2 Aim of the study

The purpose of this study was:
I) using the noninvasive method TDI and strain rate imaging to assess the influence of PFO closure procedure on the RV and LV function through evaluating the longitudinal mitral and tricuspid annular motion.
II) to assess the influence of PFO closure procedure on the atrial septal motion.
III) to compare the influence of different PFO occluders on the ventricular function and atrial septal motion.

3 Patients and methods

3.1 Patient groups

The study group consisted of 50 PFO patients with paradoxical embolism and TIA. There were 28 male and 22 female patients; the median age was was 41.4 years (range, 16 to 78 years). The patients were randomly divided into three groups. The PFO was closed with the Amplatzer occluder in 20 patients (group A), with the Cardioseal occluder in 14 patients (group B) and with the Helex occluder in 16 patients (group C). The size of implanted Amplatzer occluders ranged from 18 to 25 mm (median 23.5 mm), of the Cardioseal occluders from 23 to 28 mm (median 25.7 mm), and of the Helex occluders from 15 to 35 mm (median 25 mm). All patients were in sinus rhythm and had no associated congenital heart defects.

3.2 Standard echocardiography

Trans-thoracic echocardiography (TEE) was performed one day pre- and post-intervention using a Vingmed System Five Ultrasound system (GE, Horten, Norway) equipped with tissue Doppler imaging (TDI) capabilities. The patients were examined in the left lateral decubitus position with a 2.5-3.5 MHz sector probe. ECG was simultaneously recorded. Data acquisition was performed during normal respiration. Standard two-dimensional imaging, and colour and pulsed Doppler (of the mitral and

tricuspid valve) studies from the subxiphoid, apical four-chamber, and left parasternal views were performed.

The parameters used to assess the ventricular function were the M-Mode derived LV fractional shortening (FS%), the early diastolic E-wave peak, the late diastolic E-wave peak and the E/A ratio.

The raw data were stored in digital format and transferred to a computer workstation for the off-line analysis of regional velocity and strain rate.

3.3 Tissue Doppler Imaging

After standard echocardiography the machine was switched to tissue Doppler mode. Sector size and depth were chosen to achieve the optimal frame rate, which ranges from 100-130 frames per second. Gain settings, filters and pulse repetition frequency were adjusted to optimize colour saturation. An appropriate velocity scale was chosen to avoid data aliasing. Care was taken to keep each wall in the centre of the ultrasound sector in an attempt to align it as near zero degrees as possible to longitudinal motion. Three consecutive cardiac cycles (to be used for subsequent analysis) were recorded during normal quiet respiration. CDMI data were stored in digital format and transferred to a computer workstation for the off-line analysis of regional myocardial velocity and strain rate (deformation rate) curves. This was carried out using a dedicated software (TVI; GE Vingmed Echopack).

In the four-chamber view, the sample volumes were placed at the lateral mitral and tricuspid annulus. Three major velocities were recorded. One was a positive systolic velocity (Sm); the other two negative diastolic velocities were early diastolic velocity (Em) and late diastolic velocity (Am). Em /Am ratio was also recorded

In a similar way, the motion of the interatrial septum (roof of atrial septum and septal annulus) was also recorded by placing the cursor at the septal site of the annulus. Em, Am, Sm and Em/Am ratio were recorded as mitral and tricuspid annular velocities. A

mean of three consecutive cycles was used to calculate all Doppler echocardiography parameters.

3.4 Strain Rate Imaging

In the four chamber view, strain rates were measured at the septal annulus and at the roof of the atrial septum. Sector size and depth were chosen to achieve the optimal frame rate. Gain settings, filters and pulse repetition frequency were adjusted to optimize color saturation. Strain rates were estimated by measuring the spatial velocity gradient over a computation area 5.7 mm in longitudinal direction. In the ventricular strain rate three distinct waves can be seen: one negative systolic wave (S_{SR}) and two positive diastolic waves corresponding to early filling phase (E_{SR}) and late atrial contraction (A_{SR}). The atrium strain rate curve was also characterized by the three main waves systolic, early diastolic and late diastolic waves, which coincided with the ventricular systolic, early diastolic and late diastolic periods respectively. Three consecutive cardiac cycles were recorded during normal quiet respiration.

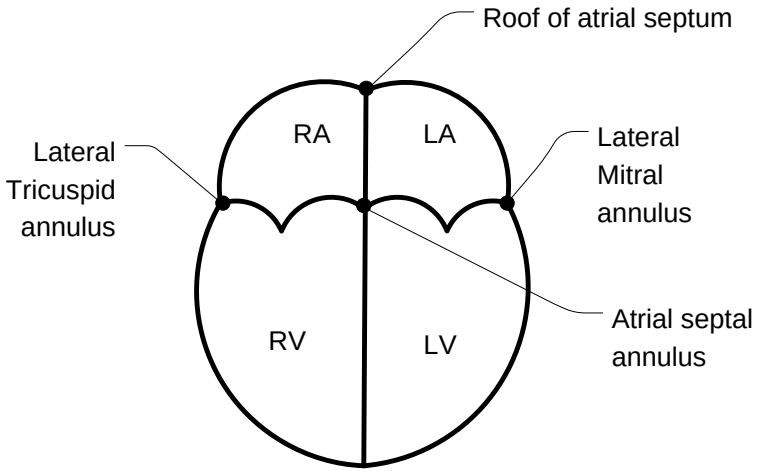

Figure 1

Positions of the pulsed-wave Doppler and strain rate sample in the four-chamber view

3.5 Devices employed in PFO closure

3.5.1 Amplatzer PFO Occluder

The Amplatzer PFO Occluder (Figure 2) is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short and thin connecting waist, allowing free motion of each disc. In order to increase its closing ability, the discs contain thin polyester fabric. This fabric is securely sewn to each disc by a polyester thread. The delivery system consists of a cable, loader, delivery sheath and dilator and a pin vise. The device was designed to be easily retrievable until it is released from the delivery wire, thereby allowing removal in the event of malpositioning. The overall technique appears simpler than that of any of the other existing devices and therefore has a shorter learning curve.

The Amplatzer occluder, with its high geometric profile, allows complete closure of patent foramen ovale but it tends to bulge into the atria and may cause mechanical complications. The main complications include device embolization, residual shunt, chronic stresses between the heart and device and cardiac perforation (45-50).

Figure 2

Amplatzer PFO Occluder device is a percutaneous, transcatheter occlusion device. It is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short and thin connecting waist allowing free motion of each disc. The large side of the occluder is positioned in the right atrium, and the small side in the left atrium. In order to increase its closing ability, the discs contain thin polyester fabric.

3.5.2 Helex occluder

The Helex occluder (Figure 3) is a new type of device designed to improve the results of transcatheter ASD and PFO closure. It comprises a single piece of nitinol wire with a patch of microporous expanded polytetrafluroethylene (ePTFE) attached along its length. The superelastic property of nitinol is used to form the wire frame into two opposing disks of equal size that bridge and occlude the septal defect. The wire frame is visible with fluoroscopy and contains three clearly marked eyelets that facilitate proper placement. The occluder is fixed in place by a unique locking mechanism that passes through the centre of the device from the left to the right atrial disk, thereby securing it in place. The ePTFE is specially designed to facilitate rapid cell penetration, thereby promoting rapid tissue ingrowth, resulting in permanent defect closure and device stability. The delivery system is a coaxial catheter assembly consisting of a 9F preshaped outer delivery catheter, an inner 6F control catheter used for deployment and/or withdrawal of the device, and a central mandrel used to configure the device and deploy the locking mechanism. An ePTFE retention suture anchored to the tip of the control catheter loops through the right atrial eyelet and is exteriorized to the operator. This suture allows for removal of the device after complete deployment and release from the catheter delivery system if desired.

The Helex occluder appears to offer a number of advantages over currently existing transcatheter occlusion devices (74). This new septal occlusion system has the following features: (a) soft, circular, atraumatic design; (b) low septal profile; (c) minimal septal distortion; (d) removability during all stages of delivery (including after deployment); (e) benign, rapid biological response; However, this device more often has a residual shunts in terms of immediate closure than other devices. The probably reason is that it is so flexible.

Figure 3

Helex is composed of a single piece of nitinol wire with a patch of microporous expanded polytetrafluroethylene (ePTFE) attached along its length. The superelastic property of nitinol is used to form the wire frame into two opposing disks of equal size that bridge and occlude the septal defect.

3.5.3 Cardioseal

The Cardioseal device (Figure 4) consists of two self-expanding umbrellas with which a polyester fabric is securely attached to the atrial septum by spring tension after implantation. Four metal arms made from the metal alloy MP35N radiate from the centre of the device, supporting each other in the centre, and are covered by sewn square Dacron patches. There are two coil joints or hinges in each arm designed to relieve the stresses placed upon the implant during the cardiac cycle, improving resistance to fatigue fracture when tested in vitro (74). Both the metal and fabric are made from the most biocompatible materials known for this application. The framework in particular has been selected for its excellent biocompatibility profile. In addition, the spring-back mechanism allows the umbrella frame to assume its original shape after being deformed during delivery and fix the device to the atrial septum.

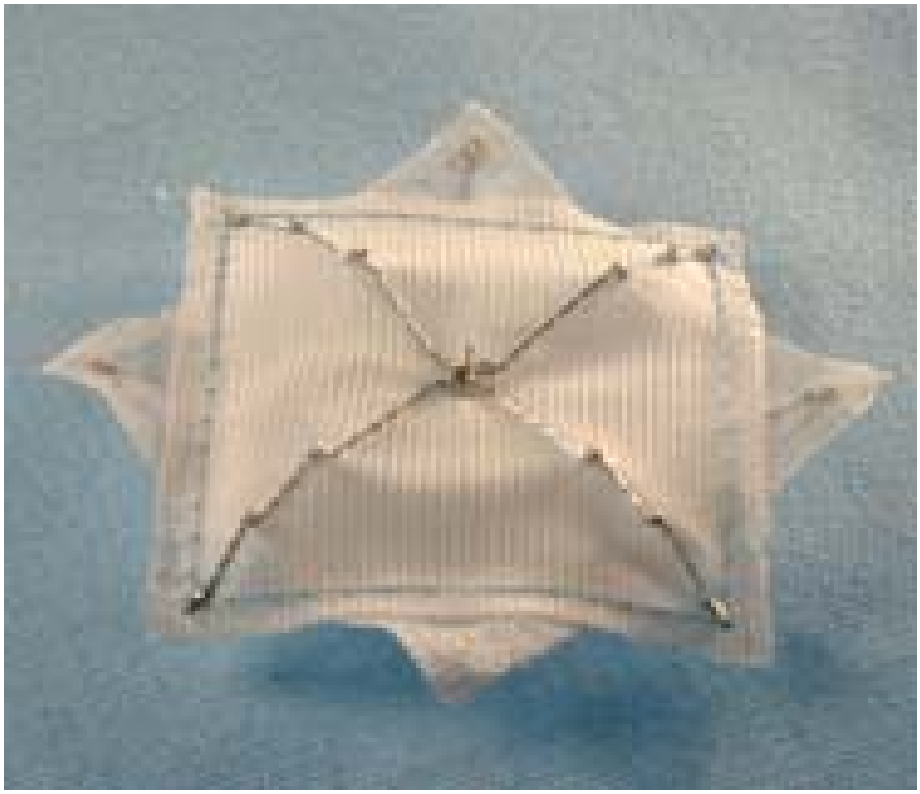

Figure 4

The Cardioseal device consists of two self-expanding umbrellas that are attached to the atrial septum by spring tension after implantation. Four metal arms made from the metal alloy MP35N radiate from the centre of the device, supporting each other in the center, and are covered by sewn square Dacron patches.

3.6 Device implantation

All procedures were performed under local anesthesia, deep sedation and with continuous transesophageal echocardiography (TEE) and fluoroscopy guidance. After percutaneous puncture of the femoral vein, pressures were recorded in the right atrium, left atrium, right ventricle and pulmonary artery. The PFO is sized using angiography and/or a sizing balloon. A suitable occluder chosen according to the diameter of the PFO was attached the delivery cable and advanced through the sheath to the left atrium where the left atrial disc was deployed, withdrawing the sheath and delivery cable gently until the left disc pressed firmly against the atrial septum when the right disc expanded. After the correct position of two discs is confirmed by TEE or contrast angiocardiography, the delivery system can be released from the delivery sheath and can be removed. Otherwise, repositioning of the device can be carried out and/or removal of the device if it is necessary.

3.7 Statistical analysis

We used SPSS 10.0 software for statistical analysis. Results data were expressed as mean value ± standard deviations. Means were compared using the non-parametric test. We used the Kruskal-Wallis test to evaluate the characteristic variable differences of patients and the differences of echocardiographic parameters among the three groups. A p value < 0.05 was considered statistically significant.