Evidence-Based Medicine

Presented by R2 謝孟書

Instructed by VS 李智雄

Outlines

- Clinical scenario
- Asking a question (*Background & Foreground questions)*
- Acquire
- Appraisal
- Apply
- Audit

Clinical scenario

- 67 y/o male with colon cancer, HTN, DM and heavy smoking presented to our ER with chest pain.
- Chest pain : retro-sternal, compression, persistent after rest, related to exertion
- EKG: V1 –V4 ST depression
- Serial cardiac enzymes

  CPK = 534, CK-MB = 65, Trop-I = 15

Clinical scenario

- Diagnosis
  - ***NSTEMI, TIMI score : 4 scores***
- Treatment
  - anti-coagulation, dual-anti platelets
  - beta-blockers, ACEi, statin
  - Early invasive approach : PCI
    - Culprit lesion : LAD 95% obstruction → DES x 1

提出background questions

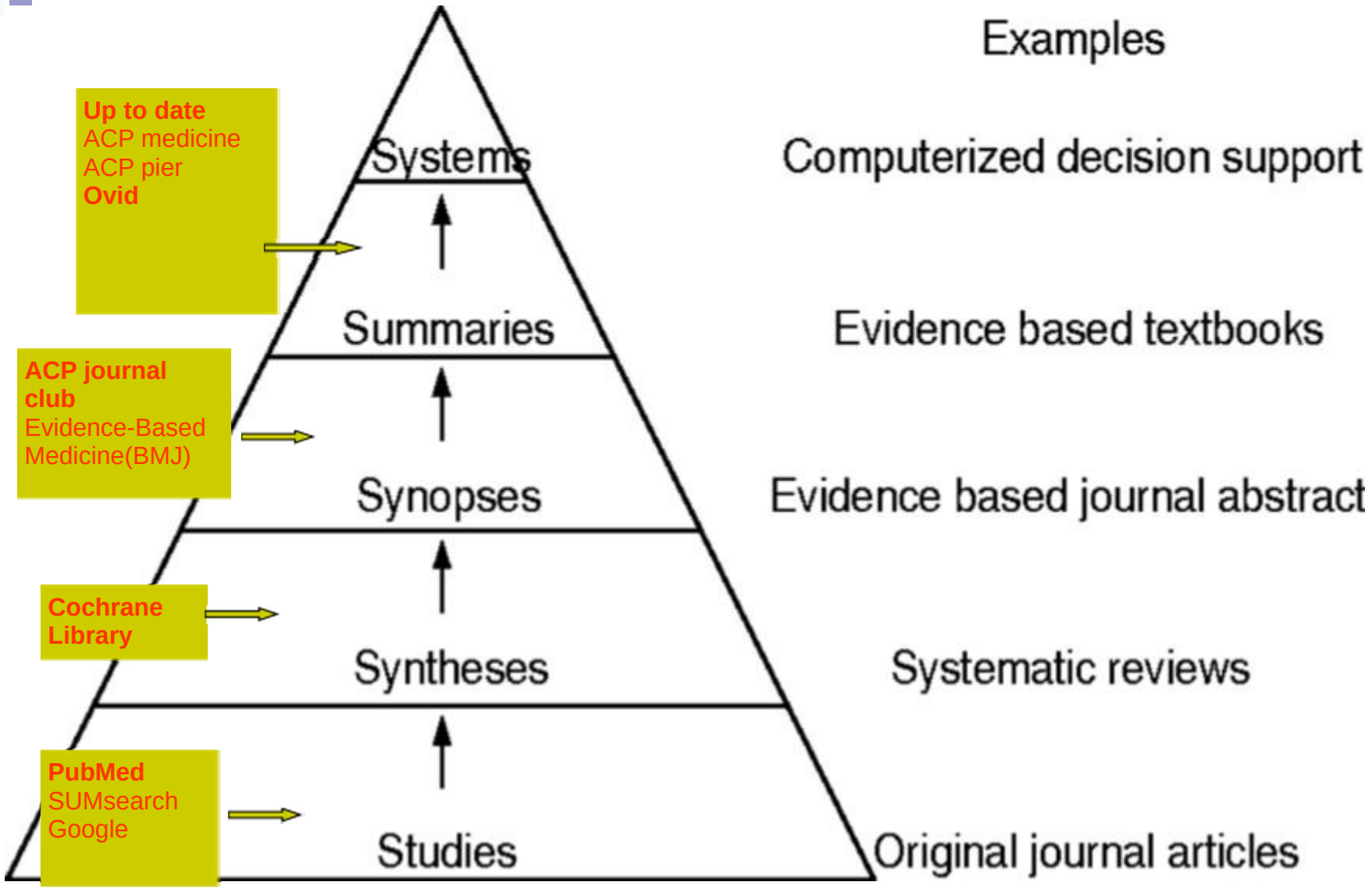
Acute management of myocardial infarction ?

- Coronary reperfusion in STEMI
- Anti-coagulation
- Dual - Antiplatelet drugs
- Anti-ischemia (Beta blockers, Nitrate, CCB)
- ACE inhibitors/ ARB
- Lipid lowering medications
- Risk factor reduction: (DM, HTN, smoking)

提出 foreground question

急性期的嚴格血糖控制是否對病人的預後有幫助？	
P:	62 y/o man with DM presented with hyperglycemia (270 mg/dL) and AMI.
I:	Oral anti-DM medication (metformin)
C:	Intensive insulin infusion control
O:	Mortality

搜尋最有用的資料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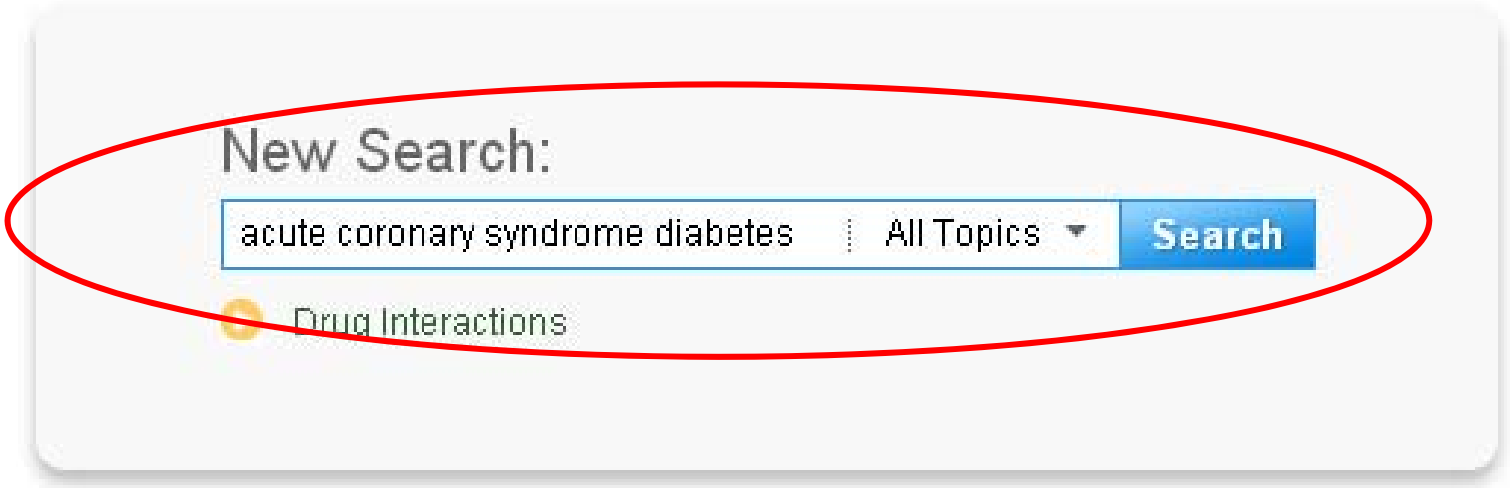
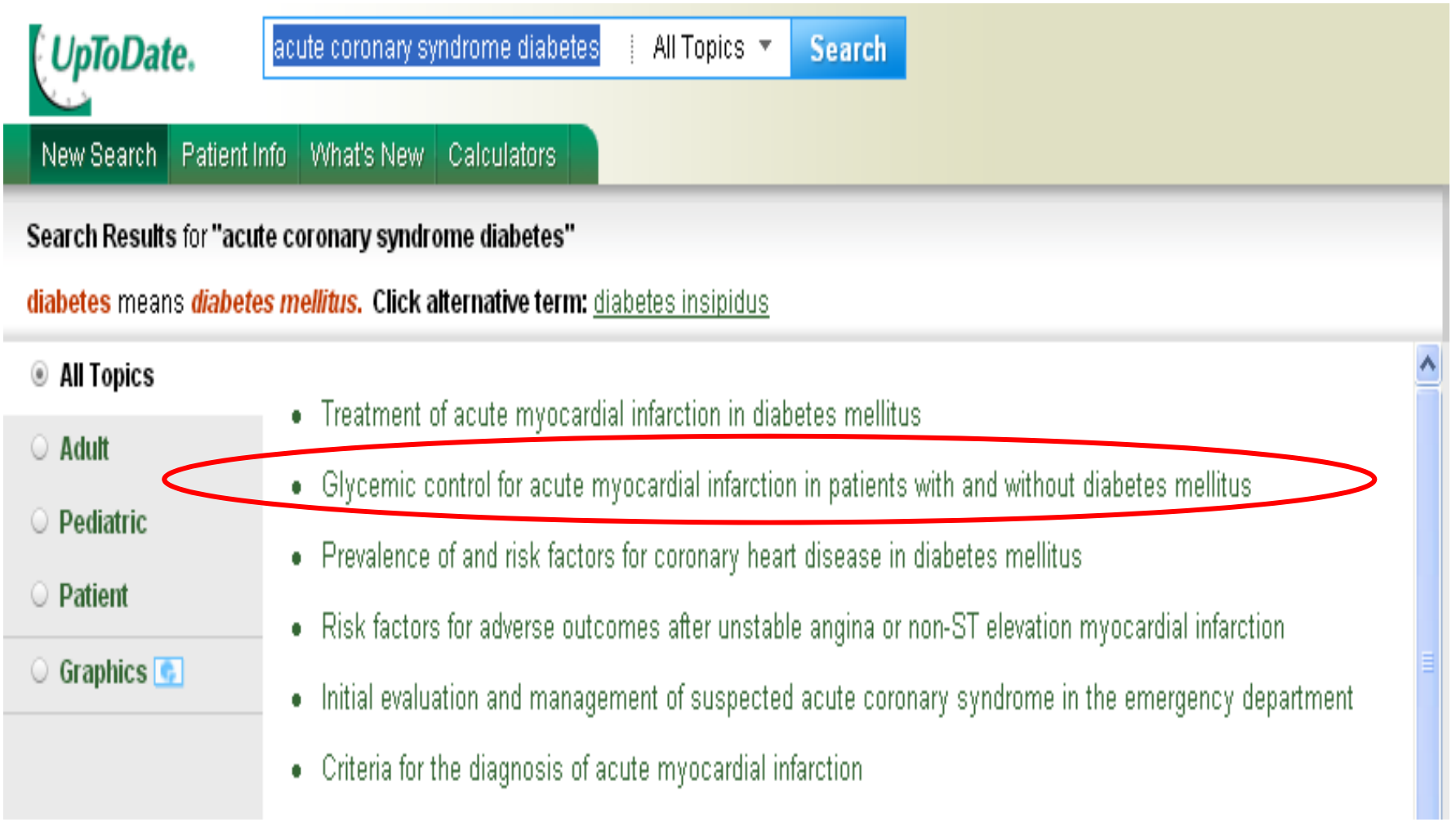
搜尋summary



Outbreak of fungal meningitis and septic arthritis in the United States

搜尋summary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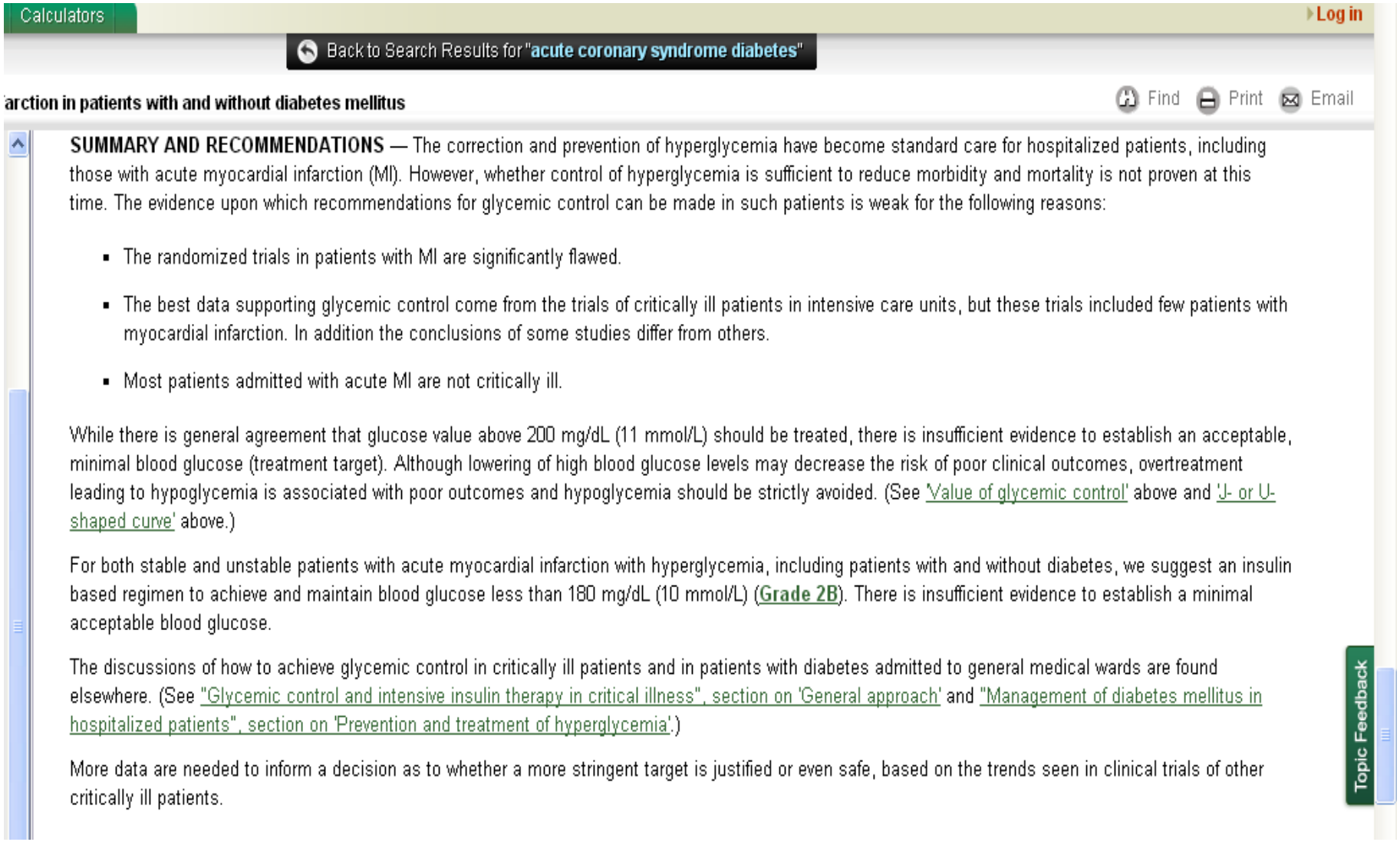
diabetes means diabetes mellitus. Click alternative term: diabetes insipidus
All Topics
Adult
Pediatric
Patient
Graphics
Treatment of acute myocardial infarction in diabetes mellitus
Glycemic control for acute myocardial infarction in patients with and without diabetes mellitus
Prevalence of and risk factors for coronary heart disease in diabetes mellitus
Risk factors for adverse outcomes after unstable angina or non-ST elevation myocardial infarction
Initial evaluation and management of suspected acute coronary syndrome in the emergency department
Criteria for the diagnosis of acute myocardial infarction

搜尋summary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arction in patients with and without diabetes mellitus
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SUMMARY AND RECOMMENDATIONS — The correction and prevention of hyperglycemia have become standard care for hospitalized patients, including those with acute myocardial infarction (MI). However, whether control of hyperglycemia is sufficient to reduce morbidity and mortality is not proven at this time. The evidence upon which recommendations for glycemic control can be made in such patients is weak for the following reasons:
The randomized trials in patients with MI are significantly flawed.
The best data supporting glycemic control come from the trials of critically ill patients in intensive care units, but these trials included few patients with myocardial infarction. In addition the conclusions of some studies differ from others.
Most patients admitted with acute MI are not critically ill.
While there is general agreement that glucose value above 200 mg/dL (11 mmol/L) should be treated, there is insufficient evidence to establish an acceptable, minimal blood glucose (treatment target). Although lowering of high blood glucose levels may decrease the risk of poor clinical outcomes, overtreatment leading to hypoglycemia is associated with poor outcomes and hypoglycemia should be strictly avoided. (See 'Value of glycemic control' above and 'J- or U-shaped curve' above.)
For both stable and unstable patients with acute myocardial infarction with hyperglycemia, including patients with and without diabetes, we suggest an insulin based regimen to achieve and maintain blood glucose less than 180 mg/dL (10 mmol/L) (Grade 2B). There is insufficient evidence to establish a minimal acceptable blood glucose.
The discussions of how to achieve glycemic control in critically ill patients and in patients with diabetes admitted to general medical wards are found elsewhere. (See "Glycemic control and intensive insulin therapy in critical illness", section on 'General approach' and "Management of diabetes mellitus in hospitalized patients", section on 'Prevention and treatment of hyperglycemia'.)
More data are needed to inform a decision as to whether a more stringent target is justified or even safe, based on the trends seen in clinical trials of other critically ill patients.
Topic Feedback

- While there is general agreement that glucose value above 200 mg/dL should be treated, there is *insufficient evidence* to establish an acceptable, minimal blood glucose (*treatment target*).

- For both stable and unstable patients with acute myocardial infarction with hyperglycemia, including patients with and without diabetes, ***we suggest an insulin based regimen to achieve and maintain blood glucose less than 180 mg/dL***

搜尋synopses


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Results 1 - 10 of about 32 for AMI glucose.
2005 - A glucose-insulin-potassium infusion did not reduce ...
2005 - Intensive insulin-glucose infusion regimens with long ...
2011 - Review: Intensive glucose lowering does not reduce ...
2003 - Pravastatin reduced major CHD events in patients with ...
2007 - Review: Rosiglitazone increases risk for MI but does ...
2007 - Rosiglitazone increased heart failure but did not differ ...
2011 - Intensive glucose control increased mortality and did ...

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17 May 2011, Vol 154, No. 10>

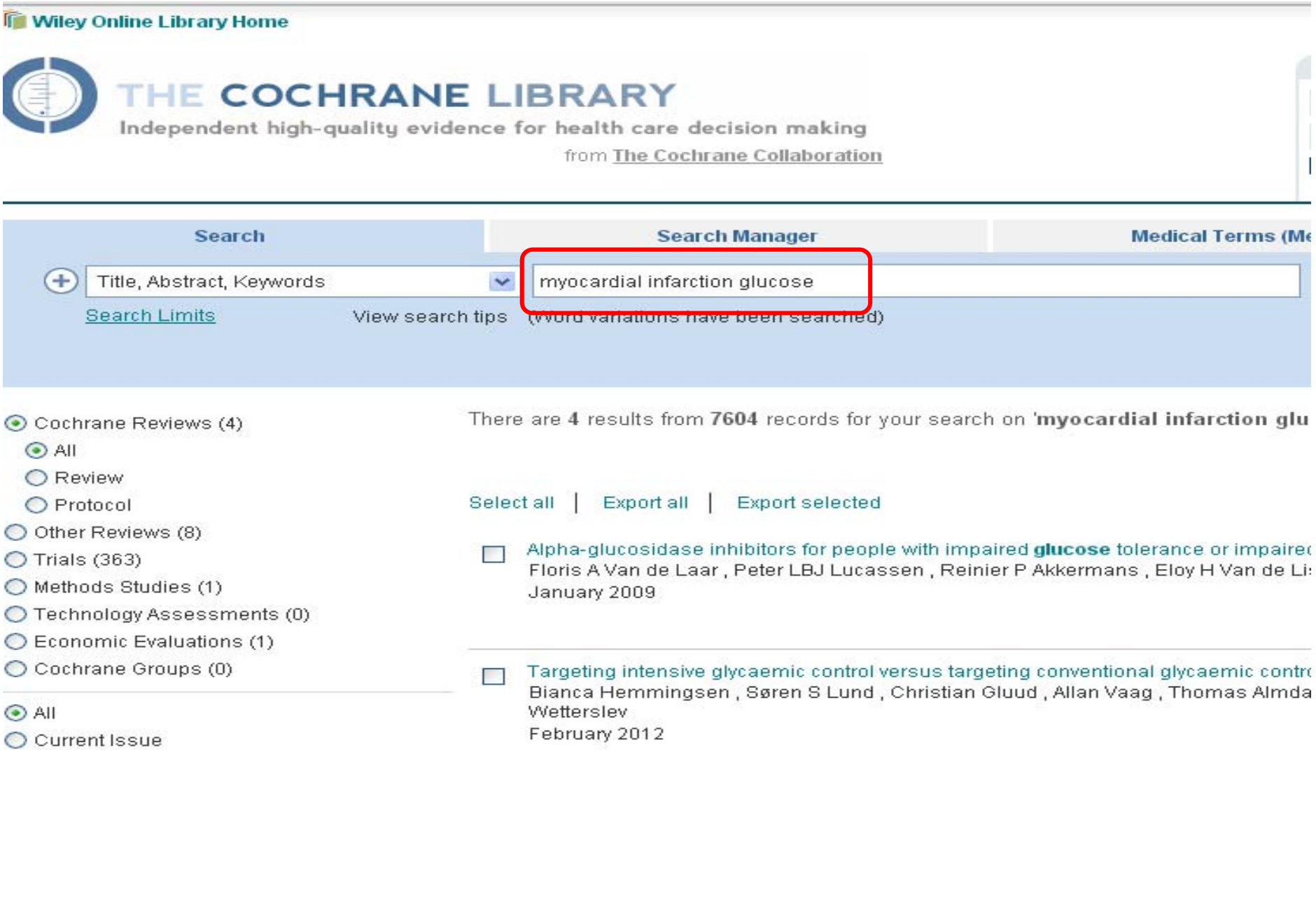
ACP Journal Club | 17 May 2011

Intensive glucose control increased mortality and did not prevent CV events compared with standard glucose control in type 2 diabetes

Rozalina Grubina, MD; and Steven A. Smith, MD

[+] Article and Author Information

Ann Intern Med. 17 May 2011;154(10):JC5-2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Protocol
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Trials (363)
Methods Studies (1)
Technology Assessments (0)
Economic Evaluations (1)
Cochrane Groups (0)
All
Current Issue
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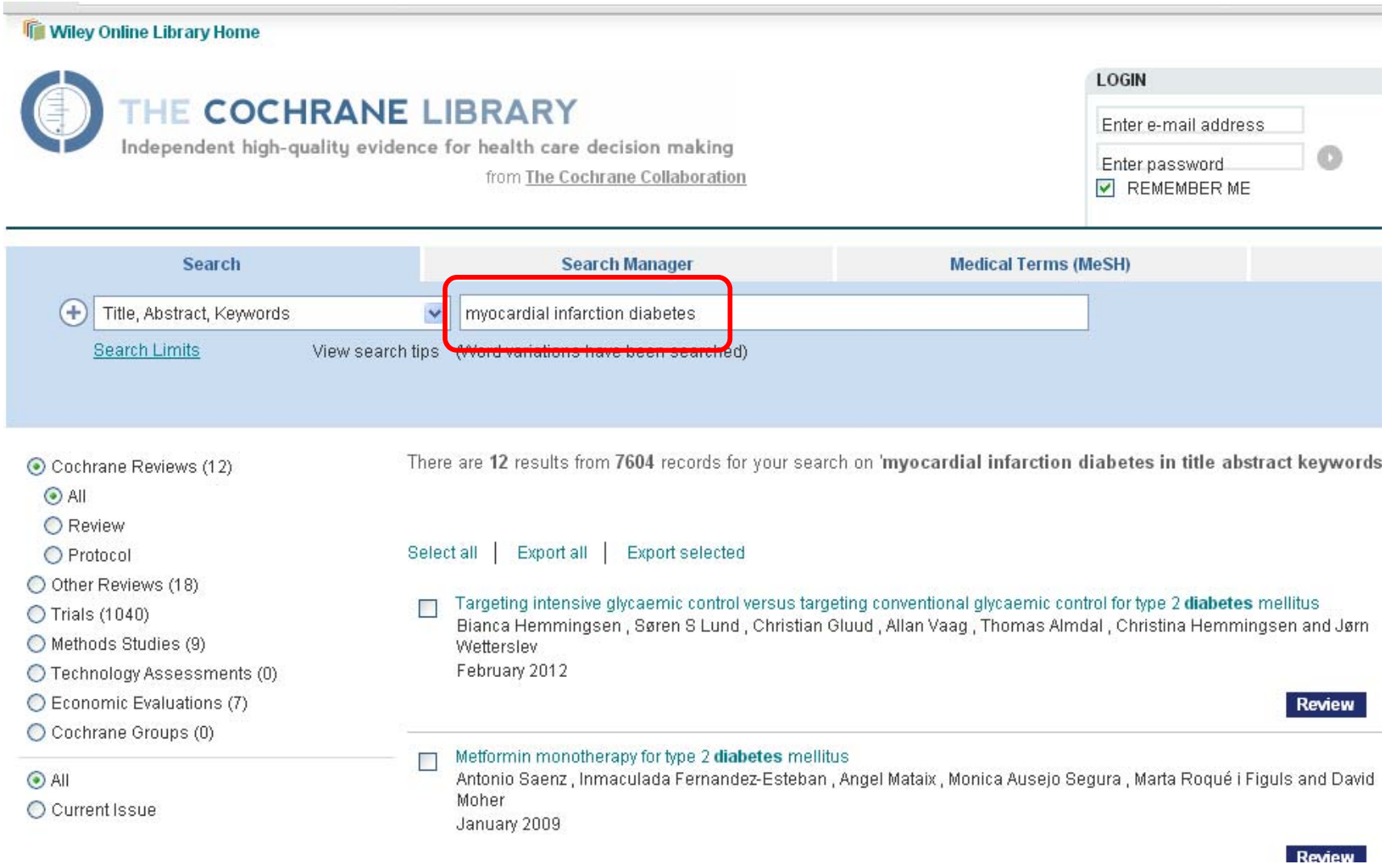
Select all | Export all | Export selected
Alpha-glucosidase inhibitors for people with impaired glucose tolerance or impaire
Floris A Van de Laar , Peter LBJ Lucassen , Reinier P Akkermans , Eloy H Van de Li
January 2009
Targeting intensive glycaemic control versus targeting conventional glycaemic contr
Bianca Hemmingsen , Søren S Lund , Christian Gluud , Allan Vaag , Thomas Almda
Wetterslev
February 2012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All
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Protocol
Other Reviews (18)
Trials (1040)
Methods Studies (9)
Technology Assessments (0)
Economic Evaluations (7)
Cochrane Groups (0)
All
Current Issue
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Select all | Export all | Export selected
Targeting intensive glycaemic control versus targeting conventional glycaemic control for type 2 diabetes mellitus
Bianca Hemmingsen , Søren S Lund , Christian Gluud , Allan Vaag , Thomas Almdal , Christina Hemmingsen and Jørn Wetterslev
February 2012
Review
Metformin monotherapy for type 2 diabetes mellitus
Antonio Saenz , Inmaculada Fernandez-Esteban , Angel Mataix , Monica Ausejo Segura , Marta Roqué i Figuls and David Moher
January 2009
Review

Study

PubMed Clinical Queries

Results of searches on this page are limited to specific clinical research areas. For comprehensive searches, use PubMed directly.

myocardial infarction glucose

Search

Clinical Study Categories

Category: Therapy

Scope: Broad

Systematic Reviews

Medical Genetics

Topic: All

Results: 5 of 1782

Lower Incidence of Recorded Cardiovascular Outcomes in Patients with Type 2 Diabetes using Insulin Aspart versus those on Human Regular Insulin:Observational Evidence From General Practices.

Rathmann W, Kostev K.
Diabetes Obes Metab. 2012 Nov 8; . Epub 2012 Nov 8.

Intraoperative high-dose dexamethasone for cardiac surgery: a randomized controlled trial.

Dieleman JM, Nierich AP, Rosseel PM, van der Maaten JM, Hofland J, Diephuis JC, Schepp RM, Boer C, Moons KG, van Herwerden LA, et al.
JAMA. 2012 Nov 7; 308(17):1761-7.

[Hyperglycaemia and Acute Coronary Syndrome.]

Grembiale A, Cloro C, Iorio F, Cufone S, Succurro E, Arturi F.
Clin Ter. 2012 Sep; 163(5):403-409.

Outcomes and lessons from the PROactive study.

Scheen AJ.
Diabetes Res Clin Pract. 2012 Sep 25; . Epub 2012 Sep 25.

Discontinuation of antihyperglycemic therapy after acute myocardial infarction: medical necessity or medical error?

Levig KO, Horwitz L, Lipska K, Kosiborod M, Krumholz HM, Inzucchi

Results: 5 of 115

Intraoperative high-dose dexamethasone for cardiac surgery: a randomized controlled trial.

Dieleman JM, Nierich AP, Rosseel PM, van der Maaten JM, Hofland J, Diephuis JC, Schepp RM, Boer C, Moons KG, van Herwerden LA, et al.
JAMA. 2012 Nov 7; 308(17):1761-7.

Effect of angiotensin receptor blockers in the prevention of type 2 diabetes and cardiovascular events: a meta-analysis of randomized trials.

Song HF, Wang S, Li HW.
Chin Med J (Engl). 2012 May; 125(10):1804-10.

Intensive Glucose Control in Diabetics with an Acute Myocardial Infarction Does not Improve Mortality and Increases Risk of Hypoglycemia-A Meta-regression Analysis.

Chatterjee S, Sharma A, Lichstein E, Mukherjee D.
Curr Vasc Pharmacol. 2012 Jun 22; . Epub 2012 Jun 22.

Meta-analysis of effect of dipeptidyl peptidase-4 inhibitors on cardiovascular risk in type 2 diabetes mellitus.

Patil HR, Al Badarin FJ, Al Shami HA, Bhatti SK, Lavie CJ, Bell DS, O'Keefe JH.
Am J Cardiol. 2012 Sep 15; 110(6):826-33. Epub 2012 Jun 15.

Results: 5 of 242

The metabochip, a custom genotyping array for genetic studies of metabolic, cardiovascular, and anthropometric traits.

Voight BF, Kang HM, Ding J, Palmer CD, Sidore C, Chines PS, Burtt NP, Fuchsberger C, Li Y, Erdmann J, et al.
PLoS Genet. 2012 Aug; 8(8):e1002793. Epub 2012 Aug 2.

[Evaluation of association between 9 genetic polymorphism and myocardial infarction in the Siberian population].

Maksimov VN, Kulikov IV, Orlov PS, Gafarov VV, Maliutina SK, Romashchenko AG, Voevoda MI.
Vestn Ross Akad Med Nauk. 2012; (5):24-9.

Nonfasting glucose, ischemic heart disease, and myocardial infarction: a Mendelian randomization study.

Benn M, Tybjaerg-Hansen A, McCarthy MI, Jensen GB, Grande P, Nordestgaard BG.
J Am Coll Cardiol. 2012 Jun 19; 59(25):2356-65.

Subcellular preconditioning of stem cells: mito-Cx43 gene targeting is cytoprotective via shift of mitochondrial Bak and Bcl-xL balance.

Lu G, Jiang S, Ashraf M, Haider KH.
Regen Med. 2012 May; 7(3):323-34.

A genetic risk variant for myocardial infarction on chromosome

Eur Heart J. 2005 Apr;26(7):650-61. Epub 2005 Feb 23.

Intense metabolic control by means of insulin in patients with diabetes mellitus and acute myocardial infarction (DIGAMI 2): effects on mortality and morbidity.

Malmberg K, Rydén L, Wedel H, Birkeland K, Bootsma A, Dickstein K, Efendic S, Fisher M, Hamsten A, Herlitz J, Hildebrandt P, MacLeod K, Laakso M, Torp-Pedersen C, Waldenström A; DIGAMI 2 Investigators.

Department of Cardiology, Karolinska University Hospital Solna, 171 76 Stockholm, Sweden.

Abstract

AIMS: Patients with diabetes have an unfavourable prognosis after an acute myocardial infarction. In the first DIGAMI study, an insulin-based glucose management improved survival. In DIGAMI 2, three treatment strategies were compared: group 1, acute insulin-glucose infusion followed by insulin-based long-term glucose control; group 2, insulin-glucose infusion followed by standard glucose control; and group 3, routine metabolic management according to local practice.

METHODS AND RESULTS: DIGAMI 2 recruited 1253 patients (mean age 68 years; 67% males) with type 2 diabetes and suspected acute myocardial infarction randomly assigned to groups 1 (n=474), 2 (n=473), and 3 (n=306). The primary endpoint was all-cause mortality between groups 1 and 2, and a difference was hypothesized as the primary objective. The secondary objective was to compare total mortality between groups 2 and 3, whereas morbidity differences served as tertiary objectives. The median study duration was 2.1 (interquartile range 1.03-3.00) years. At randomization, HbA1c was 7.2, 7.3, and 7.3% in groups 1, 2, and 3, respectively, whereas blood glucose was 12.8, 12.5, and 12.9 mmol/L, respectively. Blood glucose was significantly reduced after 24 h in all groups, more in groups 1 and 2 (9.1 and 9.1 mmol/L) receiving insulin-glucose infusion than in group 3 (10.0 mmol/L). Long-term glucose-lowering treatment differed between groups with multidose insulin (> or =3 doses/day) given to 15 and 13% of patients in groups 2 and 3, respectively compared with 42% in group 1 at hospital discharge. By the end of follow-up, HbA1c did not differ significantly among groups 1-3 (approximately 6.8%). The corresponding values for fasting blood glucose were 8.0, 8.3, and 8.6 mmol/L. Hence, the target fasting blood glucose for patients in group 1 of 5-7 mmol/L was never reached. The study mortality (groups 1-3 combined) was 18.4%. Mortality between groups 1 (23.4%) and 2 (22.6%; primary endpoint) did not differ significantly (HR 1.03; 95% CI 0.79-1.34; P=0.831), nor did mortality between groups 2 (22.6%) and 3 (19.3%; secondary endpoint) (HR 1.23; CI 0.89-1.69; P=0.203). There were no significant differences in morbidity expressed as non-fatal reinfarctions and strokes among the three groups.

- In DIGAMI 2, three treatment strategies were compared
- group 1, acute insulin–glucose infusion followed by insulin-based long-term glucose control
- group 2, insulin–glucose infusion followed by standard glucose control
- group 3,routine metabolic management according to local practice.

Results

- DIGAMI 2 recruited 1253 patients (mean age 68 years; 67% males) with type 2 diabetes and suspected acute myocardial infarction randomly assigned to groups 1 (n = 474), 2 (n = 473), and 3 (n = 306).
- The median study duration was 2.1 (interquartile range 1.03–3.00) years. At randomization, HbA1c was 7.2, 7.3, and 7.3% in groups 1, 2, and 3, respectively, whereas blood glucose was 12.8 (230 mg/dL), 12.5, and 12.9 mmol/L, respectively.
- glucose was significantly reduced after 24 h in all groups, more in groups 1 and 2 (9.1 mmol/L = 163 mg/dL and 9.1 mmol/L) receiving insulin–glucose infusion than in group 3 (10.0 mmol/L = 180 mg/dl).

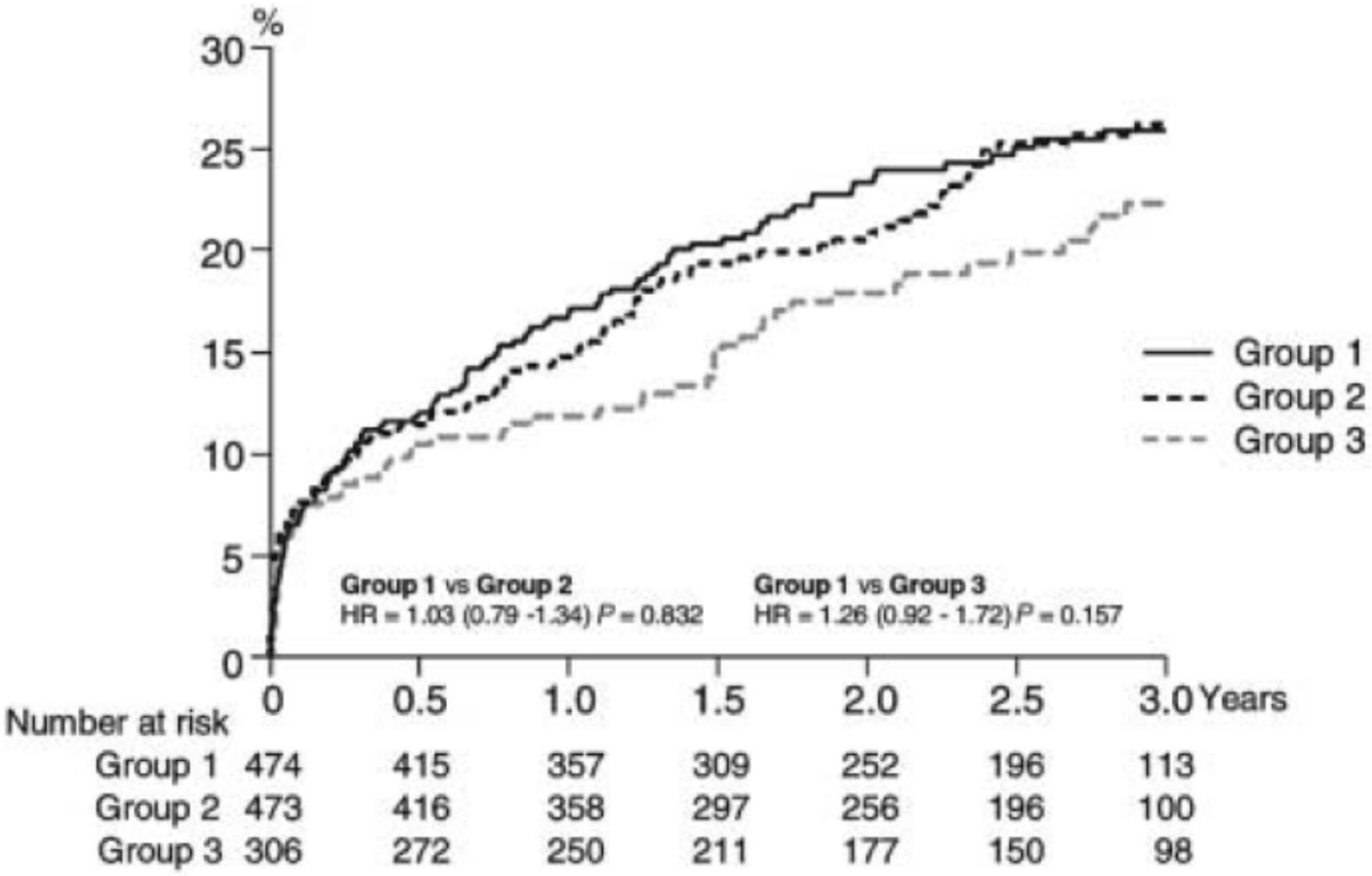

Figure 2 Mortality in groups 1, 2, and 3 (intention to treat analysis).

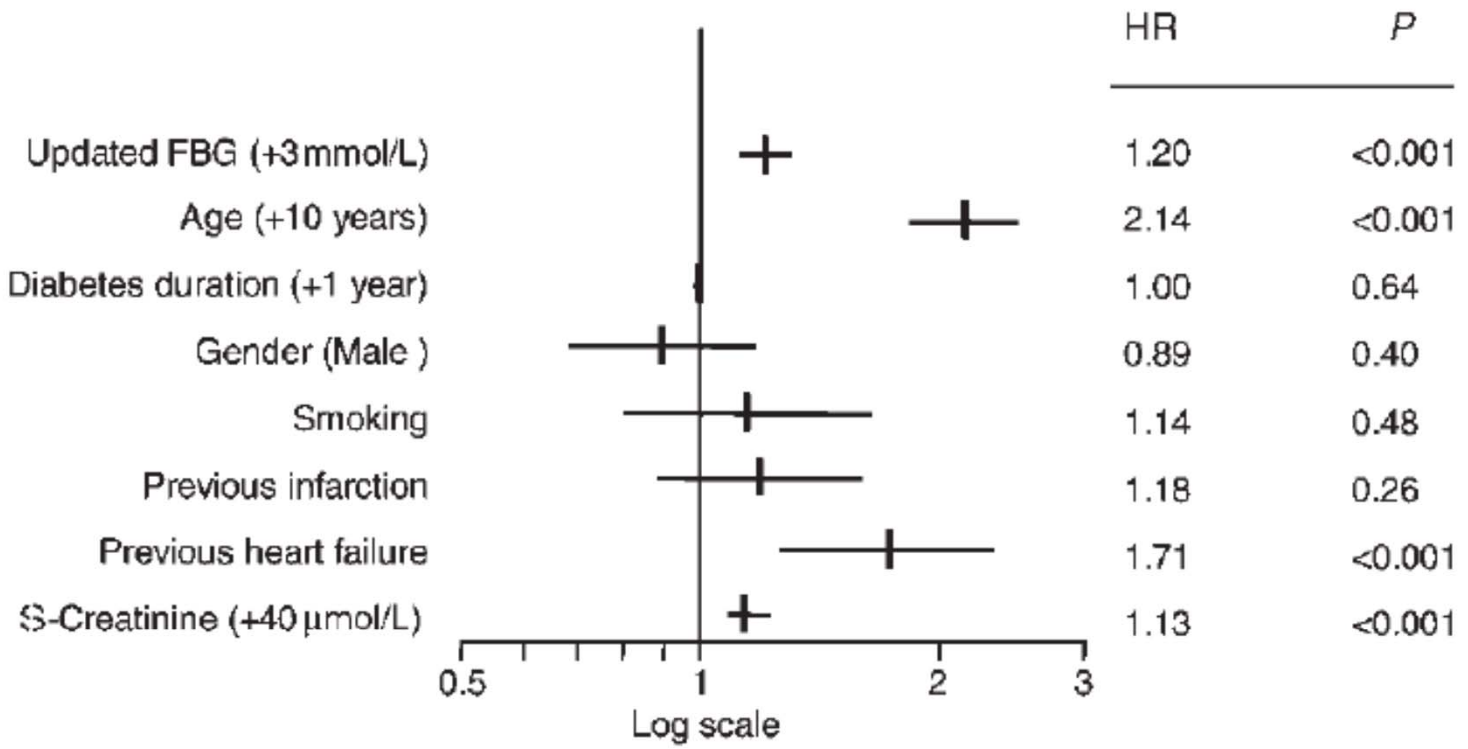

Figure 3 Independent baseline predictors for mortality. Fasting blood glucose represents updated values during the time of follow-up.

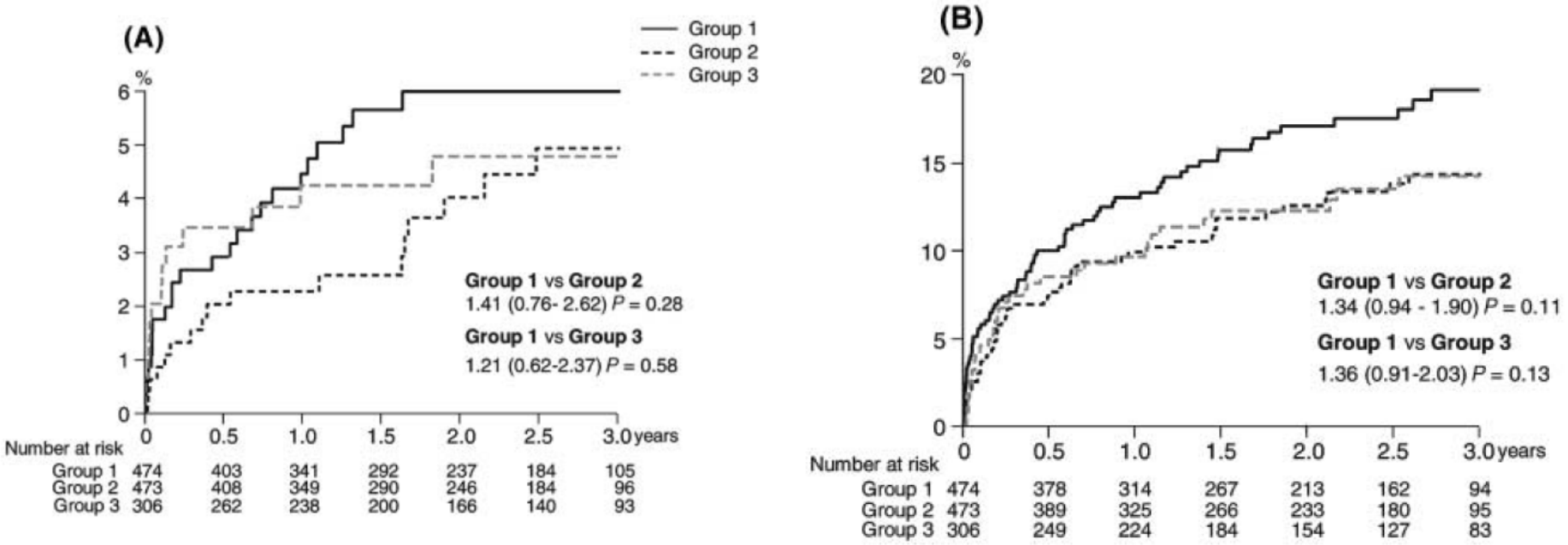

Figure 4 Time to the secondary endpoints stroke (*A*) and myocardial reinfarction (*B*).

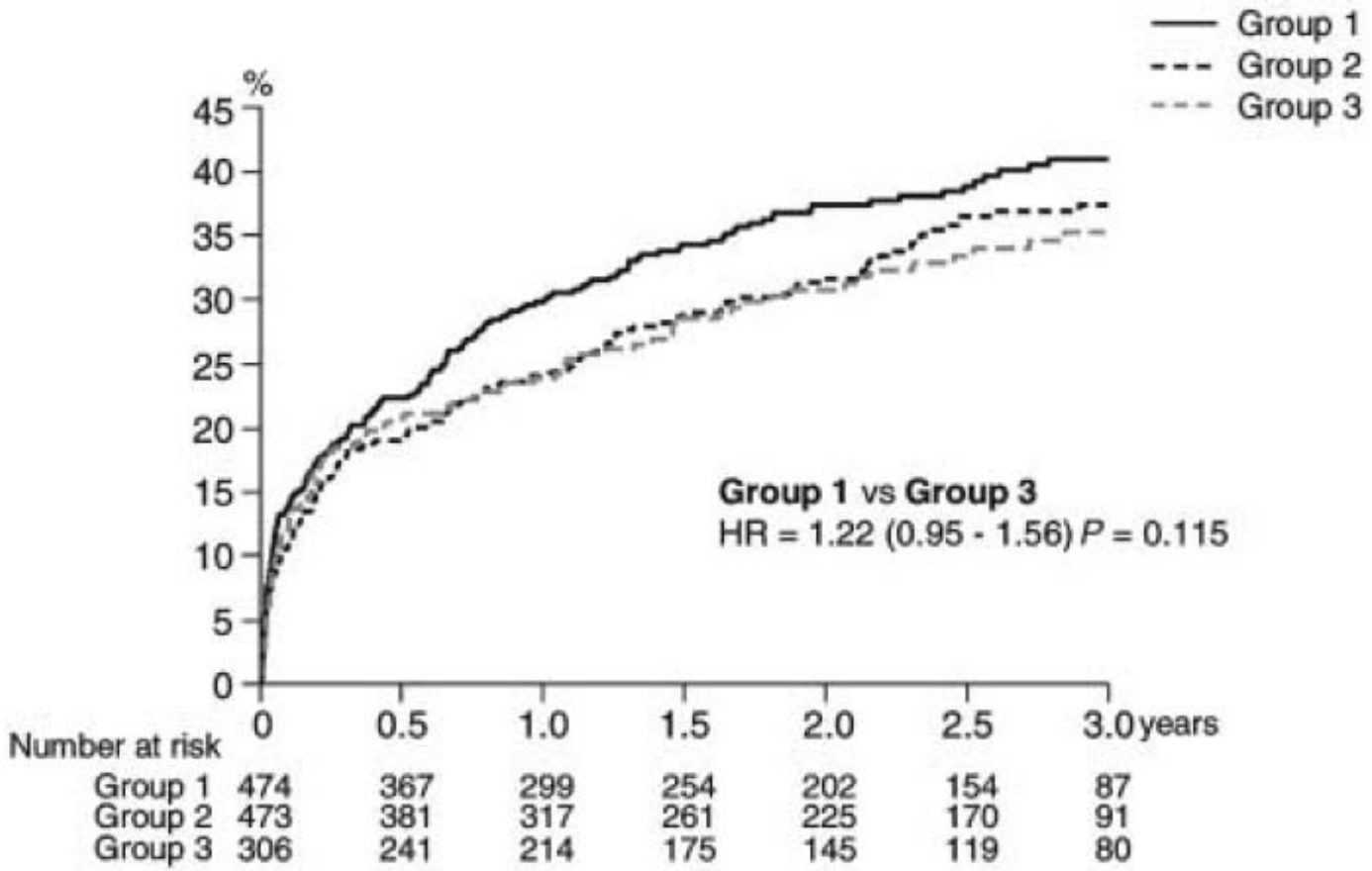

Figure 5 Time to first major event (death, reinfarction, or stroke).

Conclusion

- DIGAMI 2 did not support the fact that an *acutely introduced, long-term insulin treatment* improves survival in type 2 diabetic patients following myocardial infarction
- An epidemiological analysis confirms that the glucose level is a strong, independent predictor of long-term mortality in this patient category.

Appraisal (嚴格評讀）

CEBM

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Levels of Evidence (March 2009)

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Level **1A**	Therapy/Prevention, Aetiology/Harm Prognosis Diagnosis Differential diag/symptom prevalence Economic and decision analyses	1a SR (with homogeneity*)of RCTs SR (withhomogeneity*) 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
Level **1b**	Therapy/Prevention, Aetiology/Harm Prognosis Diagnosis Differential diag/symptom prevalence Economic and decision analyses	Individual RCT (with narrow Confidence Interval‡) Individual inception cohort study with > 80% follow-up; CDR† validated in asingle 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
Level **1c**	Therapy/Prevention, Aetiology/Harm Prognosis Diagnosis Differential diag/symptom prevalence Economic and decision analyses	All or none§ All or none case series Absolute SpPins and SnNouts†† All or none case-series Absolute better-value or worse-value analyses ††††
Level **2a**	Therapy/Prevention, Aetiology/Harm Prognosis Diagnosis Differential diag/symptom prevalence Economic and decision analyses	SR (with homogeneity*) of cohort studies SR (withhomogeneity*) 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 (withhomogeneity*) of Level >2 economic studies
Level **2b**	Therapy/Prevention, Aetiology/Harm Prognosis Diagnosis Differential diag/symptom prevalence Economic and decision analyses	Individual cohort study (including low quality RCT; e.g., <80% followup) 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

Oxford CEBM worksheet

- **Was the assignment of patients to treatments randomised?**
  - This paper: Yes
- **Were the groups similar at the start of the trial?**
  - This paper: Yes

Oxford CEBM worksheet

- **Aside from the allocated treatment, were groups treated equally?**
  - This paper: Yes
- **Were all patients who entered the trial accounted for? – and were they analysed in the groups to which they were randomised?**
  - This paper: Yes

Oxford CEBM worksheet

- **Were measures objective or were the patients and clinicians kept "blind" to which treatment was being received?**
  - This paper: Yes

How large was the treatment effect?

mortality		**Relative risk reduction (RRR)**	**Absolute risk reduction (ARR)**	**Number needed to treat (NNT)**
Usual insulin regimen control event rate (CER)	Intensive insulin regimen experimental event rate (EER)	$\frac{\textbf{CER – EER}}{\text{CER}}$	**CER-EER**	1/ARR
21.2%	23.4%	10.3 %	2.2%	1/2.2% = 45 patients

Will the results help me in caring for my patient?

- Is my patient so different to those in the study that the results cannot apply?
- Is the treatment feasible in my setting?
- Will the potential benefits of treatment outweigh the potential harms of treatment for my patient?

將EBM結果應用到病人身上

Compare the clinical question with the article's question

Clinical question	Article's question
P: AMI in diabetic p't	P: AMI in diabetic p't
I: oral Anti-DM meds	I: standard glucose control
C: intensive insulin infusion	C: intensive insulin infusion
O: mortality	O: mortality

醫療現況	病人意願
MI的治療中，LDL部分有明確的target value (< 70 mg/dl)，但對於急性期血糖控制，沒有target value做為臨床治療依據。	Intensive insulin infusion，會讓病人必須多次施打insulin以及使用pump，比起口服藥，會讓病人服藥順從性降低。
生活品質	**社會脈絡**
因為要多次施打insulin的關係病人生活品質是必會大大下降。	若有足夠的證據證實intensive glucose control能降低mortality，即使是必須長期施打insulin，但也不失為一個可行的方法。但目前尚無可靠證據支持。

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？
  - 是，會遇到
- 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？
  - 屬於治療上的問題
- 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？
  - 詢問師長，先求得臨床上的經驗

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？
  - 無法收尋到最佳證據
- 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？
  - 盡可能以白話方式解釋
- 當搜尋到的最佳證據與實際臨床作為不同時，我如何解釋？
  - 尋求師長討論

效率評估

- 這篇報告，我總共花了多少時間？
  - 幾個精神不濟的晚上
- 我是否覺得這個進行實證醫學的過程是值得的？
  - 培養獨立思考解決問題的能力
- 我還有那些問題或建議？
  - 無


Thank You!