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| Hosp No. : | HKID No.: |
| Case No. : | |
| Name : | |
| DOB : | M / F |
| Adm Date : | |
| Contact No.: | |

Procedure Information Sheet - Transcatheter Aortic Valve Implantation Procedure (TAVI)

1. Introduction

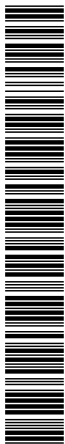
1.1. Aortic stenosis (AS) is a common heart valve problem associated with heart failure and death. Surgical valve repair or replacement is recommended if AS patients begin to develop symptoms especially shortness of breath. Generally, open heart surgery is the clinically proven treatment option to relieve symptoms and prolong life. If your risk of undergoing open heart surgery is too high due to medical or anatomical reasons and considered inoperable, another treatment option will be the Transcatheter Aortic Valve Implantation (TAVI). This is a new, minimally invasive procedure, in which a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve. Compared with open heart surgery, the complications and mortality rate of TAVI is relatively low and is even suitable for elderly patients. TAVI could be a potential alternative to medical therapy for severe AS patients who are not candidates for open heart surgery.

2. Before the Procedure

- 2.1. The doctor will review your medical record, history and current medications to confirm you are suitable for TAVI.
- 2.2. Echocardiogram (TTE) will be performed to assess and confirm the anatomy and functional significance of the aortic stenosis, to see whether you are feasible for TAVI.
- 2.3. In addition, before the procedure, clinical staffs will conduct electrocardiogram, chest X-ray, blood tests, CT scan or coronary angiography for you, to confirm your suitability to undergo the procedure
- 2.4. Our medical staffs will explain to you and your relatives the benefits and details of the procedure, together with the possible risks and complications. You will have to sign a consent form.
- 2.5. Before the procedure, your doctor will prescribe two anti-platelet medications for you to prevent blood clotting formation. You will be given antibiotic to decrease your chance of developing infection on date of procedure.
- 2.6. Anti-coagulant or Metformin (for diabetes) may have to be stopped several days before the procedure. Drugs such as steroid may be prescribed as prophylaxis for allergy.
- 2.7. Fasting of 4-6 hours is required prior to the procedure. An intravenous drip may be set up. Shaving may be required over the puncture sites.
- 2.8. If you are a female, please provide your last menstrual period (LMP) and avoid pregnancy before the procedure as this procedure involves exposure to radiation.

3. The Procedure

- 3.1. Placement of the bioprosthetic valve will be performed by cardiologists (and in some occasions, together with cardiothoracic surgeons) experienced in intervention for structural heart diseases. This TAVI will be performed in a well-equipped cardiac catheterization laboratory or hybrid operation theatre guided by fluoroscopy without or without transesophageal echocardiography (TEE).
- 3.2. This procedure is performed under sterile conditions with general anaesthesia or controlled Propofol sedation monitored by an anesthetist.
- 3.3. Electrodes will be adhered on the chest to monitor the heart rate and rhythm. Blood oxygen monitor through your finger tip will be set up. Measurement of blood pressure from your arm will be taken during the procedure.
- 3.4. The delivery catheter is introduced into the femoral artery and threaded up through the vessels into the heart. Vessels in both left and right femoral sites will be used. In some occasions, when femoral access is deemed unsuitable for this procedure, alternative approaches involving mini-thoracotomy or surgical cut-down would be adopted.



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- 3.5. Your doctor may perform TEE during the procedure if necessary. This test uses sound waves to take a closer look at the inside structures of the heart. To perform the test, you will swallow a thin flexible tube with a special tip. This tube sits in the esophagus (the tube that connects the mouth to the stomach). The special tip of the tube sends out sound waves (ultrasound) that echo within the chest wall. The esophagus is located behind the heart so these echoes are picked up and create a picture of the heart that is displayed on a video monitor. The pictures will allow your doctor to take a closer look at your valve.
- 3.6. After your doctor has taken a good look at your valve, a balloon valvuloplasty will be performed. Balloon valvuloplasty is a procedure used to widen a stiff or narrowed heart valve. A wire and catheter (a thin tube) are guided by x-rays through the heart and positioned through the diseased heart valve. A balloon is placed over the wire and inflated, enlarging the opening through the diseased valve allowing the bioprosthetic valve to be placed.
- 3.7. The femoral arterial access site would be closed by designed vascular closure devices after the procedure.
- 3.8. After device implantation, patients would be prescribed with double anti-platelets (Aspirin and Clopidogrel) for initial 3-months and then Aspirin alone indefinitely. Echocardiography would be performed at 3 to 6 months after the procedure to assess the severity of aortic valve narrowing.
- 3.9. A temporary pacing wire would be inserted through neck or groin veins during the procedure to support the operation. Permanent pacemaker may be required if patient develop severe bradycardia after the operation.

4. Potential benefits

- 4.1. The possible benefits to you are that bioprosthetic valve may reduce the severity of AS and improve your symptoms and longevity.

5. After the procedure

- 5.1. After the procedure, catheters will be removed. The wound site will be compressed to stop bleeding.
- 5.2. Nursing staff will check your blood pressure, pulse and wound regularly.
- 5.3. Bed rest may be necessary for 4 hours. In particular, please do not move or bend the affected limb. Whenever you cough or sneeze, please apply pressure on the wound with your hand.
- 5.4. You should inform your nurse if you have any discomfort in particularly chest discomfort or find blood oozing from the wound site.
- 5.5. Once diet is resumed, please take more fluid to help eliminate contrast by passing urine.
- 5.6. Please follow instruction for the use of medications.

6. Follow Up

- 6.1. Usually you can be discharged 5-7 days after the procedure.
- 6.2. The wound will be inspected and covered with light dressing. Please keep the wound site clean and change dressing if wet. In general, showers are allowed after 2 days.
- 6.3. Please avoid vigorous activities (household or exercise) in the first 3 days after the procedure. Bruising around the wound site is common and usually subsides 2-3 weeks later. If you notice any signs of infection, increase in swelling or pain over the wound, please come back to the hospital or visit a nearby Accident and Emergency Department immediately.
- 6.4. Usually your doctor has explained to you the results of the procedure before discharge. Should you have further questions, you and your close relatives can discuss with your doctor during subsequent follow-up.

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7. Risk and Complications

7.1. There is a small risk about 0.5-1% of respiratory depression, low blood pressure or heart rate associated with general anaesthesia or propofol use. The sedative process will be closed monitored by an anaesthetist to ensure safety. There is a small risk regarding TEE (less than 0.5% esophageal rupture or aspiration) but the test would be necessary in most patients to have

clear look of aortic valve, to guide the operation and to monitor development of severe complications. The procedure is associated with considerable morbidities (about 15% vascular complications or bradycardia and 5% major stroke) and mortality (about 10% death rate at 30-day follow up). The procedure may still be worthwhile because more than half of the symptomatic severe AS patients will die within two years if no treatment is given.

7.2 Broken guidewire (0.1-0.8%).

8. Remarks

8.1. It is hard to mention all the possible consequences if this procedure is refused.

8.2. The list of complications is not exhaustive and other unforeseen complications may occasionally occur. The risk quoted is in general terms. In special patient group, the actual risk may be higher.

8.3. Should a complication occur, another life-saving procedure or treatment may be required immediately.

8.4. If there is further query concerning this procedure, please feel free to contact your nurse or your doctor.

9. Reference

9.1. Hospital Authority (2016). Smart Patient. Retrieved from:

https://www.ekg.org.hk/pilic/public/Cardiac_PILIC/Cardiac_TranscatheterAorticValveImplantation_024_2_eng.pdf

I, _____ acknowledged that the above information concerning the operation or procedure has been explained by Dr _____. I have also been given the opportunity to ask questions and received adequate explanations concerning the condition and treatment plan.

Name:

Patient No.:

Case No.:

Sex / Age:

Unit Bed No.:

Case Reg. Date & Time:

Patient Signature: _____

Patient Name: _____

Date: _____

