



Cardio Mag

Volume 2 | Issue 24 | 2021

Dear Doctor,
Greetings from Micro Labs Limited. We are happy to bring you "**Cardio Mag**", which contains latest and interesting news in the field of Cardiology.

This issue contains

- ✚ *Effect of Sotagliflozin in Patients with Diabetes and Worsening Heart Failure.*
- ✚ *Atrial flow regulator in a Complex Cyanotic Patient in Congenital Heart Disease: A novel approach.*
- ✚ *Novel technology to break Blood Clots.*

Should you require any specific article or medical information, please feel free to contact us at medicalservices@microlabs.in

Looking forward to your valuable feedback.

Best Regards,

Medical Team, Micro Labs Limited

1. Effect of Sotagliflozin in Patients with Diabetes and Worsening Heart Failure.

Sodium–glucose cotransporter 2 (SGLT2) inhibitors is a major therapeutic advance in the treatment of diabetes mellitus. Several SGLT2 inhibitors have shown to lower the risk of hospitalization for heart failure among patients with type 2 diabetes

Aim of the current study is to evaluate effect of sotagliflozin on the deaths, risks of cardiovascular hospitalization for heart failure, and an urgent visit for heart failure among patients with diabetes mellitus and recent worsening of heart failure with either reduced or preserved ejection fraction when



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administered soon after an episode of decompensated heart failure.

Methods:

The SOLOIST-WHF trial is a phase 3, double blind, randomized, placebo-controlled trial. 1200 patients underwent randomization (600 to the sotagliflozin group and 600 to the placebo group).

Patients included were those with type 2 diabetes mellitus recently hospitalized for worsening heart failure.

Patients were randomized to receive 200 mg of Sotagliflozin once daily (with a dose increase to 400 mg, depending on side effects) or placebo.

Patients were followed up at 1, 2, and 4 weeks, at 4 months, and every 4 months thereafter. Patients were followed for a median of 9.0 months.

Primary endpoint was The primary end point was the total number of deaths from cardiovascular causes and hospitalizations and urgent visits for heart failure (first and subsequent events).

Exclusion criteria include end-stage heart failure or recent acute coronary syndrome, stroke, percutaneous coronary intervention or coronary artery bypass surgery, or an estimated GFR of less than 30 ml per minute per 1.73 m² of body surface area.

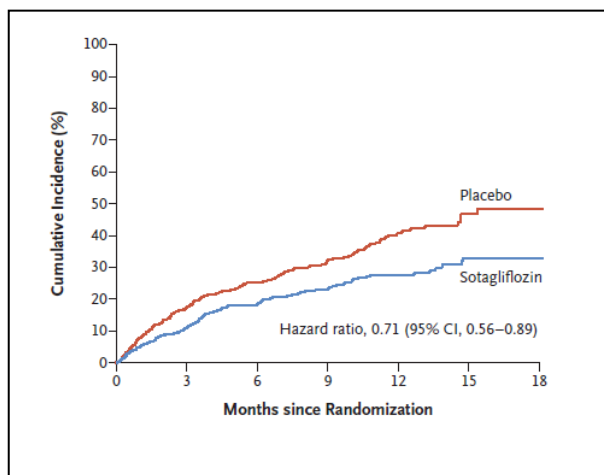
Results:

Primary end-point events occurred (240 in the sotagliflozin group and 340 in the placebo group). The rate (the number of events per 100 patient-years) of primary end-point events was lower in the sotagliflozin group than in the placebo group (51.0 vs. 76.3; hazard ratio, 0.67; 95% confidence interval [CI], 0.52 to 0.85; $P < 0.001$).

The rate of death from cardiovascular causes was 10.6 in the sotagliflozin group and 12.5 in the placebo group (hazard ratio, 0.84; 95% CI, 0.58 to 1.22); the rate of death from any cause was 13.5 in the sotagliflozin group and 16.3 in the placebo group (hazard ratio, 0.82; 95% CI, 0.59 to 1.14).

Diarrhea was more common with sotagliflozin than with placebo (6.1% vs. 3.4%), as was severe hypoglycemia (1.5% vs. 0.3%).

Percentage of patients with hypotension was similar in the sotagliflozin group and the placebo group (6.0% and 4.6%, respectively), as was the percentage with acute kidney injury (4.1% and





4.4%, respectively).

The benefits of sotagliflozin were consistent in the subgroups of patients stratified according to the timing of the first dose.

Discussion:

Sotagliflozin is a sodium-glucose cotransporter-2 (SGLT2) inhibitor, but also inhibits SGLT1, which primarily exists in the gut and appears to delay glucose absorption.

SOLOIST-WHF is the first large randomized controlled trial to show that initiation of SGLT2 inhibition in acute HF in stabilized patients prior to discharge or shortly thereafter is effective and well tolerated.

Sotagliflozin benefits are consistent in those with HF with reduced but also preserved EF.

Conclusion:

Sotagliflozin therapy resulted in a significantly lower total number of deaths from cardiovascular causes and hospitalizations and urgent visits for heart failure than placebo in patients with diabetes and recent worsening heart failure.

Reference:

Bhatt DL et al. Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure. N Engl J Med. 2021 Jan 14;384(2):117-128.

2. Atrial flow regulator in a Complex Cyanotic Patient in Congenital Heart Disease: A novel approach.

Double-inlet left ventricle (DILV) is one of the most common form of single ventricle which both AV (atrioventricular) valves communicate into a common chamber.

Most prevalent form of DILV with the hypoplastic right ventricle on the left side. Disease is associated with several heart defects, and the treatment is different based on the anatomy of the heart, but treatment methods are almost always palliative.

Current is a case of adult patient with DILV and severe left AV (atrioventricular valve) stenosis managed with a novel palliative intervention with AFR (atrial flow regulator) device implantation.



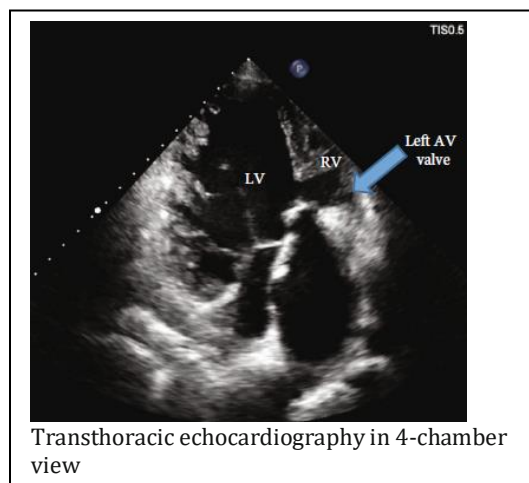
Case presentation:

A 40-year-old, a known case of DILV and Eisenmenger syndrome managed with optimal medical therapy referred with progressive dyspnea (NYHA functional class IV) and cyanosis.

On physical examination, his hemodynamic was stable with SpO_2 : 70%. Also he had severe clubbing and central cyanosis; in cardiac exam, left lateral deviation of the LV apex with loud P2 at the base of the heart and diastolic murmur grade II was heard in the left sternal border and apex.

Transthoracic echocardiography showed abdominal and atrial situs solitus, levocardia, L-looped, A-V, and V-A discordance. Morphologic LV (main ventricle) on the right side of the rudimentary right ventricle with an ejection fraction of ~35%.

A large inlet type ventricular septal defect (24mm) and very small secundum type atrial septal defect (3mm) with left-to-right shunt was illustrated. Aorta was anterior and the left side of the pulmonary artery and originated from rudimentary RV. PA derived from the main ventricle with confluent pulmonary artery branches with mild pulmonary insufficiency and severe pulmonary hypertension (mPAP:70mmHg). The thick and hypoplastic left A-V valve was remarkable with severe stenosis (MG:15mmHg, PG:21mmHg).



Cardiac catheterization rudimentary RV at the left side; severe systemic ventricle (LV) enlargement with moderate dysfunction which filled via a large inlet type VSD. PA originated from LV. Both A-V valves were connected to LV with severe left A-V valve stenosis (MG: 15 mmHg).

With respect to his refractory symptoms and significant left A-V valve stenosis and small ASD, he was scheduled for AFR implantation to reduce LA and pulmonary capillary wedge pressure.

Procedure:

Under local anesthesia and intensive hemodynamic monitoring, through the right femoral vein, after heparin injection to achieve ACT > 250 s, under TEE guidance, the ASD was crossed with multipurpose catheter which its tip was positioned in the LUPV and a floppy tip guide wire placed in the LUPV; then, sequential balloon dilatation of the atrial septum was done with peripheral balloons 10-30mm and 12-



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30mm (OTW).

Subsequently delivery sheath was crossed through the wire to mid LA, and the dilator was removed to allow back bleed.

After loading the device (AFR 10mm) and connecting to the delivery cable, the device was passed over the sheath to reach the tip of the sheath. By retracting the sheath, the distal disk was deployed in LA; then, the whole system was pulled back toward the septum; after checking the orientation of the device by TEE, the proximal disk deployed.

After complete assessment of the device position, its stability, and the degree of left to right shunt, the device was released. Immediately after device implantation, hemodynamic study showed reduction of wedge pressure to 18 mmHg.

Patient's daily visit after the procedure until discharge (one week) indicated that his shortness of breath had decreased. Lower extremity edema decreased, and blood oxygen saturation reached 79%.

After 2 months follow-up, the patient's clinical status (dyspnea and edema) improved significantly; cyanosis was decreased, and SPO₂ increased to 79%.

Follow-up echocardiography showed the AFR device in the proper position with left-to-right shunt, and the left AV valve mean pressure gradient was decreased to 7mmHg, and mPAP decreased from 80 to 50mmHg.

Discussion:

AFR device is a self-expandable double-disc nitinol wire mesh production which creates a communication between the atriums and allows blood to flow across the interatrial septum. In the initial stages it was designed initially, it was designed for patients with severe pulmonary hypertension and RV failure with refractory symptoms for decompressing the right heart chambers via permanent right-to-left shunt which leads to elevation of the cardiac output, blood pressure, and organ perfusion despite of inducing mild systemic desaturation.

Currently it could be used whenever the either atrial pressure increases; so, the device would decompress the dedicated atrium. Those with elevated left atrium pressure would create a persistent left-to-right shunt which cause the reduction of LAP, PCWP, PAP, and pulmonary congestion symptoms and increase arterial blood saturation, cardiac output, blood pressure, and organ perfusion.

Conclusion:

In selective high-risk patients with pulmonary hypertension, Transcatheter AFR device implantation could be a relatively novel palliative approach that is utilized.

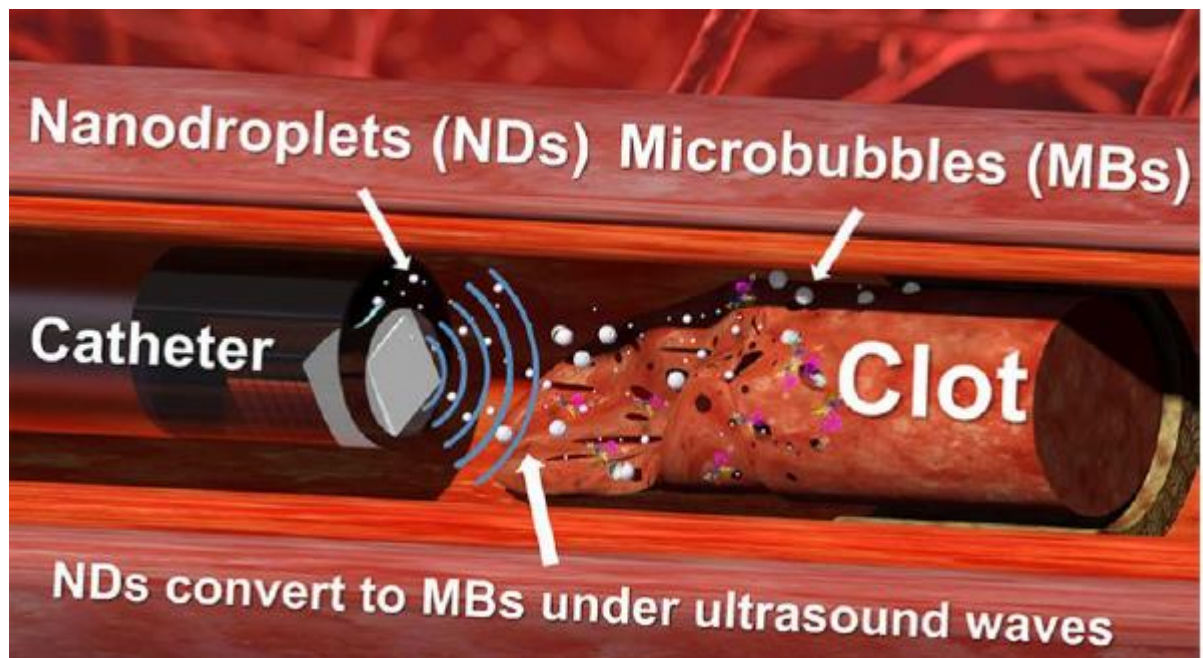
Reference:

Khajali Z et al. New Horizon of Intervention in Congenital Heart Disease: AFR in a Complex Cyanotic Patient. Case Reports in Cardiology. 2020: 8897101: 1-6 pages.



IN FOCUS

3. Novel technology to break Blood Clots.



Deep Vein thrombosis (DVT) blood clots tend to be older, denser, stiffer, and retracted as compared with unretracted clots.

Thrombolytic agent treatment such as systemic tissue plasminogen activator (tPA) administration for DVT can take over 24 hours to be effective.

Penetration of compacted and extensive blood clots has been one of the main challenges of vascular surgery. Various catheter-based devices have been invented and are in use today, but many patients present with plaques that are difficult even for the finest existing devices.



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Currently researchers have developed a new way to target blood clots that involves special nanodroplets and an ultrasound catheter that activates them.

Nanodroplets are made out of lipid spheres packed with low-boiling point liquid perfluorocarbons (PFCs). When the PFCs are released from the spheres, their tiny size allows them to get into the tiniest of crevices within a clot. Once there, a shower of ultrasound activates them to turn into expanding boiling microbubbles. Further ultrasound makes these microbubbles vibrate and break apart the clot mass.

Clots that are not cracked fully through this mechanism still end up with significant structural deterioration that allow clot dissolving drugs and other therapies to clear the clot.

According to the researchers, usage of nanodroplets, ultrasound and drug treatment is most effective in decreasing the size of the clot by 40%, plus or minus 9%. Using the nanodroplets and ultrasound alone reduced the mass by 30%, plus or minus 8%. The second best treatment involved is drug treatment, microbubbles, and ultrasound – and that reduced clot mass by only 17%, plus or minus 9%. These tests were conducted with the 30-minute treatment period.

Combined nanodroplet with tPA-mediated sonothrombolysis may provide a feasible strategy for safely treating retracted clots.

Reference: Available at: <https://www.medgadget.com/2021/01/nanodroplets-and-ultrasound-to-drill-through-blood-clots.html>. Accessed on 16-03-2021.



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