

實證醫學簡介及臨床應用

—以Vitamin C預防感冒為例—

主講人:林美吟藥師

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● 實證醫學簡介

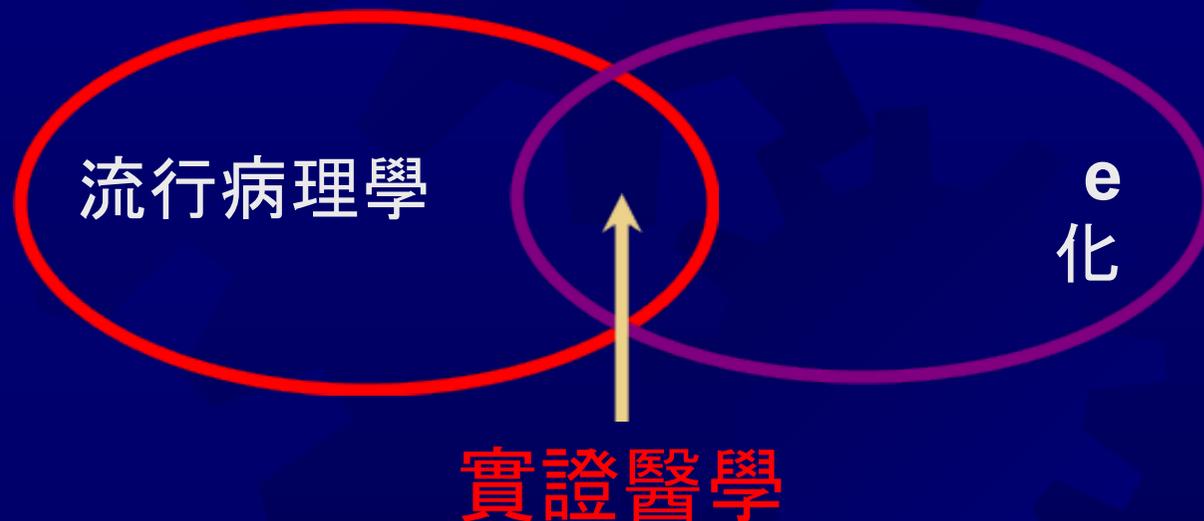
- 實證醫學的歷史及時代意義
- 實證醫學三大要素
- 實證醫學的四大臨床問題
- 執行實證醫學的五大步驟

● 臨床應用

- 以Vitamin C預防感冒為例

何謂實證醫學

- 以流行病學和統計學的方法，從龐大的醫學資料庫中嚴格評讀、綜合分析並找出值得信賴的部分，並將所能獲得的最佳文獻證據應用於臨床工作中，使病人得到最佳的照顧。



實證醫學的歷史及時代意義



Professor Archibald Lemlan Cochrane,
CBE FRCP FFCM, (1909 - 1988)

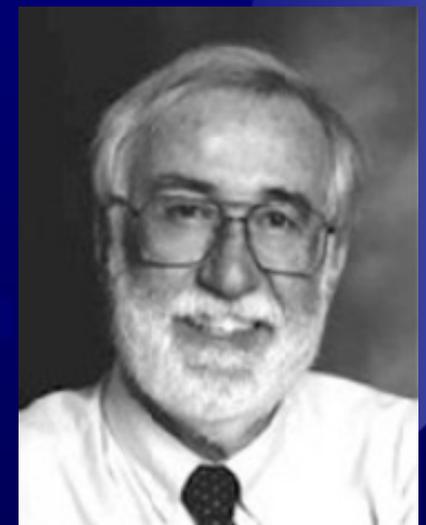
英國流行病學家

- 1972年英國臨床流行病學者Archie Cochrane提出實證醫學的概念。他表示衡量一個醫療行為是否有效，應該透過**對照研究(RCT)**的方式，同時指出醫療資源應運用於經嚴謹研究證實有效的治療方向，才能提供合理的醫療服務。

實證醫學的歷史及時代意義

- 1980年美國腎臟科醫師Sackett D.在加拿大Mc Master大學成立臨床流行病理學與統計學的碩士課程，訓練推動實證醫學的專家群。
- 1992年Evidence-based medicine一詞正式由Mc Master大學Gordon Guyatt提出，並在JAMA上連載一系列有關實證醫學的介紹性文章，將實證醫學推向國際舞台。

- 概念一：促進學習動機與興趣
- 概念二：Modified PBL學習法
- 概念三：基本態度技術與知識
- 概念四：臨床醫療行為改變



Dr. David L. Sackett

實證醫學的歷史及時代意義

- 1992年英國國家衛生部成立實證醫學中心，並以Archie Cochrane之名命名，進而促使1993年Cochrane Collaboration的設立 集合世界專家的力量，建立Cochrane Library，成為實證醫學最重要的資料庫。



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系統性評論

基準

七個隨機
對照臨床
試驗

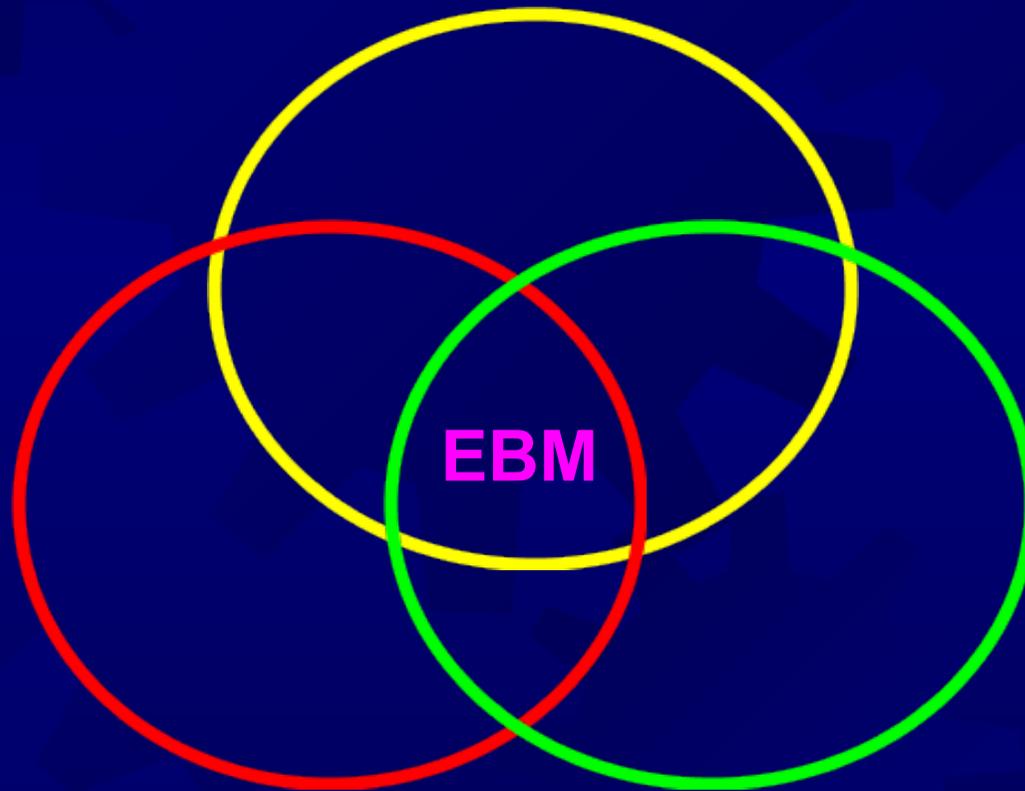
經過綜合
比較七個
RCT後的
結果

觸及到垂直線
代表試驗中的
實驗組與對照
組間無差異

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實證醫學三大要素

Clinical Expertise
臨床專業



Best Research Evidence
研究證據

Patient Values
病人價值觀

實證醫學的四大臨床問題

- **Therapy/Prevention: 治療/預防的問題**

- 研究治療或預防方法的有效性
 - 例如:服用阿斯匹林是否可以預防中風?

- **Diagnosis: 診斷問題**

- 研究檢查方法或臨床表徵對疾病診斷的有效性
 - 例如:McBurney's sign 診斷急性盲腸炎的敏感性及特異性為何?

- **Harm/Etiology: 危害/病因問題**

- 研究暴露的危害或疾病的原因
 - 例如:停經婦女使用荷爾蒙治療是否會增加乳癌的機會?

- **Prognosis: 預後**

- 建立疾病預後的預測模式
 - 例如:利用Ranson's criteria 預測急性胰臟炎死亡率為何?

執行實證醫學的五大步驟

- 1. 將資訊需求轉變成可以回答的臨床問題。
- 2. 尋找相關的醫學證據。
- 3. 以批判的方法檢驗證據的可信度。
- 4. 結論是否能應用於我的病人？
- 5. 評估執行實證醫學的效用和效率

Asking
問問題

Accessing
找資料

Appraising
分析判斷

Applying
臨床應用

Auditing
評估成果

Step1

將資訊需求轉變成可以回答的臨床問題

- 臨床問題從哪裡來？
- 臨床問題依其特異程度可以分為背景問題 (background question) 及前瞻問題 (foreground question)



Background

臨床經驗不足
使用教科書
回答問題



臨床經驗豐富
使用醫學文獻
回答問題

Foreground questions

- Ask for specific knowledge about managing patients with a disorder

- **PICO**

- **P**atient and/or problem
- **I**ntervention (exposure, test)
- **C**omparison intervention (if relevant)
- **O**utcomes

- 例子:吳先生因為家族有冠狀動脈疾病病史，經朋友介紹服用維生素E及beta-carotene，希望能降低發生冠狀動脈疾病的機會，徵詢你的意見

P: High CV risk male

I : Vitamin E and beta-carotene

C: No Vit E and beta-carotene

O: Clinical events or death

Step 2

尋找相關的醫學證據

- 資料庫的種類 Databases

- 教科書、電子書、網路電子書
 - MD Consult, Uptodate...
- 醫學期刊、電子期刊、電子資料庫
 - Medline, PubMed...
- 實證醫學文獻資料庫
 - Cochrane Library, ACP journal club...

- 搜尋技巧與策略 Searching strategies

- 檢索時遇到的問題
 - 筆數太多/少
 - 找不到相關的文章
 - 找到品質不是很好的文章
 - 因為不夠了解檢索策略和技巧, 影響檢索結果和筆數, 造成資料不完整的情形

- 證據級數高低 Hierarchy of evidence

證據等級

Level		Therapy/Prevention, Aetiology/Harm
1	a	將隨機對照臨床試驗研究(RCT)以系統性評論後(systematic review: SR)的結果
	b	具有嚴格的信賴區間的個別RCT研究
	c	無論使用何種研究方法,但其研究結果為完全正面,完全負面或完全無效的研究報告
2	a	將同質性的世代研究(cohort studies)以系統性評論後的結果
	b	個別世代研究或質量不足的RCT研究(例如低於80%follow-up)
	c	以多數結果為基礎的研究及生態學的研究
3	a	將同質性的個案對照研究(case control studies),以系統性評論後的結果
	b	個別的個案對照研究(individual case control study)
4		病例統計報告,以及質量不足的個案對照研究
5		未經嚴謹評估的專家意見或基礎生理學,一般實驗室研究

Step 3

以批判的方法檢驗證據的可信度

- 文獻的結果是否有效度？(Validity)
- 文獻的結果是否有重要性？(Importance)
- 文獻的分析判斷前需先分類，不同種類的文獻，研究方法不同，評判方式也有異。

研究方法分析1

- 原始研究 (Original Study)
 - 1. 隨機對照實驗 (Randomized Control Trial)
 - 給實驗組及對照組不同的治療，觀察其後果。
 - 例如：實驗組吃aspirin，對照組吃澱粉，比較兩組五年後中風的機率。
 - 2. 世代研究 (Cohort Study)
 - 觀察自然暴露/治療方式的影響，長期追蹤其結果。
 - 例如：比較金山鄉有吃aspirin 及沒有吃aspirin 的人，五年後新發生中風的機率
 - 3. 病例對照研究 (Case Control Study)
 - 選擇病人組及對照組，研究其暴露/治療的影響。
 - 例如：比較500 個有中風的個案及500 個沒有中風的個案，他們吃aspirin的比例。
 - 4. 個案報告 (Case Report)
 - 收集同一臨床特色之病人，回顧文獻報告加以比較。
 - 例如：收集5 位吃aspirin 預防中風結果發生消化道出血的病人，報告其臨床特徵並回顧相關文獻。

研究方法分析2

- 文獻回顧 (Review of Literature)
- 1. 系統性回顧 (systemic review)
 - 系統性的文獻回顧，將個人好惡及偏差減至最低。需引用各種文獻資料庫，並說明查詢的關鍵字，有引用文獻的明確標準，不能依作者喜好選取文獻，通常會使用統計方法 (Meta-Analysis 統合分析)，以解決臨床爭議為目的。
- 2. 非系統性回顧 (non-systemic review)
 - 傳統文獻回顧，容易有個人好惡及偏差。以作者的判斷引用文獻，通常沒有使用特殊的統計方法，以教育臨床醫師為目的。

Step 4

結論是否能應用於我的病人

- 我的病人是否與研究族群不同？
 - 人口學特色
 - 危險因子
 - 次級/次級預防
- 我的機構能提供這樣的治療嗎？
- 治療對病人的潛在的意益處或風險
- 病人的價值觀及期望
 - 投藥方式、手術方式、遵醫囑性
 - 文化、社會、經濟及倫理考量

Step 5

評估執行實證醫學的效用和效率

- 提出臨床問題的自我評估

- 我有提出結構完整的問題嗎？
- 我能將問題歸類嗎？
- 當我遇到困難時能解決嗎？

- 尋找最佳的自我評估

- 我有尋找任何證據嗎？
- 我能在許多來源中找到有用的資訊嗎？

- 批判文獻的自我評估

- 我有批判任何研究文獻嗎？
- 我對證據數字的計算越來越有效嗎？

- 綜合證據及臨床應用的評估

- 我能有效的將文獻批判整合於病人價值嗎？
- 我有進行任何臨床決策分析嗎？

實證醫學的臨床應用-- 以Vitamin C預防感冒為例

Asking
問問題

- 個案描述

- 一位成年女性病患到藥物諮詢台詢問藥師,長期服用Vitamin C是否可能預防或治療感冒?

- 提出臨床問題(PICO)

Patient	adult
Intervention	Vitamin C
Comparison	Non-Vitamin C
Outcomes	Common cold incidence, Duration

- 利用網站

- 安泰醫院圖書館

Step2

尋找相關的醫學證據

Accessing
找資料

- 資料庫:Cochrance library, PubMed, 思博網
- 關鍵字:Common cold, vitamin C, incidence

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電子資源

 西文電子期刊	 西文醫學資料庫	 中文資料庫	 實證醫學資料庫
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東港安泰醫護雜誌

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The Cochrane Library 為一個實證醫學全文型資料庫，製作單位為 The Cochrane Collaboration。其下又分為 7 個資料庫，由 Cochrane 專業團體或國際組織對文獻進行系統性評論、控制實驗與生統分析。

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AND <input type="text" value="vitamin d"/>	Record Title
AND <input type="text" value="Enter search term 3"/>	Author
AND <input type="text" value="Enter search term 4"/>	Abstract
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SEARCH TIPS

Tip No. 1:

Boolean operators AND, OR, NOT can be selected from the pulldown selection boxes or entered directly within the search text boxes. Use parentheses to separate components when entering complex search directly into a search text box with mixed Boolean operators.

Example: *(colchicine AND I²) AND (fibrosis OR cirrhosis)*

Tip No. 2:

The AND operator is used by default between search terms. The string *brain stem* will match records where both words are included in any order or proximity. Search for exact phrases by enclosing a string in quotation marks.

Example: *"colchicine therapy"*

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| <input type="checkbox"/> | Vitamin C for preventing and treating pneumonia
Harri Hemil? Pekka Louhiala
Year: 2007
Record Review |
| <input type="checkbox"/> | Vitamin C for preventing and treating the common cold
Harri Hemil? Elizabeth Chalker, Barbara Treacy, Bob Douglas
Year: 2007
Record Comment Review |
| <input type="checkbox"/> | Vitamin C for preventing and treating tetanus
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- Coffee Break, Genes & Disease, NCBI Handbook
- Electronic PCR
- Entrez Home
- Entrez Tools
- Gene expression omnibus (GEO)
- Human genome resources
- Influenza Virus Resource

NCBI H1N1 Flu Resources

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Heimer KA, Hart AM, Martin LG, Rubio-Wallace S.
J Am Acad Nurse Pract. 2009 May;21(5):295-300.
PMID: 19432914 [PubMed - in process]
[Related Articles](#)
- 2: [\[Vitamin C and immune function\]](#)
Ströhle A, Hahn A.
Med Monatsschr Pharm. 2009 Feb;32(2):49-54; quiz 55-6. Review. German.
PMID: 19263912 [PubMed - indexed for MEDLINE]
[Related Articles](#)
- 3: [\[Vitamin C and zinc tablets do not prevent or cure the common cold: scientific proof of the efficacy of food supplements is absent\]](#)
[No authors listed]
Kinderkrankenschwester. 2008 Dec;27(12):515-6. German. No abstract available.
PMID: 19189631 [PubMed - indexed for MEDLINE]
[Related Articles](#)
- 4: [Clinical significance of common cold treatment: professionals' opinions.](#)
Barrett B, Endrizzi S, Andreoli P, Barlow S, Zhang Z.
WMJ. 2007 Dec;106(8):473-80.
PMID: 18237071 [PubMed - indexed for MEDLINE]
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- 5: [Common cold.](#)
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All Adult: 19+ years

Newborn: birth-1 month

Infant: 1-23 months

Preschool Child: 2-5 years

Child: 6-12 years

Adolescent: 13-18 years

Adult: 19-44 years

Middle Aged: 45-64 years

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Cochrane Database Syst Rev. 2007 Jul 18;(3):CD000980. Review.
PMID: 17636648 [PubMed - indexed for MEDLINE]
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Arroll B.
Respir Med. 2005 Dec;99(12):1477-84.
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Sasazuki S, Sasaki S, Tsubono Y, Okubo S, Hayashi M, Tsugane S.
Eur J Clin Nutr. 2006 Jan;60(1):9-17.
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Douglas RM, Hemilä H.
PLoS Med. 2005 Jun;2(6):e168; quiz e217. Epub 2005 Jun 28. No abstract available.
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AND

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所有欄位

AND

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Vitamin C for preventing and treating the common cold (Review)

Hemilä H, Chalker E, Treacy B, Douglas B



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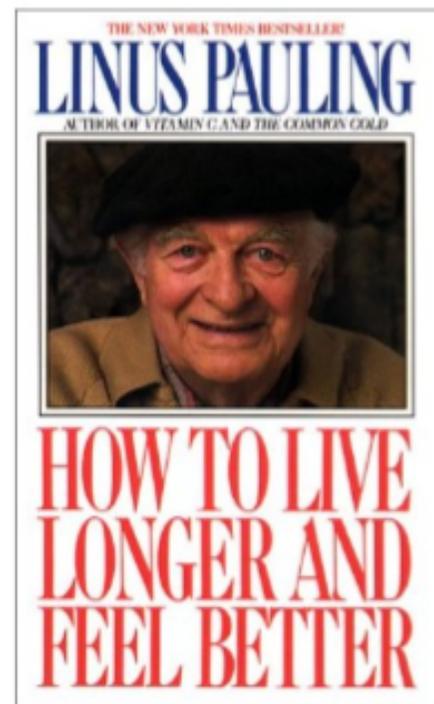
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以批判的方法檢驗證據的可信度

Appraising
分析判斷

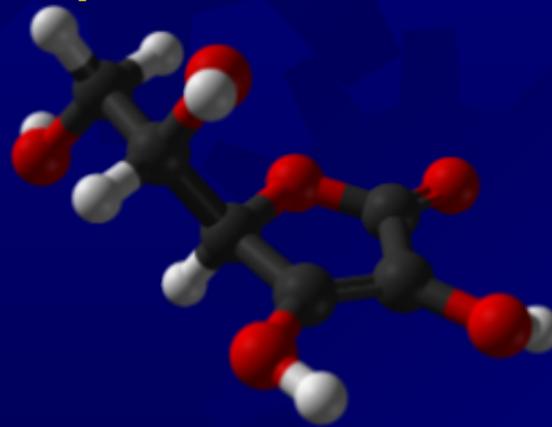
● Background背景

- The role of vitamin C (ascorbic acid) in the prevention and treatment of the common cold has been a subject of controversy for 60 years, but is widely sold and used as both a preventive and therapeutic agent.



● Objectives 目的

- To discover whether oral doses of **0.2 g or more** daily of vitamin C reduces the **incidence, duration or severity** of the common cold when used either as **continuous prophylaxis** or **after the onset of symptoms**.



Vitamin C

● Search strategy 搜尋策略

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE (1966 to December 2006)
- EMBASE (1990 to December 2006)

● Selection criteria 選擇標準

○ Excluded 排除

- dose less than 0.2 g per day of vitamin C
- no placebo comparison.

○ Included 納入

- (1) 0.2 g/day or more, and less than 1 g/day;
- (2) 1 g/day or more, and less than 2 g/day;
- (3) 2 g/day or more.

● Outcome measures 結果測量

○ 1. Incidence 發生率

- colds during prophylaxis was assessed as the proportion of participants experiencing one or more colds during the study period

○ 2. Duration 感冒時間

- mean days of illness of cold episodes

○ 3. Severity 嚴重性

- episodes was assessed in two ways:
 - days confined indoors
 - off work or off school per episode
- symptom severity scores

● Analysis 資料分析

○ 1. Prophylaxis 預防

- incidence of colds
- duration of colds
- severity of colds

○ 2. Therapeutic 治療

- duration of colds
- severity of cold episodes

○ 3. Adverse effects 副作用

- high dose vitamin C intake

Analysis 1.1. Comparison 1 Development of colds while on vitamin C prophylaxis, Outcome 1 Proportions developing one or more cold episodes during prophylaxis.

Review: Vitamin C for preventing and treating the common cold

Comparison: 1 Development of colds while on vitamin C prophylaxis

Outcome: 1 Proportions developing one or more cold episodes during prophylaxis

1.1 Prophylaxis: incidence of colds

風險比
(Risk Ratio; RR)
相對風險
(Relative Risk; RR)

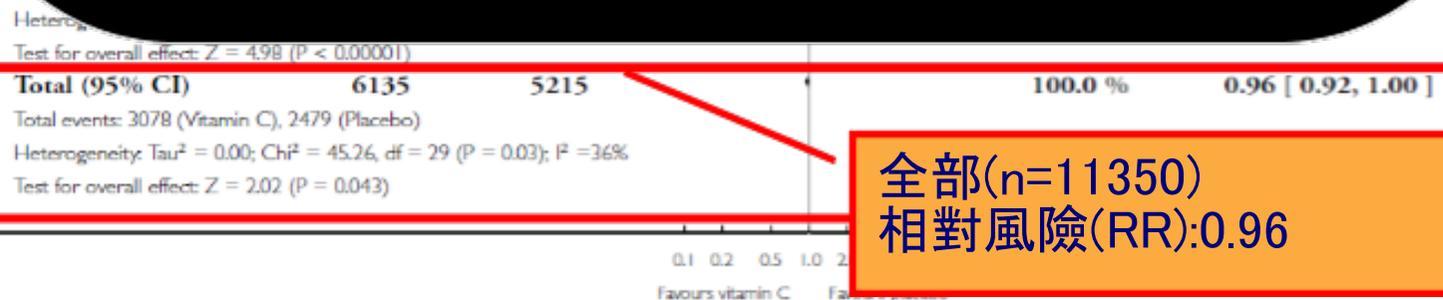
計算: 實驗組風險/對照組風險

例子: 第一型囊腫婦女得到乳癌的風險是 $12/417=0.029$ (2.9%),
第二型囊腫婦女的風險是 $2/325=0.0062$ (或0.62%)。

計算: 相對風險(RR) = $2.9/0.62=4.7$

結論: 第一型囊腫婦女得到乳癌的風險是第二型囊腫婦女的4.7倍。

Study or subgroup	Vitamin C	Placebo	Risk Ratio	Weight	Risk Ratio 95% CI
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全部(n=11350)
相對風險(RR):0.96

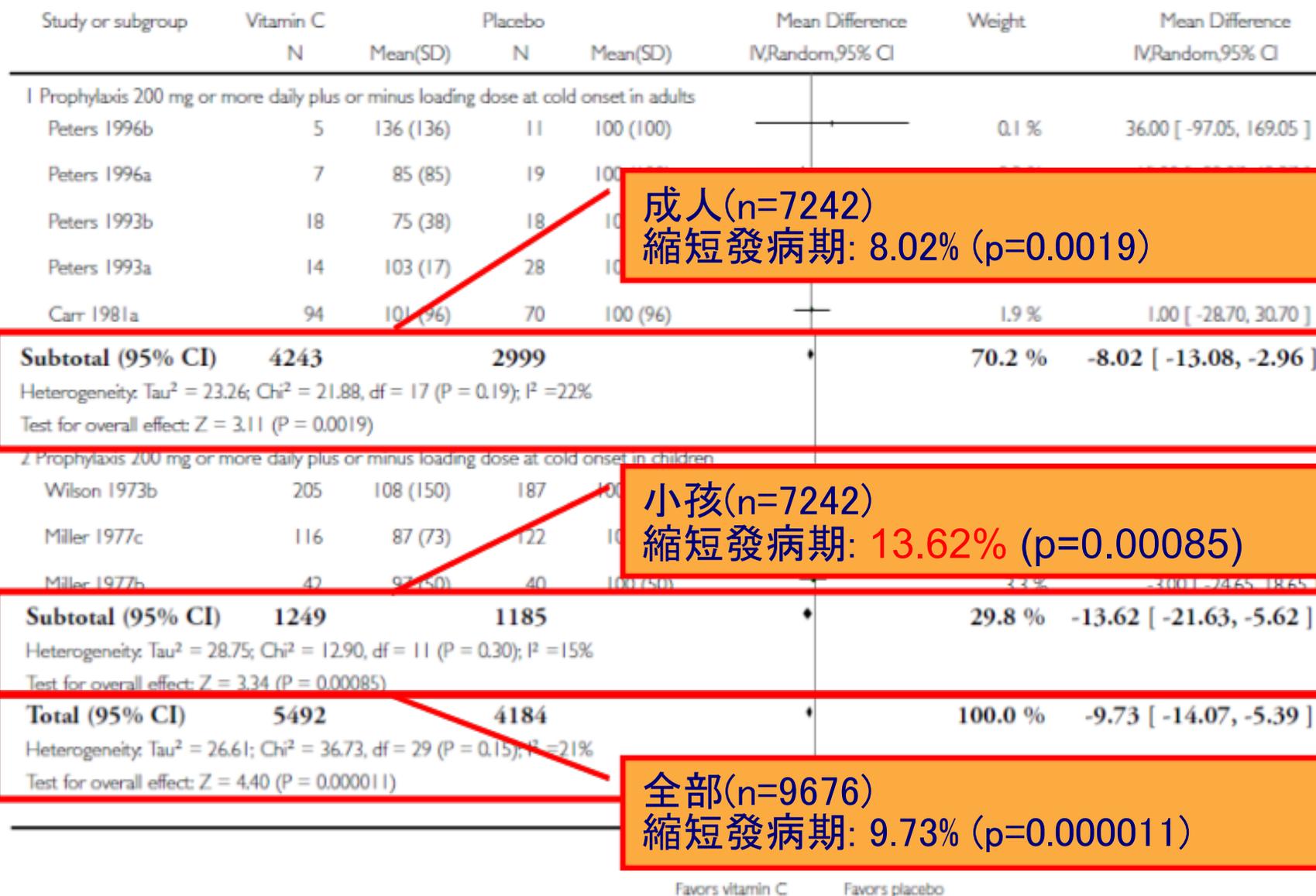
Analysis 2.1. Comparison 2 Duration of colds developing on vitamin C prophylaxis, Outcome 1 Duration of common cold symptoms (placebo group duration set as 100%).

Review: Vitamin C for preventing and treating the common cold

Comparison: 2 Duration of colds developing on vitamin C prophylaxis

Outcome: 1 Duration of common cold symptoms (placebo group duration set as 100%)

1.2 Prophylaxis: duration of colds



成人(n=7242)
縮短發病期: 8.02% (p=0.0019)

小孩(n=7242)
縮短發病期: 13.62% (p=0.00085)

全部(n=9676)
縮短發病期: 9.73% (p=0.000011)

Analysis 3.1. Comparison 3 Severity of colds developing on vitamin C prophylaxis, Outcome 1 Indicators of severity of episodes experienced while on prophylaxis.

Review: Vitamin C for preventing and treating the common cold

Comparison: 3 Severity of colds developing on vitamin C prophylaxis

Outcome: 1 Indicators of severity of episodes experienced while on prophylaxis

1.3 Prophylaxis: severity of colds

Study or subgroup	Vitamin C		Placebo		Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
	N	Mean(SD)	N	Mean(SD)			
1 Mean days indoors or off work or school per episode							
Wilson 1973b	205	4.2 (4.44)	187	3.84 (4.51)		9.1 %	0.08 [-0.12, 0.28]
Wilson 1973a	160	4.52 (6.32)	126	5.94 (6.28)		7.7 %	-0.22 [-0.46, 0.01]
Ludvigsson 1977b	423	1.47 (1.27)					
Anderson 1972	561	1.04 (1.75)					
Sabiston 1974	6	0.5 (0.8)					
Ludvigsson 1977a	62	0.95 (1.12)	55	1.9 (2.42)		4.2 %	-0.51 [-0.88, -0.14]
Anderson 1974a	1823	1.14 (1.71)	437	1.15 (1.52)		13.7 %	-0.01 [-0.11, 0.10]
Subtotal (95% CI)	3240		1826			60.6 %	-0.14 [-0.27, -0.02]
Heterogeneity: Tau ² = 0.01; Chi ² = 17.73, df = 6 (P = 0.01); I ² = 66%							
Test for overall effect: Z = 2.32 (P = 0.020)							
2 Mean symptom severity score per episode							
Miller 1977b	42	48.6 (22.6)	40	46.2 (22.6)		23 %	0.11 [-0.23, 0.54]
Miller 1977c	116	14.6 (20)	12				
Himmelstein 1998b	14	16.1 (14.59)					
Pitt 1979	600	1.87 (0.76)	619	1.97 (0.76)		13.3 %	-0.13 [-0.24, -0.02]
Subtotal (95% CI)	991		988			39.4 %	-0.11 [-0.25, 0.04]
Heterogeneity: Tau ² = 0.02; Chi ² = 11.40, df = 7 (P = 0.12); I ² = 39%							
Test for overall effect: Z = 1.41 (P = 0.16)							
Total (95% CI)	4231		2814			100.0 %	-0.13 [-0.21, -0.04]
Heterogeneity: Tau ² = 0.01; Chi ² = 29.18, df = 14 (P = 0.01); I ² = 52%							
Test for overall effect: Z = 2.86 (P = 0.0042)							

感冒期間在家中及不上班或不上課的平均天數(n=5066)
降低平均天數: 0.14% (p=0.02)

感冒期間症狀的嚴重程度程度(n=1979)
嚴重程度: 0.11% (p=0.16)

全部(n=7045)
降低嚴重程度: 0.13% (p=0.0042)

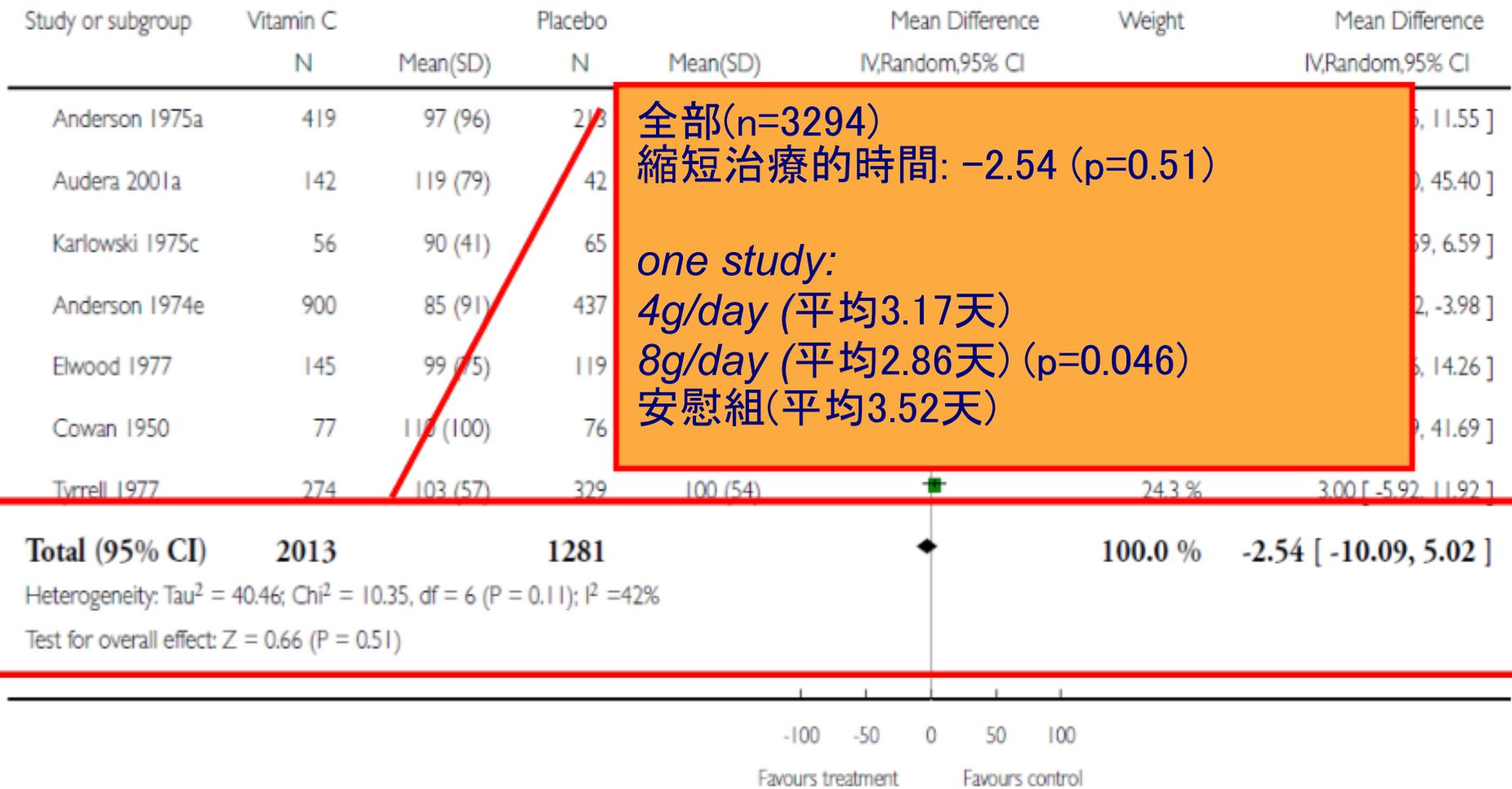
Analysis 4.1. Comparison 4 Duration of colds treated with vitamin C, Outcome 1 Mean symptom days per episode standardised against control group.

Review: Vitamin C for preventing and treating the common cold

Comparison: 4 Duration of colds treated with vitamin C

Outcome: 1 Mean symptom days per episode standardised against control group

2.1 Therapeutic: duration of colds



全部(n=3294)
 縮短治療的時間: -2.54 (p=0.51)
 one study:
 4g/day (平均3.17天)
 8g/day (平均2.86天) (p=0.046)
 安慰組(平均3.52天)

Analysis 5.1. Comparison 5 Severity of colds treated with vitamin C, Outcome 1 Indicators of severity of episodes for which vit C was used as therapy.

Review: Vitamin C for preventing and treating the common cold

Comparison: 5 Severity of colds treated with vitamin C

Outcome: 1 Indicators of severity of episodes for which vit C was used as therapy

2.2 Therapeutic: severity of colds

Study or subgroup	Vitamin C N	Placebo N	Mean(SD)	Weight	Difference 95% CI
1 Mean days indoors or off work or school					
Anderson 1975a	416	274	0.86 (1.1)	26.0 %	-0.03 [-0.17, 0.11]
Tyrrell 1977	274	329	0.53 (0.83)	42.6 %	-0.01 [-0.17, 0.15]
Anderson 1974e	900	437	1.07 (1.54)	93.3 %	-0.07 [-0.18, 0.05]
Subtotal (95% CI)	1590	979		93.3 %	-0.08 [-0.18, 0.01]
Heterogeneity: Tau ² = 0.00; Chi ² = 2.64, df = 2 (P = 0.27); I ² = 24%					
Test for overall effect: Z = 1.73 (P = 0.084)					
2 Mean symptom severity score per episode					
Audera 2001a	142	42	32.78 (37.43)	6.7 %	0.10 [-0.24, 0.45]
Subtotal (95% CI)	142	42		6.7 %	0.10 [-0.24, 0.45]
Heterogeneity: not applicable					
Test for overall effect: Z = 0.59 (P = 0.55)					
Total (95% CI)	1732	1021		100.0 %	-0.07 [-0.16, 0.02]
Heterogeneity: Tau ² = 0.00; Chi ² = 3.71, df = 3 (P = 0.29); I ² = 19%					
Test for overall effect: Z = 1.52 (P = 0.13)					

感冒期間在家中及不上班或不上課的平均天數(n=2569)
降低平均天數: 0.08% (p=0.084)

感冒期間症狀的嚴重程度(n=184)
降低嚴重程度: 0.10% (p=0.55)

全部(n=2753)
降低嚴重程度: 0.07% (p=0.13)

Summary of main results

- Effect on common cold incidence : prophylaxis trials
 - The pooled RR was 0.96 (95%CI: 0.92 to 1.00)
 - A subgroup of six trials involving a total of 642 **marathon runners, skiers, and soldiers on sub-arctic exercises** reported a pooled RR of 0.50 (95% CI: 0.38 to 0.66)
- Effect in common cold duration : prophylaxis trials
 - A consistent benefit was observed, representing a reduction in cold duration of **8%** (95% CI: 3% to 13%) for **adults** and **13.6%** (95%CI: 5% to 22%) for **children**
- Effect in common cold duration and severity: therapeutic trials
 - No significant differences from placebo were seen.
- Safe of vitamin C
 - No serious symptoms

Authors' conclusions

- The **failure** of **vitamin C** supplementation to reduce the incidence of colds in the **normal population** indicates that routine mega-dose prophylaxis is not rationally justified for community use.
- But evidence suggests that it could be justified in people exposed to brief periods of severe **physical exercise** or **cold environments**.

Step 4

結論是否能應用於我的病人

Applying
臨床應用

- **Q:** 固定攝取vitamin C可以預防感冒嗎？
- **A:** 沒有足夠的證據顯示一般民眾長期補充vitamin C對於感冒有預防的效果，但是，經常暴露在寒冷氣候與激烈體能運動者，攝取vitamin C確實可使感冒機率降低一半。
- **Q:** 感冒期間服用大量的vitamin C可以縮短感冒時間及症狀嗎？
- **A:** 感冒期間補充大量的vitamin C無法縮短感冒時間及症狀

Step 5

評估成果

Auditing
評估成果

步驟1: 在提出臨床問題

- 1 我有提出任何臨床問題?
- 2 我提出的問題結構是否完整?
- 3 是否知道自己設定的問題類型?

步驟2: 在搜尋最佳證據方面

- 1 我知道在我的臨床領域中現有的最佳證據來源嗎?
- 2 我是否擁有搜尋所需的軟體及獲得最佳證據的管道?
- 3 我在搜尋方面變得更有效率嗎?

步驟3: 在文獻評讀方面

- 1 對我而言,應用研究證據之評讀指引變的更簡單嗎?
- 2 我可以更正確更有效率的使用一些審慎評度量工具?

步驟4: 在整合證據與病患的價值觀方面

- 1 我盡力將審慎評估之結果融入治療中嗎?

結論

- 實證醫學是良知、明確的和明智地利用當前的最佳證據作出照顧個別的決擇。

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