--EBM report--

Off-pump versus On-pump CABG in patients with Coronary artery disease

部門：外科部
報告：R2　賴衍翰
指導: 陳懷民　助理教授

12th, Aug. 2009

Clinical Scenario

- Patient: 朱 x 熹, male, 68 y/o; chart No.: 16814257
- Shortness of breath
- DM, Hypertension
- CAD s/p CABG in 1998
- TPR: 36.8 /160 / 35, BP: 148/98 mmHg
- Lab
  - WBC/Hb/PLT: 6400/13.5/183000
  - GOT/GPT: 17/17
  - BUN/Cr: 18.5/0.98
  - TG/Chol/UA: 117/201/7.5
  - Na/K/Cl: 140/2.6/100
  - SpO2 : 93 %
  - CK/CK-MB/Troponin-I: 264/26.3/3.7
- Chest PA: cardiomegaly; pulmonary edema with bilateral pleural effusion
- EKG: mild ST elevation over II, III, avF
- Thallium scan; Angiography: suspected restenosis

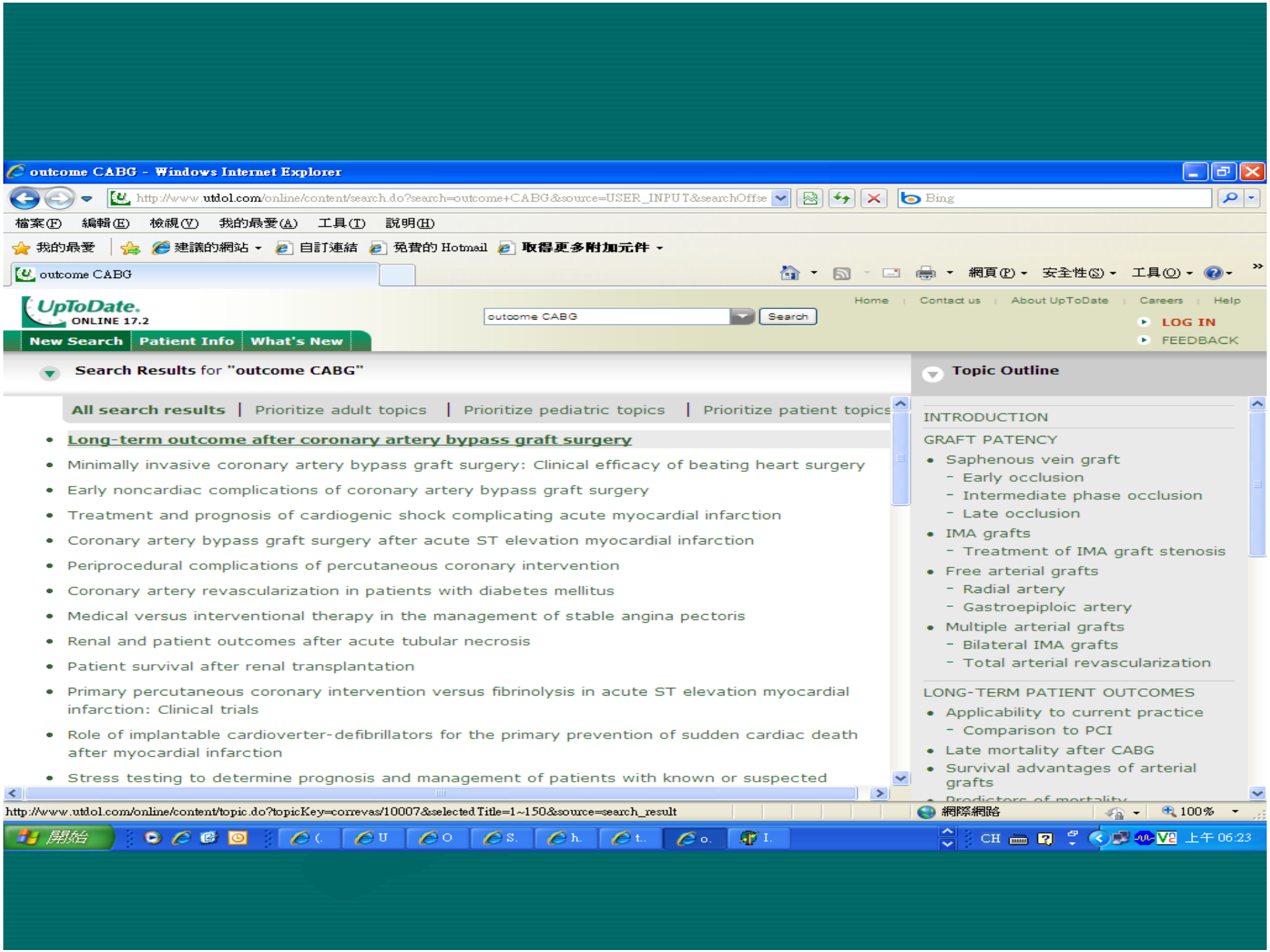
Forming a Background Question

- How to evaluate the outcome of the coronary artery bypass grafting (CABG)?

Searching for UptoDate

- Key word: outcome CABG
- Title:
  - Long-term outcome after coronary artery bypass graft surgery

    (Last literature review version 17.2: 五月 2009 | This topic last updated: 四月 15, 2009)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Long-term outcome after coronary artery bypass graft surgery
Minimally invasive coronary artery bypass graft surgery: Clinical efficacy of beating heart surgery
Early noncardiac complications of coronary artery bypass graft surgery
Treatment and prognosis of cardiogenic shock complicating acute myocardial infarction
Coronary artery bypass graft surgery after acute ST elevation myocardial infarction
Periprocedural complications of percutaneous coronary intervention
Coronary artery revascularization in patients with diabetes mellitus
Medical versus interventional therapy in the management of stable angina pectoris
Renal and patient outcomes after acute tubular necrosis
Patient survival after renal transplantation
Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials
Role of implantable cardioverter-defibrillators for the primary prevention of sudden cardiac death after myocardial infarction
Stress testing to determine prognosis and management of patients with known or suspected
Topic Outline
INTRODUCTION
GRAFT PATENCY
Saphenous vein graft
Early occlusion
Intermediate phase occlusion
Late occlusion
IMA grafts
Treatment of IMA graft stenosis
Free arterial grafts
Radial artery
Gastroepiploic artery
Multiple arterial grafts
Bilateral IMA grafts
Total arterial revascularization
LONG-TERM PATIENT OUTCOMES
Applicability to current practice
Comparison to PCI
Late mortality after CABG
Survival advantages of arterial grafts
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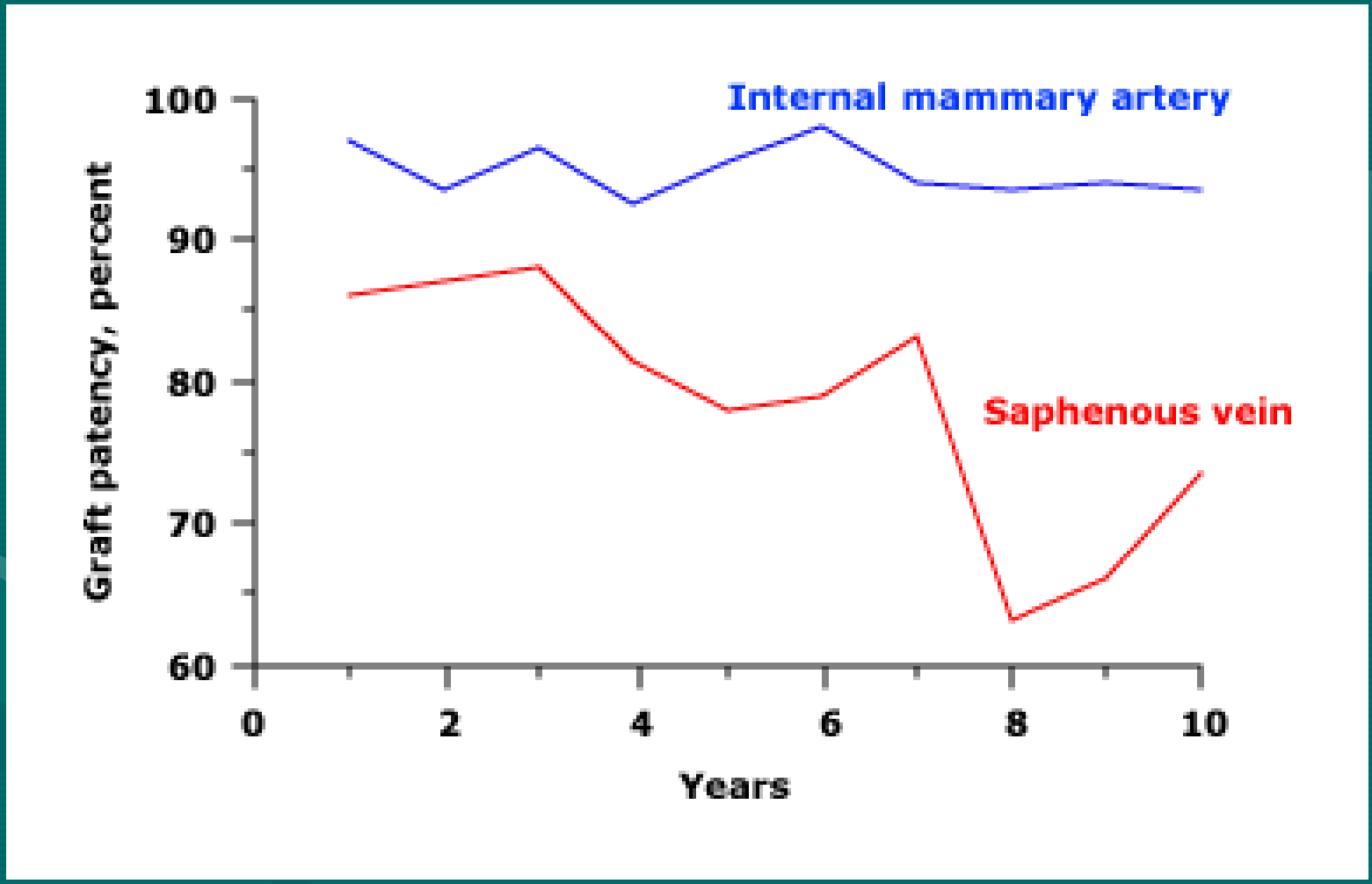
Long-term outcome after coronary artery bypass graft surgery

- Risk factor reduction
  - LDL-cholesterol < 100 mg/dl
  - BP < 130/80 mmHg
  - Strict glycemic control
- Comparison to PCI
- 10-year survival benefit
  - One vessel disease: 93 versus 88 % for SVGs
  - Two vessel disease: 90 versus 80 %
  - Three vessel disease: 83 versus 71 %

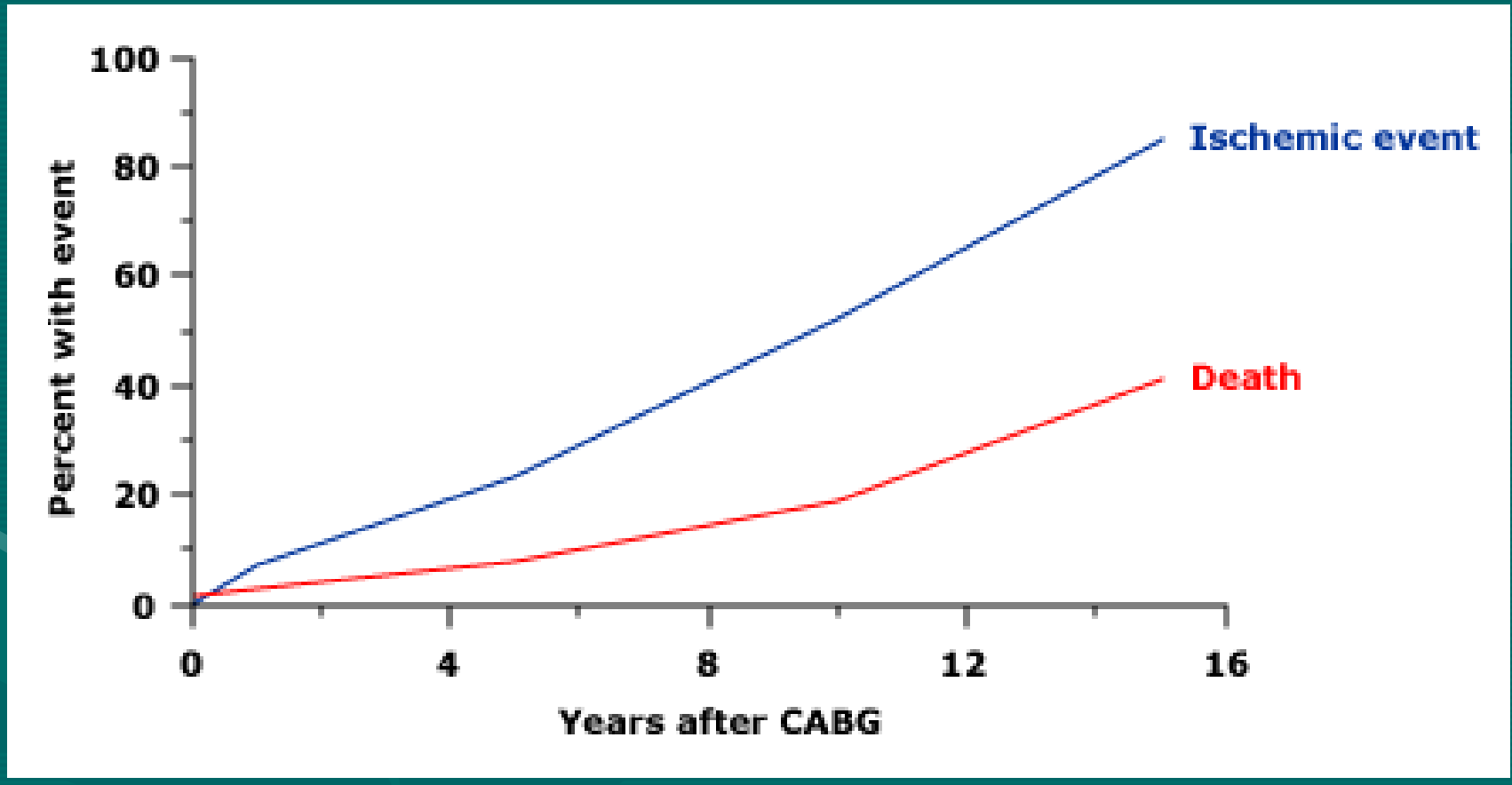
Graft patency



Long-term outcome after coronary artery bypass graft surgery

- Predictors of mortality
  - Perioperative MI
  - Cardiovascular risk factors
    - Age: relative risk 1.54/decade
    - Total cholesteral: 1.11/50 (mg/dl)
    - DM: 1.45
    - Hypertension: 1.28
    - Smoking: 1.33
  - Incomplete revascularization
  - Chronic kidney disease
  - Atrial fibrillation
  - Depression

Long-term outcome



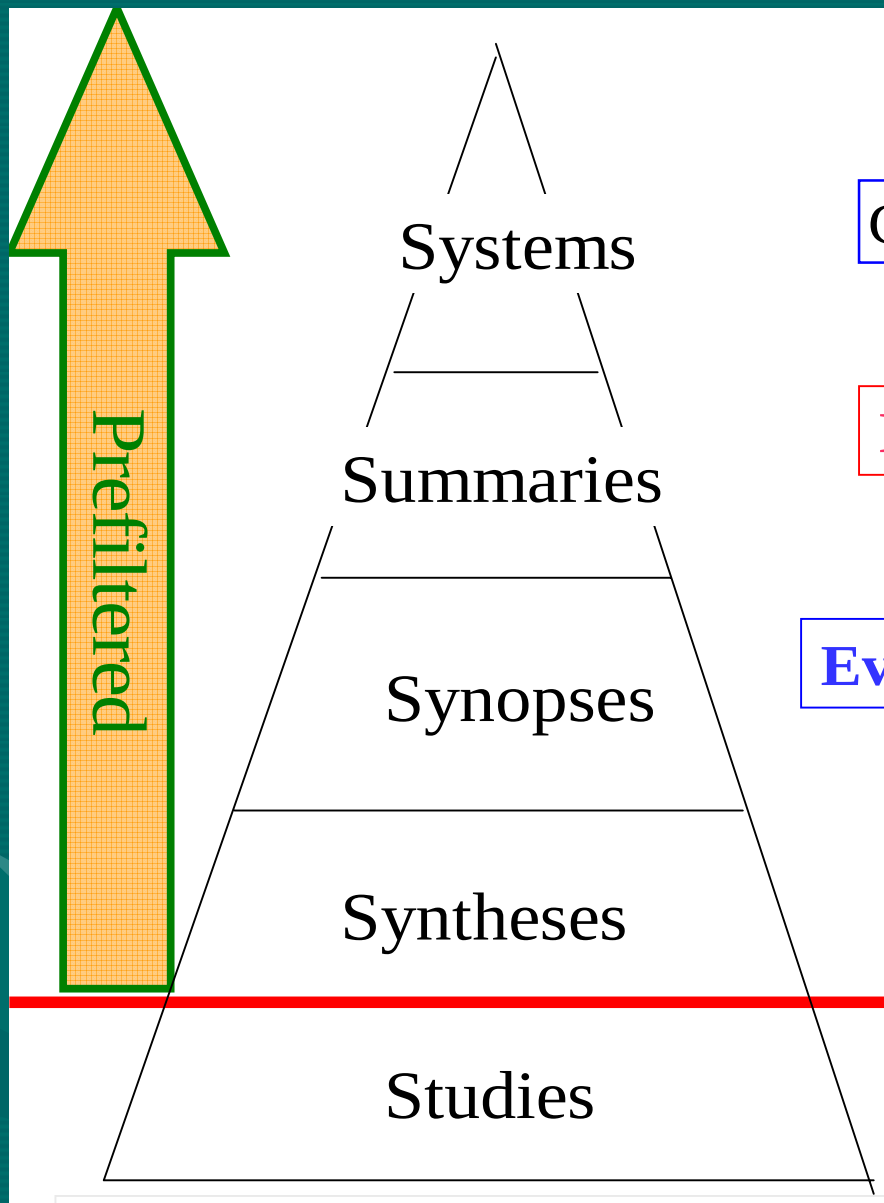
Forming a foreground Question

- Dose off-pump CABG show more benefits than on-pump CABG in patients with coronary artery disease (CAD)?

List the Question in PICO

P	Patient with CAD
I	Off-pump CABG
C	On-pump CABG
O	Mortality and Morbidity result

5S Levels



Computerized decision support

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Evidence-based textbooks

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Evidence-based journal abstracts

↓

Systematic Reviews

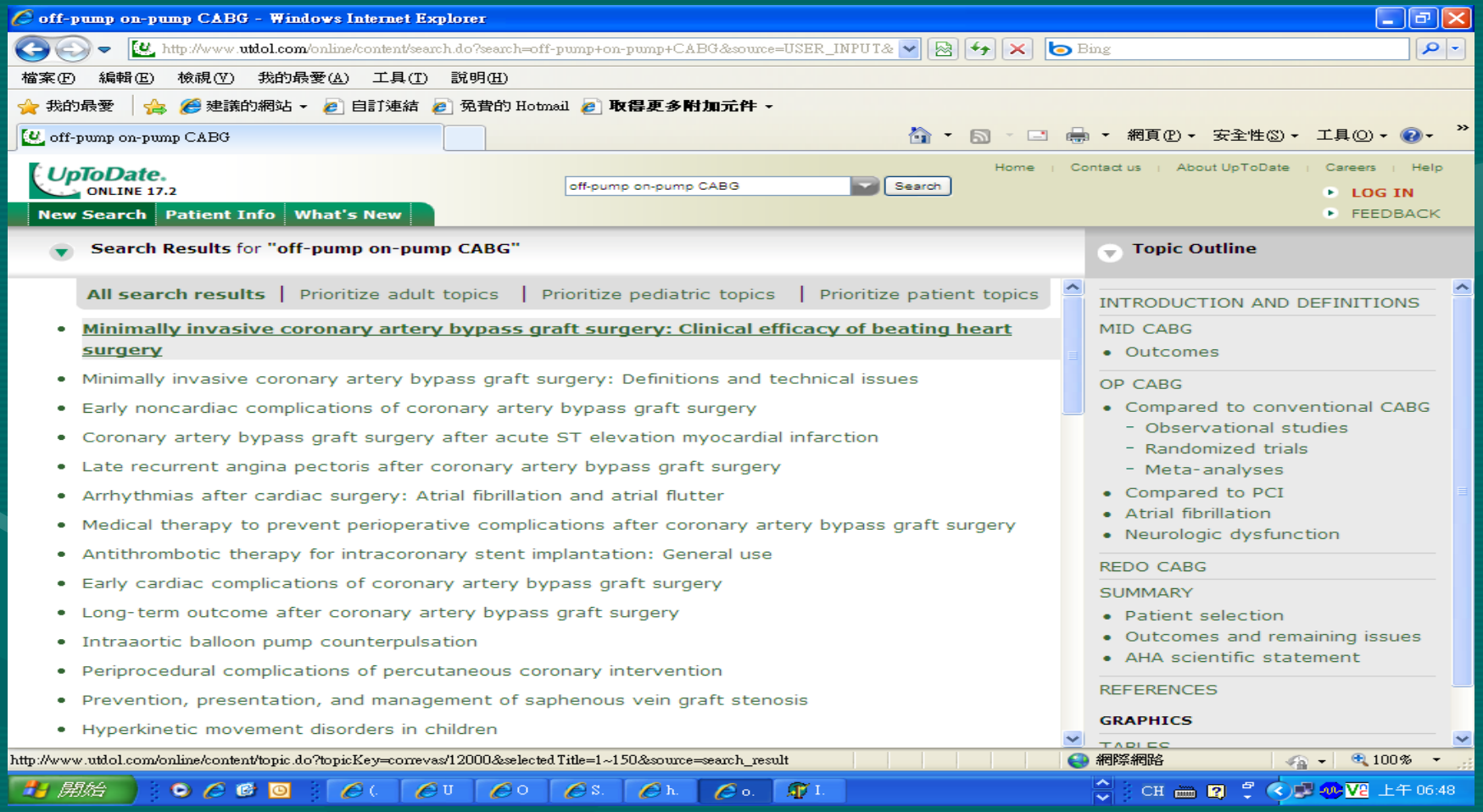
↓

Original journal articles

Modified from R Brain Haynes et al.: ACP Journal Club Nov/Dec 2006 | Vol 145 • Number 34;A8-A9.

搜尋Summary

- Database：UpToDate
- Key word:
  - Off-pump on-pump CABG
- Result:
  - **Minimally invasive coronary artery bypass graft surgery: Clinical efficacy of beating heart surgery (Last literature review version 17.2: 五月 2009 ｜ This topic last updated: 十二月 27, 2007)**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Minimally invasive coronary artery bypass graft surgery: Definitions and technical issues
Early noncardiac complications of coronary artery bypass graft surgery
Coronary artery bypass graft surgery after acute ST elevation myocardial infarction
Late recurrent angina pectoris after coronary artery bypass graft surgery
Arrhythmias after cardiac surgery: Atrial fibrillation and atrial flutter
Medical therapy to prevent perioperative complications after coronary artery bypass graft surgery
Antithrombotic therapy for intracoronary stent implantation: General use
Early cardiac complications of coronary artery bypass graft surgery
Long-term outcome after coronary artery bypass graft surgery
Intraaortic balloon pump counterpulsation
Periprocedural complications of percutaneous coronary intervention
Prevention, presentation, and management of saphenous vein graft stenosis
Hyperkinetic movement disorders in children
Topic Outline
INTRODUCTION AND DEFINITIONS
MID CABG
Outcomes
OP CABG
Compared to conventional CABG
Observational studies
Randomized trials
Meta-analyses
Compared to PCI
Atrial fibrillation
Neurologic dysfunction
REDO CABG
SUMMARY
Patient selection
Outcomes and remaining issues
AHA scientific statement
REFERENCES
GRAPHICS
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Minimally invasive coronary artery bypass graft surgery: Clinical efficacy of beating heart surgery

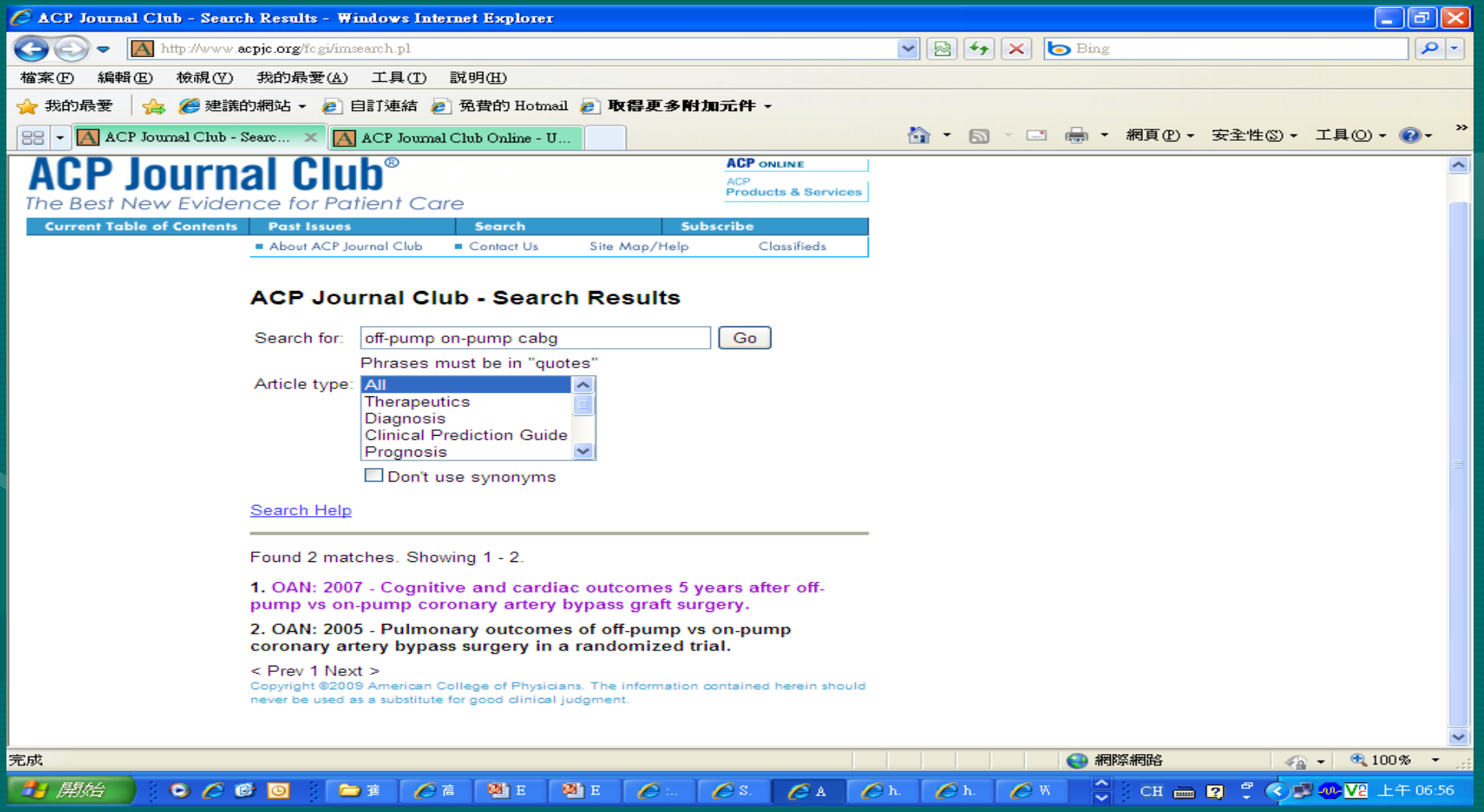
- Efficacy in patient with
  - single vessel disease
  - Left main disease
  - High preoperative risk
- Retrospective study from New York State
  - Off-pump versus on-pump: 14,000 versus 36,000
  - significantly lower in OP CABG
    - Mortality rate (CI 0.68-0.97)
    - Perioperative stroke (1.2 versus 1.5 %)
    - Respiratory failure (3.7 versus 4.2 %)
  - No significant difference in 3-year survival (90%)

Minimally invasive coronary artery bypass graft surgery: Definitions and technical issues

- Possible advantages
  - Reductions in the inflammatory response
  - Postoperative infection
  - Atrial fibrillation
- Possible disadvantages
  - Thromboembolic complication (1%)
  - Aortic dissection (rare, but may be greater than on-pump)
  - Vessel wall injury(?)

搜尋 Synopses

- Database: ACP journal club
- Key word:
  - Off-pump on-pump CABG
- Result: 2
  - 1. OAN: 2007 - Cognitive and cardiac outcomes 5 years after off-pump vs on-pump coronary artery bypass graft surgery.
  - 2. OAN: 2005 - Pulmonary outcomes of off-pump vs on-pump coronary artery bypass surgery in a randomized trial.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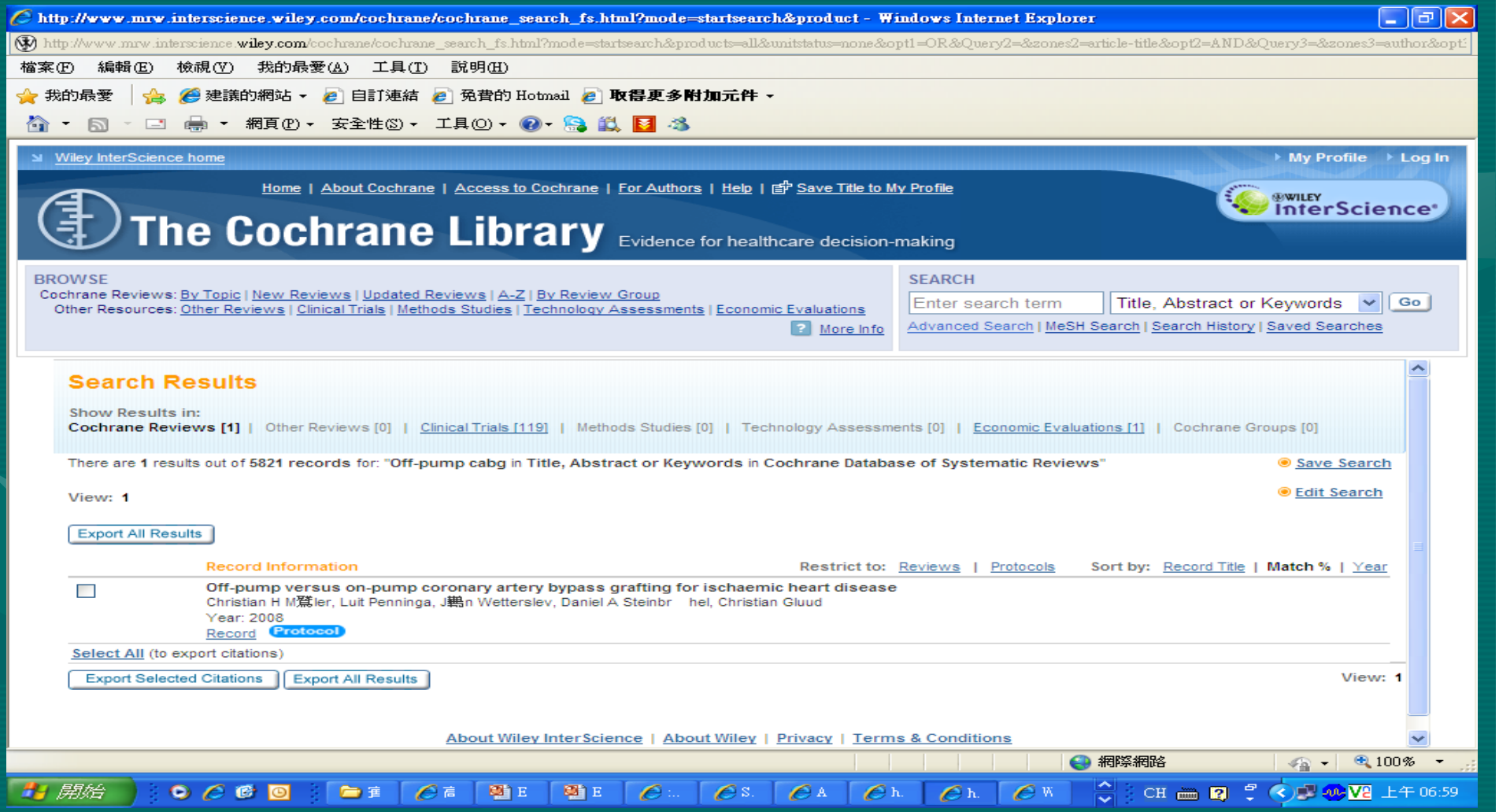
搜尋 Syntheses

- Database: Cochrane Library
- Key word:
  - Off-pump on-pump CABG
- Result: 1
  - **Off-pump versus on-pump coronary artery bypass grafting for ischaemic heart disease** (2008)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搜尋 Studies

- Database: PubMed (Clinical Queries)
- Key word:
  - Off-pump on-pump CABG
- Result:
  - Meta-analysis of short-term and mid-term outcomes following off-pump coronary artery bypass grafting
  - Off-pump versus on-pump coronary artery bypass: meta-analysis of currently available randomized trials

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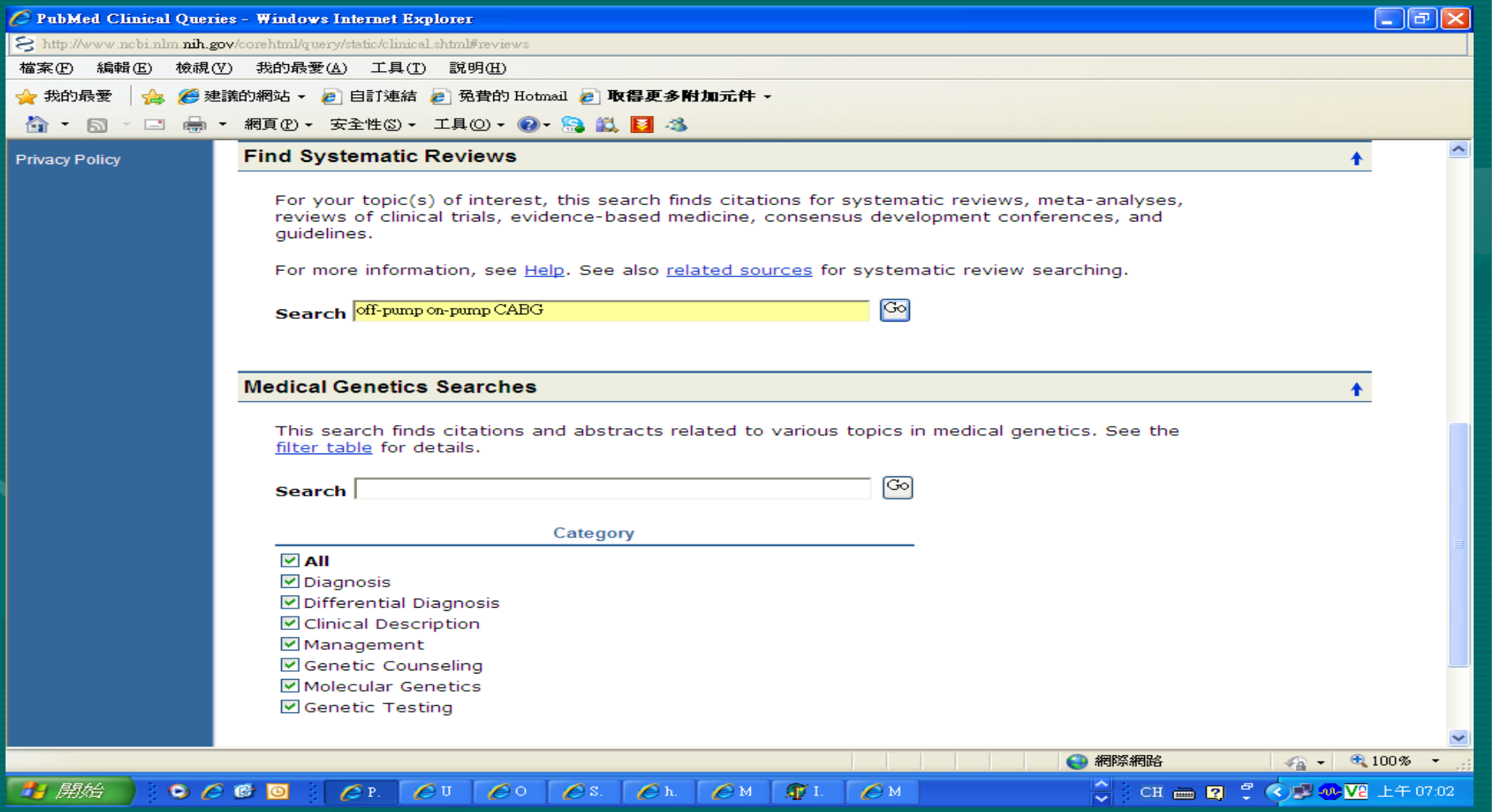
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Sistino J.
Perfusion. 2008 Sep;23(5):255-60.
PMID: 19346262 [PubMed - indexed for MEDLINE]
Related Articles
2: Synchronous carotid endarterectomy and off-pump coronary bypass: an updated, systematic review of early outcomes.
Fareed KR, Rothwell PM, Mehta Z, Naylor AR.
Eur J Vasc Endovasc Surg. 2009 Apr;37(4):375-8. Epub 2009 Feb 10. Review.
PMID: 19211276 [PubMed - indexed for MEDLINE]
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3: Performance of EuroSCORE in CABG and off-pump coronary artery bypass grafting: single institution experience and meta-analysis.
Parolari A, Pesce LL, Trezzi M, Loardi C, Kassem S, Brambillasca C, Miguel B, Tremoli E, Biglioli P, Alamanni F.
Eur Heart J. 2009 Feb;30(3):297-304. Epub 2009 Jan 13. Review.
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Meta-analysis of short-term and mid-term outcomes following off-pump coronary artery bypass grafting

- **Method:**
  - Reviewed 180 published studies :
  - 40 lacked a conventional CABG control group
  - remaining 140 studies, 87 did not meet our other inclusion criteria or were earlier versions of studies that we included. 53 studies met our criteria for inclusion in this report.
  - Short-term outcomes : length of hospital stay, operative mortality, and the following operative morbidities: myocardial infarction (MI), stroke, reoperation for bleeding, atrial fibrillation (AF), renal failure, and wound infection.
  - Midterm outcomes : need for reintervention with percutaneous transluminal coronary angioplasty (PTCA) or CABG, angina recurrence, and overall

Results

- 10 RCTs,
- 5 prospective controlled studies,
- 38 retrospective controlled studies.
- 18 studies were from the United States and 35 were from non-U.S. centers
- enrolled 46,621 patients who received OPCABG
- No statistically significant differences were observed between the results of RCTs
- RCTs showed a larger effect (favoring OPCABG) than non-RCTs for7of 10 outcomes, including one outcome (AF) that was significantly different between study designs (p 0.009)

Table 1. Summary of Meta-Analytic Results for Short-Term and Mid-Term Outcomes of OPCABG Versus CABG

Outcome[a]	Number of Studies	Total Numbers of Patients	References	Summary Estimate	95% CI	*p*
Short-term outcomes						
Length of stay[a]	27	16,042	9–13, 19, 23–27, 29, 32, 33, 37, 41–44, 46, 48–50, 56, 57, 60	1.16[b]	0.80 to 1.53	<0.0000001
MI	26	24,322	1, 10–14, 19, 21–23, 26, 28, 32–34, 36, 39, 40, 43, 44, 46, 50, 51, 53, 57, 60	0.58	0.44 to 0.76	0.00009
Stroke	38	34,126	1, 10–15, 19–24, 26, 28–38, 40, 41, 43, 45, 46, 50, 51, 53, 55–57, 59, 60	0.55	0.43 to 0.69	0.0000006
Reoperation for bleeding	24	33,442	1, 10, 13, 14, 19, 22–24, 26–28, 30, 32–34, 36, 40, 41, 44, 46, 50, 51, 53, 57	0.54	0.44 to 0.67	<0.0000001
Renal failure	17	20,845	17, 19, 20, 23, 28–32, 34, 36, 37, 40, 46, 50, 51, 55	0.62	0.50 to 0.78	0.00003
Operative mortality	43	39,647	1, 10–16, 18–34, 36–38, 40, 41, 43–47, 49, 50, 53–57, 60	0.64	0.54 to 0.75	<0.0000001
Wound infection[b]	17	16,039	1, 13, 14, 19, 26, 27, 30–32, 36, 37, 40, 45, 46, 50, 55, 57	0.55[c]	0.37 to 0.83	0.004
AF[b]	28	22,092	1, 11, 13, 14, 18, 19, 21, 23, 24, 26, 27, 30, 31, 33, 35, 36, 39, 41, 43, 45, 46, 50, 51, 53, 55, 57–59	0.69[c]	0.58 to 0.81	0.00001
Mid-term outcomes						
Angina recurrence[b]	7[d]	2,765	1, 13, 26, 41, 51, 60	1.28[c]	0.79 to 2.05	0.309
Repeat intervention	7[d]	2,823	1, 13, 26, 41, 51, 60	3.63	1.91 to 6.78	0.0001
Overall mortality	7[d]	1,883	1, 13, 26, 41, 56, 60	0.49	0.29 to 0.82	0.008

[a] Length of stay is expressed as the weighted mean difference in days. All other summary estimates are odds ratios. [b] Due to heterogeneity in the fixed-effects model, the random effects summary statistic is presented for length of stay, AF, wound infection, and angina recurrence. [c] Odds ratios calculated by nonexact methods. [d] Reference 1 presented mid-term results from two randomized controlled trials (BHACAS 1 and 2).

AF = atrial fibrillation; CABG = coronary artery bypass grafting; CI = confidence interval; MI = myocardial infarction; OPCABG = off-pump coronary artery bypass grafting.

Appraisal the Article

Meta-analysis of short-term and mid-term outcomes following off-pump coronary artery bypass grafting

Ann Thorac Surg. 2003 Nov;76(5):1510-5. Review

Level of Evidence

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998.

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

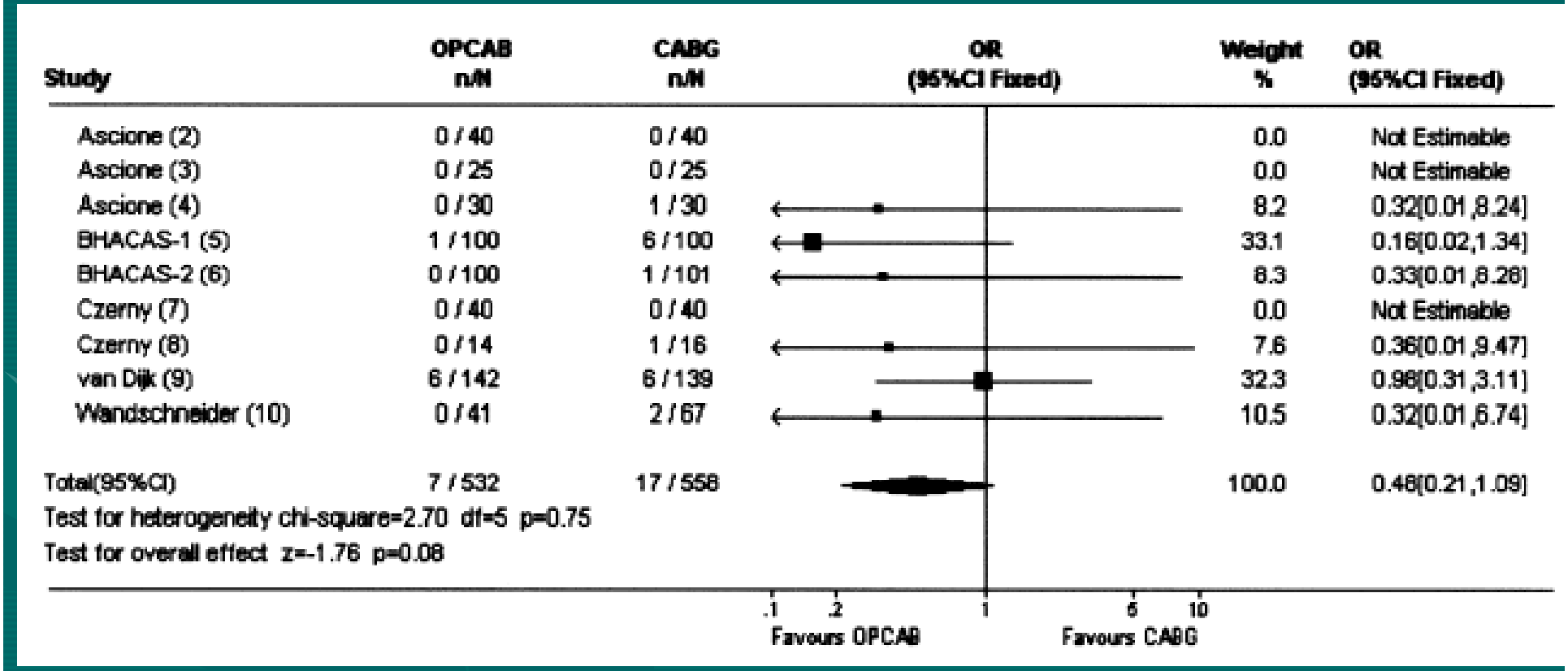
Grades of Recommendation

A	*Consistent level 1 studies*
B	consistent level 2 or 3 studies *or* extrapolations from level 1 studies
C	level 4 studies *or* extrapolations from level 2 or 3 studies
D	level 5 evidence *or* troublingly inconsistent or inconclusive studies of any level

Are the results of this systematic review of therapy valid ? (效度如何)	
Is it a systematic review of randomised trials of the treatment you're interested in?	Yes
Does it include a methods section that describes:	
finding and including all the relevant trials?	Yes
assessing their individual validity?	Yes
Were the results consistent from study to study?	Yes

Can you apply this valid, important evidence from a systematic review in caring for your patient?	
Do these results apply to your patient?	Yes
Is your patient so different from those in the overview that its results can't help you?	No
How great would the potential benefit of therapy actually be for your individual patient?	
To calculate the NNT for any OR and PEER: $NNT = \frac{1 - \{PEER \times (1 - OR)\}}{(1 - PEER) \times PEER \times (1 - OR)}$	different by each variable
Are your patient's values and preferences satisfied by the regimen and its consequences?	
Do your patient and you have a clear assessment of their values and preferences?	Yes
Are they met by this regimen and its consequences?	Yes

Off-pump versus on-pump coronary artery bypass: meta-analysis of currently available randomized trials



Conclusions

- No significant difference of long-term survival rate in two groups
- RCTs showed more benefits in OP CABG groups
- Lack of long-term data of OP CABG
- Better application of OP CABG in the future with better devices?

Audit（自我評估）

在「提出臨床問題」方面的自我評估

- 我提出的問題是否具有臨床重要性？yes
- 我是否明確的陳述了我的問題？
  - 我的foreground question 是否可以清楚的寫成PICO？yes
  - 我的background question是否包括what, when, how, who等字根？只有How
- 我是否清楚的知道自己問題的定位？（亦即可以定位自己的問題是屬於診斷上的、治療上的、預後上的或流行病學上的），並據以提出問題？可以
- 對於無法立刻回答的問題，我是否有任何方式將問題紀錄起來以備將來有空時再找答案？可以

在「搜尋最佳證據」方面的自我評估

- 我是否已盡全力搜尋？是
- 我是否知道我的問題的最佳證據來源？是
- 我是否從大量的資料庫來搜尋答案？是
- 我工作環境的軟硬體設備是否能支援我在遇到問題時進行立即的搜尋？是
- 我是否在搜尋上愈來愈熟練了？是
- 我會使用「斷字」、布林邏輯、同義詞、MeSH term，限制(limiters)等方法來搜尋？不完全
- 我的搜尋比起圖書館人員或其他對於提供病人最新最好醫療有熱情的同事如何？未比較

關於「嚴格評讀文獻」方面的自我評估

- 我是否盡全力做評讀了？是
- 我是否了解Number needed to treat 的意義？是
- 我是否了解Likelihood Ratios的意義？是
- 我是否了解worksheet每一項的意義？是
- 評讀後，我是否做出了結論？是

關於「應用到病人身上」的自我評估

- 我是否將搜尋到的最佳證據應用到我的臨床工作中？尚未
- 我是否能將搜尋到的結論如NNT,LR用病人聽得懂的方式解釋給病人聽？應該可以
- 當搜尋到的最佳證據與實際臨床作為不同時，我如何解釋？尋問相關臨床經驗豐富的老師

改變「醫療行為」的自我評估

- 當最佳證據顯示目前臨床策略需改變時，我是否遭遇任何阻止改變的阻力？不知道
- 我是否因此搜尋結果而改變了原來的治療策略？做了那些改變？無改變

效率評估

- 這篇報告，我總共花了多少時間？7 hours
- 我是否覺得這個進行實證醫學的過程是值得的？是
- 我還有那些問題或建議？更多實用資料庫的搜集以及外科相關EMB的資料庫

Thank you for your attention!