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實證醫學

嚴謹文獻評讀方式介紹

影像醫學科
品管教學組長 陳嘉宏

Learning Objectives

To 了解文獻設計型態，搜尋適合臨床問題之證據

To 嚴謹評讀文獻之分析判斷技巧 V.I.P.

偏誤(Bias)之分類

選擇性偏差	參與研究對象都有相同機率被分派到實驗組或控制組
評估偏差	實驗主持者參與研究數據測量與結果評估 (主觀 vs 客觀)
實驗過程退出偏差	研究組或對照組若中途退出太多(> 20%)，必須探討其原因，推論統計亦應注意。
干擾因子	與臨床問題無關、對觀察的結果有決定性影響、實驗組與控制組間分佈不平均
儀器或測量偏差	–儀器之保養與校正 –測量標準作業流程 SOP
回憶性偏差	研究組成員較對照組成員容易記起疾病相關因素: 血癌兒童之父母較常記起住家附近有變電所或高壓電塔。

研究的偏差來源及解決方式

Type of Study Design

- Case Series / Report
- **Cross Sectional Study**
- Case Control Study
- Cohort Study
- Randomized Control Trial

Type of Study Design

- Case Series / Report

Case Series report new diseases or health related problems

They may provide some descriptive data on exposures to potential causal factors

Type of Study Design

- Cross Sectional Study

existing disease and current exposure levels
some indication of the relationship between the disease and exposure or non-exposure
sample at one point in time

Type of Study Design

- Cross Sectional Study

Advantages	Disadvantages
• **cheap** and simple • can study multiple exposures or multiple outcomes or diseases • **ethically** safe	• not a useful type of study for establishing **causal** relationships • only **prevalence** can be estimated (incidence)

Type of Study Design

- Case Control Study

identify existing disease and look back in previous years to identify previous exposures to causal factors

Analyses examine if exposure levels are different between the groups

Case

those who have a disease

Control

those without a disease

Type of Study Design

- Case Control Study

Advantages	Disadvantages
• Best design for **rare diseases** • cheap and quick • **ethically** safe	• Can **not calculate incidence**, population relative risk or attributable risk • high potential for **bias**

Type of Study Design

- Cohort Study

Incidence / Relative risk

subjects with an exposure to a causal factor are identified and the incidence of a disease over time is compared with that of controls

subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both

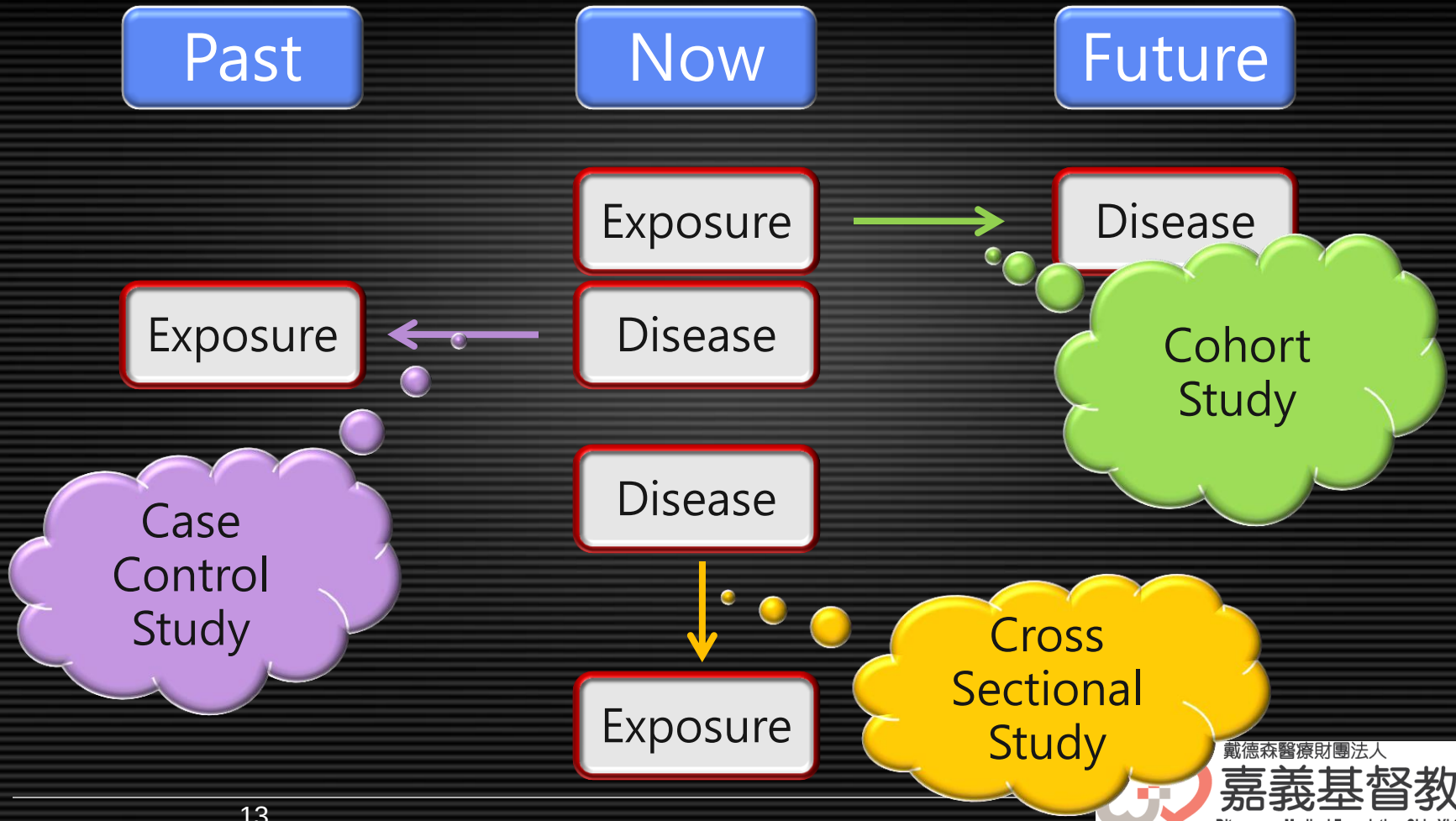
Type of Study Design

- Cohort Study

Advantages	Disadvantages
• estimate overall and specific disease rates （ **incidence** ） • lower potential for bias - **no** recall bias	• blinding is **difficult** • randomization not present • **large sample size** or **long follow-up** is necessary

Type of Study Design

- Comparison



Type of Study Design

- Randomized Controlled Trial

NNT / Confidence Interval

An experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism

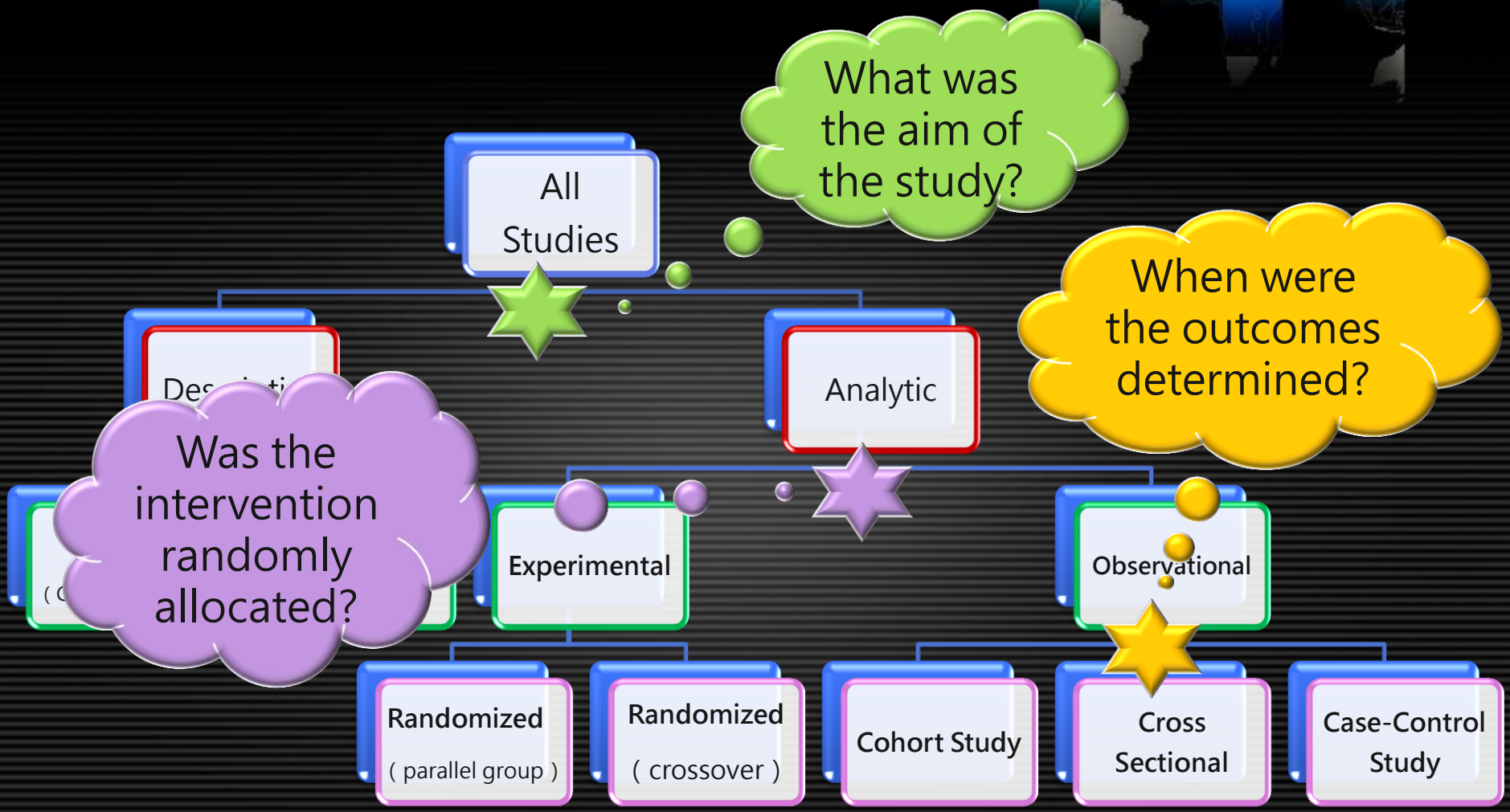
Best for study the effect of an intervention

Type of Study Design

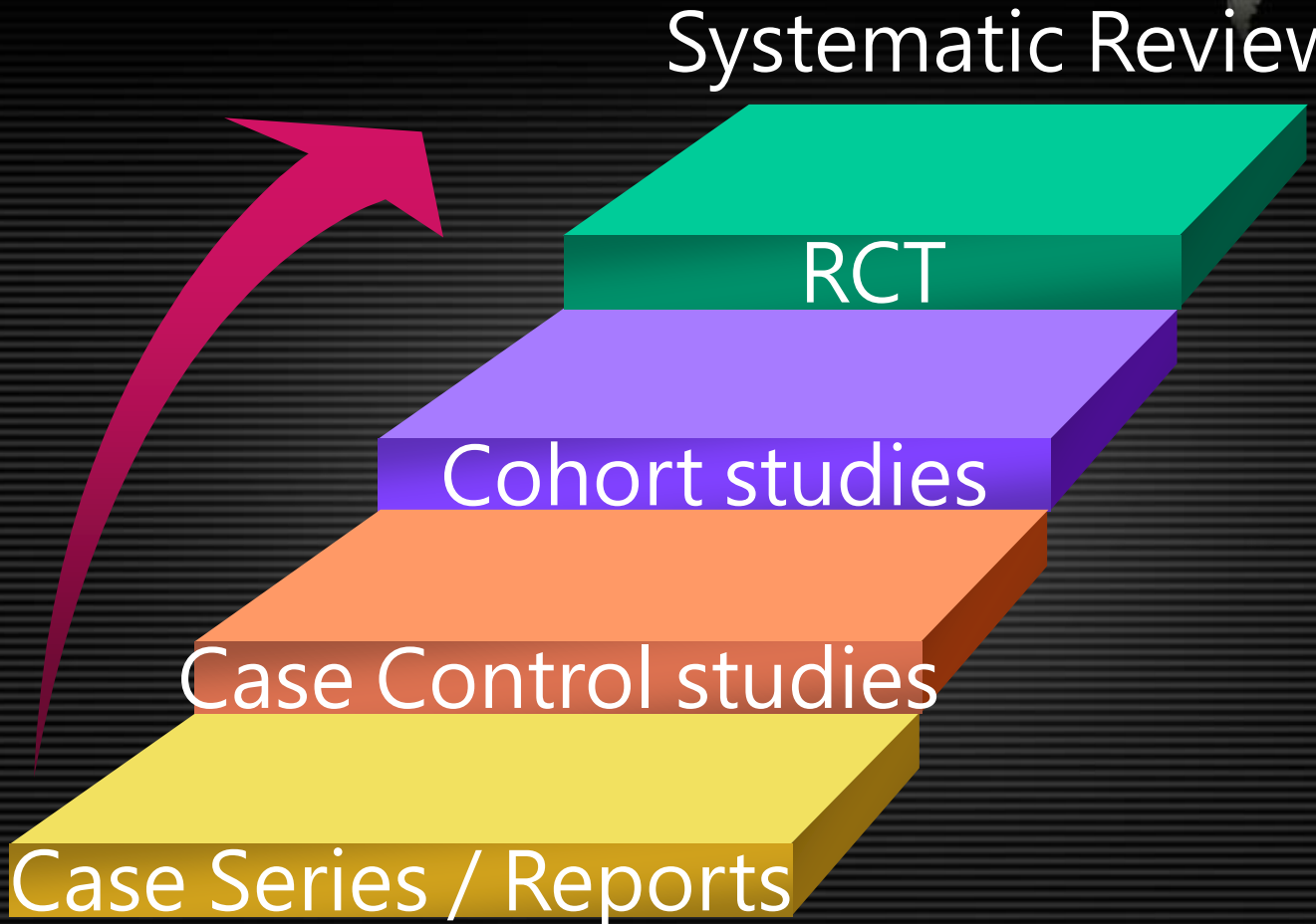
- Randomized Controlled Trial

Advantages	Disadvantages
• unbiased distribution of confounders • **blinding** more likely • randomization facilitates **statistical analysis**	• **expensive** （time、money） • volunteer bias • ethically problematic at times

Study Design Tree



Level of Evidence



Editorials/Expert Opinion

Type of Study Design

Question type	Study design
Diagnostic test	Prospective，blinded cross-sectional study comparing with gold standard
Prognosis	Cohort study > Case control study > Case series
Etiology	Cohort study > Case control study > Case series
Therapy	Randomized Controlled Trial
Prevention	Randomized Controlled Trial

分析判斷(文獻效度與重要性)

Validity 效度/信度

- Can we believe it？研究方法的探討

Importance 重要性

- We believe it ! But does it matter? 研究結果的分析

Practicability 臨床適用性

- If we believe it - does it apply to our patients?

分析判斷(文獻效度與重要性)

Validity 效度/信度

- 研究族群是否隨機 randomize
- 評估者是否blind

Were patients aware of group allocation?
Were clinicians aware of group allocation?
Were outcome assessors aware of group allocation?

- 追蹤率 > 80%

(Intention-to-treat analysis)

Was follow-up complete ?

Intention to treat analysis)

Validity 效度/信度

- 治療意向分析
  分析資料時依照原來分組的所有病人都納入分析，包括中途退出或遺失數值的病人

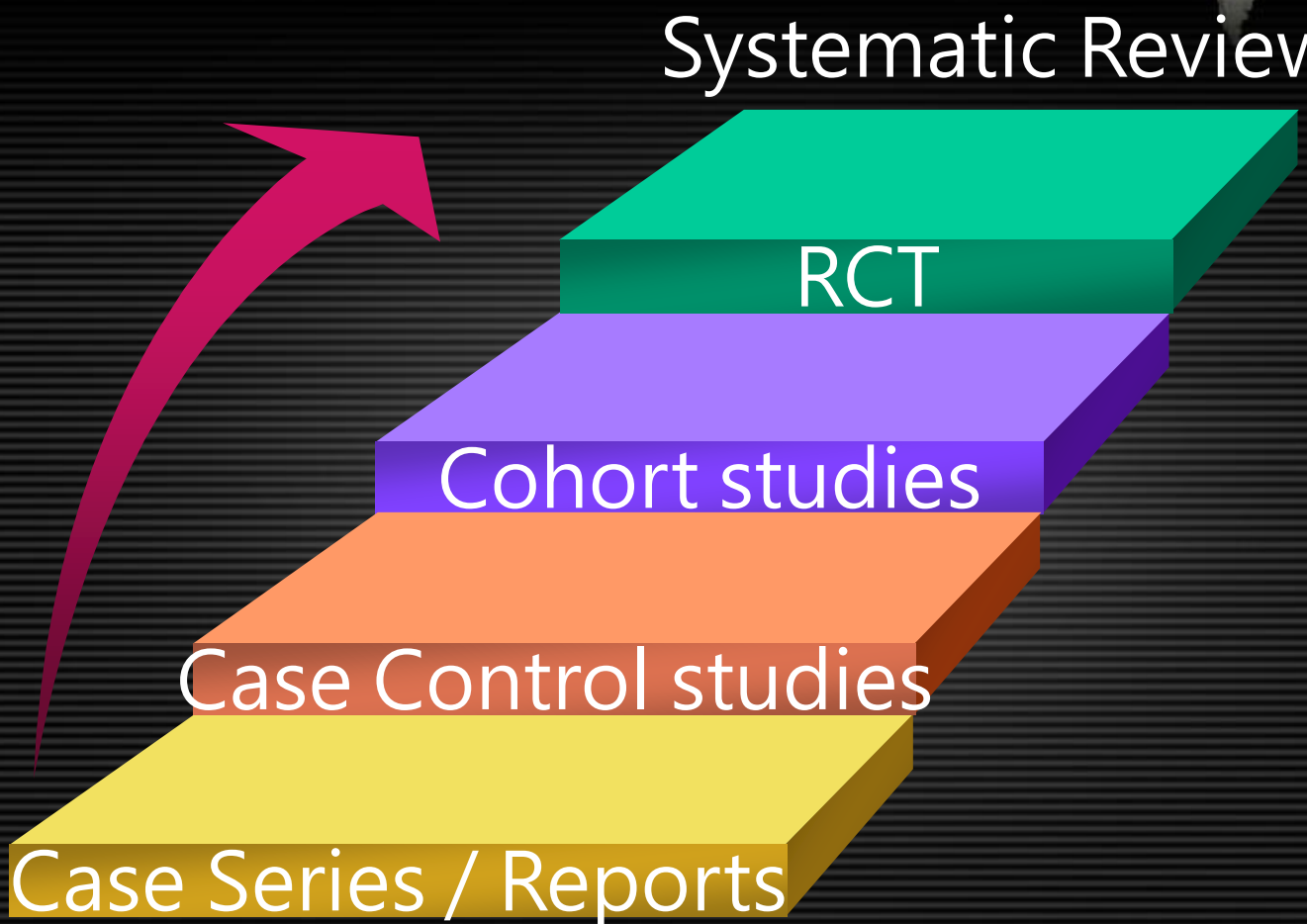
好處

–依治療意願分析是為了維持隨機化的意義。
achieved by randomization
–減少因遺失數值missing values所產生的偏誤，可能造成研究結果扭曲。

壞處

–低估治療效果

Level of Evidence



Editorials/Expert Opinion

Levels of Evidence

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

How to cite the Levels of Evidence Table

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence".

Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

** OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*

Levels of Evidence

Level of Evidence	Therapy/Prevention, Aetiology/Harm	Prognosis
1a	SR (with homogeneity*) of RCT	SR (with homogeneity*) of inception studies, or a CPG validated on a test set
1b	Individual RCT (with narrow Confidence Interval)	Individual inception cohort study with ≥80% follow-up
1c	All or none	All or none case-series
2a	SR (with homogeneity*) of cohort study	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs
2b	Individual cohort study (include low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up untreated control patients in an RCT; or CPG not validated in a test set.
2c	"Outcomes" Research	"Outcomes" Research
3a	SR (with homogeneity*) of case-control studies	
3b	Individual Case-Control Study	
4	Case-series (and poor quality cohort and case-control studies)	Case-series (and poor quality prognostic cohort studies)
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"

Levels of Evidence 簡易版

證據力等級	治療, 病因, 預防	預後	診斷	鑑別診斷, 症狀盛行率研究	經濟分析, 決策分析
Level 1	RCT 的系統性回顧；或 Confidence Interval 窄的 RCT	世代研究 的系統性回顧；或達到 80% 比例的世代研究；或 經驗證的臨床指引	系統性回顧 Level 1文獻；或以公認標準驗證的世代研究；或臨床指引	前瞻世代研究之系統性回顧；或追蹤完整之前瞻世代研究	系統性回顧Level 1 證據；或比較好壞方向的研究
Level 2	世代研究 的系統性回；或 低品質的 RCT或追蹤小於 80%；或預後研究%	回溯性世代研究；或追蹤 RCT 中未治療的對照組；或由小族群推測或驗證的 臨床指引；或預後研究	系統性回顧 Level 2文獻；或僅在小族群驗證的臨床指引	回溯世代研究之系統性回顧；或追蹤不全之回溯世代研究；或生態 (ecological)研究	系統性回顧 Level 2 文獻；或重要臨床方法或成本的單一研究；或預後研究
Level 3	有對照組 (controlled study)		系統性回顧 Level 3文獻；或不連續或缺乏公認標準驗證的研究	不連續或小族群的世代研究	其他臨床方法或成本的研究，包括敏感度 (sensitivity) 分析
Level 4	病例系列	病例系列	對照病例研究 (case- control study)	病例系列	未分析敏感度
Level 5	專家意見	專家意見	專家意見	專家意見	專家意見

評讀證據

- 先從文獻的Topic找研究方法
- 若文獻的Topic沒有說明,再從Abstract的method中去判斷

1: Cochrane Database Syst Rev. 2009 Jan 21;(1):CD000563.

1 1a
2 1b
3 2a
4 2b

Post-operative radiotherapy for ductal carcinoma in situ of the breast.

Goodwin A, **Parker S**, **Ghersi D**, **Wilcken N**.

Cancer Genetics, Westmead Hospital, Hawksberry Road, Westmead, NSW, Australia, 2145.

BACKGROUND: The addition of radiotherapy (RT) following breast conserving surgery (BCS) was first shown to reduce the risk of ipsilateral recurrence in the treatment of invasive breast cancer. Ductal carcinoma in situ (DCIS) is a pre-invasive lesion. Recurrence of ipsilateral disease following BCS can be either DCIS or invasive breast cancer. Randomised controlled trials (RCTs) have shown that RT can reduce the risk of recurrence, but assessment of potential long-term complications from addition of RT following BSC for DCIS has not been reported for women participating in RCTs. OBJECTIVES: To summarise the data from RCTs testing the addition of RT to BCS for treatment of DCIS to determine the balance between the benefits and harms. SEARCH STRATEGY: We searched the Cochrane Breast Cancer Group Specialised Register (January 2008), Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2008, Issue 1), MEDLINE (February 2008), and EMBASE (February 2008). Reference lists of articles and handsearching of ASCO (2007), ESMO (2002 to 2007), and St Gallen (2005 to 2007) conferences were performed. SELECTION CRITERIA: RCTs of breast conserving surgery with and without radiotherapy in women at first diagnosis of pure ductal carcinoma in situ (no invasive disease present). DATA COLLECTION AND ANALYSIS: Two authors independently assessed each potentially eligible trial for inclusion and its quality. Two authors also independently extracted data from published Kaplan-Meier analysis (survival curves) and reported summary statistics. Data were extracted and pooled for four trials. Data for planned subgroups were extracted and pooled for analysis.There were insufficient data to pool for long-term toxicity from radiotherapy. MAIN RESULTS: Four RCTs involving 3925 women were identified and included in this review. All were high quality with minimal risk of bias. Three trials compared the addition of RT to BCS. One trial was a two by two factorial design comparing the use of RT and tamoxifen, each separately or together, in which participants were randomised in at least one arm. Analysis confirmed a statistically significant benefit from the addition of radiotherapy on all ipsilateral breast events (hazards ratio (HR) 0.49; 95% CI 0.41 to 0.59, P < 0.00001) and ipsilateral DCIS recurrence (HR 0.64; 95% CI 0.41 to 1.01, P = 0.05). Pooled analysis for invasive recurrence did not reach statistical significance. All the subgroups analysed benefited from addition of radiotherapy. No significant long-term toxicity from radiotherapy was found. No information about short-term toxicity from radiotherapy or quality of life data were reported. AUTHORS' CONCLUSIONS: This review confirms the benefit of adding radiotherapy to breast conserving surgery for the treatment of all women diagnosed with DCIS. No long-term toxicity from use of radiotherapy was identified.

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1 1a
2 1b
3 2a
4 2b

Meta-analysis of N-acetylcysteine to prevent acute renal failure after major surgery.

Ho KM, Morgan DJ.

Intensive Care Unit, Royal Perth Hospital, Perth, WA 6000, Australia. kwok.ho@health.wa.gov.au

BACKGROUND: Acute renal failure after major surgery is associated with significant mortality and morbidity that theoretically may be attenuated by N-acetylcysteine. DESIGN: Meta-analysis of relevant studies sourced from the Cochrane Controlled Trial Register (2007 issue 4), EMBASE, and MEDLINE databases (1966 to February 1, 2008) without language restriction. SETTING & POPULATION: Adult patients undergoing major surgery without the use of radiocontrast. SELECTION CRITERIA FOR STUDIES: Randomized controlled studies comparing N-acetylcysteine with a placebo perioperatively. DATA ANALYSIS: Categorical variables are reported as odds ratio (OR) with 95% confidence interval (CI), and continuous variables are reported as weighted-mean-difference (WMD) with 95% CI. OUTCOME MEASURES: Effects of N-acetylcysteine on mortality and acute renal failure requiring dialysis were the main outcomes of interest. Additional outcome measures included an incremental increase in serum creatinine concentration greater than 25% above baseline, surgical reexploration for bleeding, amount of allogeneic blood transfusion, and length of intensive care unit stay. RESULTS: 10 studies involving a total of 1,193 adult patients undergoing major surgery were considered. N-Acetylcysteine use was not associated with a decrease in mortality (OR, 1.05; 95% CI, 0.58 to 1.92), acute renal failure requiring dialysis (OR, 1.04; 95% CI, 0.45 to 2.37), incremental increase in serum creatinine concentration greater than 25% above baseline (OR, 0.84; 95% CI, 0.64 to 1.11), or length of intensive care unit stay (WMD in days, 0.46; 95% CI, -0.43 to 1.36). N-acetylcysteine did not appear to increase the risk of surgical reexploration for bleeding (OR, 1.16; 95% CI, 0.57 to 2.38) or amount of allogeneic blood transfusion required (WMD in units, 0.31; 95% CI, -0.21 to 0.84). LIMITATIONS: Most studied patients had cardiac surgery and normal renal function preoperatively. CONCLUSIONS: There is no current evidence that N-acetylcysteine used perioperatively can alter mortality or renal outcomes when radiocontrast is not used.

1 1a
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Utility of N-acetylcysteine to prevent acute kidney injury after cardiac surgery: a randomized controlled trial.

Adabag AS, Ishani A, Koneswaran S, Johnson DJ, Kelly RF, Ward HB, McFalls EO, Bloomfield HE, Chandrashekhar Y.

Division of Cardiology, Veterans Affairs Medical Center, University of Minnesota, Minneapolis, MN 55417, USA. adaba001@umn.edu

1 1a
2 1b
3 2b
4 3b

BACKGROUND: Acute kidney injury (AKI) after heart surgery is associated with increased mortality. We sought to determine whether prophylactic perioperative administration of N-acetylcysteine (NAC) prevents postoperative AKI in patients with chronic kidney disease undergoing cardiac surgery (clinical trials.gov identifier NCT00211653). METHODS: In this prospective, randomized, placebo-controlled, double-blinded clinical trial, 102 patients with chronic kidney disease who underwent heart surgery at the Minneapolis Veterans Affairs Medical Center were randomized to either NAC (n = 50) 600 mg PO twice daily or placebo (n = 52) for a total of 14 doses (3 preoperative). The primary outcome was maximum change in creatinine from baseline within 7 days after surgery. Secondary outcome was AKI (ie, >0.5 mg/dL or >or=25% increase in creatinine from baseline). RESULTS: Creatinine increased in both groups (0.45 +/- 0.7 mg/dL in NAC vs 0.55 +/- 0.9 mg/dL in placebo, P = .53) and peaked on postoperative day 5. Acute kidney injury occurred in 41 patients (22 NAC vs 19 placebo, P = .44) by postoperative day 5, but persisted in only 14 (7 NAC vs 7 placebo, P = .94) by day 30. In multivariable analysis, perioperative NAC was unassociated with AKI (relative risk 1.2, 95% CI, 0.8-1.9, P = .34). Five patients (3 NAC vs 2 placebo, P = .68) underwent hemodialysis, and 5 (2 NAC vs 3 placebo, P = 1.0) died perioperatively. There was no difference in lengths of stay in the intensive care unit (4.9 +/- 7 days in NAC vs 6.5 +/- 9 days in placebo, P = .06) and the hospital (13.2 +/- 13 days in NAC vs 16.7 +/- 17 days in placebo, P = .12). CONCLUSION: Prophylactic perioperative NAC administration does not prevent AKI after cardiac surgery.

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分析判斷(文獻效度與重要性)

Importance 重要性

- How large was the treatment effect?
- How precise was the treatment effect?

分析判斷(文獻效度與重要性)

Importance 重要性

- 研究常用統計

*顯著水準(significance level，p value)
*信賴區間(confidence interval，CI)
*相對危險性(relative risk，RR)
*危險對比值(odds ratio，OR)
*相對危險性降低度(relative risk reduction，RRR)
*絕對危險性降低度(absolute risk reduction，ARR)
*治療需要數(number needed to treat，NNT)
*傷害需要數(number needed to harm，NNH)

分析判斷(文獻效度與重要性)

Importance 重要性

- **NNT** (Number Need to Treat) 治療需要數
  - ~ 要預防一位不良結果發生所需治療的病人數

	一年的死亡人數	一年的存活人數
接受某治療	300	700
不接受某治療	800	200

實驗組事件發生率(EER)
= 300 / (300+700) = 30%

對照組事件發生率(CER)
= 800 / (800+200) = 80%

相對危險性，風險比(Risk ratio. RR)= EER / CER = 0.3 / 0.8 = 0.375

絕對危險性降低度(ARR)= CER-EER = 80% - 30% = 50%

相對危險性降低度(RRR)=(CER-EER) / CER= (80%-30%) / 80% = 62.5%

NNT = 1 / ARR = 1/50% = 2 (每治療2位，會有1位存活)

EER：Experimental event rate　　ARR：Absolute risk reduction
CER：Control event rate　　RRR：Relative risk reduction

分析判斷(文獻效度與重要性)

Importance 重要性

某一研究追蹤二年，對照組死亡率20%，治療組死亡率10%， 結果的呈現方式有：

呈現方式	代表的意義
Relative Risk (相對風險性) RR = 0.10 / 0.20 = 0.5	治療組發生風險相對於對照組的倍數 (EER/CER) RR=1兩組無差別，RR<1治療可降低風險，RR>1治療會增加風險 RR<1表示治療可降低死亡的風險
Absolute Risk Reduction (絕對危險性降低度) ARR = 0.20 – 0.10 = 0.10 or 10%	治療組與對照組發生風險的絕對差異(EER-CER) 治療的益處是降低10%的死亡率
Relative Risk Reduction (相對風險性降低度) RRR = 1 – 0.50 = 0.50 or 50%	相對於對照組，治療組降低風險的比率 (1 – RR) (最常見的呈現方式) 相對於對照組，治療可以降低死亡的機率是50%
Number Needed to Treat (益一需治數) NNT = 1 / ARR = 1 / 0.10 = 10	要預防一位不良結果發生所必需治療的病人數 必需治療10位病人2年才能預防1人死亡

分析判斷(文獻效度與重要性)

Importance 重要性

- CI (Confidence Interval) 95%信賴區間

45% (CI : 40% ~ 50%)

45% (CI : 1% ~ 99%) 信心區間太寬，可能是樣本數太少。

45% (CI : -2% ~ 53%) 信心區間跨越原點0，不具統計意義。

- CI 的寬度代表該研究的精確度(precision)，如果CI 越窄，代表我們越有信心評估治療的療效
- 如果研究顯示該治療的確有顯著療效，且CI 的下限仍有臨床意義，則可確定該治療具有重要的臨床價值

分析判斷(文獻效度與重要性)

Practicability 臨床適用性

- How can I apply the results to my patient care ?

*Were the study patients similar to my patient ?

*Were all patient-important outcomes considered?

*Are the likely benefits worth the potential harms and costs?

分析判斷(文獻效度與重要性)

Practicability 臨床適用性

- 可否用來照顧我的病人？
  回頭看文章的PICO，是否和臨床問題相符？

- 4E：Evidence、Expectation、
  Experience、Environment

Applying、Auditing

- 在實證醫學的執行過程中，您的表現如何？您可做下列自我評估：

  *提出可以回答的問題

  *發現最佳外部證據

  *審慎評讀證據的正確性與實用性

  *專業知識的整合及應用的臨床的務實變醫療行為


Thanks for your Attention