# 實證醫學 病例討論報告
# Evidence-Based Medicine

職級：PGY1

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# Clinical scenario

Patient profile

- This 72 years old female is a case of:

1. Aortic valve regurgitation
2. Hypertension
3. Dyslipidemia

- Cardiac sonography showed:
  - Aortic valve thickening with moderately-severe AR
  - Moderate MR
  - Aortic root, LV dilatation
  - LV eccentric hypertrophy
  - LV abnormal relaxation
- Coronary angiography
  - Normal coronary artery
  - 3-4 degree of AR.

# Background questions

- Question :
  - What are the indication of aortic valve replacement or repair in aortic regurgitation's patients?

- J Am Coll Cardiol 2006; 48:e1.

- Class I
  - There is evidence and/or general agreement
- Class IIa
  - The weight of evidence or opinion is in favor of the following setting
- Class IIb
  - The weight of evidence or opinion is less well established the following settings
- Class III
  - There is evidence and/or general agreement that is NOT indicated in patients with the following setting

# ACC/AHA Guideline Summary

- Indications for aortic valve replacement or repair in chronic aortic regurgitation
- Class I
  - Symptomatic patients with severe chronic AR, irrespective of left ventricular ejection fraction (LVEF).
  - If the presence of symptoms in patients with severe chronic AR is equivocal, the development of symptoms during an exercise test.
  - Asymptomatic patients with severe chronic AR and an LVEF ≤50 percent at rest.
  - Patients with severe chronic AR who undergo coronary artery bypass graft surgery (CABG) or surgery on the aorta or other heart valves.

# ACC/AHA Guideline Summary

- Class IIA
  - Asymptomatic patients with severe chronic AR and a normal LVEF (LVEF >50 percent) who have severe left ventricular dilatation (end-diastolic dimension >75 mm or end-systolic dimension >55 mm).

# ACC/AHA Guideline Summary

- Class IIB
  - Patients with moderate chronic AR who undergo CABG or surgery on the ascending aorta.
  - Asymptomatic patients with severe chronic AR and an LVEF >50 percent in whom the end-diastolic dimension is >70 mm or the end-systolic dimension is >50 mm, and there is evidence of progressive left ventricular dilatation, declining exercise tolerance, or an abnormal hemodynamic response to exercise.

# ACC/AHA Guideline Summary

- Class III
  - Asymptomatic patients with mild, moderate, or severe chronic AR and an LVEF >50 percent at rest in whom the degree of left ventricular dilatation is not moderate or severe (end-diastolic dimension <70 mm or end-systolic dimension <50 mm).

# ACC/AHA Guideline Summary

- Criteria for selection of an aortic valve in patients undergoing aortic valve replacement
- Class I
  - A mechanical valve in patients who already have a mechanical valve in the mitral or tricuspid position.
  - A bioprosthetic valve in patients who will not take or are incapable of taking warfarin or have a major contraindication to warfarin therapy.

# ACC/AHA Guideline Summary

- Class IIa
  - A bioprosthesis in patients ≥65 years of age who do not have risk factors for thromboembolism.
  - Patient preference can be considered in patients less than 65 years of age:
    → A mechanical valve is reasonable in patients who do not have a contraindication to warfarin therapy.

# ACC/AHA Guideline Summary

- Class IIa
  - A bioprosthetic valve may be chosen after a detailed discussion of the risks of warfarin therapy compared to the likelihood of repeat valve replacement in the future.
  - A homograft when aortic valve re-replacement is performed for active prosthetic valve endocarditis.

# ACC/AHA Guideline Summary

- Class IIb
  - A bioprosthesis in women of child-bearing age to avoid the problems associated anticoagulation during pregnancy.

# Foreground Questions

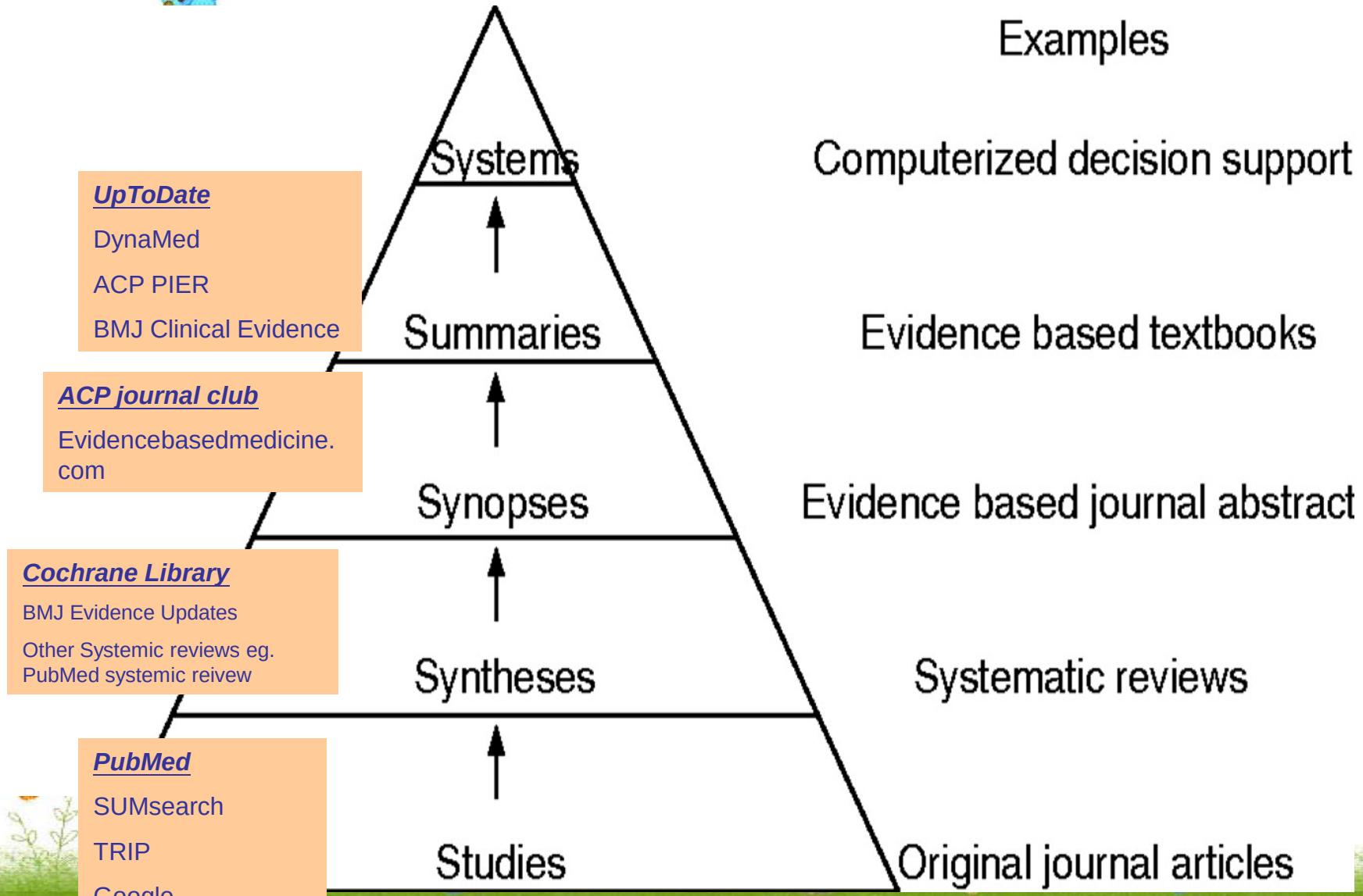
- Should the patient receive the aortic valve replacement (AVR) surgery, in considering the old age?
- What kind of aortic valve in our patients undergoing aortic valve replacement (AVR) is suitable?

# PICOT

- Patient/Problem
  - This 72 years old female had 1. Aortic valve regurgitation, 2. Hypertension, 3. Dyslipidemia
  - Aortic valve thickening with moderately-severe AR
  - Aortic root, LV dilatation
  - Normal LV systolic function
- Intervention
  - Medical treatment
  - Received Surgery with Mechanical valve
- Comparison
  - Bioprosthetic valve
- Outcome
  - Mortality or Morbidity
- Time - Not confined

# The "5S" levels of organisation of evidence from healthcare research

**Brian Haynes, R Evid Based Med 2006;11:162-164**

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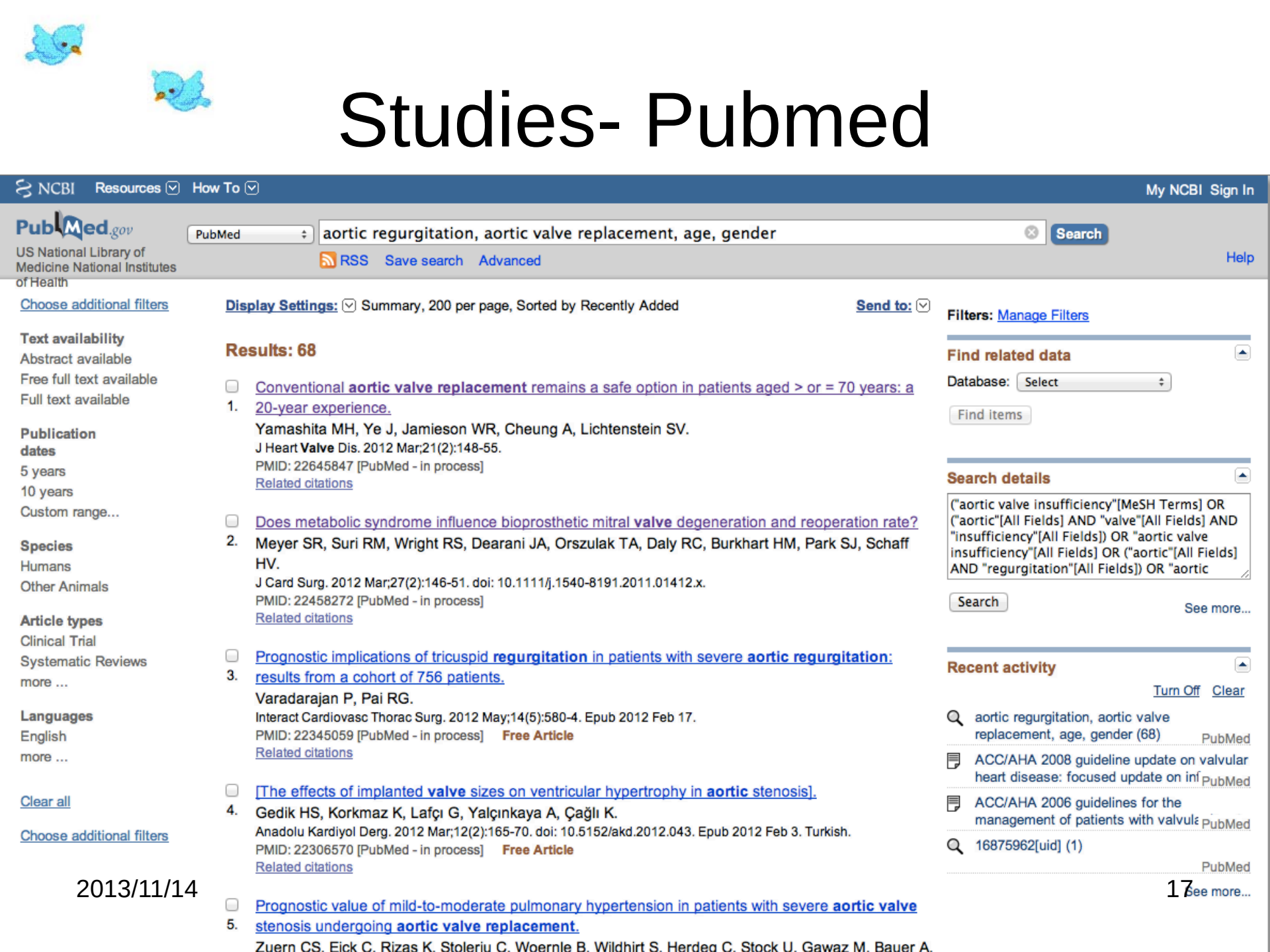

# Articles

- Conventional aortic valve replacement remains a safe option in patients aged > or = 70 years: a 20-year experience.
  - *J Heart Valve Dis. 2012 Mar;21(2):148-55.*

- Surgical management of aortic valve disease in the elderly: A retrospective comparative study of valve choice using propensity score analysis.
  - *J Heart Valve Dis. 2008 Jul;17(4):355-64; discussion 365.*

Conventional aortic valve replacement remains a safe option in patients aged > or = 70 years: a 20-year experience.

# Background

- Increased life expectancy has resulted in the elderly frequently presenting with severe aortic stenosis.
- It has therefore become important to define indications for conventional aortic valve replacement (AVR) and transcatheter aortic valve implantation (TAVI) in this patient population.
- Thus, patients aged > or = 70 years undergoing conventional isolated AVR were evaluated for predictors of early and late mortality.

# Methods

- A retrospective analysis was conducted of prospectively collected data available from 1,061 consecutive patients (age range: 70-94 years) who underwent isolated AVR between 1982 and 2002.
- The patient age groups were 70-74 years (n = 466), 75-79 years (n = 367), and > or = 80 years (n = 228). The mean follow up was 6.0 +/- 4.4 years, and the total follow up 6,390 patient-years.

# Results

- Early mortality was higher in patients aged > or = 80 years than in those aged 70-79 years.
- Early mortality in patients aged > or = 80 years was lower between 1998 and 2002 than between 1982 and 1997.
- Multivariate predictors of early mortality were age > or = 80 years, operative status, previous intervention, renal failure, and mitral regurgitation.

# Results

- The early nonfatal complication rate was similar for patients aged 70-79 years and > or = 80 years, but late mortality was lower between 1998 and 2002 than between 1982 and 1997 in patients aged 70-79 years, and in those aged > or = 80 years.
- The 10-year actuarial survivals after AVR in patients aged 70-74, 75-79, and > or = 80 years were 54 +/- 3.0%, 43 +/- 3.8% and 17 +/- 3.9%, respectively.

# Results

- Multivariate predictors of late mortality were age 75-79 years, age > or = 80 years, peripheral vascular disease (PVD) and chronic obstructive pulmonary disease (COPD).
- Female gender was shown to be protective.

# Conclusion

- Early mortality was higher in patients aged > or = 80 years undergoing AVR, though this has declined recently and is currently at an acceptable level.
- Other important predictors of mortality in elderly patients undergoing AVR are operative status, previous interventions, renal failure, mitral regurgitation, male gender, PVD, and COPD.
- Thus, conventional AVR remains a safe treatment option for the elderly patient.

# Surgical management of aortic valve disease in the elderly: A retrospective comparative study of valve choice using propensity score analysis.

# Background

- Aortic valve dysfunction is the most common form of valvular heart disease. As the population continues to age, a greater number of patients will become candidates for aortic valve replacement (AVR); hence, prosthetic valve choice becomes of paramount importance.

# Methods

- A retrospective analysis was conducted on 801 patients aged > or =65 years who underwent isolated AVR or AVR + coronary artery bypass grafting (CABG) between January 1989 and June 2003 with a Carpentier Edwards Perimount (CEP) pericardial bioprosthesis (n = 398) or a St. Jude Medical (SJM) mechanical valve (n = 403).

# Methods

- The mean age of CEP patients was 74.5 years (range: 65-89 years), and of SJM patients 73.9 years (range: 65-90 years).
- The follow up was 96.2% and 96.5% complete for CEP and SJM patients, respectively.

# Results

- The operative mortality was 4.0% (n = 16) among CEP patients and 6.5% (n = 26) among SJM patients.
- Predictors of hospital mortality included:
  - peripheral vascular disease (p = 0.018)
  - surgical urgency (p = 0.010)
  - preoperative intra-aortic balloon pump (IABP) (p = 0.010)
  - intraoperative perfusion time (p = 0.046)
  - intraoperative IABP (p = 0.001).

# Results

- Postoperative morbidities were similar for the two groups.
- The mean follow up was 72.4 and 59.2 months for CEP and SJM patients, respectively.
- The five-year actuarial survival was 70.9 +/- 2.3% for CEP and 71.8 +/- 2.4% for SJM patients; at 10 years the actuarial survival was 32.6 +/- 3.3% and 38.2 +/- 3.8%, respectively.

# Conclusion

- In comparable elderly patients, the outcomes of CEP and SJM valves after AVR showed no significant differences in hospital morbidity, mortality, mid-term survival or late cardiac events.
- However, the cumulative risk of lifelong anticoagulation with a mechanical valve is a serious consideration that must be factored into the selection algorithm.

# 證據等級

| Level | 與[治療/預防/病因/危害]有關的文獻 |
|---|---|
| 1a | 用多篇RCT所做成的綜合性分析(SR of RCTs) |
| 1b | 單篇RCT(有較窄的信賴區間) |
| 1c | All or none |
| 2a | 用多篇世代研究所做成的綜合性分析 |
| 2b | 單篇cohort及低品質的RCT |
| 2c | Outcome research / ecological studies |
| 3a | SR of case-control studies |
| 3b | Individual case-control studies |
| 4 | Case-series(poor quality :cohort / case-control studies) |
| 5 | 沒有經過完整評讀醫學文獻的專家意見 |

# Apply to the Patient

- In this patient, she had the symptomatic AR with normal LVEF.
- She was indicated for aortic valve replacement surgery.
- There was no significant difference of long term outcome between of mechanical or  bioprosthesis valve.
- However, we need evaluate the risk of long term using anticoagulant medicine.


# Thank for your attention

# Risk factors for venous thrombosis

- Inherited thrombophilia
- Factor V Leiden mutation
- Prothrombin gene mutation
- Protein S deficiency
- Protein C deficiency
- Antithrombin (AT) deficiency
- Elevated levels of Factor VIII
- Rare disorders
- Dysfibrinogenemia

# Risk factors for venous thrombosis

- Acquired disorders
- Malignancy
- Presence of a central venous catheter
- Surgery, especially orthopedic
- Trauma
- Pregnancy
- Oral contraceptives
- Hormone replacement therapy
- Tamoxifen, Thalidomide, Lenalidomide
- Immobilization,Congestive failure
- Antiphospholipid antibody syndrome
- Myeloproliferative disorders
- Polycythemia vera
- Essential thrombocythemia
- Paroxysmal nocturnal hemoglobinuria
- Inflammatory bowel disease
- Nephrotic syndrome