

EC4

A Novel Emboli Protection Cannula During Cardiac Surgery: First Animal Study

Shani, Liran¹; Cohen, Oved¹; Beckerman, Ziv¹; Dilmony, Benny²; Hirshorn, Ori²; Antebi, Yonatan²; Gil, Bolotin¹

¹Rambam- Health Care Campus, Haifa, Israel; ²Cardiogard Ltd., Or-Yehuda, Israel

Objective: Stroke after open heart surgery is a major cause for morbidity and mortality. Up to 60% of intraoperative cerebral events are caused by emboli generated by manipulations of the aorta during surgery. This is the first animal study to evaluate the safety and efficacy of a novel aortic cannula designed to produce simultaneous forward flow and backward suction in order to extract solid and gaseous emboli from the distal aorta upon their release during cardiac surgery.

Methods: The research group consisted of seven domestic pigs connected to cardiopulmonary bypass using a Cardiogard 24F aortic cannula. Three pigs cannulated with a standard aortic cannula were defined as the control group. Several main flow and suction regimens were carried out. Osseous particles of different sizes were injected into the proximal aorta so as to simulate emboli. An external filter was located on the suction tube in order to evaluate the amount of solid emboli caught by the cannula. The flow inside the carotid artery, with and without the backward suction, was documented by ultrasound during injection of the particles (figure 1).

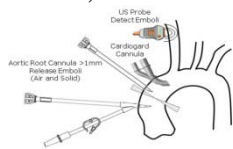


Figure 1. The experimental diagram of the research group.

Results: The Cardiogard cannula demonstrated an overall emboli retrieval rate of 77%. A rate of 88.45% was demonstrated during the low-flow regimen clinically used during aortic manipulation (figure 2). Gaseous and solid emboli were eliminated by suction, as demonstrated by epi-carotid ultrasound. No significant changes were observed in the hemodynamics and laboratory parameters for the research group (Cardiogard cannula) versus the control group

during and after surgery.

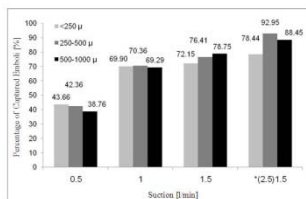


Figure 2. The emboli capturing results according to particles' sizes in the research group.

Net flow of 4 l/min was maintained during each suction values.

*Suction of 1.5 min and forward flow of 2.5 liter/min, simulating low flow conditions

Conclusions: The research cannula is as simple to use as the regular aortic cannula currently commercially available, having a similar safety profile and proven efficacy in capturing intraoperative emboli in vivo.

Expandable External Support Device to Improve Saphenous Vein Grafts Patency After CABG

Ben-Gal, Yanai¹; Taggart, David²; Williams, Matthew³; Orion, Eyal⁴; Aviram, Galit⁵; Banai, Shmuel⁶; Yosef, LYad⁴; Bolotin, Gil⁷

¹Tel Aviv Medical Center, Cardiothoracic Surgery, Tel Aviv, Israel; ²Oxford, John Radcliffe Hospital, Cardiothoracic Surgery, Oxford, United Kingdom; ³Columbia University Medical Center, Cardiothoracic Surgery, New York, USA; ⁴Radbiomed, VGS, Tel Aviv, Israel; ⁵Tel Aviv Medical Center, Radiology, Tel Aviv, Israel; ⁶Tel Aviv Medical Center, Cardiology, Tel Aviv, Israel; ⁷Rambam Medical Center, Cardiothoracic Surgery, Haifa, Israel

Objective: Low patency rate of saphenous vein grafts (SVG) remains a major predicament in surgical myocardial revascularization. We developed a novel expandable external support system to mitigate causative factors for early and late vein grafts failure.

Methods: For the preclinical study fourteen adult sheep underwent off pump revascularization using two vein grafts for each; one to the LAD and the other to the largest obtuse marginal. One graft was supported with the device while the other served as a control. The target vessel was alternated in every case. The animals underwent immediate and late (12 weeks) angiography and then were sacrificed for histopathologic evaluation.

Results: There were three perioperative deaths that were unrelated to the device implanted and all animals but one survived the follow-up period. Among the surviving animals, three grafts were thrombosed and one was totally occluded, all in the control group ($p= 0.043$). In quantitative angiographic evaluation, there was no difference between groups in the immediate postoperative level of grafts uniformity (coefficient of variance (CV) of control grafts was 7.39 vs. 5.07 in the supported grafts, $p=0.082$). At 12 weeks, there was a significant non uniformity in the control grafts versus the supported grafts (CV = 22.12 vs. 3.01, $p<0.002$ respectively).

Moreover, in histopathologic evaluation the mean neointimal area of the control grafts was significantly larger than in the supported grafts (23.1mm² vs. 11.1mm² $p<0.02$, respectively). There was no difference in the level of inflammation or intimal injury between groups.

Conclusion: The expandable SVG external support system was found to be safe and efficacious in reducing SVG's non uniform dilatation and neointimal formation in animal model early after CABG. This novel technology may have the potential to improve SVG patency rates after surgical myocardial revascularization.

Numerical Model of Aortic Cannula Hemodynamics for Evaluation of Risk for Atheroembolism

Avrahami, Idit¹; Dilmoney, Benny²; Bolotin, Gil³

¹Ariel University Center of Sameria, Mechanical Engineering, Ariel, Israel; ²Cardiogard, R&D, Ariel, Israel; ³Rambam Medical Center, Department of Cardiac Surgery, Haifa, Israel

Objective: Atheroembolism from the ascending aorta is a major cause of noncardiac complications following cardiac surgery. The hemodynamics of the aortic cannula has been proven to play a significant role in atheromatous emboli generation. The design of aortic cannula is a main determinant of the flow pattern and flow velocity within the patient's aorta. The current study presents a detailed 3D numerical simulation of the flow inside the clamped aorta during cardiopulmonary bypass (CPB) and compares the flow characteristics of several cannulae designs.

Methods: Numerical models of different cannulae designs placed in a clamped aorta are presented. The models were subjected to physiological blood flow in several conditions during CBP and different cannulae orientations were examined. The numerical models were validated using in-vitro measurements of pressure drop and velocity.

Risk evaluation and hemodynamic parameters are compared, including emanating jet velocity, aortic wall reaction, emboli path lines, distribution between upper and lower vessels, risk for hemolysis, stagnation regions, and pressure drop. The simulations utilized the commercial software ADINA (ADINA R&D Inc., MA) to solve the set of fluid equations using the finite elements scheme.

Results: Cannula with straight tip generate large reaction on the aortic wall and divert more emboli from the clamp region to the descending aorta. However, cannula with sharp angled tips exhibit stronger emanating jet, higher shear stress in the cannula, more stagnant flow near the clamp region, and highly disturbed flow. Cannula with moderate angled tip demonstrate less reaction on the aortic wall and divert more emboli from the clamp region to the upper vessels.

Conclusions: The simulation results prove the significant role of cannula design and orientation in atheromatous emboli generation. The tip angle and cannula orientation in the aorta are crucial parameters in all hemodynamic aspects.

Multi-Disciplinary Outpatient Clinic for VAD Patients With an Intensive Surveillance Protocol

Abuhazira, Miri¹; Golobov, Dimitry¹; Yaari, Viki²; Gelkop, Marta¹; Porat, Eyal¹; Valdman, Andrey²; Ben-Gal, Tuvia²; Medalion, Benjamin¹

¹*Rabin Medical Center, Beilinson Campus, Cardiothoracic Surgery, Petach Tiqva, Israel;*

²*Rabin Medical Center, Beilinson Campus, Cardiology, Petach Tiqva, Israel*

Background: With the increasing number of heart failure patients, and with the relatively constant low number of heart transplants, more patients are supported with left ventricular assist devices (LVAD). The current LVADs allow the patient to ambulate and to return to activity at home. An intensive surveillance protocol (ISP) clinic was established based on 3 areas of practice:

-A multi- disciplinary clinic including a cardiologist, cardiothoracic surgeon, and a VAD coordinator. Also included clinical pharmacist, social worker, dietician and a heart rehabilitation team.

-Weekly phone call conducted by the VAD coordinator.

-Visit and checkup protocol in a decreasing frequency that includes: routine checkup, echocardiography, right heart catheterization, blood tests, and cultures from the VAD driveline site insertion.

Methods: In order to examine the satisfaction of patients and community teams from the clinics activity, a primary survey was conducted on 10 ambulatory LVAD patients that are currently on our service, and in 5 relevant community clinics. The answers are given on a scale of 1-4 (1- lowest, 4 - highest).

Results: Patient questioner:

Satisfaction from the device - 3.9. Improvement in daily activity - 3.6.

Satisfaction of treatment's quality - 4. VAD team's availability - 4.

Improvement in exercise capability - 2.5. Back to work cycle - 1.6.

Improvement in CHF symptoms - 3.5. Caregiver availability - 3.2.

Community team's questioner:

Satisfaction of contact frequency - 3.1. Satisfaction of contact quality - 3.3.

Knowledge about VAD before ISP - 1.2.

Knowledge about VAD following ISP - 2.5.

Awareness to complications - 2.2. Availability of VAD team - 3.7.

Conclusions: Operating a clinic according to ISP, improves patients satisfaction. Most VAD patients are satisfied with the surgery and report improvement in quality of life. Community caregivers are satisfied with the ISP but lack of knowledge was noticed and requires further improvement.

VAD Driveline Infections Along Two Different Periods of Treatment

Abuhazira, Miri¹; Golobov, Dimitry¹; Yaari, Viki²; Galkop, Marta¹; Porat, Eyal¹; Ben Gal, Tovia²; Medalion, Benjamin¹

¹Rabin Medical Center, Cardio-Thoracic Surgery, Petach Tikva, Israel; ²Rabin Medical Center, Cardiology, Petach Tikva, Israel

Background: The main complication of long-term LVAD surgery is infection around the Drive Line. To reduce the rate of infection, and improve the quality of care a unique system was established for treating and monitoring these patients. The purpose of this work to examine the incidence of infections in both time periods, before and after implementation of the unique treatment.

Methods: In 2008, we began LVAD implantation in our department, until the end of 2009 the patients were treated as ordinary patients. In order to improve the outcomes and work processes, many changes and activities have been introduced in the management of these special patient care. A clinic was Established according to 3 criteria: monitoring by a surgeon, cardiologist and vad coordinator as well as a broad multidisciplinary team, visits by protocol, blood tests, right heart catheterization, and Echo, and a weekly phone call for early detection of complications. The surgical technique has been modified - the cable is mostly left in abdominal wall. in addition the technique for dressing the wound around DL has been improved (sterile technique, anti-bacterial dressings, double fixing) training program have been establish to educate hospital staff and the community caregivers.

Results: in 2008-2009 were analyzed 7 patients had surgery, 5 of them were released to their home ,all of them suffered deep infections around DL, requiring broad-spectrum antibiotics for long periods of time, two of them required debridement surgery.

In 2010-2011 after these changes were implemented 17 patients had surgery, 13 were released to their home, only one patient had a deep infection of DL, 2 patients had superficial infection treated with oral antibiotics, use a double concentration antimicrobial dressing and they recovered.

Preoperative Determinants of Transfusion and their Effects on Transfusion Rates in Cardiac Surgery

*Freedman, John; Vernich, Lee; Howell, Alanna; Luke, Katherine
St Michaels Hospital, University of Toronto, Toronto, Canada*

Preoperative anemia is a major determinant of perioperative transfusion. Data is presented on cardiac surgery patients seen in 2010.

In CABG patients seen by the Transfusion Coordinator, 23.2% were transfused vs 32.4% if not seen. Transfusion rates were affected by gender and age, hemoglobin (Hb) levels, lead times prior to surgery, and by preoperative treatment of anemia. Women were twice as likely to be transfused (50.6% vs 22.9%). Mean initial Hb was 128+15 and 142+13 g/L in women and men respectively: in those transfused, mean initial Hb was 129 and 121 g/L, in contrast to 143 and 133 g/L in nontransfused men and women respectively). Transfusion rates were 56% when initial Hb <130 g/L, 17% when >130 g/L and 10% when >140 g/L. Transfusion rates were inversely proportional to lead time and were 40.7% when <7 days, 25.7% when 7-15 days and 20.3% when >14 days. As lead time increased, there was increasing use of preoperative blood conservation. 4.4% of CABG patients, 13% of CABG+valve, 15% of valves, and 7% of minimally invasive cardiac surgery patients received erythropoietin (EPO; mean dose 100,000 IU and mean Hb increase was 14.9 g/L); mean Hb increase with IV iron was 10.6 g/L. Patients treated with EPO and/or IV iron had lower transfusion rates than those not treated. Length of stay and infection rates were significantly lower in nontransfused patients and thrombotic events were not higher in those who received EPO. Transfusion rates have decreased progressively since program inception (60.1% in CABG in 2002 vs 23.6% in 2010) and transfused patients receive fewer units (0.6 units in 2010 versus 2.0 units in 2002).

While other factors, including intra- and post-operative patient blood management measures, education and 'culture change', also play important roles, appropriate anemia management can significantly reduce transfusion rate and improve quality of care.

Predictors of Long In-Hospital Stay After Cardiovascular Surgery

Kerbage, Soraya; Giunta, Gustavo; Abud, Jose; Dulbecco, Eduardo; Raffaelli, Hector; Favaloro, Roberto

Favaloro Foundation, Cardiac Surgery, Buenos Aires, Argentina

Introduction: Cardiovascular surgery is the first option treatment in many diseases. Long in-hospital stay after CVS has direct impact in CVS costs/effectiveness ratio. The predictors of LHS are not consistently determined in literature. Objectives: To describe the population and evaluate predictors of LHS. Materials & Methods: Male and women older than 18 years old, referred to CVC in Favaloro Foundation between 2004 and 2007, were included. The procedures were divided in coronary bypass graft (CABG, n=1209), valve replacement or repair (VRR, n=703) or both (COMB, n=444). The data of post surgery in-hospital stay were separated in tertiles. LHS was defined as an in-hospital stay in the 3rd tertile for each surgery (CABG > 10, VRR > 12 and COMB > 10 days). Baseline characteristics of patients were assessed and compared in the three groups. Independent predictors of LHS were calculated by multiple logistic regression. Results: Patient baseline characteristics are present in Table 1. VRR group had more women than the others (VRR 45.5%, CABG 16%, COMB 26.8%, p<). CABG group revealed a high prevalence of coronary risk factor (diabetes 27.9 %, p<0.0001; hypertension 70.4%, p<0.0001; dyslipidemia 80.6%, p<0.0001; smoking 61.5%, p<0.0001). Multivariate analysis showed age (p<0.0001), ejection fraction (p<0.01), urgent-emergent (p<0.0001) and chronic kidney disease (p<0.005) as independent predictors of LHS in CABG. In VRR group, independent variables associated with LHS are urgent-emergent (p<0.001), chronic kidney disease (p<0.005), diabetes (p<0.05) and tricuspid intervention (p<0.01). Finally, urgent-emergent (p<0.05), ejection fraction (p<0.005), chronic kidney disease (p<0.01) and mitral intervention (p<0.01) independently predicted LHS in COMB group.

	CABG	VRR	COMB	p (Kruskal-Wallis ANOVA)
n	1209	703	444	
Age (years)	63.9 ± 9.6	58.9 ± 15.2	69.4 ± 9.3	< 0.0001
In-hospital stay	11 ± 11.8	13.2 ± 12	16.5 ± 17.8	< 0.0001

Conclusion: Association of independent variables is a useful tool in prediction of LHS. Development of scores that include combination of this variables, adjusted to CABG, VRR and COMB may be of great utility.

A Novel and Exceptional Approach to Acute Ischemic Stroke after Cardiac Surgery

Ishay, Y.¹; Matsa, M.¹; Abramov, Dan¹; Lev-Ran, O.¹; Ruderman, L.¹; Raichel, L.¹; Ifergan, G.²; Sahar, G.¹

¹Soroka Medical Center, Cardiothoracic Surgery Department, Beer Sheva, Israel; ²Soroka Medical Center, Neurology Department, Beer Sheva, Israel

Postoperative permanent stroke continue to be a devastating complication after open heart surgery with a reported incidence ranging from 1.3% to 4.3%. Although the causes of neurologic events after surgery are multifactorial, embolic phenomena are a major factor (62.1%).

Regardless of mechanism, strokes predominantly occurred within the first postoperative day (24 hours in 22.8% and after 24 hours in 77.2%).

Intravenous administration of rtPA (tissue plasminogen activator) is the only FDA-approved medical therapy (1996) for treatment of patients with acute ischemic stroke within 3 hours of stroke onset. However major surgery within previous 14 days constitutes a relative exclusion criterion for Fibrinolytic Therapy.

We have treated successfully 3 patients that developed from early ischemic stroke after CABG by Intravenous administration of rtPA with impressive clinical improvement and without any complication.

Being in a center of primary stroke care (PSCs). We have adopted a novel strategy and protocol for emergency evaluation and treatment of patients with suspected stroke after cardiac surgery that is the same as the 2010 American Heart Association Guidelines except the fact that our patients have a relative exclusion criterion for fibrinolytic therapy and the "time to treatment" is usually shorter than 3 hours.