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2012 ISHLT ACADEMY:
Core Competencies in Mechanical Circulatory Support
April 17, 2012
Prague, Czech Republic
Jeff Teuteberg MD, David S Feldman MD PhD, and Andreas Zuckermann MD

In response to goals developed at the ISHLT 2006-2007 Strategic Planning Meeting, the Society established the ISHLT Academy. The ISHLT Academy draws on the wealth of experience and expertise within the Society to deliver high quality educational experiences with the goal of enabling our members to improve and maintain the highest possible standards in the care of patients with advanced heart and lung disease and those undergoing heart or lung transplantation. The ISHLT Academy represents the ‘brand name’ that will be associated with the educational opportunities offered by the ISHLT to its members and interested non-members.

The purpose of the ISHLT Academy is to develop an enduring resource of education in core competencies in the field of cardiopulmonary transplantation, mechanical and biological support of the failing heart, advanced lung disease (including pulmonary vascular disease) and cell replacement therapy. These educational endeavors will complement the ISHLT’s existing activities in the promulgation of new science, registry analyses, guideline statements and monograph series as a consolidated activity designed to train and educate young clinicians, trainees and those looking for a refresher course in clinical practice mandates in the field. The opportunities provided by the ISHLT Academy will be multi-modality and multi-disciplinary and will be guided by the identified educational needs or ‘practice gaps’ of ISHLT members. When available, core curriculum and competency documents for different disciplines within the society will guide content of ISHLT Academy activities.

Tuesday, April 17, 2012, the day prior to the 2012 ISHLT Annual Meeting in Prague, ISHLT will be conducting the third ISHLT Academy: Core Competencies in Mechanical Circulatory Support. This course will provide a concise review of clinical knowledge and essential professional skills to facilitate the surgical and medical management of patients with advanced heart failure who are being assessed for and who have received durable mechanical circulatory support. The course consists of focused presentations covering a broad array of topics for both inpatient and outpatient management with an emphasis on a practical approach to patient care, implementing best practices, and clinical problem solving. All lectures will be delivered by internationally recognized experts in the field and include cardiologists, cardiac surgeons, critical care physicians, and VAD coordinators.

Audience participation and interaction with the faculty will be actively encouraged throughout the Academy with Question and Answer sessions following each major topic and by limiting the enrollment to 200 participants. While all members are invited to enroll, this course is primarily designed to be of benefit for clinicians and allied professionals who are in the early stages of their careers or who are in training, are part of a new program, or desire an update on the current state of the field.
You may register for the ISHLT Academy via the registration form for the 2012 Annual Meeting, which will be available online and distributed to all members in November, 2011. Registration for the Annual meeting is NOT required in order to register for the Academy. Please register early as attendance is capped at 200 delegates.

The educational workforce of the Mechanical Circulatory Support Council of the ISHLT is confident this will be the most comprehensive and valuable summary for practitioners in the field of mechanical circulatory support.

**MECHANICAL CIRCULATORY SUPPORT PROGRAM HIGHLIGHTS**

Josef Stehlik MD MPH, Evgenij Potapov MD PhD, Soon Park MD

MCS Program Committee Representatives

The mechanical circulatory support field continues to grow, and so will its representation at the ISHLT 32nd Annual Meeting and Scientific Sessions. A comprehensive MCS program will start on Tuesday with the ISHLT Academy dedicated to mechanical support this year.

During pre-meeting symposia didactic sessions will include “Optimizing Outcomes in Patients with Right Heart Failure in Need of Mechanical Circulatory Support”, providing an overview of different RV risk assessment approaches before LVAD implant. “Cardiogenic Shock Before And After Heart Transplantation” will review options, from ECMO to total artificial heart, that are available for patients in severe cardiogenic shock before and after heart transplantation. “New Devices, New Approaches” will explore new developments in LVADs and their clinical applications. Current approaches to MCS in children will be highlighted in “MCS in Congenital Heart Disease & Pediatrics”. The final pre-meeting symposium will be “The Longer The Better - Chronic Medical Management Of MCS” focusing on how to optimize long-term MCS.

During the main meeting, the MCS Concurrent symposia on Thursday and Friday will include “MCS: When is it too soon or too late?” providing the latest information on patient selection for device therapy at both ends of the heart failure spectrum – specifically when is a patient too sick to receive a VAD and how early in the HF disease trajectory can we consider VAD implant and. “MCS Recovery – How Do We Get There”, intended to showcase our understanding of this process and possible approaches that could make myocardial recovery a treatment goal.

A number of abstract sessions, mini-orals and poster sessions with focus on MCS will provide ample opportunity for discussing new research as well as pondering old problems. Finally, topics with direct relevance to the MCS field will be addressed at a closing plenary session titled Incorporating Information Technology into Pre and Post-Transplant Care.

**ISHLT Academy: Core Competencies in Mechanical Circulatory Support**

**LEARNING OBJECTIVES**

At the conclusion of this meeting, participants will have improved competence and professional performance in their ability to:

1. Recognize the various types of mechanical circulatory support, their outcomes, and rates of adverse events.
2. Identify the clinical signs and risk factors of advanced heart failure in order to optimally time implantation.
3. Recognize the medical and social factors which impact patient outcomes on MCS.
4. Optimize implantation techniques and pump selection.
5. Manage patients after MCS in the intensive care unit, as an inpatient, and as an outpatient.
6. Diagnose and manage common clinical dilemmas and adverse events in patients after MCS.
Today is your long-awaited venture outside of Prague. You have a hard time saying goodbye to the city of a thousand spires, even for one day... but you promised your Czech friend back home that you would make at least one or two daytrips to his favorite places.

‘The most adventurous part of today may be getting to the Main Train Station (“Hlavní Nádraží”) and buying a train ticket to the correct location,’ you think to yourself as you stand in line.

“Karlštejn,” you try to say slowly – pronounced as Karlshteyn – to the little old lady behind the tiny grated window.

“Zpáteční lístek??” she asks.

You stare at her until she gets tired of waiting for your response and says, “Return ticket?”

“Oh, yes” you nod vigorously, relieved that you will not have to sleep at the castle tonight.

And just 2-or-so Euros later, there you go, clickety-clacking out of the city, through residential neighborhoods, along the Barrandov mountains famous for fossils and renowned cinema studios, by the Chuchle horse track stadium, through fields and pastures, and across the valleys of Vltava and Berounka rivers. After 45 minutes you exit the train at the Karlštejn station and follow the small crowd of tourists walking towards the castle.

And there it stands, rising above you on a hill. Just like in the pictures... or maybe more like in those fairy tales. The morning had looked promising with some sunshine through the clouds; but by now, the sky has darkened, adding to the dramatic image in front of you. You follow the steep winding path up the hill, your gaze fixed upon the white fortress with dark gray-blue roofs and spires perched on the rocks.

By the time you arrive to the entrance to the castle, it has started pouring. You make it just in time across the drawbridge and inside the gate. You are standing underneath an awning, awaiting the tour that you diligently reserved the day prior. You are looking at the gray curtain of raindrops and the tall stonewall with lit windows across the courtyard. Your thoughts wander into your childhood and the books you read a
long time ago … and you just cannot help thinking that this would be the ideal place for a Halloween party. You and your friends would dress as knights with armor and all and play hide-and-seek in and around the spiral staircases and narrow hallways.

You notice the tour guide is standing nearby, waiting for more visitors to make their way to the castle through the deluge. You move closer to your English-speaking captive audience. “Do you ever hold Halloween parties in here?” you ask. The tour guide laughs. “Good thing I know what Halloween is,” she says. “It doesn’t really exist in the Czech Republic, although some people are starting to copy the tradition from the Anglo-Saxon countries. I spent some time as an au pair in Chicago and saw the Halloween festivities in action. I read that the origin is an old Celtic tradition celebrating the transition from summer into winter and from life to death. People used to wear masks to protect themselves from evil spirits. Anglo Saxon countries kept the tradition of wearing masks … we kept the tradition of celebrating the dead. The holiday here in the Czech Republic is called All Saints Day or Day of the Souls (Dušičky) celebrated with special trips to the graves of your deceased friends and family and lighting a candle. Not as much fun as trick-or-treating.”

“Do you decorate pumpkins?”

“No, we just eat them and make compote out of them.”

You persevere with your questioning. “So, if you did celebrate Halloween, what would Czech kids dress as?”

“In reality, they would probably dress as Harry Potter or Princess Leia. But I’m sure there would be enough traditionalists who would dress as a White Lady of-the-Castle (Bílá paní), a water sprite (Vodník), or the water nymph, Rusalka, from Bohemian myths and legends.”

The tour begins. You learn that this castle was founded by the very prolific Bohemian king and Roman Emperor Charles IV in 1348. The main purpose of the fortress was to keep safe the royal coronation jewels. The jewels were kept, along with the state archive documents, in a secret room with four doors and nineteen locks, in the Chapel of the Holy Cross in the Great Tower.

Walking through the courtyard, you bug the tour guide with another question. “Where did the White Lady live?” She laughs again. “There is no white lady at this castle. But they say she dwells in Rožmberk in South Bohemia. She was tortured there by her evil husband during her lifetime long ago and now her spirit will haunt the castle forever.”

On the way back to Prague, your head swarms with knights, ghostly creatures and white ladies. You were already eager to see the famous Czech opera “Rusalka” by Antonín Dvořák, but now, you are even more intrigued by this old Slavic mythology story of a water nymph that seduces a human prince.

Upon returning to the city, you go ahead and buy tickets to an evening showing of “Rusalka” at the National Theater, a short distance from the congress center.
Thanks to technological advances, implantable ventricular assist devices (VADs) are becoming a widely used strategy not only to effectively bridge patients to transplant, but also to prolong life in patients with contraindications to transplant. The cost of the procedure, however, may represent a limitation to the number of VAD implants, and full satisfaction of the need for VADs could be an excessive cost burden. On the other hand, denying the implant to a patient only because of cost issues could be unethical. Moreover, other unanswered questions ranging from candidate selection to determining when to list for heart transplantation and managing listed patients with VADs remain on the table and require a consensus of defined policies from the Society.

To determine how members around the world feel about these issues, we interviewed international experts from centers with high and low VAD volumes and from countries with mainly public healthcare systems.

Dr Heather Ross from the Toronto General Hospital in Canada leads a center which started implanting VADs in 2001. In 10 years they have implanted 95 devices, mostly in the last 3 years. The majority of patients have been implanted as a bridge to transplant with very few for destination therapy. Recovery has been observed in about 10% of patients.

Potena: Heather, how are patients with a VAD prioritized on your transplant waiting list?

Ross: We have a very complex listing system. In general we prioritize with the highest status only patients with complicated VAD, while the others are at intermediate priority (Status 3).

P: Who is paying for the VAD in your Center?

R: Two sources - our healthcare system and also through hospital foundation. However, cost is usually not a limitation to our indications for a VAD.

P: Do you think a VAD implant should be regulated by healthcare authorities (for example indicating a number of VADs/year in the country or limited to a handful of authorized centers) or do you think it should be left free to any cardiothoracic surgery center, like any other non-transplant surgery?

R: There should be clear criteria for VAD implant, close follow-up of criteria and outcomes. I do not believe the healthcare authorities should be able to dictate who should or should not get a VAD - they have not had the necessary training. It should be based on criteria established by national/international bodies (as with Tx indications) and closely followed and revised as necessary. I think that every transplant center should have a VAD program. But I don’t think every VAD program requires a transplant center - it does however require expertise and volumes and to demonstrate outcomes.

Dr Pascal Leprince is an experienced member of the Cardiac Surgery and Cardiac Transplantation team at La Pitié-Salpetriere in Paris. La Pitié has one of the world’s long-lasting programs in implantable mechanical circulatory support dating back to 1986 with the total artificial heart program. Since then they have implanted more than 200 total artificial hearts and about 300 VADs.

Leprince: In Paris, we consider “bridge to transplant” the main indication for VAD implant, although I believe that in the future VADs have the capability to overcome transplantation. We had good experience also with patients over 70 years old and although cost may be an issue, it does not prevent us to implant a device. I agree with the concept that healthcare authorities should not interfere with indications, restricting the number of devices allowed. Similarly, the number of centers allowed should be left free, although I believe that any transplant center should have a VAD program.

Berlin MCS history is only a little younger than Paris, starting in 1987 with the Berlin Total Artificial Heart. But the impressive amount of devices implanted (over 2000 in about 1700 patients) makes Deutsches Herzzentrum the largest MCS center in Europe, and perhaps in the world. Dr Evgenij Potapov is one of the surgeons involved mostly in VAD implantation in Berlin.

Potena: Evgenij, with such a large amount of VADs implanted, is bridge to transplant still your main indication?

Potapov: Yes, the whole scope of VAD implant is still heart transplant, although in most cases we implant a VAD to make a patient transplantable who would otherwise never get a heart. However, these patients are prioritized only if the VAD gets complicated. On the other hand, we also have reasonable experience in implanting as destination therapy very old patients. Our oldest VAD recipient is 82.
Potena: And how about upper age limits for heart transplant?
Potapov: Our general limit is 65, but it is an individual decision, depends on biological age.

Potena: How do you manage the cost of the device?
Potapov: Cost does not represent a limitation to implant in our center, since it is reimbursted by patients’ medical insurance, private or governement. Moreover, increasing number of foreign patients are self-pay.

Potena: Do you think that all transplant centers should have a VAD program?
Potapov: Yes, I also think, however, that non-transplant centers may be allowed to implant VADs as well. However, MCS is a very complex and highly specialized business. Thus, concentration in specialized centers, as it is in Germany, would improve the outcome and decrease the costs.

Potena: What is your vision for the future?
Potapov: In the next 10 years is likely that people will more than double the current number of implants. Reliable telemonitoring, transcutaneous energy and information transfer and individually tailored anticoagulation management are however unmet needs of our current technology that need to be addressed.

In Spain, a very well conceived law on organ donation allowed the country to reach in a few years the top number of transplants performed in Europe. Nevertheless, few Centers developed VAD programs in parallel to heart transplantation. Juan F. Delgado is the medical director of the transplant program of the Hospital 12 de Octubre, in Madrid, where the VAD program was started in 1992.

Delgado: As compared with other European Centers our VAD program may seem limited, since we implanted 75 devices since 1992, mostly as bridge to transplant. Although our program is one of the largest in the country, our implant capability is limited by the cost of the device, in particular in the current critical economic situation: healthcare system is public in Spain, and the cost of devices and procedures is completely reimbursted.

Potena: Thus your healthcare authorities regulated VAD implant?
D: Formally they don’t, but I think that the system should be somehow regulated. The new devices provide excellent results, good quality of life of patients, and with the limited number of donors for transplantation that we are seeing also in our country, the need of implants will significantly increase. However, I do not think this procedure can be left free to all cardiac surgery centers, because of costs and expertise. It would be reasonable to designate a limited number of centers, generally those with a heart transplant program.

Our short tour in the world of VAD implanters ends in Italy, where we met Maria Frigerio, Cardiologist and Director of the Cardiovascular Department and the Heart Failure and Heart Transplant Program in Niguarda Hospital in Milan, and Giorgio Arpesella, Cardiac Surgeon, Director of the Heart Transplant Program in Bologna.

Niguarda is among the first Centers where heart transplantation started in Italy, in 1985, and is the largest VAD center in the country, with a program that started in 1989 and currently conducts 10 to 12 implants per year. Bologna, on the other hand, started the transplant program in 1991, becoming in the latest 5 years the second largest transplant center in the country. After a long experience in the management and development of extracorporeal mechanical circulatory support, Arpesella recently converted to the religion of VAD believers, and started a VAD program in Bologna. However, his viewpoints seem heretical in the context of the opinions of the professional VAD implanters.

Arpesella: For many years we were able to keep a good pace between new patients listed and transplants performed. We did not have a real need to bridge anyone to transplant with a device, except for those with an acutely deteriorating CHF who were put on ECMO and transplanted with a high urgency protocol (about 10 to 15% of the total number of transplants). We were used to transplanting 35-45 patients/year, however in the last 3 years we are down to 25-30/yr. Thus we are experiencing a donor shortage (and consequently have an increase in waiting list mortality). This led us to start an implantable VAD program in 2010.

Frigerio: As opposed to this strategy, in Milan we started our VAD program quite long ago because we thought that it could maintain waiting list equity. We now prioritize only complicated VADs, applying strict criteria we developed in Italy to have a high urgency national priority, while stable VADs are locally prioritized as compared with stable outpatients taking oral medications (UNOS status 2)

Potena: Thus your indication for a VAD is bridge to transplant?
F: Yes, a very long bridge though, with waiting times exceeding 2 years…
A: Bridge to Transplant is our starting point. However we are facing a greater need of “bridge to transplantability”, and I would also implant destination therapy in selected patients with a contraindication to transplant. Moreover, I have a great hope in the bridge to recovery strategy.

P: Is the cost of the device a limitation to the implant?
A: Yes. In our Country public healthcare system covers entirely the expenses, and in the current context of treasury cuts to public expenditures, my hospital administration is very picky in allowing me to spend more money than last year.
F: I agree, and we also have to face the resources (personnel, ICU beds) for post-operative care that are limited.
P: Thus your healthcare authorities regulate VAD implants?
A: Currently they do not; any cardiac surgeon can put in as many VADs as he wants, if his hospital pays. But I believe this matter should be somehow regulated. In my region we are working to a system of net referral involving all cardiac surgery and cardiology departments that is defining indications and authorized centers with extracorporeal and implantable MCS. I believe that only transplant centers should be authorized for implantable VADs, given their expertise in managing indications and surgery in patients with advanced heart failure.

F: Given our public system, I think that some planning should be made on a national basis. VAD implanters should be accredited centrally, and we should develop a national registry like INTERMACS, and like we are now doing for transplant. This would be a tool to ensure transparency and to verify quality of the centers. The number of authorized centers must then be limited, not necessarily transplant centers though, to ensure a decent number of implants per year to have enough experience/skill.

P: What is your vision for the future?
A: A greater advance in technology that can improve power transmission and anticoagulation management. I also crave for methods that would allow us to predict or induce recovery.

F: I believe that VAD therapy will more and more compete with heart transplantation, being a long-term strategy, somehow comparable to dialysis in the context of kidney failure. I think... hope... that in the future only patients with contraindications for a VAD, and those with a complicated VAD, will receive a transplant.

Our short survey in the world of VADs within countries with a public healthcare system reveals a great diversity of experiences balanced by a rather similarity of opinions... with few exceptions. Public healthcare seems unable to afford to cover entirely the cost of VADs: the largest center interviewed relies on private insurances, and the smaller ones are limited by healthcare system cuts. A good strategy has been put in place in Toronto, where public healthcare expenses are supported by a foundation. VAD experts seem “allergic” to the interference of healthcare authorities in VAD policy. However, the expertise and the results of centers implanting VADs should be verified and somehow certified, to allow the procedure to be fully reimbursable with public money.

How these opinions fit in the US, the country where the greatest number of VADs are implanted, and where healthcare expenses are currently in the middle of the ford between private and reformed public healthcare systems, will be explored in a future issue of our newsletter. Nevertheless, we need further exploration to allow for better collaboration and ultimately a consensus on the best approach to VADs ultimately endorsed by the ISHLT.

The Links editorial board is grateful to the members who kindly replied to our survey.

2011 UPDATE ON MECHANICAL CIRCULATORY SUPPORT

Francis D Pagani, MD, PhD
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Mechanical circulatory support (MCS) is of growing importance to the treatment of advanced heart failure throughout the world. With this growth, there has been an increasing understanding of the improved survival outcomes associated with this therapy as well as its limitations and associated adverse events. Nowhere is this better reflected than in the August issue of the Journal of Heart and Lung Transplantation where the first seven papers discuss issues of MCS ranging from arteriovenous malformations (AVMs) and the association with gastrointestinal (GI) bleeding, the impact of right heart dysfunction on MCS outcomes, to the survival outcomes with transplantation following MCS.

In the first of these papers, Demirozu et. al. performed a retrospective review of 172 patients who received a continuous flow rotary pump between 2003 and 2010. Thirty-two (19%) patients presented with GI bleeding localized to the upper GI tract in 16, lower GI tract in 15 and both in 1. GI AVMs were identified as a source of GI bleeding in 10/32 (31%) of patients. It is well established that GI AVMs are a risk factor for GI bleeding and the prevalence is believed to be related to increasing age. The authors concluded that AVM-related GI bleeding is a significant but medically-manageable complication.

The impact of pre-transplant MCS support on transplant outcomes was analyzed in a paper by Nativi et. al. based upon an analysis of the registry of the International Society of Heart and Lung Transplantation. The authors identified improved survival for patients bridged to transplantation with a pulsatile pump when comparing eras January 2000-June 2004 to July 2004-May 2008. Patients bridged to transplantation in the most recent era with
a continuous flow pump had similar survival to patients bridged with a pulsatile pump. Post-transplant survival and graft rejection for patients in the most recent era supported with a pulsatile and continuous flow pump were not different from that of the non-LVAD group. These data provide evidence that pre-transplant MCS support does not adversely affect post-transplant outcomes with respect to survival and rejection.

Four of the papers in the August issue of the Journal of Heart and Lung Transplantation focused on the diagnosis, management and impact of right ventricular dysfunction on outcomes following institution of MCS therapy and highlighted the importance of the right ventricle to successful MCS outcomes.

The first of these papers by Cleveland et. al. reported on the survival outcomes of patients supported with biventricular assistance from the Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS) from June 2006 to September 2009. The distribution of primary device implants included 1440 LVADs and 206 BiVADs. Patients with BiVAD support presented with a lower INTERMACS Profile, 93% in Profile 1 or 2, compared with 73% for patients supported with LVAD alone. Survival at 6 months was 86% for patients support with LVAD alone, and only 56% for patients support with a BiVAD. Adverse event rates for patients supported with a BiVAD for infection, bleeding, neurologic events, and device malfunction were significantly higher compared to patients on LVAD support alone. Following 6 months of BiVAD support, 40% of patients underwent transplantation, 35% died on support, 21% remained alive on support, and 4% of patients were explanted. Older age, higher body surface area, presence of ascites at implant, higher creatinine, bilirubin, and INR emerged as risk factors for worse outcome following BiVAD support. These data confirm the severity of illness of patients requiring BiVAD support and the adverse impact of significant multi-organ dysfunction on MCS outcomes.

In a prospective, randomized, double-blind, multicenter, placebo-controlled trial, Potapov et. al. examined the use of nitric oxide in prevention of right ventricular dysfunction following LVAD implantation. The authors demonstrated that use of 40 ppm of nitric oxide in the perioperative phase of LVAD implantation did not achieve significance for the primary end point of reduction in right ventricular dysfunction. This is an important trial examining the efficacy of nitric oxide in the perioperative period. Although, the intention-to-treat analysis did not find efficacy for nitric oxide in reducing right ventricular dysfunction, a number of significant limitations of the study cloud the final conclusions. First, there was a very high rate of crossover from placebo to nitric oxide in the study (20/77 patients). Second, the investigators selected patients with a pulmonary vascular resistance of > 200 dynes/sec/cm² as entry criteria. This assessment alone may not uniquely identify patients at significant risk of right ventricular dysfunction. Thus, significant numbers of patients at lower risk of right ventricular dysfunction may have been included in the trial and the trial was not powered to detect differences in treatment effects with a lower than expected event rate in the placebo arm.

In the third paper on the topic of right heart dysfunction, Baumwol and colleagues examined the predictors of early post-operative right heart failure and its subsequent consequences, termed “failure to thrive”. The classification of “failure to thrive” was based upon a subjective assessment of symptomatic status, number of re-hospitalizations and presence of unstable ventricular rhythms. Patients with failure to thrive were of older age, had a lower rate of survival to transplantation, experienced progression of further right ventricular dysfunction with time, and by definition had significantly higher rates of rehospitalization. The recognition of the late consequences of perioperative right ventricular dysfunction is of increasing importance as more patients are evaluated for MCS for destination therapy. Risks factors for the late effects of right ventricular dysfunction should be identified to improve patient selection and subsequent management.

In the last paper on the topic of right ventricular dysfunction, Garcia-Alverez and colleagues examined the feasibility and utility of cardiac computed tomography (CT) in the postoperative assessment of right ventricular function following LVAD implantation. These investigators identified that right ventricular ejection fraction determined by cardiac CT correlated highly with the right ventricular fractional area change determined by echocardiography, cardiac CT identified relevant postoperative findings in 50% of patients, and the right ventricular assessment by cardiac CT was highly reproducible and superior to that of echocardiography. These data suggest that cardiac CT is a useful adjuvant to the assessment of the right ventricle following LVAD implantation.

Lastly, Pamboukian et. al. reported on the effects of implementation of a disease-management model termed “intensive surveillance protocol (ISP)” on 2 year outcomes following LVAD implantation. The elements of the ISP included: 1) a weekly phone call from the MCS coordinator to the patient to identify problems; 2) a multi-disciplinary approach...
“2011 Update...” continued

clinic including surgeon, cardiologist, and MCS coordinator; 3) a schedule of clinic visits and a protocol of routine diagnostics; and 4) continued non-cardiac-related health maintenance. After adjustment for covariables, the ISP was associated with a 70% reduction in the hazard for death for the entire cohort. The importance of the observations of Pamboukian and colleagues from the University of Alabama that implementation of an ISP improves MCS outcomes cannot be overstated. These data again emphasize the need for a well-organized and multidisciplinary approach to the care of the MCS patients to achieve excellent outcomes.

References:

A REPORT: GORDON RESEARCH CONFERENCE ON ASSISTED CIRCULATION

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The Gordon Research Conference (GRC) on Assisted Circulation was held from June 12–17, 2011, at Waterville Valley Resort, Waterville Valley, NH, USA, and chaired by Mr. Timothy Baldwin and Dr. Michael Acker. The main theme of this GRC was “The Inflection Points of a Needed Therapy,” with the following nine important subjects presented and discussed:

1. Thirty years and counting: Heart failure & mechanical circulatory support in 2011
2. The physiology of supported circulation: How and why adverse events occur
3. The physiology of supported circulation and organ function: The wave or the flow?
4. Right and total heart failure
5. Assisted circulation for pediatrics
6. Circulatory support bioengineering
7. MCS therapy optimization: Which device, which patient, when?
8. Recovery: Great promise or simple pipedream?
9. The science of patient-centered decision making

An international registry of heart transplantation was first formed in 1982. Along with the great increase in number of heart transplantations, mechanical circulatory support (MCS) devices including total artificial hearts have been applied for patients waiting for heart transplantation as a bridge to transplant (BTT). In the 1990s, implantable left ventricular assist systems (LVAS) began to be used not only in heart transplant candidates as BTT, but also in heart transplant non-eligible patients, while the REMATCH study showed the superiority of an implantable LVAS for medical therapy. Myocardial recovery due to MCS use has also been reported from the mid-1990s, and several non-pulsatile blood pump systems were introduced to the clinical field and applied to heart failure patients. In the 2000s, reports of several types of MCS devices including pulsatile and non-pulsatile, and extracorporeal and implantable used in severe heart failure patients as BTT, bridge to recovery (BTR), and destination therapy were presented. With this background in
mind, INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) was established for advancement of the understanding and application of MCS for heart failure patients to improve MCS therapy, and more than 1200 cases were enrolled in the registry in 2010.

This GRC was held at this important time of MCS development with the past 30 years of experience and results summarized and discussed. Of those, the timing of application of MCS devices is one of the important issues related to their use. According to the INTERMACS registry, Profile 2-3 (Sliding on inotropes / Dependent stability) patients are more suitable for an implantable MCS device as compared to Profile 1 (Crash and burn) patients. Application of MCS for less sick patients is a new frontier to be explored, as is MCS for pediatrics. At the next GRC, these themes will be primary topics.

In Japan, two types of implantable non-pulsatile blood pumps, the EVAHEART and DuraHeart, were approved in December 2010 and their use is now covered by national medical insurance for BTT patients. Furthermore, J-MACS (Japanese registry for Mechanically Assisted Circulatory Support) was established and began data enrollment in 2010. Our hope is that the Japanese data will contribute to the next GRC as well as improvements in MCS therapy.

MRSA, KING OF CARDIOTHORACIC INFECTIONS

Stanley I Martin MD
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Throughout human history Staphylococcus aureus has always been a potentially deadly pathogen. As a chronic colonizer of the skin and nares, S. aureus has gone where we have gone, ready at a moment’s notice to take advantage of any opportunity and become something more than just a colonizer. As medicine evolved, as antimicrobial therapy evolved, and as we have evolved with invasive procedures and our patients over the years, S. aureus also evolved. In today’s complicated medical world, S. aureus has adapted by becoming increasingly resistant to antibiotics and causing problematic infections. We created methicillin-resistant S. aureus (MRSA) and now vancomycin-resistant S. aureus (VRSA). However, more subtle changes appear to be evolving in MRSA’s ability to respond to antibiotic therapy beyond these simple acronyms, for every new anti-MRSA agent to come along, a new resistance is reported.

S. aureus remains the most common cause of surgical site infections in intensive care units and one of the major causes of healthcare-associated and now even community-associated infections. Though its presence varies widely, in the United States, MRSA accounts for over 50% of all S. aureus strains in the hospital setting.

Because MRSA is the leading cause of mediastinitis and other surgical site infections, it has always been a concern in cardiothoracic transplantation and mechanical circulatory support procedures. Risk factors for MRSA infection such as prolonged device use, renal failure, diabetes mellitus, prolonged hospital stay, preoperative exposure to antibiotics and preoperative colonization with MRSA, are common among patients requiring heart and lung transplantation. Heightened awareness of these issues and the ever changing world of therapeutic options are necessary in managing modern day cardiothoracic and mechanical circulatory support patients.

Unlike us humans, we are just starting to understand that not all MRSA organisms are created equal. Not only do different isolates have different genetics, causing different severities of disease, we are witnessing different degrees of “resistance” to antibiotics beyond the usual alterations in binding proteins. The MIC (Minimum Inhibitory Concentration) of a particular pathogen to an antibiotic is defined as the lowest concentration of an antibiotic needed to inhibit the visible bacterial growth overnight in vitro. Official MIC numbers are designated “Susceptible”, “Resistant” and “Intermediate” determined by consensus of an international guidelines committee. Historically, MIC’s for vancomycin to MRSA were established as being: MIC < 4 susceptible, and an MIC > 32 resistant. Clinical evidence started to accumulate suggesting that
The fact that mechanical circulatory support is now the most effective treatment of patients with severe heart failure and that the outcome is meanwhile comparable with the “gold standard” – heart transplantation – is well known and generally accepted among physicians and is enjoying increasing acceptance in society.

The burning question is not whether to implant or not to implant, but which kind of support is optimal in the individual patient. The right ventricle (RV) has been recognized as a leading obstacle in the early postoperative period, causing significant mortality.

The most important question is the effectiveness of the left ventricular assist device alone and the options to avoid early and late right ventricular failure.

The problem should be discussed with regard to the following questions:

1. Pre-operative prediction of right ventricular failure
2. Medical preconditioning in patients with high risk for RV failure
3. Surgical strategy in patients with evident biventricular failure
4. Intraoperative technique to avoid or to reduce the risk in high-risk patients
5. Strategies during long-term follow-up

We summarize the experience regarding these questions.

1. The preoperative prediction of RV failure is now possible, based on preoperative clinical status and hemodynamic and echocardiographic data, and has reduced the
incidence of RV failure to 10% in patients with chronic severe heart failure. Despite the numerous risk factors identified in many studies and the development of risk factor profile scores, this still continues to be a challenging problem. However, the lower incidence of RV failure following LVAD implantation in the current era is encouraging, suggesting a favorable relationship between RV unloading and function, and continuous-flow physiology. In our institution the geometry of the RV and the severity of tricuspid valve regurgitation in relation to pulmonary vascular resistance and, finally, the global RV function are key parameters for risk stratification.

2. The preoperative medical conditioning of patients with a "poor" right ventricle is a valuable option to avoid RV failure. We apply moderate inotropic support with dobutamine, aggressive volume control with diuretics and, if necessary, dialysis for at least 1 week. Once the central venous pressure is decreased below 10-12 mmHg echocardiography is repeated and the decision made. However, this strategy works mostly in patients with acute RV decompensation. Patients with chronic RV failure presenting congestion based ascites and dermatosis do not respond well to the conditioning. In these patients biventricular support is the only option open.

3. Biventricular support is possible employing three options. The first is paracorporeal biventricular assist devices such as the Thoratec or Berlin Heart Excor. Both systems are widely used for bridge to transplantation. However, long-term or even permanent support is less accepted due to high risk for infection and low quality of life. The second option is an implantable LVAD and an additional temporary paracorporeal RVAD with hope for subsequent RV recovery. In the worst case the patients stay ICU-dependent until heart transplantation (HTx). In non-HTx candidates – and high titer of panel reactive antibodies, stroke or similar events precluding HTx may occur in any patient after LVAD implantation – this strategy is not an optimal solution. In these patients the use of implantable continuous flow devices for biventricular support is the best option. There is positive experience with the HeartWare HVAD as a BVAD or TAH in different centers in Europe, Canada and the USA. As a third option, a combination of HeartMate II for the left and Jarvik 2000 for the right ventricle or HeartMate II as a TAH has been described.

4. Since biventricular failure occurs in 10 to 15% of chronic (not acute) severe heart failure, the need for primary BVAD support is correspondingly low. Most important, and used in nearly half of the patients, are intraoperative strategies to avoid RV failure, in particular repair of the incompetent tricuspid valve. Some surgeons perform valve repair for moderate regurgitation; others do not. There are pro and con studies with this approach, but limited to small numbers of patients. Only a prospective randomized and, desirably, multi-center study will definitely answer this question. At our institution severe tricuspid regurgitation is an indication for biventricular support. We perform tricuspid repair in the case of structural defects, mostly due to pacemaker or defibrillator leads or chordal rupture. In patients with postoperative RV failure we prefer early implantation of temporary RV support using the Levitronix paracorporeal pump. Support is given for 7-10 days with subsequent gradual weaning under echocardiographic monitoring. Optimal patient selection and early decision for LVAD implantation have reduced the incidence of postoperative RV failure to 10% and most of these patients at our institution could be effectively treated with a temporary RVAD. If weaning is not possible, implantable RV support using the HeartWare HVAD or Jarvik 2000 is a valuable option.

5. With life-long support with a LVAD becoming routine and the duration of support dramatically increasing, late RV failure has become evident. However, there are no data about incidence or impact on survival or quality of life. In our experience few patients develop RV failure during follow up, sometimes several years after surgery. In these patients aggressive volume management during hospital admissions and in some chronic inotropic support at home using a port and dobutamine pump have been effectively applied.

Although the incidence of postoperative RV failure has decreased with improvements in patient selection and perioperative management, it remains the main cause of death in the early postoperative period. Standard institutional protocols employing preoperative screening and scoring for risk for RV failure and strict adherence to the institutional intraoperative strategy to avoid RV failure are crucial.

Additionally, with increased numbers of patients requiring long-term mechanical circulatory support and increased duration of support, the late onset of RV failure has been recognized as an additional problem that diminishes quality of life and outcome. This problem requires further evaluation and solution.
Mechanical circulatory support is routinely used and is now probably the most effective treatment of severe acute and chronic heart failure. It has become an established therapy and its acceptance in the medical community and in society is rapidly growing. The present issue of ISHLT Links is the best example.

However, there are, as usual in medicine, more questions than answers. I cordially invite you to our 7th Biennial Symposium on Mechanical Circulatory Support, which will take place in Berlin, Germany, on November 4-6, 2011.

Our Symposium will again address the most pertinent areas of support in acute heart failure, current achievements and perspectives in pediatric MCS treatment, new developments in myocardial recovery, and problems in life-long support. In addition to focusing on interactions between the body and the implantable pump during long-term support, the Symposium will discuss ways to avoid right ventricular failure after left ventricular assist device implantation and the first clinical results of the implantable biventricular assist device employing continuous flow pumps. Leading experts in the field will present complex cases and discuss creative solutions to surgical problems.

Below is a link to the program in which you will find the main topics scheduled for discussion during the Symposium and the list of invited faculty.

**7th Biennial Symposium Program**

More information is available on our website: www.dhzb.de.

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**INTERNATIONAL TRAVELLING SCHOLARSHIP AWARD**

**REMINDER:** The next deadline for the International Travelling Scholarship Award is December 1st. The purpose of this award is to facilitate the exchange of knowledge and techniques regarding heart and lung transplantation and the treatment of end stage heart and lung failure and to build relationships between individuals, institutions, and countries. The Scholarships may be used to learn new techniques in the clinic, operating room, or laboratory or just to experience first-hand how others deal with challenging problems. Please note the following:

- Each award will be in an amount of up to $6,000
- ISHLT will fund a minimum of ten Travelling Scholarships annually. To date, two scholarships have been awarded.
- All members of the Society are eligible to apply for a scholarship.
- It is anticipated that each scholarship will be for up to one month, however no absolute time is stipulated.
- Visits of less than 2 weeks will not be funded.
- The funding may be used for travel, accommodation, and/or subsistence for the recipient.
- The funding may not be used to cover other costs, such as accompanying family members or salary, nor to cover any associated costs borne by the recipient’s home institution, such as for the back-filling of clinical duties or for indirect costs/institutional overhead.

The award application is available on the ISHLT website at http://www.ishlt.org/awards/awardIntlTravelScholar.asp.

Applications will be accepted twice annually. Applicants will be informed of the decision within 1 month following the application deadline. Please review the eligibility requirements stipulated in the award instructions before completing and submitting the application.
Patients with a Left Ventricular Assist Device (LVAD) either as a bridge to transplantation or destination therapy pose a challenge to health care providers. Many parameters need to be taken into consideration, several technical details managed with precision, and every potential complication predicted. In this context, the importance of LVAD patients’ mental well-being, threatened by an extremely stressful everyday reality, may be underestimated. These patients receive complex regimens and undergo painful procedures, have to deal with uncertainty on a day-to-day basis, and may have to come to terms with their own death. Stress responses and emotional reactions, often clinically significant, arise and can interfere with clinical care.

Emotional dysregulation and mental illness may affect the well-being of these patients in several ways. It has been shown that a concomitant psychiatric diagnosis predicts worse outcomes in patients with heart failure and patients with an LVAD, whereas psychiatric treatment can improve cardiovascular outcomes. Psychiatric disorders impair patients’ ability and motivation to adhere to their regimen, which is of the utmost importance in the complex clinical scenarios involving LVADs. Moreover, depression and other psychiatric disorders are independent determinants of quality of life and should be among the priorities when treating patients with chronic illnesses. Finally, end-stage heart failure represents a severe chronic stressor for both patients and family members; this may ‘burn out’ caregivers and weaken social support, adversely affecting patient outcomes.

Early identification and treatment of mental illness in patients with LVADs requires a high index of suspicion and a low threshold for utilizing effective interventions. These interventions should be individualized to the patient’s needs and may range from supportive counseling to inpatient psychiatric care. An empathic and supportive approach is often the most decisive intervention. Active listening to the patient’s experience and empathic statements may improve dysfunctional attitudes toward disease and increase compliance rates. Exploring the meaning that end-stage heart disease holds for patients and family members and understanding their coping and defense mechanisms can be very informative. Defense mechanisms (e.g. denial) should not necessarily be viewed as dysfunctional attitudes that need to be eradicated, but rather as unconscious efforts to minimize anxiety and as opportunities to learn something about the patient. Family caregiving is a significant contributor to recovery, but is particularly burdensome to caregivers. Constant education of family members and access to support systems may ameliorate caregiver burden and improve outcomes. Counseling, stress management, and psychiatric consultation can be used for both patients and caregivers, and should ideally be provided in the setting of interdisciplinary teams.

References:
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COLLABORATION, CONFORMITY AND CONSENSUS

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The ISHLT is a professional organization dedicated to improving care of patients afflicted with advanced heart and lung diseases. Our Society comprises various individuals across the globe and many professional disciplines further grouped into Councils, Committees and Boards. Each member, new and old, from different genders and nationalities, contributes to our organization yielding a widely diversified group of experts with the same mission or goal. As all of us are leaders in our own centers and communities, we must be cognizant of the strengths and weaknesses of groups working together. The success of our mission stems primarily through collaboration, conformity and consensus. Allow me to share with you these concepts as gleaned from my understanding of the books by Michael Roberto: Why Great Leaders Don’t Take Yes for an Answer and Know What You Don’t Know.

First, none of us are as smart as all of us. When groups of individuals synergize, work in harmony, and/or have mass collaboration, then two or more heads can be smarter than one. However, groups can perform worse than the best individual performer among them. Ideally, groups, committees, councils or boards allowing independent aggregation of individual information, judgments, or opinions can generate better plans or make better decisions than an individual can make on their own. From his book, The Wisdom of Crowds, James Surowiecki devised important criteria justifying the wisdom of crowds over an individual.

1. Diversity – we have this within the ISHLT which includes many different disciplines and perspectives that are well represented
2. Decentralization – the dispersion of local and specific knowledge
3. Compilation of information – difficult to achieve, but doable, a means of including all individual judgments
4. Independence

Independence of team members is frequently violated, which is the main reason why groups or teams cannot achieve their potential. To maintain independence we cannot create circumstances where social, emotional and even political influences could persuade or sway the thoughts, judgments or opinions of each member of the group. Frequent meetings, for example, can result in too much interaction which in turn evokes interdependence thus violating the important independence criteria.

This loss of independence to interdependence sets the stage for conformity, our next topic. Unfortunately, despite the ISHLT’s collective cohesiveness, great intellect, knowledge, ambition, diversity and good intentions, we could fall and probably have fallen victim to conformity (groupthink) many times.

What is groupthink? I refer you to the book, Victims of Groupthink, by the Social Psychologist from Yale University, Irving Janis. He describes groupthink as the tendency for groups to minimize conflict leading to consensus without sufficiently evaluating and analyzing all disparate ideas or opinions. The pressures of conformity constrain critical thinking of the group. The team prematurely converges to an answer, judgment, opinion or solution at the expense of critical thinking.

Early symptoms of groupthink emerge when a team feels invulnerable, rationalizes away from contradictory data and fails to heed warnings (falling victim to confirmatory bias), believing they are better than their rivals and suppress dissenting views. Most importantly and more commonly, it is the individual team member who self-censors his differing opinion in fear of being ostracized. In short, groupthink could be merely a means of going along to get along.

It’s the mission of this newsletter to permit dissenting or contradictory opinions. Our intention is to develop the Links as a means of mass collaboration within the ISHLT similar to Wikipedia – a lofty but achievable goal for our society of over 2500 members. The Links will permit any input, feedback or idea that should be free from any social, emotional or political persuasion, coercion or retribution. There should be no fear of being marginalized or ostracized.

The primary benefit of submitting information electronically with mostly grammatical emendations is the maintenance of independence. Also, the potential for unencumbered creative thoughts, opinions or concepts freely expressed out in the open for the ISHLT is to allow review and critical analysis which sets the stage for a “true consensus.”

Consensus (which, according to Webster’s Third International
Unabridged Dictionary, is defined as harmony, cooperation, or sympathy especially in different parts of an organism, group solidarity in sentiment and belief, or general agreement, is the key ingredient to implementation. We must recognize that consensus is not and does not require unanimity. Consensus is not a majority vote; every opinion counts. Consensus allows for dissent, addresses dissent but does not always accommodate dissent. Consensus is better defined as the combination of commitment and shared understanding. Commitment without shared understanding is blind devotion. Is that what tyrants want? Do we want blind devotion to duty? Do we want thoughtless perfunctory minions within a group or team that cannot decide for themselves during minor ambiguous situations? This is what micro-managers prefer.

A professional group or organization without any understanding of the mission or plan will have no consensus. At the same time, shared understanding without commitment will result in no dedication or cooperation. Consensus requires commitment and understanding. We should not give in, conform, or lock ourselves into groupthink. When collaborating we should be able to express our dissenting views within a group with the ultimate goal of reaching a consensus. In science where consensus is most important, unanimity is virtually impossible.

An example of outstanding collaboration and consensus is what the AOL 31 Days of Horror countdown named in 2007 as the greatest horror movie of all time, John Carpenter's *Halloween*. The success of *Halloween* is a testimony to the collaboration and consensus of John Carpenter, Debra Hill, Irwin Yablans, Moustapha Akkad, Nick Castle (Carpenter’s friend from college who played “The Shape,” the masked Michael Myers) and many others including Jamie Lee Curtis in her film debut. This group turned an estimated $325,000 investment into $60 million dollars making it one of the most profitable independent films. Imagine the profit margin that the Theme Music to *Halloween* by John Carpenter reportedly created overnight on the critical advice of others. What could the ISHLT do with such collaboration and consensus?

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**A BRIDGE OF LIFE**

*Children’s Med Dallas* is an unprecedented look behind the walls of an extraordinary hospital and into the world of the doctors, nurses and medical professionals that dedicate their talents, passions and lives to the pursuit of caring for children.

The season finale includes 2-year-old Rylynn Riojas who was born with Hypoplastic Left Heart Syndrome and was placed on the transplant list in Dec. 2010. Rylynn’s heart condition worsened, and the only way to bridge Rylynn to transplantation would be to implant a Berlin Heart.

Watch ISHLT member Dr. Kristine Guleserian, surgical director of Pediatric Cardiac Transplantation at Children’s, to save Rylynn’s life. [http://www.youtube.com/watch?v=liUmyR2MCiY](http://www.youtube.com/watch?v=liUmyR2MCiY)

To view the entire episode, go to [www.childrensmeddallas.com](http://www.childrensmeddallas.com).