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Editorial

Heart Failure: Insights into Device Therapy

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Although pharmacologic therapy has made impressive advances in the past decade and is the mainstay of therapy for heart failure (HF), there is still a large unmet need, because morbidity and mortality remain unacceptably high. Implanted medical devices are gaining increasing utility in this group of patients and have the potentials to revolutionize the treatment of heart failure. The majority of devices in clinical use or under active investigation in HF can be grouped into 1 of 4 categories: devices to monitor HF condition, devices to treat rhythm disturbances, devices to improve the mechanical efficacy of the heart and devices to replace part or all of the hearts function.[1] The management of HF has changed significantly over the last 30 years, leading improvements in the quality of life and outcomes, at least for patients with a substantially reduced left ventricular ejection fraction (HFrEF). Device therapy in HF includes the implantable cardioverter defibrillator (ICD) and Cardiac resynchronization therapy (CRT). Beyond improving the quality of life and reducing the morbidity, CRT has also shown mortality benefit in selected patients.[2]

Chronic heart failure with reduced EF:

Use of cardiac intervention in chronic HF is mostly limited to implantation of ICD for primary or secondary prevention of sudden cardiac death (SCD) and implantation of CRT according to the indications as directed by guidelines of ESC, ACC/AHA etc. ICD reduces the risk of SCD and all causes mortality. CRT improves cardiac function and also improves HF symptoms and QOL (Quality of life) by restoring synchronous contraction of heart. The COMPANION trial and CARE-HF trials have showed superiority of CRT and CRT-D over optimal medical therapy in selected HF patients, in reducing mortality and HF related hospitalization.[3,4]

Cardiac contractility modulation:

Chronic HF patients that remain symptomatic with medical management or cannot tolerate maximum medical therapy and do not fulfil the criteria for CRT implantation, require new approach of treatment or new devices. CCM is a newer form of implantable device approved by FDA in March' 2019 for HFrEF patients who remain symptomatic despite medical therapy and not a candidate of CRT. It gives non excitatory electrical stimulation to ventricles during the absolute refractory period to enhance cardiac contractility without activating extra systolic contraction. It is being evaluated in patients with HFrEF who are in NYHA III or IV and found to improved exercise tolerance (↑peak Vo2), 6 min walk distance and QOL (Quality of life)[5].

Percutaneous ventricular restoration therapy:

Restoration of LV geometry and function is being considered by isolating damaged and nonfunctional muscle segments from functional myocardium to decrease the LV volume for patients with ischemic HF. It is done by trans catheter implantation of cardiokinetix parachute device. PARACHUTE IV trial is a multi-center RCT which is going on in different centers of USA & Canada evaluating the efficacy of this device on outcomes for patients with ischemic HF.[6,7]

For heart failure with preserve EF

LA Decompression:

Left HF is associated with resting or exercise induced increase in LAP and pulmonary

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congestion. There is also volume overload in HF patients, especially in HFrEF group. Medical management of HF is mainly aimed at reducing total body volume and intravascular pressure, especially in HFrEF but not in HFpEF. For the later group of patients, reducing LAP may confer symptomatic benefits. Scientists have developed devices to make communication between LA and RA and these reducing LAP.[8]

Three device systems are now available for maintaining the inter-atrial communications such as IASD system, V-wave device and AFR (Atrial flow regulator). IASD and AFR maintains bidirectional flow and v-wave device maintain unidirectional flow from LA to RA. These devices are deployed after trans-septal puncture. This device usually creates a shunt where Qp: Qs remains < 1.3. So, RA and RV can withstand with the extra load from LA for decades without compromising RV function. REDUCE – LAP – HF trial, phase I have evaluated IASD system, corvia medical, in patient of HFpEF and HFmrEF (EF≥40%). This study revealed 97% implantation success, 95% 1-year survival, improved NYHA class (P≤0.001), improved 6min walking distance by 33m (P≤0.001), significant fall in LVEDP (P≤0.001), significant rise in RVEF (P≤0.001) and reduced hospitalization (P≤0.05). Based on this study IASD system received CE mark approval for patients with HF with EF ≥40%.[9,10] A large scale trial REDUCE-LAP-HF II, is going on at this moment.[11]

'V' wave atrial septal shunt device has received break through status by FDA following a small clinical trial on 16 patients.[12] A large is under way called "RELLEVE-HF" trial which would include 500 patients.[13] Atrial flow regulator has also received breakthrough status by FDA following AFR-PRELIVE trial. All of these inter-atrial shunt devices are in their early stages of evaluation and large studies would reveal their safety and efficacy.[14,15]

Implantable Heart Failure monitor:

It is one of the important advancements by scientists for HF patients. Currently St. Judes Cardio MEMS HF system is the only FDA approved device which is inserted into pulmonary artery (PA) via a trans catheter approach. It detects the PA pressure and monitor the fluid retention due to worsening HF symptoms. Adjustments of medications can be made according to the pressure parameters and thus HF related hospitalization and expenditure can be reduced.[16,17]

Mechanical circulatory support in right heart failure (MCS):

Mechanical circulatory support is reserved for patient refractory to optimal management of acute or chronic right heart failure, to bridge to recovery, to bridge to heart, lung or heart lung transplantation and as destination therapy (permanent use). 42% to 75% may recover to allow MCS device explantation in acute form of heart failure.

In spite of its substantial benefits, CRT is underutilized even in developed countries like US & Europe. The number of CRT implants increased from 13,000 to 55,000 per year from 2002 to 2005 in USA: after 2005 the number of implants did not increase.[18] Hence even the developed nation citizens are finding it difficult to adopt such a promising but costly therapy. The situation is obviously worse in developing countries in the background of a strained healthcare economy. The cost burden it imparts to a developing economy remains its Achilles heel. For cost consideration we often only think about the first implantation; the cost of delayed complications and generator replacement should also be considered. The main hindrances for optimal use of cardiac implantable electronic devices (CIED) in HF patients include cost, understanding of the disease from patient and physician perspective, risk involved with implantation procedure, availability of experienced implanters in many areas, lack of dedicated HF clinic for specialized management of HF and need for long term follow up and management.[2]

Device therapy is a boon for HF patients but should be considered only after exhausting aggressive GDMT. Since the patients of developing countries like Bangladesh spend out-of-pocket for their health, the available therapies are unaffordable to the vast majority of the population. So, there is an urgent need to intervene to make the therapy affordable and available to HF patients. Development of national guideline for device therapy and follow up protocol according to national economy, development of trained manpower for device implantation and dedicated heart failure centres to ensure specialized service and research

work to give insights into the ethnic variation of management.

Conflict of Interest - None.

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