

Fustar™ Steerable Introducer Case Reports

Fustar™ Steerable Introducer

– A New Steerable Sheath for Difficult ASDs

INTRODUCTION

Doctor Yat Yin Lam is an Associate professor, from the Department of Medicine & Therapeutics at Prince of Wales Hospital in Hong Kong. His special areas of expertise are Congenital Heart Disease, PFO and LAA.

He has recently conducted the initial experience using Fustar Steerable Introducer to facilitate the closure of inter atrial communications (PFO, ASD & VSD) at Prince of Wales Hospital, Hong Kong.

During the CSI 2011, Doctor YY Lam used the Fustar to achieve precise access for deployment of difficult Septal Defects and performed a live case closing difficult ASDs.

In this interview with Lifetech, doctor Lam explains why he chooses Fustar Steerable Introducer when it comes to closing difficult ASDs.

PHYSICIAN EXPERIENCE

What are considered to be difficult ASDs and why?

There are 2 types of difficult ASDs; the **Large-sized ASD** and the **Double ASD**. Large-sized ASD is difficult to be closed by transcatheter approach because of the relative insufficient tissue rims to hold the device. The left atrial disc prolapses easily into right atrium during deployment. To close Double ASD with borderline inter-defect distance is also challenging because the part of the smaller device needs to be sandwiched by the larger device. Dislodgement of the smaller device during

deployment of the larger device may occur as a result of inter-device interference.

What are the current delivery methods for difficult ASDs?

The common methods used to prevent prolapse of of left atrial disc in Large-sized ASDs are:

1-To prevent the prolapse of LA disc to RA by *anchoring method* (stiff wire or balloon) or *left upper pulmonary vein (LUPV) method*.

2-To align the deploying axis of occluder in perpendicular to inter-atrial septum by:

- a) Usual deployment method with sheath rotation
- b) Delivery sheath with modified curve (Hausdorf)
- c) The Steerable delivery sheath

The possible strategies to reduce inter-device interference in Double ASDs include:

1- To avoid undersizing and oversizing of small and large ASD, respectively

2- Try to align the delivery axis of the large ASD in parallel to the small ASD.

Why do you choose the FuStar Steerable Delivery sheath to deliver difficult ASD?

Because the FuStar Steerable Delivery Sheaths comprise various sizes (5-14 French) and lengths (550/700/900mm) that would be applicable to most ASD devices and patients with different body heights. The tip of the catheter could be bent to 180 degree allowing you to obtain the desired delivery axis.

What tips do you recommend when using the FuStar for Difficult ASDs?

There is an inherent step-up noted between the dilator and the distal tip of delivery sheath which contains the steering hub. Generous pre-dilation of femoral access wound is therefore recommended to facilitate

introduction of delivery sheath into femoral vein. Up sizing of the sheath (+1 French) is needed for the commonly used Amplatzer devices.

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Application of FuStar Steerable Introducer for Cardiovascular Interventions: First Clinical Results in Man

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ABSTRACT

Background:

Catheter positioning, stability and navigability are recognized challenges in transcatheter cardiovascular interventions. Using a manually steerable sheath is an appealing option to overcome some of the problems. This study reported the first-in-man safety and feasibility data of using FuStar™ Steerable Introducer (FSI, Lifetech Scientific Inc., Shenzhen, China) in patients with congenital cardiac defects or peripheral arterial diseases (PAD).

METHODS

A consecutive of 15 patients (5 males, age 45 [IQR 34-63 years], 6 patent foramen ovale, 5 secundum atrial septal defects, 1 perimembranous ventricular septal defect and 3 lower limb PAD) received FSI from December 2010 to March 2011 were recruited. Catheter-related adverse events (kinking, breakage, steering failure, thrombus formation or allergic reaction) were collected. Performance measures were specifically evaluated in congenital (recapturing the device without damaging the catheter tip, aligning the catheter in perpendicular to the septum and successful occluder deployment) and PAD (reaching contralateral iliac artery by steering of the catheter tip, tracking the sheath to contralateral femoral artery

without clinking and successful balloon angioplasty/stenting) patients.

RESULTS

No adverse event was observed with catheter use. All performances measures were achieved in patients with congenital defects (n=12). Successful crossing and tracking of the catheter to the contralateral arteries was achieved in 1 out of 3 PAD patients. No balloon angioplasty/stenting was performed in the patient because the haemostatic valve was not leakfree with guidewire in-situ.

CONCLUSIONS

Our preliminary data suggested FSI is safe and feasible in facilitating deployment of occluders for congenital cardiac defects. However, routine use of FSI in lower limb peripheral vascular procedures cannot be recommended. Further large-scaled randomized trials are needed to show whether this novel technology would improve procedural time and success.

KEYWORDS

FuStar steerable introducer, congenital cardiac defects, peripheral arterial diseases

INTRODUCTION

Doctor César A. Esteves is an interventional cardiologist, MD, PhD, who works at "Instituto Dante Pazzanese de Cardiologia" and Hospital Beneficência Portuguesa," both in São Paulo, Brazil. At "Instituto Dante Pazzanese" he is the Chief of the Medical Section of Intervention in Acquired Valvulopathies.

He performs hundreds of procedures annually.

Doctor Esteves performed a case of Mitral Paravalvular Leak this July 2011 in "Instituto Dante Pazzanese" and chose to use FuStar™ Steerable Introducer for the first time.

After the procedure, Doctor Esteves shared with Lifetech his experience, impressions and tips about the FuStar™ Steerable Introducer.

PHYSICIAN EXPERIENCE

Why did you choose FuStar to perform a Mitral Paravalvular Leak Procedure?

By transeptal approach, to cross mitral leaks, mainly between 9 and 3 o'clock (looking from LA view), the use of a deflecting sheath facilitates the procedure. I chose to use the FuStar™ Steerable Introducer because of the sizes availability. In my particular case, I selected a 7Fr FuStar sheath.

What was your Impression when using the Fustar™ Steerable Introducer?

To cross the mitral leak was very, very easy as the tip of the sheath can be angled after we take the dilator out. I could find the leak easily and could cross it with a hydrophilic 0.032" wire (sheath angled approximately 90°). Other advantage is that even with a 0.032" hydrophilic wire, the sheath could be advanced over it into the LV. Then, I could advance through the sheath other two 0.035" stiff wires and over them, now with the sheath out, I positioned two 7Fr MP catheters and left the hydrophilic wire, just in case, in the descending aorta until the end of the procedure.

In which other procedures would you consider using the Fustar™ Steerable Introducer?

This was my first time with this introducer, but another indication will probably be in large ASDs with deficient rims. Instead of using other techniques such as opening the LV disc in the upper left or right pulmonary vein or using the Hausdorf Sheath; the FuStar™ will be an interesting option because you can change your angle of attack to the Atrial Septum and make the procedure safer and easier to do.