We Share ...

KTPL has always been on the lookout for innovative products and services related to Indian health sector. Since the life style diseases such as cardiac problems are on the increase in our country, KTPL brought MGuard Coronary Stenting Systems to India.

It is satisfying to note that the acceptance of MGuard amongst interventional cardiologists in India is on the increase and its usage is showing satisfactory results. A few case studies on the successful usage of MGuard in this issue of ‘Share & Care’ makes an interesting reading.

It will be heartening to note that KTPL is starting a national registry on MGuard in STEMI.

To enlarge its scope of service to the cardiac fraternity KTPL is launching Non-Invasive Cardiac Systems (NiCaS) which allows for estimation of Cardiac Output Index (CI), Stroke volume Index (SVI) and Total Systematic Vascular Resistance (TSVR) through whole body bioimpedence monitoring. It will be another ‘first time in India’ solution for cardiac diagnostics. Abstracts from the studies based on the usage of NiCaS appear on page 6.

Happy reading and best wishes.

Amardeep Sethi
C.E.O.

World’s Leading Opinion Leaders from India
Sharing their Experience about MGuard™

Prof. Upendra Kaul
Fortis Group of Hospitals, New Delhi
“I find MGuard stents to be extremely useful in thrombus laden vessels. The chances of slow or No flow are minimized with very good TIMI flow in primary Acute STEMI.”

Dr. Ashok Seth
Fortis Group of Hospitals, New Delhi
“MGuard is quite an innovative stent and is extremely effective in trapping thrombus and soft plaque as is seen in acute MI and Saphenous Ven Graft. In many cases it may be invaluable for preventing distal embolization.”

Dr. Praveen Chandra
Medanta – The Medicity, Gurgaon
“The MGuard device shows excellent performance in highly complex lesions. In our preliminary experience there was an absence of angiographic and procedural complications. It can solve or control the problem of friable plaques and thrombus.”

Dr. M. S. Hiremath
Ruby Hall Clinic, Pune
“Based on my current clinical experience the MGuard stent appears to be superior to any other devices in overcoming the distal embolisation in highly thrombotic lesions.”

Dr. Thomas Alexander
Kovai Medical Center and Hospital, Coimbatore
“MGuard is undoubtedly a major advance in management of patients with STEMI. I particularly think that young patients with STEMI who have a very high thrombotic load will derive the greatest benefit from this stent.”

Dr. C. G. Bahuleyan
Ananthapuri Hospitals & Research Institute, Trivandrum
“I have used MGuard in patients with Acute Coronary syndrome. Most of the lesions were thrombus containing. I found it is effective against distal embolization and it enhances the achievement of optimal myocardial perfusion.”

Dr. Anand Shenoy
Manipal Hospital, Bengaluru
“I found MGuard stent to be very useful in difficult cases where we want to keep procedure time short, avoid aspiration and distal protection device in ACS, AMI cases. It is easy to cross lesions to prevent slow flow/no reflow phenomenon.”

Dr. G. Sengottuvelu
Apollo Heart Institute, Chennai
“The MGuard stent is extremely useful in trapping the blood clots without further breaks. This gives a high procedural success, compared to other devices, with low rates of clot dislodgement into the distal branches during deployment.”

Dr. Sameer Dani
Apollo Heart Institute, Ahmedabad
“When I used MGuard stent for the 1st time in a SVG lesion, I was a bit sceptical. But the result with MGuard have been consistently good not only in SVGs but in other thrombotic lesions of native coronaries as well. It is a very interesting concept.

Dr. Keyur Parikh
Care Institute of Medical Sciences, Ahmedabad
“MGuard is an innovative device to improve embolic protection for PCI specially in MI and SVG, with outstanding results in heavily thrombotic lesions especially in primary PCI.”

Dr. Brian Pinto
Holy Family Hospital, Mumbai
“This is a simple and practical approach to treat thrombus containing lesions. Based on my experience I was able to treat very complex lesions without the need of distal protective devices.”

Happy reading and best wishes.

Amardeep Sethi
C.E.O.
Mr. Rajesh Kumar, 37 years old male was admitted with acute inferior wall MI on 9 Feb. 2012. He was found to have large thrombus before crux in RCA. Slow flow and thrombus persisted in spite of repeated aspiration by 7F thrombuer. Patient had complete heart block so TPI was done. 4.0 x 29 mm mesh covered MGuard stent was placed across the lesion with residual thrombus. Brisk flow was achieved after MGuard Stenting. We have done 20 cases of Primary PTCA with MGuard Stenting in whom significant residual thrombus was there inspite of aspiration by the export or thrombuser catheter. Brisk flow was achieved after MGuard stenting in all these patient inspite of slow or no re-flows before stenting.

Fig. 1 : Angiographic Study

Fig. 2 : Angiographic Study

Fig. 3 : MGuard Deployment

Fig. 4 : MGuard Deployment

Fig. 5 : Post Deployment

Dr. S.S. Bansal is the Director, Metro Heart Institute & Multispeciality Hospital, Faridabad. He is an eminent cardiologist and has been active in the field of interventional cardiology with a vast experience in various coronary catheterization procedures including peripheral & vascular angiography & angioplasty.
Unique Cases of MGuard™ Deployment

Alessio La Manna, Salvatore Davide Tomasello, Corrado Tamburino, “Treatment of a large thrombus containing lesion with the MGuard protective net coronary stent system: optical coherence tomographic evidence of complete plaque sealing” Clin Res Cardiol (2010) 99: 605-608 LeManna

79-year-old female with mild hypertension and dyslipidemia, previously treated with dual chamber pacemaker implant admitted for coronary angiography following an inferior ST elevation myocardial infarction and treated with a partial effective systemic thrombolytic therapy with reteplase.

Quoted from the case study “Although the patient treated in this report had a very high risk of distal embolization, MGS use provided a good result, confirming the previous findings obtained by other studies in the setting of STEMI patients.”

Alberto Hendler, Saar Minha, Ricardo Krakover, “A Novel Concept in Endovascular Stenting for the Treatment of Old Severely Degenerated Saphenous Vein Graft in the Urgent Setting” Catheterization and Cardiovascular Interventions 2010

64-years-old man admitted for a clinical, electrocardiographic, and enzymatic picture of NSTEMI. Subsequently, the patient developed severe post-MI angina with pulmonary congestion. He underwent CABG 19 years ago, with LIMA to the LAD and SVG to the OM and RCA. Cardiac catheterization showed a critically narrowed distal left main coronary artery (LMCA) and occlusion of the three major epicardial arteries. The SVG to the OM was chronically occluded showing a string sign pattern, the LIMA connected to the LAD was patent, and the SVG to RCA was subtotal occluded at its proximal segment with TIMI flow 0-1. It was decided to revascularize the SVG-RCA, which seemed to be the culprit vessel.

In this case it was not possible to use a distal protection device, and thus a 3.5/19 MGuard stent was implanted at the very proximal obstruction, inflated at 16 atm pressure. The result was very good and visualization clearly showed the distal vessel without evidence of slow or no-reflow. Following this, 3 additional MGuard stents were implanted 3.5/39, 3.5/19 and 3.5/12 successfully. Quoted from the case study: “The angiographic final result showed a wide open vein graft and native RPDA, with TIMI 3 flow and myocardial blush 3.”


61 year old patient, diabetic, hypertension, dyslipidemia, who underwent coronary artery bypass grafting in 1993 after an extensive anterior myocardial infarction. LIMA to LAD, two SVGs to large first diagonal branch and the posterior descending branch of the RCA, and a free RIMA to second obtuse marginal branch of the LCx artery.

Predilation was performed with a 4.0×12 mm semi-compliant balloon. A 4.0 × 24 mm MGuard stent, inflated at 16 atm for 10 seconds, was successfully deployed. A successful angiographic result with final. TIMI flow 3 was achieved.
A 41 year old female smoker, with no prior history of cardiac illness, presented with a 1 h history of chest pain at rest, the ECG showed anterior STEMI. She underwent diagnostic angiography, which confirmed thrombotic occlusion of the proximal LAD. Anterograde flow was restored after passage of a 0.014 @ angioplasty guidewire, but chest pain and ST segment elevation on the ECG persisted. The stenosis in LAD was predilated and treated with 3.5 3.24 mm LiberteTM bare metal stent. This resulted in distal displacement of thrombus; this was visible as mobile thrombus adherent to the exit of the stent. In an attempt to avoid distal embolization, this area was covered with 3.5 3.12 mm MGuard stent. The final result was excellent with TIMI III flow within LAD, no visible thrombus within the treated vessel, and no angiographic evidence of distal embolization.

**Fig. 7 :** Angiogram showing a thrombotic occlusion of the left anterior descending artery, before and after MGuard stent implantation.

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**New stent clears blocked artery, saves life**

**KOLKATA:** When 43-year-old M Pyne was wheeled into a city cardiac hospital last month, he was breathing heavily and his blood pressure had dropped. His pulse rate was plunging and his heart beats were slowing down. Struck by a massive cardiac arrest, Pyne didn’t respond to conventional treatment that failed to dissolve his arterial clots. It was a metal stent - MGuard - that finally saved his life. Pyne has recovered sufficiently to resume normal activities.

“The patient had an acute, extensive anterior wall myocardial infarction which, in ordinary parlance, means a massive heart attack. An angiography showed that one of his left coronary arteries had 99% blockage with multiple blood clots. For patients with acute heart attack, we normally use clot aspiration catheter to clear the blood clot from the artery. But in this case, the clots were too severe,” said Tarun Praharaj, senior consultant cardiologist at BM Birla Heart Research Centre, who treated Pyne.

Despite the use of aspiration catheter, there was no improvement in Pyne’s condition. The blocked artery remained filled with blood clots and they were now migrating down with no improvement in blood flow. Since the patient was going into a cardiogenic shock, with very low blood pressure, he could soon have died. “It was at this point that we decided to use the newly-introduced device known as MGuard. It effectively covered up the entire length of the lesion which was filled with clot. After deployment of the stent, there was significant improvement of blood flow and the patient gradually turned stable. His life was saved,” said Praharaj.

MGuard is a non-drug coated stent with a thin polymeric membrane. It’s the latter which prevents migration of clot. “This is particularly useful for patients with multiple clots that can’t be removed through catheterization. It can’t dissolve the clots but clears up the artery and prevents migration of the blockages,” explained Praharaj. MGuard has recently been introduced in India after being successfully used in several countries abroad.

**Times of India, Aug 20, 2011**

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**Cardiac stem cells can restore heart muscles, says study**

Infusion of cardiac stem cells into persons who suffered heart attack recently can help to regenerate their heart muscles, says a study published on February 14, in The Lancet.

Phase I of the study was conducted on 17 patients, who received stems cells, and eight, who received standard care (control group), at the Cedars-Sinai Heart Institute in Los Angeles and Johns Hopkins Hospital, Baltimore. All of them had had heart attacks about a month before the study began in May 2009. The stem cells were created from the patients’ heart tissues.

Visible improvements were seen in those who received infusion of stem cells, compared with the control group at the end of six months and a year. While no change in the scar size was seen in the control group, there was more than 12 per cent reduction in the size at the end of six months in the treatment group.

As scar size is directly related to scar mass, a reduction of 8.4 gram (28 per cent) and almost 13 gram (42 per cent) in scar mass was seen in the treatment group at the end of six months and 12 months.

Surprisingly, scar mass reduction was accompanied by an increase in viable myocardial mass. In fact, on an average, the increase in viable myocardial mass was “about 60 per cent more than scar reduction.” This is significant as it had led to a “partial restoration of lost left ventricular mass in patients with CDCs [cardiosphere-derived cells],” the authors of the study noted.

The study thus “challenges the conventional wisdom that once established, cardiac scarring is permanent, and that, once lost, healthy heart muscle cannot be restored.”

However, a change in scar size was accompanied by only 2 per cent increase in ejection factor (the amount of blood pumped by the heart), which is not considered significant.

While “the reasons for the discrepancy are unclear,” the study noted that “ejection factor at baseline was only moderately impaired, leaving little room for improvement.”

Of the six patients in the treatment group who had serious adverse events, only one was found to be related to the study.

**The Hindu, Chennai, February 14, 2012**
With more than a decade of research and development by leading scientists from around the world, NI Medical presents the NICaS (Non Invasive Cardiac Surveyor) - an innovative, noninvasive hemodynamic monitoring technology to India. The NICaS has received US FDA 510(K), CE Mark, Canadian MDL, and Japanese MHLW regulatory clearances.

“The NICaS CS is intended to monitor and display a patients hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, total peripheral resistance, and the Granov-Goor Index), in males and females with known or suspected cardiac disorders needing cardiac assessment.”

The NICaS provides data on Cardiac, Vascular, Respiratory, and Body Fluids parameters that can be used to facilitate diagnosis, guide therapy, and identify high risk patients. The accuracy of its primary parameter, cardiac output has been documented in five peer-reviewed journal articles, comparing more than 1,200 simultaneous measurements of thermodilution and NICaS. Data from two of these studies are shown below:

### NICaS Accuracy

* r = 0.96; Bias = -0.114; Precision = 0.982

The NICaS reports present the data in easy to understand and clinically powerful formats, as shown in the Patient Series Report. These data and reports:

- facilitate proper diagnoses,
- guide medical management, and
- identify patients at high risk.

Clinicians have discovered that these reports particularly helpful in

- heart failure,
- hypertensive,
- dyspnea, and
- critically ill patients.

Additionally, these data can facilitate pacemaker optimization.

NICaS determinations of cardiac output meet the US FDA's standards for claiming statistical bioequivalence to thermodilution-determined cardiac output.

Because the NICaS is noninvasive and easy to use, it can be used in hospitals, outpatient clinics, pharma clinical trials, and even in home health care settings.
Whole Body Bioimpedance Monitoring for Outpatient Chronic Heart Failure Follow up

Yusuke Tanino, MD; Junya Shite, MD; Oscar L Paredes, MD; Toshiro Shinke, MD; Daisuke Ogasawara, MD; Takahiro Sawada, MD; Hiroyuki Kawamori, MD; Naoki Miyoshi, MD; Hiroki Kato, MD; Naoki Yoshino, MD; Ken-ichi Hirata, MD

Background: Although cardiac output index (CI), stroke volume index (SVI), and total systemic vascular resistance (TSVR) are important hemodynamic parameters for the prognosis of chronic heart failure (CHF), they are difficult to measure in an outpatient setting. Whole body bioimpedance monitoring using a Non-Invasive Cardiac System (NICaS) allows for easy, non-invasive estimation of these parameters. Here, whether NICaS-derived hemodynamic parameters are clinically significant was investigated by relating them to other conventional cardiovascular functional indices, and by evaluating their predictive accuracy for CHF readmission.

Methods and Results: Study subjects of 68 patients with CHF were enrolled in the study immediately upon discharge from the hospital. NICaS-derived CI, -SVI, and -TSVR values obtained at an outpatient clinic were significantly related with left ventricular ejection fraction (LVEF) measured by echocardiography, serum B-type natriuretic peptide (BNP), and exercise tolerance. During the 100±98 days follow up, 15 patients were readmitted to our hospital for CHF recurrence. Multivariate analysis indicated that LVEF, NICaS-derived CI, NICaS-derived SVI, and plasma BNP were significant indicators (receiver operating characteristic curve cut-off point, LVEF: 37%, NICaS-derived CI: 2.49 L · min⁻¹ · m⁻², NICaS-derived SVI: 27.2 ml/m², plasma BNP: 344 pg/ml) for readmission.

Conclusions: Hemodynamic parameters derived by NICaS are applicable for the non-invasive assessment of cardiac function in outpatient CHF follow up.

Advance Publication by J-STAGE

Impedance cardiography revisited

G Cotter, A Schachner, L Sasson, H Dekel and Y Moskovitz; Divisions of Clinical Pharmacology and Cardiology, Duke University Medical Center, Durham, NC, USA; Angela & Sami Shamon Cardiothoracic Surgery Department, Woffson Medical Center, Israel; Department of Cardiac Surgery, Assuta Hospital, Petah Tikva, Israel

Abstract: Previously reported comparisons between cardiac output (CO) results in patients with cardiac conditions measured by thoracic impedance cardiography (TIC) versus thermodilution (TD) reveal upper and lower limits of agreement with two standard deviations (2SD) of approximately ±2.2 L/min, a 44% disparity between the two technologies. We show here that if the electrodes are placed on one wrist and on a contralateral ankle instead of on the chest, a configuration designated as regional impedance cardiography (RIC), the 2SD limit of agreement between RIC and TD is ±1.0 L/min, approximately 20% disparity between the two methods. To compare the performances of the TIC and RIC algorithms, the raw data of peripheral impedance changes yielded by RIC in 43 cardiac patients were used here for software processing and calculating the CO with the TIC algorithm. The 2SD between the TIC and TD was ±1.7 L/min, and after annexing the correcting factors of the RIC formula to the TIC formula, the disparity between TIC and TD further declined to ±1.25 L/min. Conclusions: (1) in cardiac conditions, the RIC technology is twice as accurate as TIC; (2) the advantage of RIC is the use of peripheral rather than thoracic impedance signals, supported by correcting factors.


Impedance Cardiography for Cardiac Output Estimation Reliability of Wrist-to-Ankle Electrode Configuration

Oscar Luis Paredes, MD; Junya Shite, MD; Toshiro Shinke, MD; Satoshi Watanabe, MD; Hiromasa Otake, MD; Daisuke Matsumoto, MD; Yusuke Imuro, MD; Daisuke Ogasawara, MD; Takahiro Sawada, MD; Mitsubishi Yokoyama, MD

Methods and Results: To evaluate the reliability of NICaS derived CO (NI-) CO), 50 CO measurements were taken simultaneously with thermodilution (TD-CO) and modified Fick (Fick-CO) in 35 cardiac patients, with the TD-CO serving as the gold-standard for the evaluation. Overall, 2-tailed Pearson’s correlation and Bland Altman limits of agreement between NI-CO and TD-CO were r=0.91 and –0.106 and 0.68 L/min and between Fick-CO and TD-CO, r=0.89 and –1.52 and 0.88 L/min, respectively. Good correlation was observed in patients with loading conditions altered by nitroglycerin and also in patients with moderate valvular diseases.

Conclusion: Agreement between NI-CO and TD-CO is within the boundaries of the FDA guidelines of bioequivalence. NI-CO is applicable for non-invasive assessment of cardiac function.

Circ J 2006; 70: 1164–1168

Accurate, Non-invasive Continuous Monitoring of Cardiac Output by Whole-Body Electrical Bioimpedance

Gad Cotter, MD; Yaron Moskowitz, MD; Edo Kaluski, MD; Amram J. Cohen, MD, FCCP; Hilton Miller, MD†; Daniel Goor, MD; and Zvi Vered, MD

Accuracy of CO monitoring by the non-invasive cardiac system (NICaS) was compared to the Fick-CO and thermodilution CO (TD-CO) and the correlation between NICaS and TD-CO was r=0.886, with a small bias (0.0009 ± 0.684 L) [mean ± 2 SD], and this finding was consistent within each group of patients. Thermodilution readings were 15% higher than NICO when CI was > 1.6 L/min/m², and 5% lower than NICO when CI was > 3 L/min/m². The NICO has also accurately detected CI changes during coronary bypass operation and vasodilator administration for acute CHF.

Conclusion: The results of the present study indicate that whole-body bioimpedance CO measurements obtained by the NICO are accurate in rapid, noninvasive measurement and the follow-up of CO in a wide range of cardiac clinical situations.

CHEST 2004; 125:1431–1440
# Summary of MGuard™ Clinical Outcomes

**October 2011**

<table>
<thead>
<tr>
<th>Author/PI</th>
<th>No. of patients</th>
<th>Highlights</th>
<th>Publications/scientific meetings</th>
</tr>
</thead>
</table>
| Dariusz Dudek  
Institute of Cardiology, Krakow, Poland  
(MAGICAL Trial) | 60 | STEMI patients, multi-center  
90% TIMI flow 3  
73% Blush grade 3  
0% MACCE at 30 days  
1.7% MACCE at 6 months*  
The native stroke event | EuroIntervention, 2010  
Nov;8(5):S82-9 |
| Alexandre Abizaid  
Institute Dante Pantanese de Cardiology, Sro Paulo, Brazil  
(INSPIRE Trial) | 30 | SVG and native coronaries including ACS  
No EPD used  
3.3% MACE at 30 days  
17% TVR at 1 year  
0% Death at 1 year | Cat. and Cardiov. Int. Vol. 76  
Issue 1, Pages 86 - 92; 2010  
J. Am. Coll. Cardiol.  
2010;55:A180,E1680 |
| Eberhard Grube,  
Siegburg, Germany  
(First in Man Trial) | 41 | Stable angina in SVG and native lesion  
No EPD used  
3% MACE at 30 days  
19.5% TLR 6 months  
22% MACE at 6 months | The Journal of Invasive Cardiology : Vol. 20  
Issue 10 ; 2008 |
| Eugenio Martuscelli,  
Rome, Italy | 22 | SVG patients  
No EPD used  
91% TIMI 3  
0% angiographic evidence of no-reflow | ESC 2009 abstract (ESC P4087) |
| Federico Piscione,  
Naples, Italy | 100 | STEMI patients (n= 84, excluding cardiogenic shock)  
100% Device success  
Final cTFC = 17.2  
90% MBG 3  
90% Complete ST-segment resolution | Cat. and Cardiov. Int. Vol. 75  
Issue 5, pages 715-721 ; 2009 |
| Jain Ajay, Roshan Weerackody—London Chest Hospital, London, UK | 51 | STEMI patients (n= 49, excluding cardiogenic shock)  
0% death or MI at 12 months  
6% TVR at 12 months  
96% ST Segment resolution (>50%)  
100% TIMI 3 flow  
100% Procedural success | Cat. and Cardiov. Int. Vol 74  
Issue 1, pages 88-93 ; 2009  
Eurointervention Vol. 6  
Supp. H ; May 2010 |
| Hana Vaknin-Assa, Ran Kornowski Rabin Medical Center, Petach Tikva, Israel | 41 | 41 patients (83% with SVG lesions)  
100% Procedural success  
98% Final TIMI 3 flow  
7.3% MACE at 30 days  
22% MACE at 6 months | Cat. and Cardiov. Int. Vol. 74  
Issue 7 ; 2009  
Israel cardiology society congress, 2010 |
| Varshitzky, Boguslavsky, Loncar, Danenberg, Admon, Nassar, Lotan, Hadasah, Jerusalem, Israel | 38 | 38 patients (45% STEMI, 32% SVG)  
100% procedural success  
89% final TIMI 3 flow  
Clinical follow-up at a mean of 5±2.3 months:  
2.6% Death, 8% Restenosis, 2.6% TLR | Israel cardiology society congress, 2010 |
| Abizaid, Danzi, Lotan | 382 | Sub-analysis on 203 patients with STEMI and in whom only MGuardTM was implanted;  
98% visible thrombus  
98% TIMI 3 flow  
98% Procedural success  
2.8% Cumulative MACE at 30 days | TCT 2011 |

**Total Patients** 765
Bringing health and happiness to millions of patients.

**KTPL Updates**

Dr. Praveen Chandra, Chairman, Division of Interventional Cardiology, Medanta, making a presentation during TCT, 2011 held at San Francisco.

MGuard stall at TCT, 2011. Seen in the picture (left to right) Dr. Suman Bhandari, Director - Interventional Cardiology at Fortis Escorts Heart Institute, New Delhi; Mr. Miki Olsher; Renny Mathew, G.M.- Cardiovascular Division, Kirloskar Technologies and Prof. Sigmund Silber, Professor of Medicine.

Dr. M. S. Hiremath, Consultant Cardiologist & Director – Cardiac Cath Lab at Ruby Hall Clinic, Pune sharing his experiences about MGuard at the Evening Symposium held on the sidelines of ACVS, 2011 at Hyderabad.

(Left to Right) Amardeep Sethi, C.E.O., Kirloskar Technologies with Mr. Miki Olsher, Director Sales and Business Dev., InspireMD and Dr. Brian Pinto, Chief of Cardiology, Holy Family Hospital, Mumbai at ACVS, 2011, Hyderabad.

McGuard stall at TCT, 2011. Seen in the picture (left to right) Dr. Suman Bhandari, Director - Interventional Cardiology at Fortis Escorts Heart Institute, New Delhi; Mr. Miki Olsher; Renny Mathew, G.M.- Cardiovascular Division, Kirloskar Technologies and Prof. Sigmund Silber, Professor of Medicine.