg	The implantation of the micro axial pump using a Seldinger technique was impossible in this case therefore the right subclavian approach was performed	1/1	1/1
Toggweiler(10) 2008 Abs (Switzerland)	1	Impella® Recovery LP 2.5	high-risk PCI	Rare complication Impella® device was dislocated with the shaft on the anterior mitral leaflet causing mitral stenosis	1/1	1/1
Patane(28) 2007 (Italy)	1	Impella® Recovery P7	ischaemic cardiogenic shock. Acute VSD	Reanimated patient post cardiac arrest in conjuction with IAOP . Weaned at eight days. Patient discharged on the 35th day following the heart transplant	1/1	1/1
Cohen(29) 2007 (France)	1	Impella® Recovery LP 2.5	high-risk PCI	Impella® output maximal at 2.3 L/min Device was removed after 1 day Patient discharged 7 days later	1/1	1/1
Ramondo(30) 2006 (Italy)	1	Impella® Recovery LP 2.5	high-risk PCI	Procedure successful Device removed immediately after procedure **Thrombectomy** required 2 days later.	1/1	1/1
Valgimigli (31) 2005 (Netherlands)	1	Impella® Recovery LP 2.5	high-risk PCI	No complications, uneventful recovery of patient	1/1	1/1
Windecker (32) 2005 (Switzerland)	1	Impella® Recovery LP 2.5	high-risk PCI	Provided partial circulatory support during high-risk intervention without complications.	1/1	1/1
TOTAL	**143 -6 =137**				**137/137(100%)**	**131/137(96%) (95%CI 0.93,099)****

* Cardiogenic shock. Not high risk PCI

** Using the random effects generalize linear mixed model for meta-analysis

Table II: Publications on Use of Impella® in other clinical contexts

Author year (country)	N	Device used	Type of patients	Comments	% Weaned	% Survival
RCT.Impella vs IABP						
Seyfarth(2) 2008 (Germany)	11 (13)	Impella® 2.5 IABP	Ischemic Cardiogenic Shock	Greater increase in cardiac index and BP with Impella® than with IABP	6/11 (4/13)¶	6/11 (4/13)¶
Thiele(3) 2005 (Germany)	21 (20)	Impella® 2.5 IABP	Ischemic Cardiogenic Shock	Better haemodynamic response with Impella but more complications.	17/21 (16/20)¶	12/21 (11/20)¶
Isgro(4) # 2003 (Germany)	15 (23)	Impella100 Microaxial vsNo pump	Coronary revascularization of beating heart	1/15 Impella® patients required conventional pump 8/23 without Impella® required conventional pump	15/15 na/23	15/15 na/23
Case Series						
Dens(11) 2006 (Europe)	33	Impella® Recovery LP 2.5	11 cardio shock 22 high-riskPCI	With IABP in 9'.Hemodynamic improvement all. 5 access related complications. 3 malfunctions No hemolysis >80 mg/dl after pump modification.	9/11 (22/22)*	5/11 (22/22)*
Siegenthaler(33) 2004 (Germany)	24	Impella Recovery	Postcardiotomy 21 unweanable From bypass. IAPB, 6	Impella® support average 61 hours. Device related complications minimal. Outcomes judged better than 198 comparable patients who did not receive Impella®.	na/24	13/24
Meyns(34) 2003 (Belgium)	16	Impella® LP5	Cardio. Shock Postcardio 10 IAPB 11, ECMO 3	Impella® support (mean 4 days) increased mean CO (4.1 to 5.9), mean BP(57 to 80), mean Lactate(2.7 to 1.3)	11/16	na
Garatti(35) 2006 (Italy)	12	Impella Recovery LD, LP 5.0	Shock. Cardio-myopathy,6 . Myocarditis ,3. Ischemic,3.	Mean support time 8.8 days(3-18).First 5 patients in series previously published in Garatti et al., 2004 and Garatti et al., 2005.1 case previously published by Colombo et al, 2003	6/12	3/12
Sjauw(14) 2008 (Netherlands)	10	Impella® LP 2.5	patients with large anterior STEMI post- PCI	20 consecutive patients alternately assigned to 3 days support on Impella® or no support (or IABP).Haemodynamic improvement in all.. Haemolysis occurred only within first 24 hrs.	10/10	10/10

Table 2. continued

Author year (country)	N	Device used	Type of patients	Comments	% Weaned	% Survival
Schmidt(36) 2003 (Germany)	8	Impella® elect 600	Bivent support beating heart revascularisation	No device-related complications	8/8	8/8
Jurmann(37) 2004 (Germany)	6	Impella® Recovery	Postop. left heart failure.	Impella® LVAD.Av 169 hrs. Av flow 5L/min moderate hemolysis, reduction in platelet count	4/6	4/6
Vecchio(24) 2008 (Italy)	11	Impella Recover LP2.5	6 Isch shock 5 High risk PCI	Bleeding 7.Thrombocytopenia 1	na/5 (6/6)*	2/5 (6/6)*
Bautista-Hernandez(22) 2007 (Spain)	7	Impella 2.5/5.0	Ischemic Cardiogenic Shock.ECMO	Shock not reversed in 2 patients,1 with MS, 1 with AS.. In 2 shock was reversed but they died in hospital of unrelated causes.	4/7	2/7
Sassard(8) 2008 (France)	2	Impella® Recovery LP 5.0	Bridge to trans-plant or recovery	Axillary art approach. Duration 2 and 18 days. No complications.	2/2	2/2
Case Reports						
La Rocca(38) 2005(US)	1	Impella® LP5.0	Acute MI, post CABG.Shock	After 3 days Impella® support, transferred to HeartmateXVE, then heart transplant.	1/1	1/1
Rossiter-Thornton (39) 2008 (Australia)	1	Impella® Recovery LP 5.0	Intra-operative cardiogenic	First Australian use of Impella® R LP 5.0 Patient succumbed due to the left ventricular failure 30 days after the original procedure	1/1	0/1
Dahlin(40) 2008 (Sweden)	1	Impella®	Post CABG Ventric rupture	Serious complications. Full recovery.	1/1	1/1
Onorati(41) 2006 (Italy)	1	Impella® Recovery LP 2.5	Cardiomyopathy. Post mitral repair	Unweanable from IABP .Impella® used for 39 hrs. No significant hemolysis. IABP also used.	1/1	1/1
Strauch(42) 2005 (Germany)	1	Impella® Recovery 100	Post Cardiotomy CABG+aort. valve.	IABP for postcardiotomy failure, deterioration, Death, ,multiorgan failure after 4 days Impella.	0/1	0/1

Author year (country	N	Device used	Type of patients	Comments	% Weaned	% Survival
Lauten (2)(43) 2007 (Germany)	1	Impella® Recovery	MI.Post Cardiotomy Shock	Used Impella® for 8 days	1/1	1/1
Strecker(44) 2004 (Germany)	1	Impella® Recovery 100	End-stage ischemic cardiopathy	Pump was implanted pre CABG, used with IABP.Successfully weaned average 5 days postoperatively	1/1	1/1
Vlasselaers(45) 2005 (Belgium)	1	"Impella® Device"	Cong HD+ Septic shock	Impella® support for five days. Death due to irreversible sepsis.	0/1	0/1
Catena(46) 2004(Italy)	1	Impella® Recovery 100	Ischemic ,CCF, Shock	Recovery to transplantation after two days Impella® support	1/1	1/1
Colombo(47) 2003 (Italy)	1	Impella® Recovery 100	septic shock acute fulminant myocarditis	Impella® support for 18 days Satisfactory LV, RV function at 3 months.	1/1	1/1
Patanè(28) 2007	1	Impella® Recovery P7	Ischemic shock VSD	Bridge to transplant. Transplanted day 12. Discharged day 35	1/1	1/1
Total Impella®	**187 -(57) =131**				**102/131(78%) (95%CI** 0.70, 0.94)**	**90/144(63%) (95%CI*** 0.52, 0.89)**

* High-risk PCI , not cardiogenic shock; # Matched controls , not randomized; ¶ Managed with IABP, not Impella.
** excludes Siegenthaler et al. and Vecchio et al. for not reporting % weaned;*** excludes Meyns et al. for not repoting %survival

Table 3. Impella® experience at the MUHC

Patient ID	1	2	3	4	5	6	7	8
Type of Device Implanted	Impella LP 5.0	Impella LP 5.0	Impella LP 5.0	Impella LP 2.5	Impella LP 2.5	Impella LP 5..0	Impella LP 5.0	Impella LP 2.5
Age	53	51	36	86	57	17	41	60
Gender	F	m	m	m	m	m	f	f
Indication for Impella	acute transplant rejection	viral myocarditis shock	Dilated Cardiomyopathy. Severe CCF.Shock	high-risk PCI	End stage ischemic Caddiomyopathy	Myocarditis Cardiogenic shock	Fulminant Viral Myo pericarditis	isch card myocarditis
Pre-Impella Cardiac Index	1.1	1.4	<1.8		2.8	3.5	1.1	1.6
Pre-Impella LVEF	15%	15%	10%		15%	5%	20%	20%
Pre-Impella Systolic BP(mm.Hg)	<90	120	<100	152 on nitro	140	90	100	105
Pre-Impella Central VP(cm H2O)	22	na	na	na	1.0	14	18	23
Pre-Impella PC Wedge(mm.Hg)	na	na	na	na	na	26	18	20
Pre-Impella Mixed venous O2 sat	49.5	33	na	na	na	61.4	na	67
Pre-Impella Lactate	12.3	12	6.3	na	na	5.4	4.6	14.1
Pre-Impella Inotropes	Dobutamine, Adrenaline Levophed	Dobutamine, Levophed, Eepinephrine	Dobutamine Milrinone,Phenylephrine Levophed	None	none	Levophed, milrinone vasopressin, epinephrine,	Levophed, Epinephrine, Dobutamine	Epinephrine,Levophed Vasopressin Milirinone
Other Mechanical support	IABP	IABP	None	none	none	IABP	none	IABP
Treatment Goal	Recovery	Recovery	Bridge to transplant	Support during PCI	HD support duringr cholecystectomy	recovery	Recovery or bridge To transplant	recovery
Concomitant Interventions	IABP,	none	None	PCI x 2	none	none	none	CABG, Mitral V repair
Duration of Support	7.0 days	7.4 days	5.0 days	2.3 Hrs	4h10min	6.5 days	1.5 days	2.3 days
Device Flow. Min, Ave, Max	3.4, 4.7. 5.0	3.8, 4.3, 4.8	1.8, 3.5, 4.6	not recorded	1.9, 2.1, 2.3	4.0, 4.4, 4.6	4.0, 4.4, 4.6	1.5 ,2.0, ,2.3
Device-Related Complications	Lt pleural effusuion	none	Hemolysis	none	none	kinked line,	DIC	none
Weaned (yes or No)	yes	yes	yes	yes	yes	yes	No. Replaced	yes
Survival (30 day or discharge)	yes	Brain death at 3 days.	yes	yes	yes	Brain death	Yes Bridged to recovery	Death. Day 6 .Necrosis of leg. .Surgery refused
Reason for Device Removal	Haemodynamic Recovery	Haemodynamic Recovery	Replaced by Abiomed5000 to await Transplant	PC I completed	Cholecystectomy completed	Hemodynamic recovery	Poor HD result Replaced by BiVad	Haemodynamic recovery
Complications	FA tear	FA injury	None	None	None	None	Pump replaced	None

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