Catheterization and Cardiovascular Interventions 00:00–00 (2016)

Original Studies

Techniques for Transcatheter Retrieval of the Occlutech ASD Device United Kingdom–European Multicenter Report

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Aims: To gather current experience in Occlutech ASD device retrieval, to determine whether snaring is an effective technique and to highlight alternative retrieval techniques; Methods and Results: United Kingdom and European Occlutech ASD device implanters reported their experience in dealing with device embolization and retrieval. Six operators reported 12 retrieval cases. Retrieval was successful in 92% (11/12), although in most cases it was not straightforward and required multiple attempts using different techniques and equipment. When each different technique or equipment combination was considered separately, there were a total of 23 retrieval attempts. Fifteen attempts involved snaring the ball on the right atrial disc of the device ("the RA pin"). In 12/15 of these attempts the snare slipped off the RA pin. In 8/15 attempts snaring eventually failed. In two cases retrieval was facilitated by elongating the device in a blood vessel. In three cases retrieval was achieved by grasping the RA pin with the jaws of the Occlutech Flex II delivery cable; Conclusions: Snares do not grip the RA pin sufficiently to reliably retrieve the device. Funnelling the device into a blood vessel or grasping the RA pin with the jaws of the delivery cable may be successful alternatives.

Key words: occlutech ASD device; embolization; retrieval; snare

Additional Supporting Information may be found in the online version of this article.

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Received 12 April 2016; Revision accepted 12 October 2016

DOI: 10.1002/ccd.26838
Published online 00 Month 2016 in Wiley Online Library (wileyonlinelibrary.com)

INTRODUCTION

Device embolization occurs in approximately 0.5% cases of transcatheter atrial septal defect (ASD) closure [1]. Previous studies have shown that percutaneous retrieval of the Amplatzer Septal Occluder (St. Jude Medical, Inc. St. Paul, MN) can be achieved by withdrawing the device into a long sheath with a gooseneck snare [1]. However, operators have observed that the Occlutech Figulla ASD device (Occlutech International AB, Helsingborg, Sweden) may be more difficult to retrieve using this technique. The right atrial (RA) disc of the Occlutech device uses a ball, rather than a screw thread, to attach to its delivery cable (Fig. 1). There have been suggestions that the snare has insufficient grip on this ball to allow the device to be successfully retracted into the delivery sheath during retrieval. As there is no published information on this issue, we set out to gather current experience in dealing with Occlutech device embolization, to discover whether snaring is effective and to identify alternative retrieval techniques.

METHODS

United Kingdom and European congenital heart disease interventional cardiologists were contacted to identify operators who had experience with Occlutech ASD device retrieval. Six operators reported a total of 13 attempted retrievals in 12 patients between 2011 and 2014. The operators were asked to submit detailed information on each case. Data included patient age, ASD size, device size, reason for retrieval, size of retrieval sheath, retrieval equipment, retrieval technique, and the outcome of each attempted retrieval technique. Operators also sent angiograms from each case to clarify the techniques that they used. Table I describes the basic details of each device implantation and the reason for device retrieval.

RESULTS

The 13 device retrieval procedures are summarised in Table II. The ball on the right atrial disc of the device, by which it attaches to the delivery cable, is designated the "RA pin." At procedure end 12/13 percutaneous retrievals were successful, without complication. Retrieval was unsuccessful in case 11 because the snare slipped off the RA pin every time the operator attempted to withdraw the device into the long sheath (Supporting Information Moving Image 1). Alternative retrieval techniques were not attempted as the largest available device had embolized, which made surgery inevitable. The device was removed during surgical ASD closure.

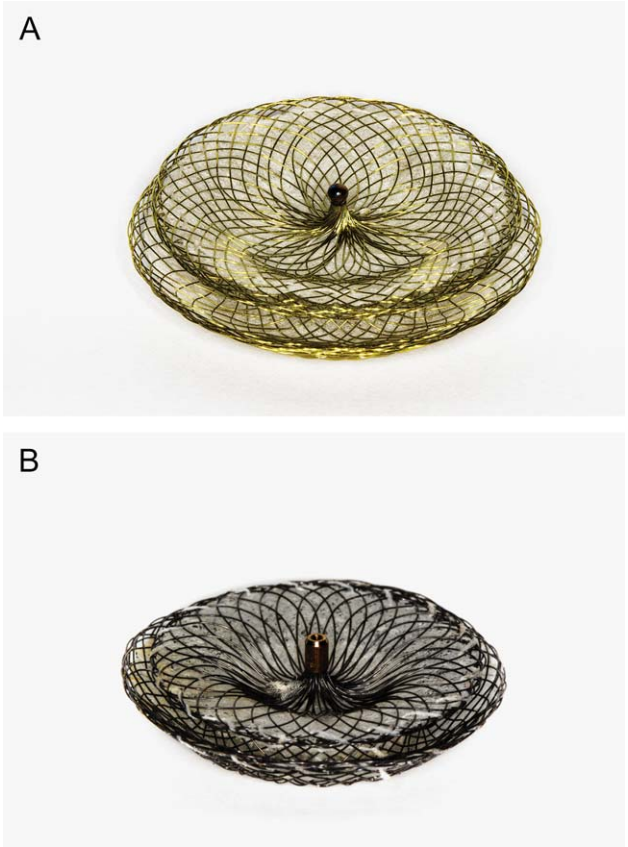

Fig. 1. A: Occlutech Figulla Flex II device; "Leicester author's collection." B: Amplatzer ASD Occluder; "Leicester author's collection." [Color figure can be viewed at wileyonlinelibrary.com]

Technical Difficulties Snaring the RA Pin

Case 1 highlights the problems experienced during snare retrieval. The operator attempted to retrieve a 24 mm device from the atrial septum because there was a significant residual shunt. Echocardiography suggested that the device had been implanted into the smaller component of a fenestrated defect. The RA pin of the device was snared, but the snare repeatedly slipped off during attempts to withdraw the RA disc into the long sheath. When the RA disc was finally retracted into the sheath, the snare slipped off again as the operator attempted to retract the left atrial (LA) disc. The RA pin was snared within the sheath, but the LA disc could not be retracted, as the snare slipped off on every attempt. The snare was therefore used to fix the position of the RA disc within the sheath and the snare, device and sheath were withdrawn together as a unit. This maneuver retracted the LA disc into the RA, where it was withdrawn into the long sheath. However, the device could not be withdrawn from the long sheath because the snare failed to retain connection with the

TABLE I. Details of Cases and Devices Used

Case number	Operator	Date of procedure	Patient age (years)	ASD size (mm)	Device type and size (mm)	Reason for retrieval
1	1	03/11	42	24 (balloon sizing)	24 Flex I	Elective retrieval from septum as significant residual shunt
2	1	05/11	45	9 (color flow)	10.5 Flex I	Device embolized because undersized
3	1	03/14	20	20 × 15 (2D TEE) 29 × 15 (3D TEE)	30 Flex II	Deployed from SVC as IVC interrupted. Device embolized on release because of tension on delivery cable, same device used successfully through transhepatic approach
4	1	07/14	2	11 (color flow) 15 (balloon sizing)	15 Flex II	Elective retrieval from septum as large residual right-to-left shunt in Ebsteins anomaly
5	2	01/13	4	15 × 13 (color flow) 17 (balloon sizing)	15 Flex II	Device embolized because undersized
6	2	07/14	15	9 × 10 (color flow)	9 Flex II	Embolized after 1 day because undersized
7	3	09/13	9	15 (2D TEE) 16 (balloon sizing)	18 Flex II	Embolized because premature release from delivery cable
8	3	02/14	15	25 (2D TEE) 28 (balloon sizing)	30 Flex II	Device retrieved when partly in sheath after accidental detachment from delivery cable while in sheath
9	4	02/11	7	16 × 12 (2D TEE)	18 Flex II	Retrieved from septum 4 days after implant as complete heart block not responding to steroids
10	4	12/14	54	13 × 12 (2D intracardiac echo)	16 Flex II	Device embolized because undersized
11	5	09/13	67	34 (balloon sizing)	40 Flex II	Late embolization detected after 8 weeks. Device embolized because undersized
12	6	05/14	56	10 (color flow)	10.5 Flex II	Device embolized because undersized

Abbreviations: SVC= superior vena Cava, IVC= Inferior vena cava, TEE= Trans esophageal echocardiography.

RA pin. The sheath and device were therefore removed together, but as a result vascular access was lost (Supporting Information Moving Image 2). The 24 mm device was re-implanted, but despite attempts to deploy it across the larger component of the fenestrated defect, there was once again a significant residual shunt after release from the delivery cable. The device was therefore retrieved a second time. A larger 14 French (F) long sheath was used, the RA pin was snared and the RA disc of the device was withdrawn into the sheath. The snare was again used to fix the position of the RA disc within the sheath while the snare, device and sheath were withdrawn as a unit, retracting the LA disc from the septum into the RA. The LA disc was withdrawn into the inferior vena cava (IVC), so that it was funnelled into an elongated configuration. Following this maneuver the LA disc was easily withdrawn into the sheath (Supporting Information Moving Image 3).

Efficacy of Snaring the RA Pin

In Table II, a retrieval attempt is considered separately whenever a different technique or different combination of equipment was used. In total there were 23 retrieval attempts. Fifteen attempts involved snaring the RA pin of the device. In 12/15 of these attempts, the snare slipped off the RA pin as in the case above, either with the device at the tip of the sheath or when only the RA disc was within the sheath. In 8/15 attempts snaring eventually failed and was followed by a more successful technique (listed below) or surgical extraction. When snaring failed, the retrieval sheath was a median of 2 (range 0–3) French sizes larger than the minimum sheath size required to deliver the device. In 7/15 attempts snaring succeeded, though repeated snaring was required in four cases, as the snare initially slipped off. When snaring succeeded, the retrieval sheath was a median of 3 (range 1–5) French sizes larger than that required to deliver the device.

Techniques Used to Assist Snare Retrieval

In 3/7 successful snare retrievals oversizing the sheath was sufficient to allow the device to be retracted. In 1 of these retrievals the sheath was 3F larger than the size required to deliver the device (case 6) and in two cases the sheath was 5F larger (cases 9 and 10). In 2/7 successful snare retrievals the device was elongated in a blood vessel to assist its extraction. In the first of these retrievals (case 1) the LA disc was funnelled into the IVC and retrieved into a sheath 3F larger than that required to deliver the device. In the second such retrieval (case 7) the RA pin of the device was snared in the left ventricle and the fully expanded device was pulled across the aortic valve into the ascending aorta. The device was then funnelled into an elongated configuration in the descending aorta (DAo). This maneuver aligned the RA pin with the long axis of the sheath. The device was then successfully retracted into a sheath only 1F larger than that required to deliver the device (Supporting Information Moving Image 4). In one procedure (case 12) the end of the

TABLE II. Retrieval Details

Case number	Device size (mm)	Minimum sheath size required for device (French)	Size of sheath used for retrieval (French)	Site of retrieval	Retrieval equipment	Retrieval technique	Outcome
1							
First retrievalattempt 1	24	11	12	septum	10 mm gooseneck snare (ev3)	Snare around RA pin, RA disc retracted into sheath	Failure (snare slipped off repeatedly trying to pull LA disc into sheath)
First retrieval attempt 2			12	septum	10 mm gooseneck snare (ev3)	Snare around RA pin, when RA disc in sheath whole device retracted into RA, then LA disc retracted into sheath	Success
Second retrieval			14	septum	10 mm gooseneck snare (ev3)	Snare around RA pin, RA disc retracted into sheath, whole device retracted off septum and LA disc funnelled into IVC before retracted into sheath	Success
2							
	10.5	7	12	DAo	25 mm gooseneck snare (ev3)	Snare around waist of device, folded device into sheath	Success
3							
Attempt 1	30	12	14	RVOT	2 x 25 mm gooseneck snare (ev3)	2 x Snares around RA pin of device	Failure (snares slipped off)
Attempt 2			14	RVOT	Occlutech Flex II delivery cable	tip of sheath over RA pin, cable jaws grasped pin	Success
4							
Attempt 1	15	9	10	septum	15 mm gooseneck snare (ev3) and Occlutech Flex II delivery cable	Gooseneck snare used to retract RA pin into tip of sheath, attempt to grasp pin with cable jaws	Failure (jaws poorly aligned to pin)
Attempt 2			10	septum	Occlutech Flex II delivery cable	Tip of sheath close to RA pin, cable jaws grasped pin	Success
5							
Attempt 1	15	9	9*	LA	10 mm multisnare (PFM)	Snare around RA pin of device	Failure (snare slipped off)
Attempt 2			12	LA	12–20 mm EN Snare (Merit)	Snare around RA pin of device	Failure (snare slipped off)
Attempt 3			12	LA	ONE Snare (Merit)	Snare around RA pin of device	Failure (snare slipped off)
attempt 4			12	LA	catcher catheter (Osypka)	Catcher forceps grasped RA pin	Success
6							
	9	7	10	DAo	10 mm multisnare (PFM)	Snare around RA pin of device	Success on fourth attempt (snare slipped off 3 times)

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

TABLE II. *Continued*

Case number	Device size (mm)	Minimum sheath size required for device (French)	Size of sheath used for retrieval (French)	Site of retrieval	Retrieval equipment	Retrieval technique	Outcome
7							
	18	9	10	LV	10 mm gooseneck snare (ev3)	Snare around RA pin of device, device funnelled into DAo before pulled into sheath	Success
8							
Attempt 1	30	12	12*	sheath	5 mm gooseneck snare (ev3)	40 mm Lassos snare (Osypka) used to hold extruded LA disc during retrieval attempts. 5 mm snare around RA pin of device	Failure (snare pulled off)
Attempt 2				sheath	5F biopsy forceps (Cook)	Attempt to grasp RA pin within the sheath using the forceps	Failure (could not grasp RA pin)
Attempt 3				sheath	Occlutech Flex II delivery cable	Cable jaws grasped RA pin within the body of the sheath	Success
9							
	18	9	14	septum	15 mm gooseneck snare (ev3) via 5F R coronary catheter	Snare around RA pin of device	Success
10							
Attempt 1	18	9	14	transverse Ao arch	25 mm gooseneck snare (ev3)	Snare around waist of device	Failure (would not retract into sheath)
Attempt 2			14	transverse Ao arch	15 mm gooseneck snare (ev3)	Snare around RA pin of device	Success
11							
Attempt 1	40	12	14	LA	25 mm gooseneck snare (ev3)	Snare around RA pin of device	Failure (snare slipped off 3 times
Attempt 2				LA	7 mm microsnare (ev3)	Snare around RA pin of device	Failure (snare slipped off 2 times)
12							
	10.5	7	10	DAo	15 mm gooseneck snare (ev3)	Snare around RA pin of device and end of sheath bevelled	Success on sixth attempt (snare slipped off 5 times)

Abbreviations: DAo = Descending aorta, RA = right atrium; LA = left atrium; LV = left ventricle; RVOT = right ventricular outflow tract.
Mullins sheaths (William Cook Europe, Bjaeverskov, Denmark) were used for retrieval except cases marked by * where the Occlutech ASD sheath was used.
ev3 (Plymouth, MN).
PFM medical ag, Koln, Germany.
Merit (Merit medical Systems Inc. South Jordan, UT).
Osypka ag, Rheinfelden-Herten, Germany.

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
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Mullins sheath (William Cook Europe, Bjaeverskov, Denmark) was bevelled and the sheath was oversized by 3F to assist retracting the device. One retrieval (case 1) was only partially successful as the device was retracted into a sheath that was only 1F larger than that required for device delivery, but could not be removed from the sheath.

Alternative Retrieval Techniques

In two cases, a 25 mm gooseneck snare was used to snare the device around its waist. In both cases, the retrieval sheath was oversized by 5F. In case 2, the device was successfully retrieved, folding on itself as it entered the sheath. In case 10, the device could not be brought into the sheath, but was later successfully extracted by snaring the RA pin.

Four attempts involved capturing the RA pin of the device with the jaws of the Occlutech Flex II delivery cable. In case 8, the ASD device accidentally detached from its delivery cable when part of the LA disc had been exposed. The RA disc and part of the LA disc remained within the long sheath. The device was stabilized by holding the LA disc with a 40 mm Lassos snare (Osypka ag, Rheinfelden-Herten, Germany). Attempts to remove the device by snaring the RA pin failed as the snare repeatedly slipped off. It was not possible to grasp the RA pin with 5.2F myocardial biopsy forceps (William Cook Europe, Bjaeverskov, Denmark) as the jaws could not open within the sheath. However, the RA pin was successfully grasped by the jaws of the Occlutech Flex II delivery cable and the device was safely withdrawn (Supporting Information Moving Image 5). During the retrieval the device moved forward but was kept within the sheath by the Lassos snare. In case 3, two gooseneck snares were used simultaneously to grasp the RA pin of a device that had embolized to the right ventricular outflow tract. Both snares slipped off when attempting to retract the device, leaving the RA pin in the tip of the long sheath. The RA pin was then successfully grasped by the jaws of the Occlutech Flex II delivery cable (Supporting Information Moving Image 6). In case 4 a similar technique was attempted to electively retrieve an ASD device from the atrial septum. A snare was used only to guide the RA pin into the tip of the Mullins sheath. An attempt was then made to capture the RA pin with the jaws of the delivery cable, but the RA pin was obliquely orientated to the tip of the sheath and the ball of the pin could not be grasped. However, when the Mullins sheath was withdrawn slightly to expose the RA pin and the jaws of the delivery cable were advanced out of the tip of the sheath, the Mullins sheath could be used to steer the jaws toward the pin and the pin could be grasped easily allowing the device to be successfully removed (Supporting Information Moving Image 7).

The Osypka catcher catheter (Osypka ag, Rheinfelden-Herten, Germany) was used in case 5 (Fig. 2). The forceps of the catheter successfully closed around the RA pin and allowed the device to be extracted easily through a sheath 3F larger than the minimum size required for the device (Supporting Information Moving Image 8).

DISCUSSION

The IRFACODE registry reported a 0.3% embolisation rate in 1333 patients who underwent ASD closure with an Occlutech device [2]. In our series transcatheter device retrieval was successful in 92% (11/12) of cases and 88% (7/8) of cases where the device had embolized. Immediate surgical retrieval remains the procedure of choice in a few cases, when the device is trapped in the mitral valve support apparatus or the patient is too unstable to tolerate catheter manipulation to extract the device. It is arguable that surgery is also the best option when the largest device has embolised, as cardiopulmonary bypass is required in any event, in order to carry out patch closure of the ASD.

During snare retrieval the force required to withdraw a device into the sheath depends on the degree of alignment of the RA pin or hub to the tip of the sheath and the size of the retrieval sheath. The RA hub on the Amplatzer ASD occluder (Fig. 1) can usually be held securely by a snare. Therefore, although the RA hub is often perpendicular to the tip of the sheath as the device is withdrawn, bench testing has shown that successful retrieval is possible with a sheath only two French sizes larger than the minimum size required for the Amplatzer device [1].

When the RA pin of an Occlutech device is snared, the loop of the snare tightens just below the ball of the pin (Fig. 1). In 80% of snare retrieval attempts in this study the snare slipped off the pin as the operator tried to retract the device into the sheath. The snare did not grip the pin sufficiently to withstand the traction required to retrieve the device. The likely explanation is that a loop snare slips off a small smooth ball more easily than it slips off a hub that houses a screw thread. Changing the type of snare does not solve the problem.

Recognized techniques to assist Amplatzer device retrieval include using larger retrieval sheaths, creating a bevel or notch at the tip of the retrieval sheath or using a bioptome to pull on the LA disc of the device to help align the screw mechanism to the tip of the sheath [1,3]. In Occlutech device retrieval, oversizing the sheath by 3F did not consistently avoid the snare slipping off the pin of the Occlutech device. Oversizing the sheath by 5F was successful, but oversizing to this

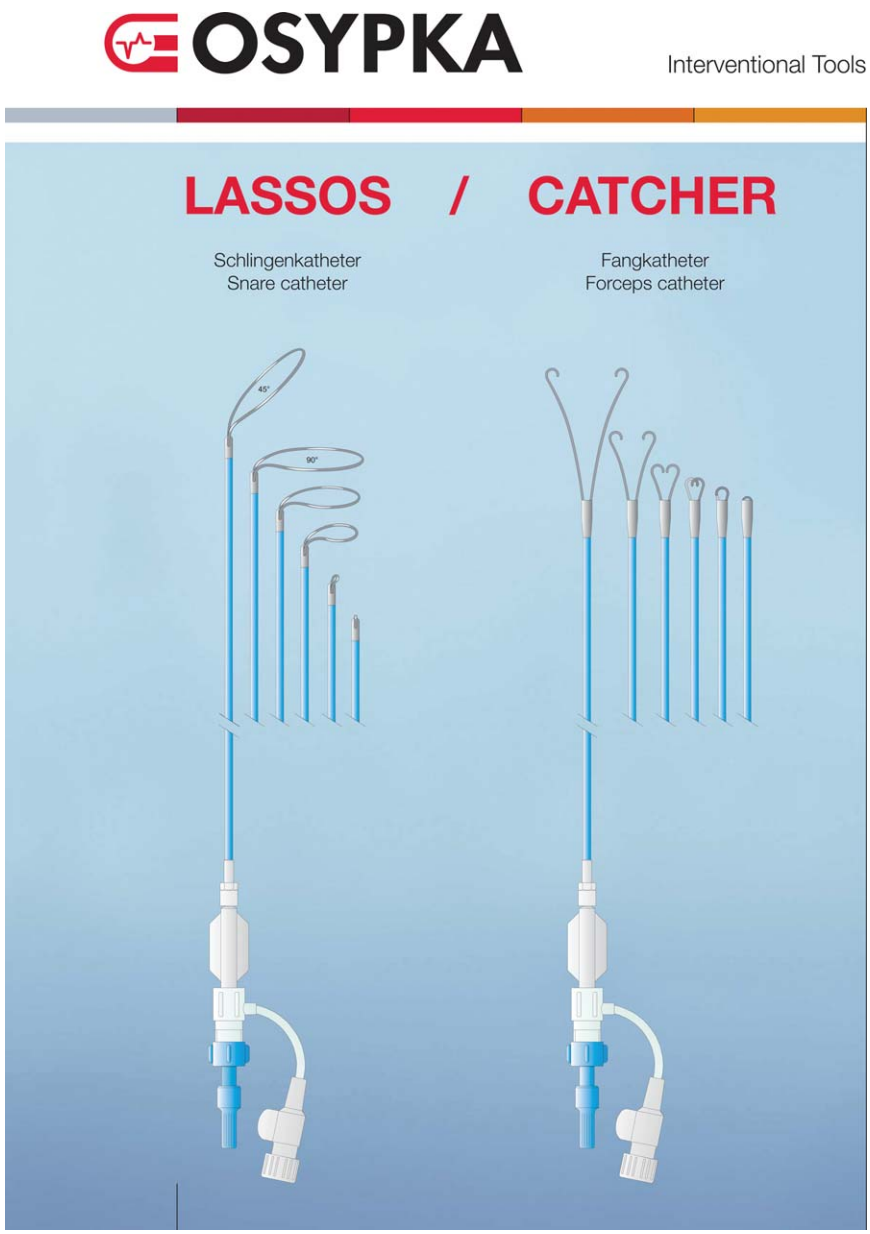

Fig. 2. Osypka Lassos and Catcher catheter; "with permission from Osypka company." [Color figure can be viewed at wileyonlinelibrary.com]

degree may not be practical in children, as it may result in vascular damage. Moreover, some catheter laboratories do not routinely stock 16F and 18F sheaths, which are required to achieve this degree of oversizing when retrieving larger devices. It is not clear whether bevelling the end of the sheath assisted retrieval in case 12 as, despite this modification, the snare slipped off 5 times before the device was finally withdrawn. It is also not clear whether funnelling the LA disc into the IVC assisted retrieval in case 1, as upsizing the retrieval sheath to 14F may have been a more important factor in success. In case 7, when the device was elongated in the DAo, the RA pin was aligned with the long axis of the retrieval sheath. We propose that it was possible to retrieve this device into a sheath only 1F larger than the minimum sheath size required for device implantation because less traction force is required to withdraw a device when the RA pin is aligned with the tip of the sheath.

Another effective technique to retrieve the Occlutech device was to grasp the RA pin with the jaws of the Occlutech Flex II delivery cable. The jaws were able to open within the Mullins sheath and close around the ball of the RA pin when the device was within the

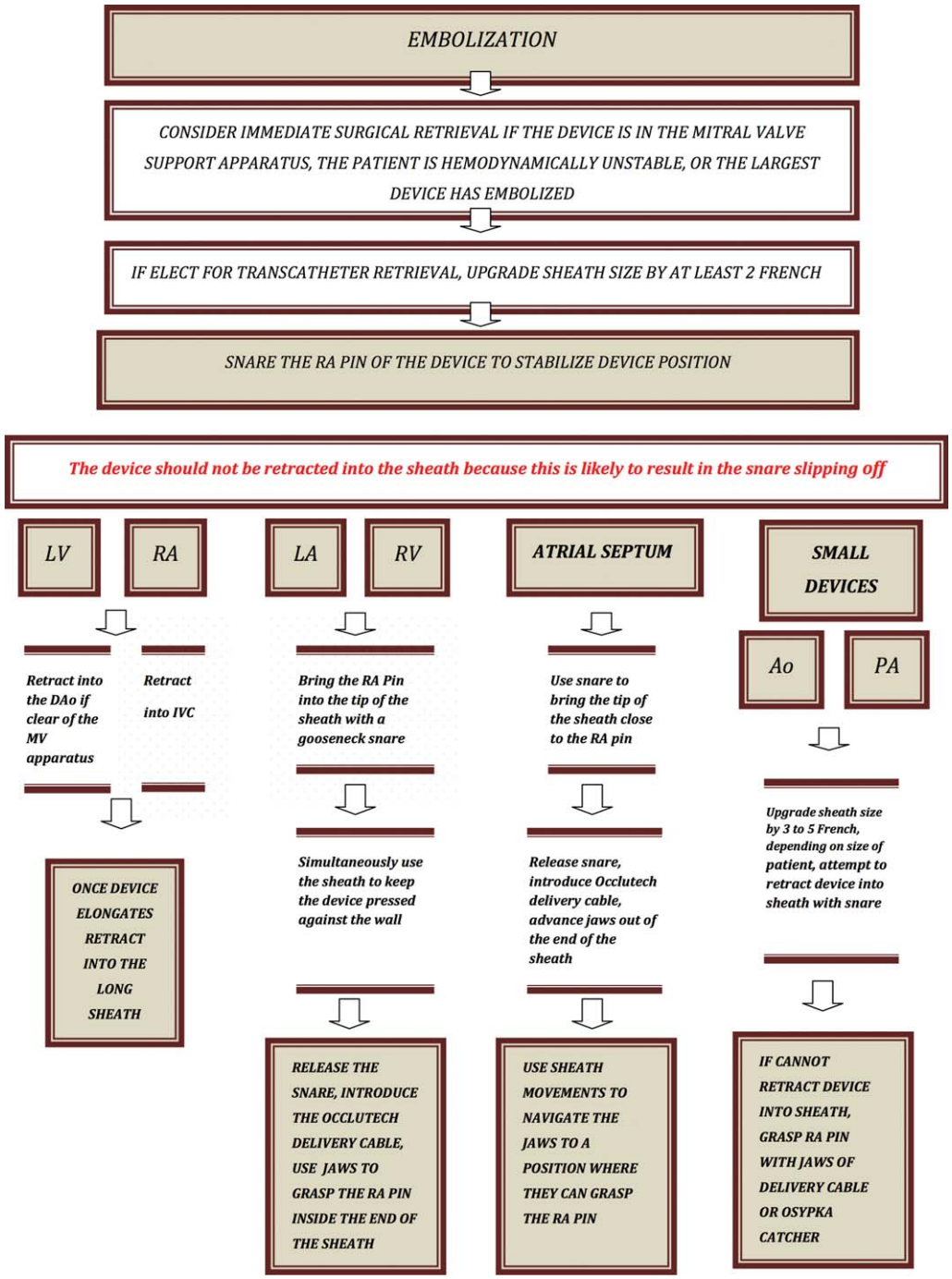

Fig. 3. Algorithm for Occlutech device retrieval.Abbreviations: Ao = aorta, DAo = descending aorta, IVC = inferior vena cava, LA = left atrium, LV = left ventricle, MV = mitral valve, PA = pulmonary artery, RA = right atrium, RV = right ventricle. [Color figure can be viewed at wileyonlinelibrary.com]

sheath or the RA pin was at the tip of the sheath, providing the RA pin was well aligned to the long axis of the sheath. There is a forward force on the RA pin during this process, but this is not an issue if the body of the device is held securely by a secondary snare or the tip of the sheath is pressing the device against another cardiac structure, such as the wall of the right ventricle. We suggest that this technique should be equally effective for devices held against the wall of the LA. When the RA pin is at an oblique angle to the tip of the retrieval sheath, for example, when the device is electively retrieved from the atrial septum, a different

technique is required. The tip of the sheath is brought close to the RA pin by snaring the pin and advancing the sheath over the snare catheter until it is near the device. The snare is then released and withdrawn and the jaws of the delivery cable are advanced out of the sheath to grasp the RA pin (case 4). The Osypka catcher catheter, which has forceps that can close tightly around the RA pin, can be used in the same way to grasp a device close to the tip of the long sheath.

STUDY LIMITATIONS

The main limitation of this study is the small number of patients involved. Larger numbers are required to draw definitive conclusions about the efficacy of the various retrieval techniques. Bench testing is needed to further evaluate these techniques and the optimal sheath size required for retrieval.

CONCLUSION

This is the first study documenting the technical challenges of Occlutech ASD device retrieval. Although 92% of devices were successfully retrieved, snaring the RA pin of the device is often unsuccessful as the snare slips off. Additional techniques are recommended, such as funnelling the device into a blood vessel, so that it is elongated, before pulling it into the long sheath, or grasping the RA pin with the jaws of the Occlutech Flex II delivery cable. An algorithm for device retrieval is suggested in Fig. 3.

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