

香港社會醫學學院 HONG KONG COLLEGE OF COMMUNITY MEDICINE founder College of the Hong Kong Academy of Medicine Incorporated with limited liability



## **ADMINISTRATIVE MEDICINE**

# **Part I Examination**

## Thursday 6 June 2024

## 14:30 – 16:00 (1½ hours)

# Paper IIB

## Candidates must answer all parts of these questions

Style, clear grammatical English and legibility will be taken into consideration by the Examiners. Answers should be written in a form appropriate to the audience specified in the question. The weighting of marks for each part of the question is shown in parentheses.

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#### **Background Information**

Aortic stenosis is the most common valvular heart disease in the elderly with an incidence of about 4.6% in those 75 years of age and above. Once the disease becomes symptomatic, the average survival is about 2-3 years with a high risk of sudden death. Medical treatment is not effective. Surgical Aortic Valvular Replacement (SAVR) is the gold standard, and Transcatheter Aortic Valvular Implantation (TAVI) emerges as a viable alternative in inoperable or high risk elderly patients as this does not involve open-heart surgery nor cardio-pulmonary bypass. TAVI has been introduced in Hospital Authority years ago and now available as a treatment in PWH QEH and QMH where cardiac surgical support is available. In terms of financial support, the TAVI device can be covered under the medical device list of Community Care Fund, and 80 applications were processed by Jan 2020.

This is the description about the procedure in the patient information pamphlet issued by the Central Committee on Cardiac Service version (ver 2.0, last reviewed on 15 March 2024) "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

## **QUESTION CONTINUES**

who are not candidates for open heart surgery." A similar passage could be found in patient information pamphlets of 2 other private hospitals.

Various TAVI registries to capture the outcome are available. Tay et al (AsiaIntervention 2021;7:54-59) published the initial results of the prospective Asia Pacific TAVI registry under the auspices of the Asian Pacific Society of Interventional Cardiology (APSIC) involving 7 centres involving Hong Kong, Japan, Singapore and others for severe symptomatic aortic stenosis. This series involved of 1,125 patients recruited from 2009 to 2017 showing a 30-day all-cause mortality rate of 2.5%. Two factors were associated with increased mortality, namely a baseline logistic EuroSCORE exceeding 16 (2.8-times increased) and Post-procedural stroke (4.9 times increased) was also associated with increased mortality.

#### The Scenario of the question

You are the Deputy Hospital Chief Executive (Professional Affairs) in one of the larger regional hospitals. The chief cardiologist in your hospital sent you a recent paper (*Blankenberg S, Seiffert M, Vonthein R, et al. Transcatheter or surgical treatment of aortic-valve stenosis. N Engl J Med. DOI: 10.1056/NEJMoa2400685, attached)* on a randomized controlled trial showing that in a non-inferiority trial for severe aortic stenosis in patients with low surgical risks, TAVI has performed as good as surgical aortic valve replacement and therefore should be time to consider introducing it to a bigger group of patients, i.e., your hospital. Cardiologists working outside the 3 hospitals taking care of a sizeable population in Hong Kong should also learn the skills. The cardiologists asked whether something should be done, as he is well connected with the Hospital Governing

### **QUESTION CONTINUES**

Board and also with philanthropists in the local community. Funding is not a big concern.

After you have read into the article, you seek the advice of your Hospital Chief Executive who advises you to seek further information from the literature.

#### Questions

#### Please read the article and answer the following questions.

- Non-inferiority trials have been getting popular in the last decade or so. Explain the importance of non-inferiority trials, how they are done and when should these trials be used. (10 marks)
- 2. Construct a Forest Plot on the 2-sided distribution of Hazard Ratios (similar to Figure 3 of the attached paper). Using the procedure related mortality of a new treatment compared to a conventional treatment as an example, show the various possible patterns of HR with its 95% Confidence Intervals to enable a diagnosis of non-inferiority, inferiority and superiority of the new treatment compared to new treatment. (10 marks)
- 3. Is it time to draw the conclusion that TAVI is comparable in terms of efficacy and outcome to conventional surgical treatment and should be made available as a treatment option for all patients with aortic stenosis? Are there still unanswered questions? (15 marks)

### **QUESTION CONTINUES**

4. A member of the Hospital Governing Committee who is a medical practitioner, has raised a question to your Hospital Chief Executive about the application of TAVI and wishes this to be discussed as the agenda at the coming HGC Meeting in a week's time. As you are the most knowledgeable person in this area now, HCE has asked you to write a one-page summary about the implications of this non-inferiority trial and whether TAVI should be introduced in your hospital. The summary should include something about aortic stenosis in the elderly, treatment options in the HA, the implications of the recent trial, prevailing HA mechanisms and the conclusion. **(65 marks)** 

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