

Incidence of embolized devices

- A survey of AGA proctors carried out in 2003 revealed that there were 21 embolizations out of 3,824 ASO implants (0.55%).
- The incidence in every day practice varies in the literature from 1.5 5%
- Nevertheless it remains the most common device related adverse event in the Manufacturer and User Facility Device Experience (MAUDE) data issued by the FDA.



Causes of device embolization

- 1. Undersized device
- Unsuitable anatomy such as Inadequate or floppy rims
- 3. Operator-related technical issues such as mal positioning of the device, excessive tension on delivery cable during deployment.
- 4. Malfunctioning device such as Fragmentation, dislodgment, fracture,....etc



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What about retrieval?

- In the survey conducted among AGA proctors, 15 of the embolized devices were retrieved using a trans-catheter approach (71.4%) and 6 were retrieved surgically (28.5%).
- On the other hand in the MAUDE database the device was retrieved surgically in 77.2% of cases and using a trans-catheter approach in 16.7% of cases. There were 2 deaths related to embolization.



Basic principles

- Prevention is better than cure
- Always be ready
- Know your device
- Safeguard the patient and the device
- Know when to stop
- Late embolization is not uncommon
- Embolization may be fatal so does retrieval
- Risk assessment algorithm





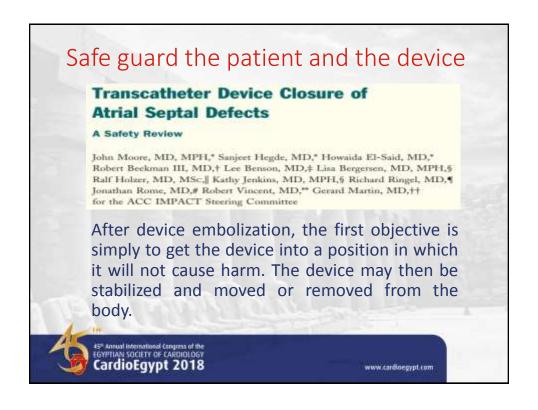












Know when to stop

- The patient is vitally stable
- The device is not interfering with the circulation

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- There is high risk of injury of intra cardiac structures
- There is high incidence of device entrapment or major vascular complication with further retrieval of the device

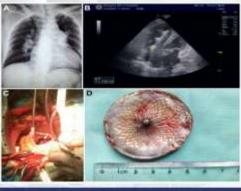


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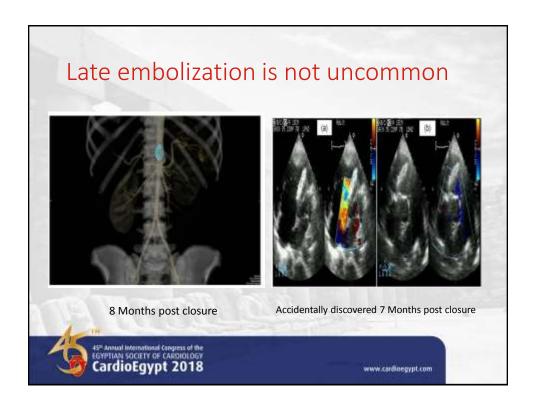
Late embolization is not uncommon

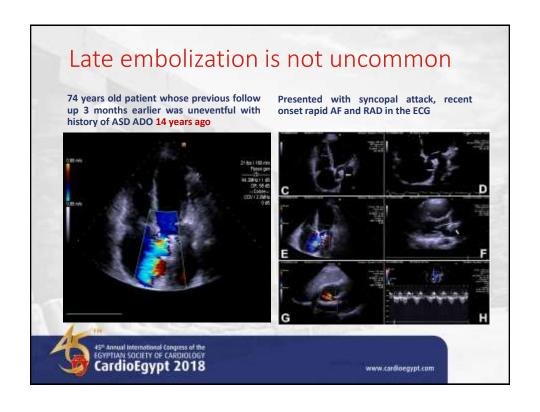
Silent Embolization of an Atrial Septal Defect Occluder Into the Right Ventricle Detected 20 Months Post-Implantation

Liang Tang, MD, Zhen-fei Fang, MD, Jian-jun Tang, MD, Xiang-qian Shen, MD, Xin-qun Hu, MD, and Sheng-hua Zhou, MD, PhD



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Embolization may be fatal so does retrieval

- Embolization interfering with flow or occluding a major vessel can be fatal perhaps in seconds as when a device occludes the RV inflow or the MPA
- Retrieval with possibility of major vessel dissection or perforation can lead to life threatening bleeding
- Retrieval with intra cardiac entrapment associated with major damage to the conduction system or the cardiac valves or resulting in cardiac perforation



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Risk assessment algorithm

What embolized?

Hard device or soft device

When it embolized?

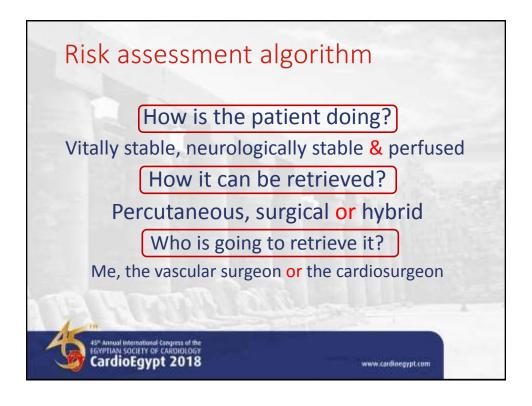
Now, yesterday or I don't know

Where it embolized?

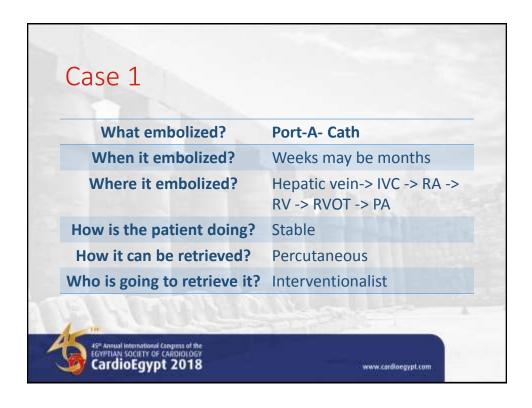
Intra cardiac or extra cardiac

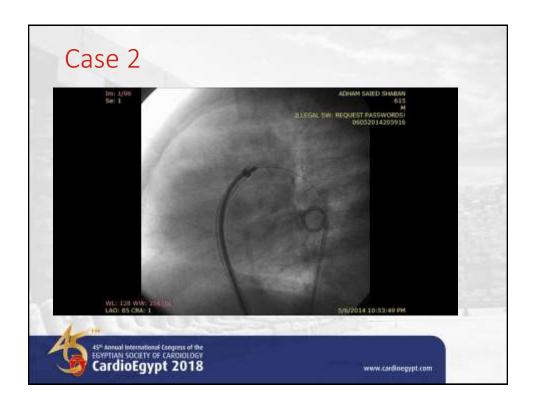
Venous or arterial











| What embolized? | PDA-R |
|------------------------------|--------------------|
| When it embolized? | IMMEDIATELY |
| Where it embolized? | PARTIALLY TO Aorta |
| How is the patient doing? | Stable |
| How it can be retrieved? | Percutaneous |
| Who is going to retrieve it? | Interventionalist |



| What embolized? | PDA-R |
|------------------------------|-------------------|
| When it embolized? | 1-24 hours |
| Where it embolized? | TO Aorta |
| How is the patient doing? | Stable |
| How it can be retrieved? | Percutaneous |
| Who is going to retrieve it? | Interventionalist |



| What embolized? | Amplatzer ASD ADO |
|------------------------------|-----------------------------|
| When it embolized? | Immediately |
| Where it embolized? | Disengaged delivery in ULPV |
| How is the patient doing? | Stable |
| How it can be retrieved? | Percutaneous/surgical |
| Who is going to retrieve it? | Interventionalist/Vascular |



| What embolized? | Occluotec ASD ADO |
|------------------------------|-------------------|
| When it embolized? | Immediately |
| Where it embolized? | Left ventricle |
| How is the patient doing? | Stable |
| How it can be retrieved? | Surgical |
| Who is going to retrieve it? | Cardiosurgery |

