Mb測量是否客觀？或所接受的治療，病人和臨床醫師是否保持盲化？

什麼是最好的？	文章中哪裡可以找到資訊
假如研究是雙盲，那是理想的—就是病人和研究者都未察覺治療的分派。假如結果是客觀的（如: 死亡），而盲化就較不重要，假如結果是主觀的（如症狀或功能），而結果評估者的盲化就是重要的。	首先，查看『method』的部份，看是否有提及治療的偽裝，如：有相同外觀的安慰劑。 第二，『method』的部分應該描述結果如何被評估和是否評估者察覺病人的治療？
這篇文章: 是☐ 否☐不清楚☐ **建議：**	

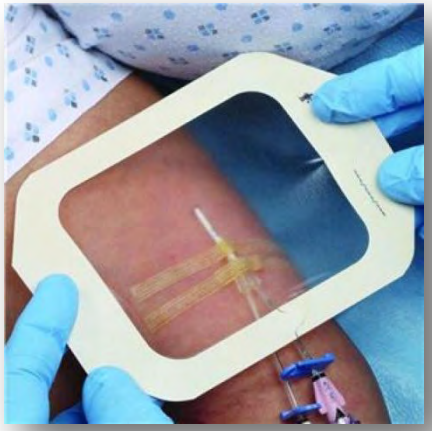
tim[illegible] than 150 seconds (eptifibatide) or less than [illegible]conds (bivalirudin). Mechanical pressure was maint[illegible]ned with the FemoStop device for 60 minutes or manually for 30 minutes in each patient. The sheath removal site was then dressed with 1 of the 3 dressings as described earlier.

All 60 nurses employed on the unit where patients were admitted after PTCA were trained to participate in the study. The nurses assessed the patients every 4 hours for complaints of discomfort in addition to the routine checking of vital signs and assessment of the groin site after sheath removal. The first assessment of the groin site was made when the dressing was applied, and additional assessments were done at 4-hour intervals after that. This frequency yielded a mean of 4.7 (SD, 0.06) assessments per patient. The nurses also recorded whether they were able to observe the groin site directly and rated the ease of assessment of the site for bleeding or hematoma formation on a scale of 1 (difficult to assess) to 5 (easy to assess). Patients' complaints about the groin site were noted during these assessments.

Patients were discharged 24 h[illegible]r admission and removed the dressing a[illegible] follow-up telephone call was made within 48 [illegible] 72 hours after discharge by a nurse investigator (T.[illegible]). Patients were asked to rate how comfortable it was to remove the dressing and to rate the condition of the groin site when the dressing was removed. In order to rate the pain, patients were asked, "On a scale of 1 (very comfortable) to 10 (painful), how comfortable was it for you to remove the dressing?" The scale used was based on the Numeric Pain Scale[5] rating of 1 through 10 used in clinical nursing practice. Patients also were asked if they had ever had a catheterization with a pressure dressing before and, if so, how this experience compared with the previous one. Patients were given the opportunity to provide additional comments about the experience. The nurse surveyor recorded the comments verbatim.

Mo除分派的治療外，組間的治療是否相同？

什麼是最好的？	文章中哪裡可以找到資訊
在不同組間除措施不同外，其餘應被同等對待？如：額外的治療或測驗	追蹤的計畫、允許的額外治療等，可查看『method』，而實際如何使用，可看『結果』
這篇文章: 是☐ 否☐不清楚☐ **建議：**	



病人分派到治療是否隨機	NO	YES
分派隱匿	NO	YES
保持盲性	NO	YES
測量是否客觀	NO	YES

- 某一新藥臨床試驗追蹤兩年，
  - 實驗組死亡率10%
  - 控制組死亡率15%...

測量什麼？	意義是什麼？
Relative Risk(相對風險)=治療組的結果風險/控制組的結果風險	相對風險告訴我們治療組事件的發生是控制組的幾倍。 當RR=1，表示兩組間無差異，因此，治療是沒有作用的，當RR < 1，表示治療減少了結果的風險發生，當RR > 1，表示治療增加了結果的風險發生。 因為RR < 1，治療減少死亡風險的發生。

RR = 0.10/0.15 = 0.67

測量什麼？	意義是什麼？
Absolute Risk Reduction(絕對危險降低度)=控制組的結果風險(CER)-治療組的結果風險(EER)，這也是我們所知的絕對風險差，此數據通常比相對風險比率差對治療效果評估較實用。	絕對危險降低度告訴我們絕對差在兩組間事件的比率和存在的基本風險、治療效果的指示。當ARR=0，表示2組間沒有不同，因此，治療沒有效果。

ARR = 0.15 - 0.10 = 0.05 or 5%

測量什麼？	意義是什麼？
Relative Risk Reduction(相對風險降低度)=絕對危險降低度/控制組結果的風險，一個計算RRR的替代方式是1-RR。	相對風險降低度是RR的補充，和可能是最常被報導來測量治療結果的，它告訴我們治療組減少結果的比率相對於控制組是多少。

RRR = 0.05/0.15 = 0.33 or 33%

測量什麼？	意義是什麼？
Number Needed to Treat(益一需治數)= ARR的倒數(1/ARR) NNT = 1/ 0.05 = 20 絕對風險增加(ARI) Absolute risk increase = (EER-CER)。	益一需治數表示我們需要去治療多少的病人和治療多久，才能避免一個壞結果的發生， NNT的大小能決定一些臨床的意義。 我們需要治療20個人2年，才可預防1個死亡。**(NNT 越少越好)** 害一需治數 Number needed to harm (NNH) =1/ARI。病患接受了實驗組的治療後，可能會有病人產生副作用，亦即對多少病人數目進行實驗組療法，與對照組做比較後，會有多一個病人產生不良副作用。**(NNH 越大越好)**

治療效果有多大？

效果表現方式	意義
Relative Risk (相對風險)	治療組發生風險相對於對照組的倍數。**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**
Absolute Risk Reduction (絕對危險降低度)	治療組與對照組發生風險的絕對差異
Relative Risk Reduction (相對風險降低度)	相對於對照組，治療組降低風險的比率 **(最常見的呈現方式)**
Number Needed to Treat (益一需治數)	要預防一位不良結果發生所必需治療的病人數

RCT常見的偏差

Bias	Source of bias	Solutions
Selection bias	Random sequence generation, Allocation concealment	Randomization
Performance bias	Blinding of participants and personnel	Double blinding
Detection bias	Blinding of outcome assessment*	Observer blinded
Attrition bias	Incomplete outcome data	ITT
Reporting bias	Selective reporting	All of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.

	定義	計算
control event rate, CER 對照組事件發生率	對照組事件發生占對照組總數百分比	
experimental event rate, EER 實驗組事件發生率	實驗組事件發生占實驗組總數百分比	
relative risk reduction (RRR) 相對危險降低	相對於對照組，治療組降低風險的比率	(|CER−EER|/CER)
absolute risk reduction (ARR) (or the risk difference) 絕對危險降低	治療組與對照組發生風險的絕對差異	|CER−EER|

	定義	特性
Number needed to treat (NNT) 益一需治數	在試驗期間，需要使用試驗性療法治療多少病人，才能預防一個額外的不良結果。	1 / ARR
Number needed to harm (NNH)	造成一位病人受害所需治療病人數	1 / ARI

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On this page you can download CATmaker, the CEBM's venerable computer-assisted critical appraisal software, and use our interactive EBM calculators.

Please note that you will need the Shockwave plug-in to view the calculators. If you do not have Shockwave installed, you will be presented with the opportunity to download it. We recommend you do so, as this adds functionality to your browser.

CATmaker

CATmaker is a computer-assisted critical appraisal tool, which helps you create Critically Appraised Topics (CATs), for the key articles you encounter about Therapy, Diagnosis, Prognosis, Aetiology/Harm and Systematic Reviews of Therapy.

Download CATmaker (3MB, PC format only) – the full version

All-purpose 2×2 table EBM calculator

RECOMMENDED CONTENT

Critical Appraisal tools

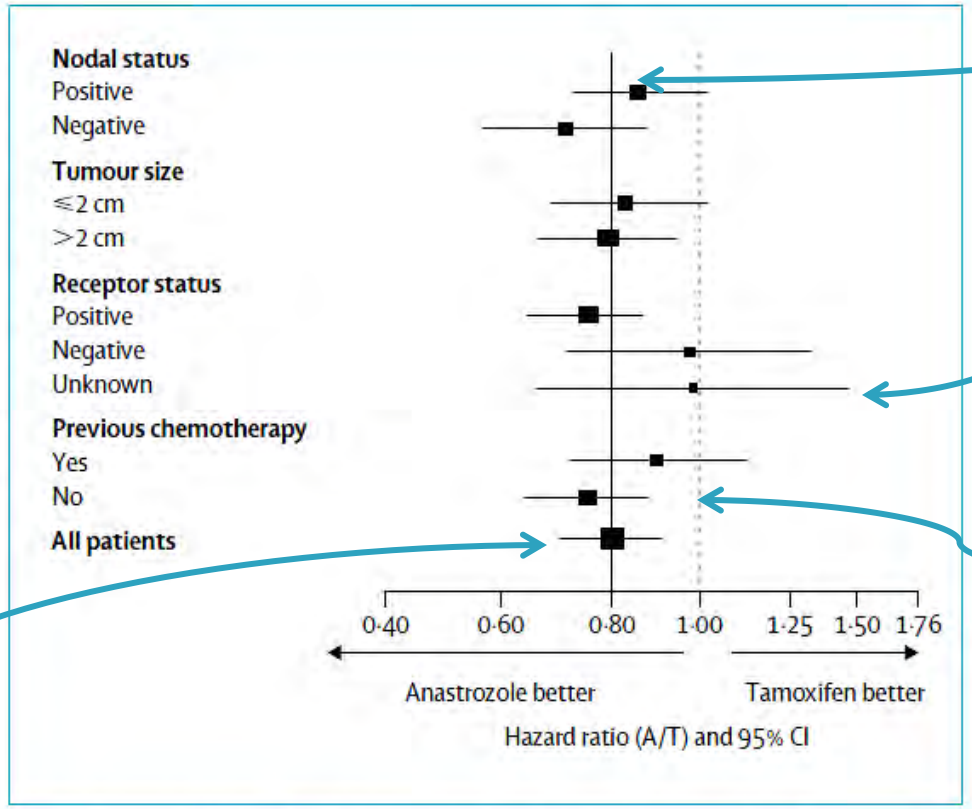
Critical appraisal worksheets to help you appraise the reliability, importance and applicability of clinical evidence.

Likelihood Ratios

方法	定義	特性
Intention-to-treat (ITT) 意圖治療分析	所有接受隨機分派的受試者都應該納入分析	意圖治療分析是為了維持隨機化的意義，減少因遺失數值(missing data)所產生的偏誤所導致研究結果扭曲。
Per-protocol (PP) 實際治療分析	完整接受治療到最後的受試者納入分析	破壞了當初隨機分派的平衡狀態，可能導致選樣偏差(selection bias)

RCT中森林圖之判讀

子族群



點估計值

95%信賴區間

無效線

整體效果

Figure: Suggested modification as applied to time to recurrence in subgroups of the ATAC trial[3]
Dotted line shows no effect point, and (new) bold line shows overall treatment effect point.

治療型文獻之森林圖

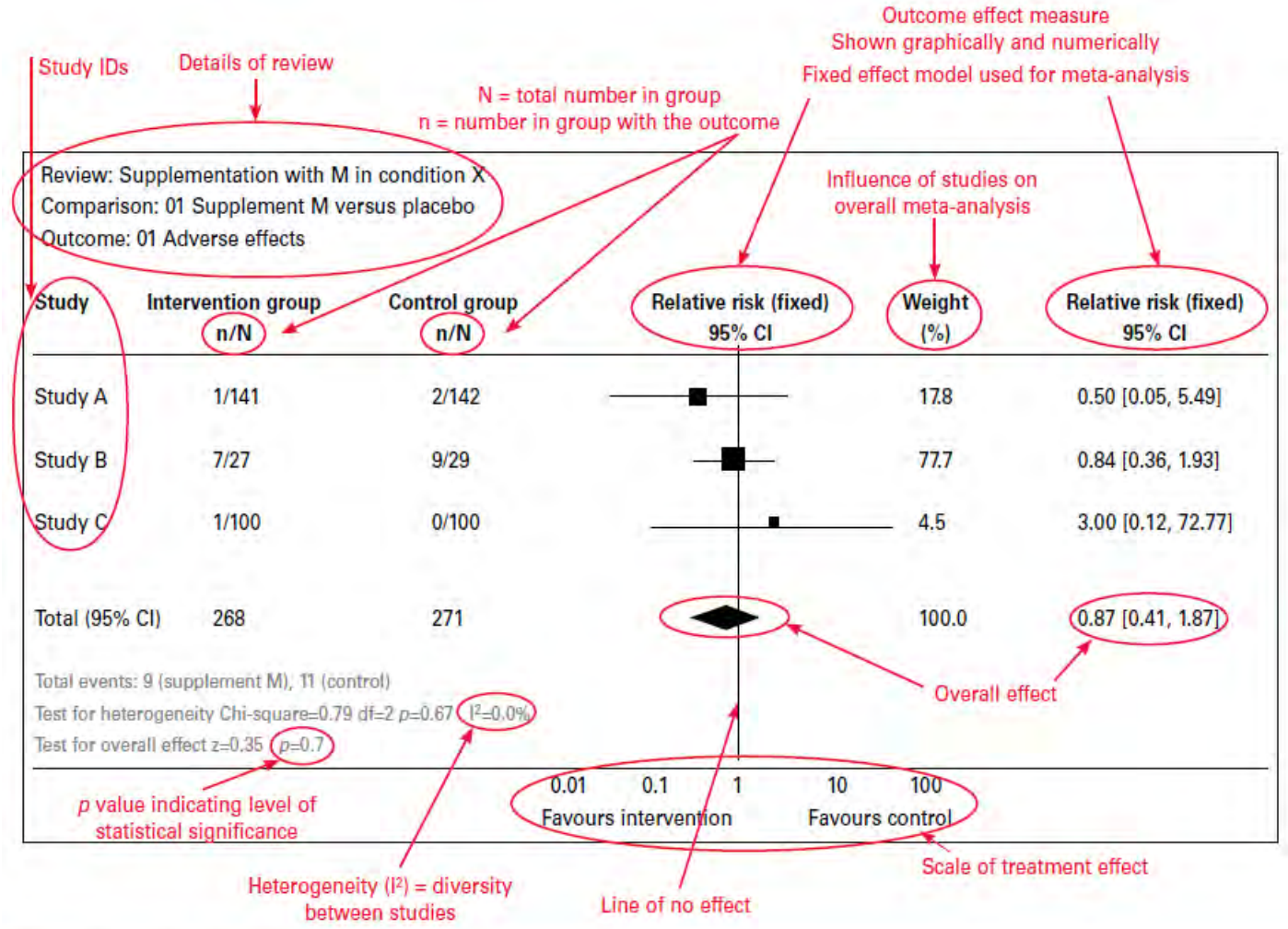


Figure 1. Meta-analysis of binary outcome measure

- P value
  - 拒絕虛無假設之最小顯著水準(level of significance)，稱為P值。
  - P 值 < α時，代表「統計上達到顯著」，應拒絕虛無假設。
  - P 值 ≧ α時，代表「統計上不顯著」，不應拒絕虛無假設。
- 95%信賴區間
  - 在此區間中，有95%的機率**包含**母群體的真值。
  - 估計值±1.96 × 標準誤（SE）
  - 95% CI愈窄表示愈精準。

- 第一類型誤差（α）
  - 兩種實驗結果為相同時，偵測兩組間具統計顯著的機率（偽陽性的機會）
- 第二型誤差（β）
  - 兩種實驗結果實際上有差異時，偵測兩組間不具統計顯著的機率（偽陰性的機會）
- 檢定力（1－β）
  - 兩組結果實際上很不相同時，偵測兩組間具統計顯著的機率（真陽性的機會）

	實際治療有效	實際治療無效
試驗結果有效	(1−β)	α
試驗結果無效	β	

一般來說：

$\alpha < 0.05$

$(1-\beta) > 0.8$

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

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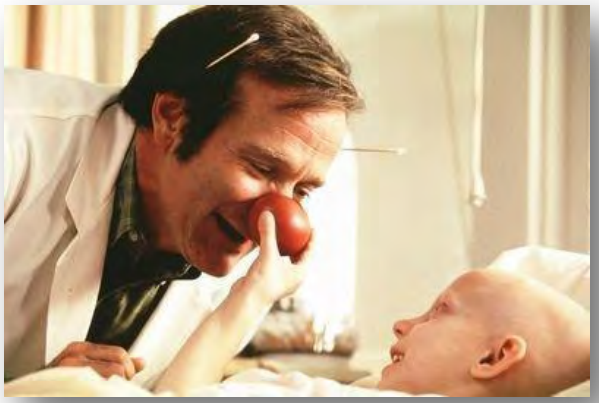
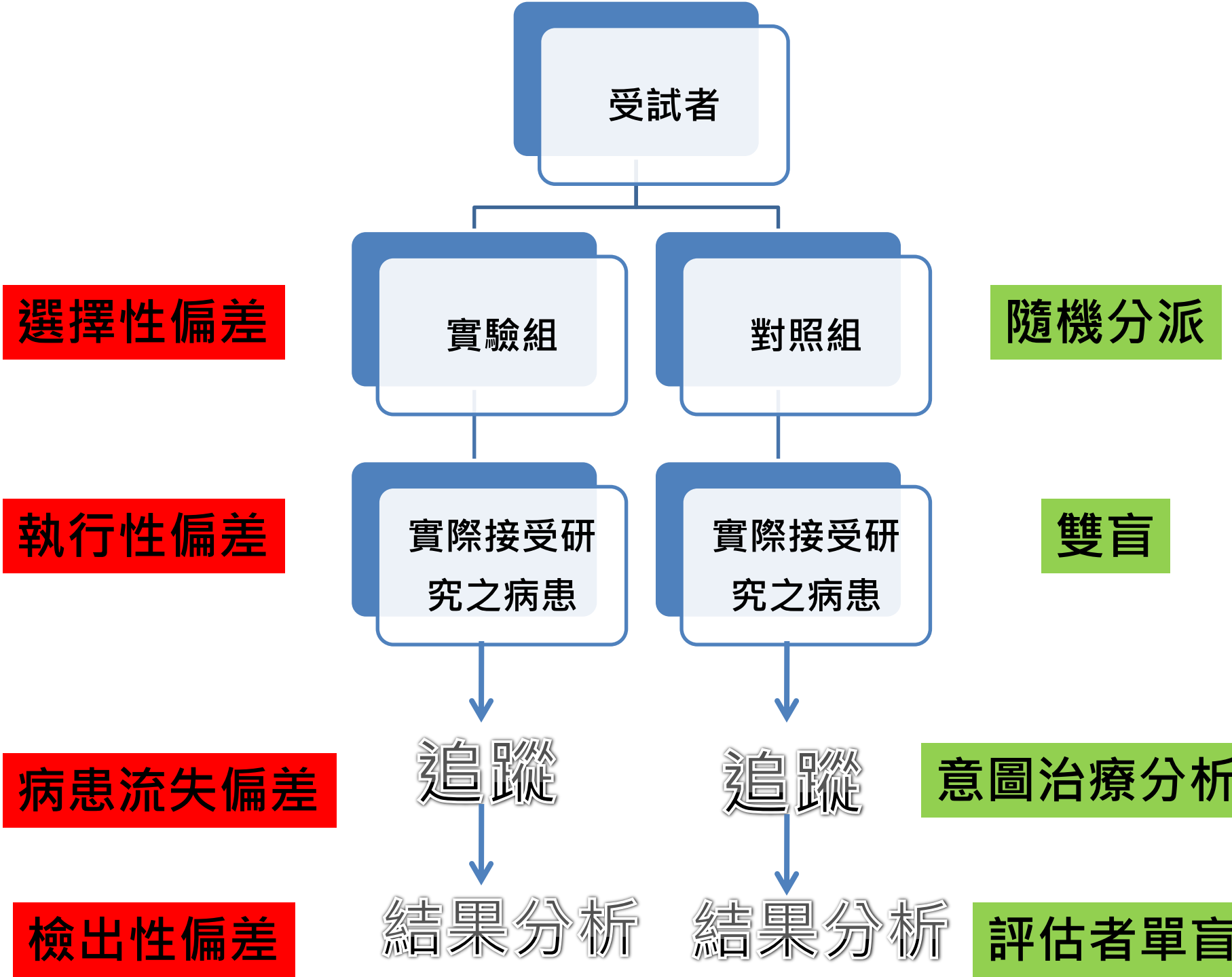
應用性 (Applicability)



- 我們的病人是否與研究中的病人非常不同，以致於無法應用這研究結果？
- 這個治療適用於我們的醫療機構嗎？
- 病人能從治療中得到好處或壞處？
- 對於治療，病人的價值觀與期望為何？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實驗組
對照組
實際接受研究之病患
實際接受研究之病患
追蹤
追蹤
結果分析
結果分析
選擇性偏差
隨機分派
執行性偏差
雙盲
病患流失偏差
意圖治療分析
檢出性偏差
評估者單盲

說穿了，文獻評讀就是一套檢視臨床試驗的過程！