Healthy Heart

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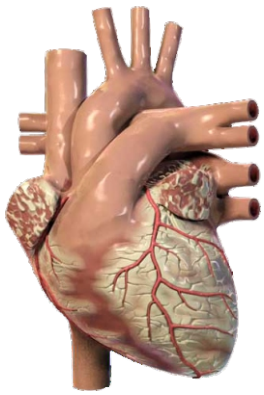

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From the desk of Editor:

Over the last several months, results of various important studies have been published. In this article, results of some of these studies have been discussed. These trials may increase our understanding of various diseases, how we should approach the patients and manage them thus being useful in our day to day practice.

Small studies done years back with glucose-insulin-potassium (GIK) drip have been found to be useful in MI after reperfusion. But there was lack of large randomized study. ***IMMEDIATE*** *study was a large randomized controlled trial where GIK was used very early (before reperfusion) in both AMI and ACS. In* ***ROMICAT II*** *trial, emergency department patients with chest pain suggestive of evaluation to strategy incorporating Coronary Computed Tomography Angiography (CCTA) early on significantly reduces length of stay and time to diagnosis, increases direct emergency department discharge rates without apparent increase in missed ACS. Off pump bypass surgery came before several years with the hope of improving survival and reducing complication of bypass surgery.* ***CORONARY*** *assessed effectiveness of off-pump compared with on-pump technique among patients undergoing coronary artery bypass grafting (CABG). Percutaneous aortic valve replacement is big achievement for patients with aortic valve disease. The results of* ***PARTNER*** *conducted to compare percutaneous transcatheter vs. surgical aortic valve replacement for high risk patients and intermediate term (2 year) were published recently. Aspirin and clopidogrel are standard treatment following recent ACS. Adding another anticoagulant, rivaroxaban-an oral factor Xa inhibitor, was assessed in* ***ATLAS ACS 2- TIMI 51*** *trial. Some of neutrally mediated syncope patients have asystole. Logically, pacemaker therapy should be useful in these patients. This was addressed in* ***ISSUE 3*** *trial.* ***CLOSURE*** *trial evaluated percutaneous closure of a patent foramen ovale (PFO) compared with medical therapy among patients with a cryptogenic stroke or transient ischemic attack (TIA).*

Dr. Urmil Shah

Recent Landmark Cardiovascular Trials of 2012

1) IMMEDIATE

A Double-Blinded Randomized Controlled Trial of Intravenous Glucose, Insulin & Potassium (GIK) for Acute Coronary Syndromes (ACS) in Emergency Medical Services

Experimental studies show that glucose-insulin-potassium (GIK) myocardial metabolic support, started immediately in cardiac ischemia, followed by reperfusion improves glucose, glycogen, energy metabolism and maintains cellular ATP levels, supports cardiac function and delays necrosis, decreases plasma and cellular Free Fatty Acid (FFA) levels. Previous studies have not evaluated GIK immediately after ACS and before reperfusion as well as not in ACS (done for AMI).

IMMEDIATE is a landmark randomized study conducted to test out-of hospital emergency medical service (EMS) administration of GIK in the first hours of suspected ACS. Intravenous GIK (30% glucose + 50U insulin + 80mEq KCL per liter @1.5 ml/kg/hr) solution was administered to 411 patients and a 5% glucose placebo was administered to 460 patients in the out-of-hospital setting and continued for 12 hours. The primary end point was the progression of ACS to MI.

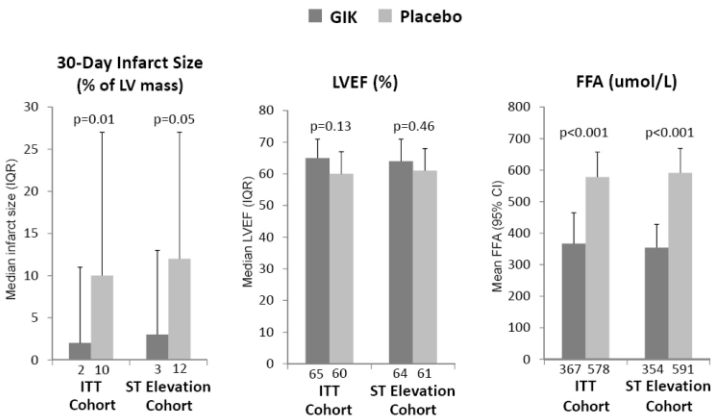


Figure-1

There was a statistically significant 52% reduction in the composite end point of cardiac arrest or in-hospital mortality (odds ratio 0.48; p=0.01). The rate of cardiac arrest or in-hospital mortality was 4.4% in the GIK-treated patients and 8.7% in the placebo arm.

Immediate EMS administration of GIK very early in the course of ACS and STEMI, consistent with preclinical research, can be done in a wide range of communities and EMS systems. Progression to infarction, the primary endpoint, was not prevented, but infarct size was significantly diminished. Composite endpoint cardiac arrest or acute mortality was significantly reduced, and FFA levels were lower, consistent with the proposed FFA link to arrhythmias. Risks and side effects rates from GIK are very low, and GIK is inexpensive, potentially available in all communities, and deserves further evaluation in trials for widespread EMS use.

2) ROMICAT II - Rule Out Myocardial Ischemia/ Infarction Using Computer Assisted Tomography

Chest pain (CP) suggestive of ACS is the most common presentation to the Emergency Department (ED). Current strategies to rule out ACS has limitation and that leads to overcrowded ED's, and unnecessary admissions. Despite a low threshold to admit patients up to 2% of patients discharged from EDs with missed ACS.

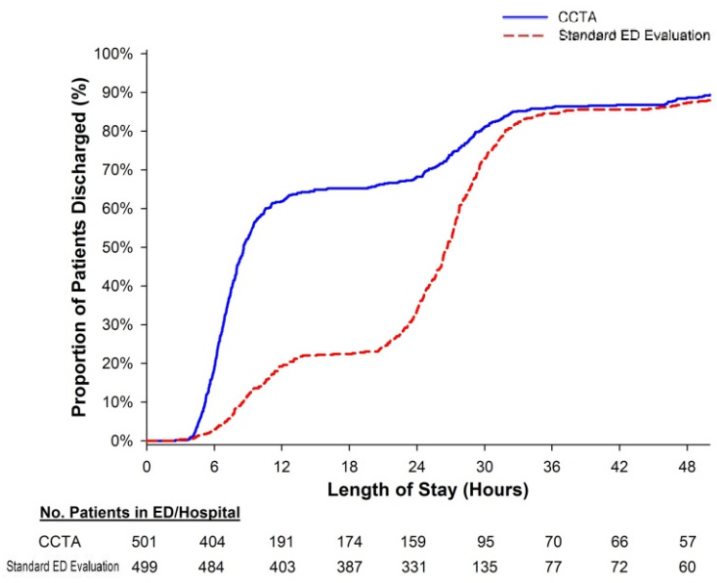


Figure-2

ROMICAT II study compared CCTA screening approach to standard care left to the discretion of the physician. The primary end point of ROMICAT II was length of stay. The average time to diagnosis was 10.4 hours in the CCTA group and 18.7 hours in the control group (p=0.001). By reducing the time to diagnosis of patients in the CCTA group were much more likely to be discharged directly from the emergency department (46.7% vs 12.4%). The safety of the CCTA-based approach was comparable to that of the standard approach. There were no missed ACS cases in either group, and major adverse events within 30 days were statistically similar in both the CCTA and standard-care groups (0.4 and 1.0, p=0.37).

In ED patients with chest pain suggestive of ACS, an evaluation strategy incorporating CCTA early on

significantly reduces length of stay and time to diagnosis, increases direct ED discharge rates without apparent increase in missed ACS. Moreover, there is no increase in costs of care despite more diagnostic testing in the CCTA arm when compared to current standard ED evaluation.

3) CORONARY: The Coronary Artery Bypass Grafting Surgery Off or On Pump Revascularization Study

The objective of the CORONARY study was to evaluate off-pump compared with on-pump technique among patients undergoing Coronary Artery Bypass Grafting (CABG). Patients with multivessel coronary artery disease undergoing CABG were randomized to have the procedure off-pump (n = 2,375) versus on-pump (n = 2,377). The first co-primary outcome was a composite of death, nonfatal stroke, nonfatal myocardial infarction or nonfatal new renal failure requiring dialysis at 30 days after randomization.

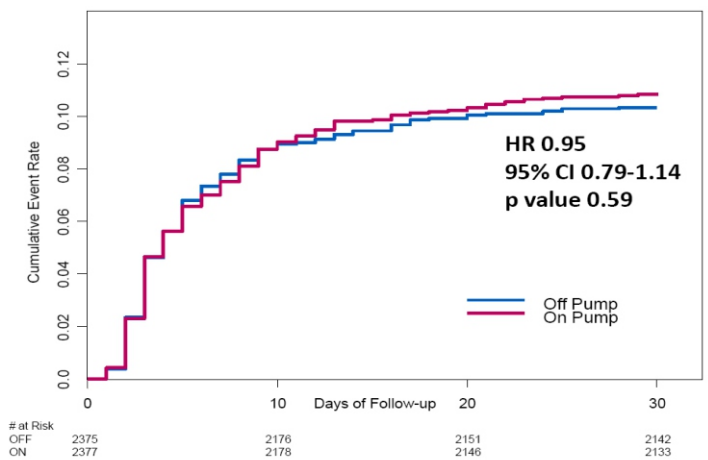


Figure-3

Among patients with multivessel coronary artery disease undergoing CABG, the off-pump technique did not improve the primary composite outcome of death, myocardial infarction (MI), stroke, or renal failure requiring dialysis. Although hard clinical outcomes were not improved, off-pump CABG reduced the need for transfusion, reoperation for bleeding, acute kidney injury and respiratory complications. Repeat revascularization was slightly increased with off-pump CABG and slightly fewer bypass grafts were performed.

In summary, there was no significant difference between off-pump and on-pump CABG with respect to the 30-day rate of death, myocardial infarction, stroke or renal failure requiring dialysis.

4) PARTNER Cohort A: TAVR vs. Surgical AVR

Patients with severe Aortic Stenosis (AS) considered at high risk (STS Score ⩾ 10%) for surgery were randomized to either Transcatheter Aortic Valve Implantation (TAVI) (transfemoral or transapical) or surgical Aortic Valve Replacement (AVR). Patients were followed up. Mortality rate, 30 day and 1 year were shown to be similar in PARTNER study. 2 year outcome data for the same study has been published recently.

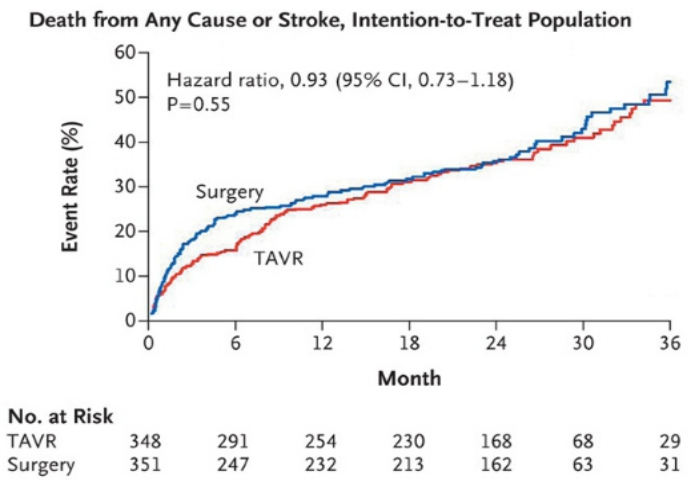


Figure-4

There was no difference in 2-year mortality (33.9% with TAVR vs. 35% with surgery; hazard ratio [HR], 0.90; 95% confidence interval [CI], 0.90-1.15; p = 0.41) or frequency of stroke (HR, 1.22; 95% CI, 0.67-1.22; p = 0.52). Endocarditis was uncommon (1.5% vs. 1%) and improvement in valve area was maintained at 2 years in both arms. Paravalvular regurgitation was more common with TAVR and was an independent predictor of death on follow-up.

5) ATLAS ACS 2- TIMI 51

Rivaroxaban in Patients with a Recent Acute Coronary Syndrome (ACS)

This study was conducted to see the effect of Rivaroxaban, oral direct factor Xa inhibitor, in patients with a recent ACS in addition to dual antiplatelet agent. A total of 15,526 patients with recent ACS were randomly assigned to receive twice-daily doses of either 2.5 mg or 5 mg of rivaroxaban or placebo for a mean of 13 months and up to 31 months. The primary efficacy end point was a composite of death from cardiovascular causes, myocardial infarction or stroke.

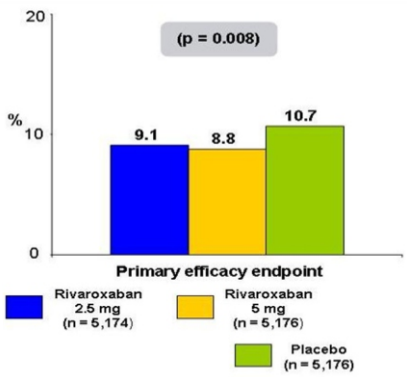


Figure-5

Rivaroxaban significantly reduced the primary efficacy end point, as compared with placebo, with respective rates of 8.9% and 10.7% (hazard ratio in the rivaroxaban group, 0.84; 95% confidence interval [CI], 0.74 to 0.96; P=0.008), with significant improvement for both the twice-daily 2.5-mg dose (9.1% vs. 10.7%, P=0.02) and the twice-daily 5-mg dose (8.8% vs. 10.7%, P=0.03). The 2.5-mg twice-daily dose had the better benefit/risk balance, due to a lower bleeding risk than the 5-mg twice-daily dose.

In summary, in patients with recent ACS, rivaroxaban reduced the risk of the composite end point of death from cardiovascular causes, myocardial infarction or stroke. Rivaroxaban increased the risk of major bleeding and intracranial hemorrhage but not the risk of fatal bleeding.

6) ISSUE 3

Pacemaker Therapy for Patients with Neurally-mediated Syncope and Documented Asystole: A Randomized Controlled Double-blind Trial

Previous two RCTs failed to prove superiority of cardiac pacing over placebo of unselected Neurally-Mediated Syncope (NMS) patients with positive tilt testing. Logically, pacing therapy should be effective for preventing syncope recurrence in patients with NMS and documented asystole. Those patients with NMS who has documented evidence of asystolic syncope ⩾3 seconds or nonsyncopal asystole ⩾6 seconds underwent Permanent Pacemaker (PPM) placement. Patients were then randomized to having the PPM turned on (DDD-RDR) or off (ODO).

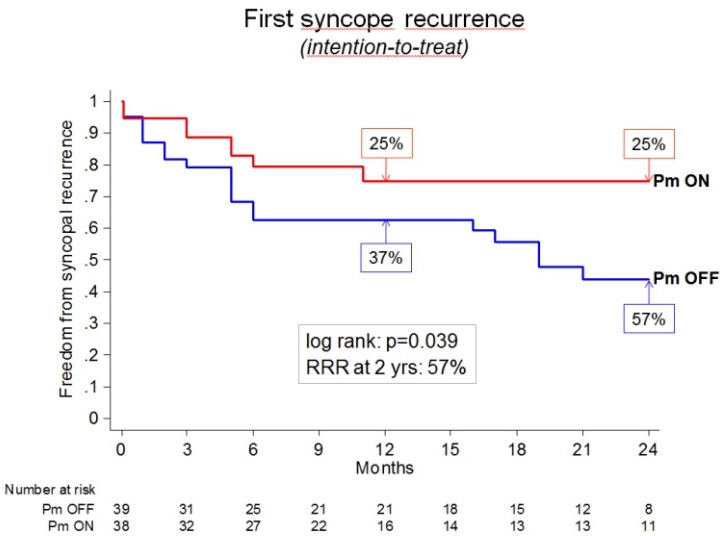


Figure-6

A total of 77 patients were randomized, 38 to PPM on and 39 to PPM off. Baseline characteristics were fairly similar between the two arms. About 12% had evidence of structural heart disease. The median total number of events in these patients was seven, with approximately five in the past 2 years. Approximately, 80% had evidence of asystole ⩾ 3 seconds and syncope; the mean length of asystole was 11 seconds. Presentation was a typical in 56% of the patients, and about 8% presented with major injuries related to fainting (fractures, concussion, etc.). The incidence of first syncope recurrence was significantly lower in the PPM on arm as compared with the PPM off arm at 24 months (25% vs. 57%, p = 0.039). Procedure-related complications were infrequent, with lead dislodgements in four patients and subclavian vein thrombosis in one patient.

The results of this trial indicate that dual-chamber permanent pacing is effective in reducing recurrence of

syncope in patients ⩾ 40 years with severe asystolic NMS. The overall strategy of using an Implantable Loop Recorder (ILR) in order to determine indication for pacing likely contributed to the positive findings and explains the discrepancy with the negative results of some previous report.

7) CLOSURE

Evaluation of the STARFlex Septal Closure System in Patients With a Stroke and/or Transient Ischemic Attack due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale

Since several years great debate is going on for Patent Foramen Ovale (PFO) closure in patient with a cryptogenic stroke or Transient Ischemic Attack (TIA). Patients with cryptogenic stroke or TIA presumably due to a PFO were randomized to PFO closure with the STARFlex device (n = 447) versus medical therapy (n = 462). Patients who underwent PFO closure were treated with clopidogrel 75 mg daily for 6 months and aspirin 325 mg daily for 2 years. Patients who received medical therapy alone were treated with aspirin 325 mg daily, or warfarin with international normalized ratio (INR) target 2 to 3, or combination aspirin and warfarin according to physician discretion.

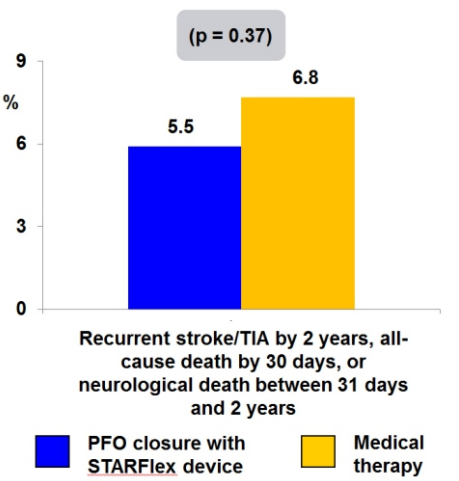


Figure-7

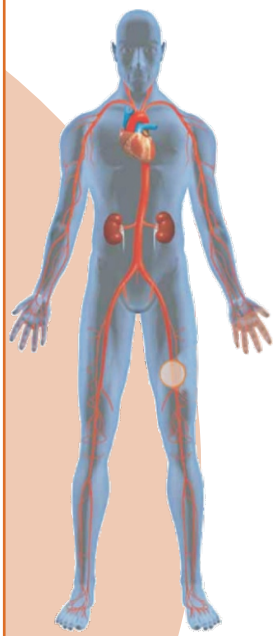
The primary outcome, recurrent stroke or TIA within 2 years, all-cause mortality within 30 days, or neurological mortality between 31 days and 2 years occurred in 5.5% of the PFO closure group versus 6.8% of the medical therapy group (p = 0.37). Within 2 years, the number of strokes that occurred was 12 versus 13 (p = 0.79) and the number of TIAs was 13 versus 17 (p = 0.44), respectively, for PFO closure versus medical therapy. Major vascular complications (left atrial perforation, groin hematoma, vascular surgical repair, peripheral nerve injury, procedure-related transfusion, and retroperitoneal bleed) occurred in 3.2% versus 0 (p < 0.001), atrial fibrillation occurred in 5.7% versus 0.7% (p < 0.001) and major bleeding occurred in 2.6% versus 1.1% (p = 0.11), respectively, for PFO closure versus medical therapy.

Among patients with cryptogenic stroke/TIA, percutaneous PFO closure with the STARFlex device did not reduce the incidence of the primary outcome at 2 years, nor did it reduce the number of strokes.

Conclusion

- IMMEDIATE is a nicely done randomized study for evaluation of GIK in very early phase of ACS and has shown definite benefit for cardiac arrest and limiting infarct size.
- Previous studies of CTA have shown usefulness in ED in patients with ACS. ROMICAT is another study which showed usefulness of CCTA for the same.
- Since many years there is big debate for on-pump and off pump bypass. The CORONARY study result clearly showed that both have similar outcome.
- Transcatheter Aortic Valve Implantation (TAVI) 2 year results are encouraging and has shown similar benefit which was found at 1 year.
- First oral anticoagulant (direct thrombin inhibitor), rivaroxaban, was found to be beneficial with an addition to dual antiplatelet agent in ACS patients.
- The neutrally mediated syncope is benign condition but sometimes associated with significant recurrence and can be dangerous in highly skilled professional. The benefits seen in ISSUE 3 study have clearly given us some guideline for usefulness of implantable loop recorder and dual chamber pacemaker.
- Since several years there is a big debate for and against putting device in patients with cryptogenic stroke or transient ischemic attack (TIA). CLOSURE study showed no advantage of putting device in this situation.

Peripheral Vascular Disease (PVD) Workshop by Dr. Ashit Jain



August 31 - September 1, 2012

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Dr. Ashit Jain is a well known Interventional Cardiologist practicing for the past 20 years in California, USA. Graduated from University of Delhi, completed Fellowship in Interventional Cardiology and Peripheral Vascular Disease at Ochsner Medical Center in New Orleans, USA, he has developed an extensive clinical research program at Washington Hospital in Fremont, California and is involved in multiple new device research technologies. He has also served as site principal investigator on over 26 multi-center clinical research trials and has written and presented many abstracts and publications in the field. A pioneer in Carotid Interventional Programs in the San Francisco Bay area, he is affiliated with five hospitals in the East Bay of San Francisco and has personally performed over 500 carotid interventions.

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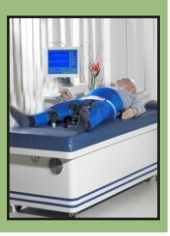

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