Forum Sanitas
Das informative Medizinmagazin
Sonderdruck aus
3. Ausgabe 2017

A new management strategy for left heart failure

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A new management strategy for left heart failure

The atrial flow regulator (AFR device)

Heart failure (left heart failure, weak heart) is a common medical problem in industrialized countries worldwide . It is estimated that about 1% of the population suffers from heart failure. For example in Germany this is about 1 million people, the rate of newly diagnosed patients is around 2-12/1000 inhabitants. Heart failure itself is the most common cause for hospitalization, especially in the elderly. Fortunately the numbers of patients dying acutely from heart failure has declined in the last few years; these patients however do suffer predominantly from shortness of breath and therefore have a significantly reduced quality of life.

Heart failure mangment ususlly medical and consists of combined pharmaceutical therapy of ß-blockers, ACE- inhibitors and diuretics, all of which have one thing in common – to relieve the work of the heart.

If medical therapy is ineffective or fails, cardiac transplantation may be an option for patients with severe disease. Based on the current guidelines, heart transplantation is only suitable for patients below the age of 65. Therefore this potentially life-saving option is not feasible for the majority of elderly patients. Transplantation itself bears substantial risks, in addition there is a shortness of donors and therefore transplantation is offered only to those patients suffering from end-stage heart failure. Subsequently it is essential to optimize all therapeutic options, to minimize the clinical symptoms and potentially support patients on waiting lists for heart transplantation.

In order to support those patients, who do suffer from the clinical burden of heart failure despite optimized medical therapy, a new device was designed – the Atrial Flow Regulator (AFR device)

Definition of heart failure

By definition heart failure describes a weakness (insufficiency) of the heart or the heart muscle; this can be for various reasons. One of the most important causes are disease of the heart muscle itself (inflammatory disease, myocarditis), progressive weakness of the musculature (cardiomyoptahy), direct effects of long standing hypertension, arrhythmias and disease of the coronary arteries (i.e heart attatck, coronary heart disease, ischemic heart disease, etc.). For all these problems it is in common that the power of the heart muscle decreases over time and therefore the left side of the heart is no longer able to pump the required amount of blood to the body. Clinically this results in reduced exercise capacity and mainly shortness of breath (SOB). Initially the patients do suffer from SOB only at exercise, but over time SOB becomes relevant even at rest. Especially these patients are at risk of cardiac death.

Different types of heart failure

HFrEF – heart failure with reduced ejection fraction

HFpEF – heart failure with preserved ejection fraction

Today we can differentiate between two major forms of heart failure: those with an apparently reduced pumping function of the heart (HFrEF – heart failure with reduced ejection fraction) and those with a preserved pumping function (HFpEF – heart failure with preserved ejection fraction)

HFrEF – this type of heart failure is characterized by a continuously decreasing mechanical power of the heart muscle. The heart is no longer able to pump the adequate amount of blood to the body. As a consequence the musculature gets thinner and the heart enlarges (dilates), this effect can easily be detected on Echocardiography. The blood cannot enter the left ventricle (main pumping chamber) and therefore the left atrium (filling chamber) is congested; this leads to a congestion and fluid overload of the lungs. In addition the blood pressure decreases and the perfusion of the body and organs is impaired, and fluid accumulates in the body (edema). The main problem for the patients however is the shortness of breath (initially only at exercise, later at rest), difficulties in breathing, reduced exercise capacity, and fatigued.

HFpEF – the other half of the patients with heart failure show heart failure with preserved ejection fraction as typically caused by cardiomyopathies (i.e. restrictive or obstructive carfiomyopathy). In most patients however there is a significant thickening and stiffening of the heart muscle itself and very often hypertrophy. This is mainly caused by long standing hypertension (high blood pressure) or just by aging of the heart muscle. The thick and sometimes fibrotic (i-e with micro scars) muscle is so stiff that the relaxation is impaired; this leads to

difficulty in filling of the heart. Filling itself is however a major process in cardiac function – without adequate filling the heart is again unable to pump the required amount of blood to the body. As a consequence cardiac output is reduced and again there is a significant congestion of the left atrium (filling chamber) and in the lung (pulmonary veins). The main difference is however that the squeezing force of the heart (contractility) is not impaired and Echocardiography shows a "normal" function. Clinically the patients show no difference to those with reduced pump function – again shortness of breath is the leading symptom in addition to reduced exercise capacity and reduced quality of life.

Management of heart failure

The main treatment options for heart failure is medical therapy. Based on the current guidelines a combination therapy is required to achieve optimal effects. Medical management aims to improve the clinical condition of the patients, improve exercise capacity, stabilize quality of life and aim to reduce the necessity for hospital admissions; in addition efforts are taken to reduce secondary organ impairment as consequence of heart failure and finally reduce mortality.

Standard therapy consists of a ß-blocker and ACE inhibitor (ACE = angiotensin converting enzyme). ß-blockers work on the ß-receptors of the heart, they calm down the heart by reducing the heart rate and the blood pressure and thereby the energy needs and oxygen consumption of the heart. The ACE-Inhibitors block an enzyme that is produced in the kidney and plays an important role in the regulation of the blood pressure. ACE inhibitors reduce the blood pressure and thereby the peripheral vascular resistance and the "afterload" of the heart. This enables the heart to pump the blood much more easily to the body.

Especially in more severe forms of heart failure, i.e. those with shortness of breath, additional medications are used – mainly diuretics (medication that increase the water excretion). By the reduction of water and electrolytes the circulating blood volume is reduced, this relieves the stressed heart, reduces the congestion of the heart and mainly of the lungs – and ultimately reduces shortness of breath.

In addition other diseases such as arrhythmias are treated as well as other secondary organ problems caused by heart failure. Organs mainly affected are the kidneys (impaired perfusion) and the liver (congestion and blood stasis). A reduction of the kidney function increases the water retention in the body and has negative impact on clinical symptoms.

If management at home is no longer suitable, hospital admission may be necessary to intensify treatment. An additional diagnostic workup, intensification of the medical therapy or forced diuretic therapy are often required to reduce water accumulation and relief symptoms. Hospitalization has however a massive impact on daily life and reduces quality of life.

As mentioned above, cardiac transplantation may be an option for younger patients; this is however a third line therapeutic option for those in end stage heart failure. The current shortness of donor organs leads to a long waiting period and thereby is linked to multiple risks and reduced quality of life.

Special considerations in patients with heart failure and preserved ejection fraction (HFpEF)

Despite the fact that half of all patients have this form of heart failure, no medical therapy has been effective to improve the clinical condition of the patients, or reduce the morbidity or mortality. The only therapeutic aim in the management of the disease is to reduce the clinical symptoms – i.e. shortness of breath. Diuretics are able to reduce the congestion and fluid accumulation in the lung and thereby reduce shortness of breath. The disease process in the heart is however not influenced at all. As all other medications have not been effective in reducing morbidity or mortality, therapeutic options therefore are limited.

The benefit of a hole in the heart (atrial septal defect (ASD))

In both forms of heart failure (i.e. HFrEF and HFpEF) shortness of breath is the leading clinical symptom. SOB is caused by a congestion of the left atrium with an increase of the pressure in the left atrium resulting in congestion of the lungs and pulmonary fluid accumulation (or even pulmonary edema). If a small hole of defined size between the left atrium and the right atrium would be created in the separating wall between these two chambers (the interatrial septum) this would lead to a decompression. The pressure and volume loaded left atrium would then cause a defined blood flow from the left to the right side (left-to-right shunt) across this hole (see picture 1).

This hole would act as a pressure relief pop-off valve of he left atrium and thereby reduce the congestion of the lungs and finally a create a reduction of the symptoms shortness of breath under exercise or at rest. A defined diameter of this hole is crucial (i.e 6 or 8 mm) in order to avoid an uncontrolled large size (larger than 10 mm) and thereby uncontrolled massive blood flow with a consequence of additional volume load resulting in clinical deterioration.

History of ASD and heart failure

The principle that a small ASD may be beneficial in patients with heart failure or elevated left atrial pressure and reduce clinical symptoms has been known for a long time. The clinician Lutembacher described over 100 years ago that patients with

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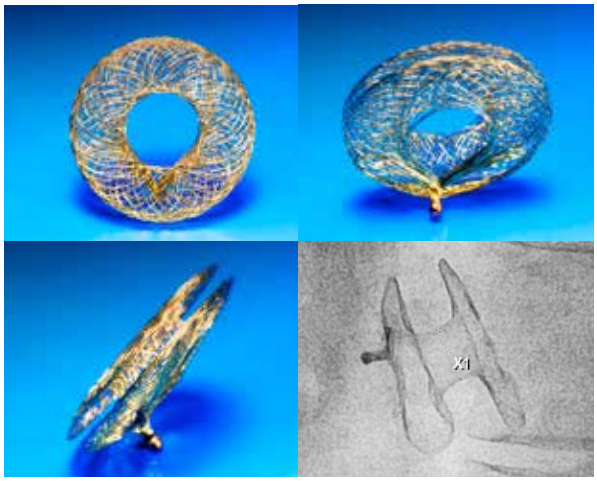

Figure 1: Details of the AFR device

Fig 1a: above, left: View on the left side shows the circular shape with the central hole

1b.: above, right: oblique view shows the hub for device delivery and manipulation.

1c.: lateral view, shows the flat profile of an AFR device with 2 mm thickness.

1d.: fluoroscopy, lateral view after implantation, AFR device with 5 mm thickness and a 6 mm fenestration, marked by X1.

mitral stenosis and a small ASD (Lutembacher Syndrome) clinically have much less shortness of breath as those without an ASD. It is also known that patients who have a very large ASD that requires closure may develop acute pulmonary edema immediately after closure because the left heart has to pump acutely a higher amount of blood and requires more filling to do so. These observations clearly show that a small ASD with a defined diameter may be beneficial in patients with various forms of atrial congestion and heart failure and reduce the symptoms like shortness of breath, resulting in an improvement to the quality of life of the affected patients.

The atrial flow regulator device

In 2016 the engineers at Occlutech developed a new device dedicated to this management strategy – the AFR device. The device was designed for patients with left heart failure, those with pulmonary hypertension or those with congenital heart defects. (see figure 1).

The design is comparable to that of an ASD closure device. It consists of a left and a right sided disc with a central hole of defined size (4 – 10 mm). The concept of this device is simple and promising based on the pathophysiology outlined above. By the implantating the device in the intratrial septum a defined hole with a precise diameter is created. This will lead to a pressure relief of the left atrium without uncontrolled volume load and left-to-right shunt – comparable to an adjustable pop-off-valve. This treatment modality is new and promiing for many patients. By the reduction of atrial pressure under exercise the amount of congestion is reduced and as such will be able to reduce the clinical symptoms. The water accumulation in the lungs is reduced and the patients will have less shortness of breath.

This therapeutic option can be used well in patients with HFrEF but especially in those patients with HFpEF, i.e those patients with a thick and stiff heart musculature, who have no medical options available so far. It may be possible that the reduction of left atrial congestion will not only reduce the clinical symptoms but may also have impact on mortality.

Implantation can be performed by a standard minimally invasive catheter procedure via vascular access in the groin. This technique in experienced centers is standard and with minimal risks; the patients can be discharged home after a short hospital stay. Currently there are clinical studies under way to evaluate the clinical outcome of this new device in patients with heart failure. The leading study centers are in Germany, such as the department for pediatric cardiology and congenital heart defects at the Grosshadern hospital, KUM, LMU Munich.

Conclusion:

There are a large number of middle-aged and elderly patients who suffer from heart failure. Half of these patients suffer from heart failure with an enlarged heart and reduced pumping function (HFrEF), the other half from heart failure with a stiff and thickened heart with reduced filling capacity (HFpEF). The leading clinical symptom in both groups is shortness of breath, initially presenting only at exercise, later even at rest. Shortness of breath is caused by left atrial congestion resulting in congestion of the lungs and finally water accumulation in the lungs. A controlled pressure reduction of the left atrium is effective to reduce congestion and thereby fluid accumulation in the lungs and shortness of breath. This therapeutic concept is now available by the newly designed AFR device (Occlutech®, Sweden). Clinical studies are currently underway.

Informationen

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