



***USARE LE REVISIONI SISTEMATICHE  
PER MIGLIORARE LA PRATICA  
ASSISTENZIALE***

Alberto Dal Molin

# Revisioni sistematiche

Una revisione sistematica è “una revisione di un quesito chiaramente formulato la quale usa metodi sistematici e espliciti per identificare, selezionare e valutare criticamente la ricerca in questione e per raccogliere e analizzare i dati degli studi che sono stati inclusi nella revisione. Possono essere usati o meno metodi statistici per analizzare e sintetizzare i risultati degli studi inclusi”

*[Cochrane Library 1998, Glossary]*

# La Revisione Sistemica

- *A systematic review* is a rigorous summary of all the research evidence that relates to a specific question, be it a question about harm, diagnosis, prognosis, or the effectiveness of health care interventions.

[DiCenso – Guyatt – Ciliaska, Evidence Based Nursing: A guide to Clinical Practice. Elsevier Mosby, 2005: pp 138]

# Gerarchia delle prove di efficacia



Revisione sistematica

VS

Revisione non sistematica

# **COME CONDURRE UNA REVISIONE**

# Processo per condurre una revisione sistemática (1)

## Formulazione del quesito

- Specificare:
  - Popolazione
  - Intervento o esposizione
  - Outcome
  - Metodologia
- Specificare criteri di inclusione/esclusione
- Descrivere eventuali restrizioni: lingua, unpublished data,...

# Processo per condurre una revisione sistemática (2)

## Condurre la ricerca bibliografica

- Decidere le fonti di informazione: database bibliografici, esperti, registri, ...
- Identificare titoli ed abstract

# Processo per condurre una revisione sistemática (3)

## Applicare i criteri di inclusione e di esclusione

- Applicare i criteri di inclusione e di esclusione ai titoli ed abstract identificati
- Ottenere i full text dei report ritenuti eleggibili dalla lettura del titolo e dell'abstract
- Applicare i criteri di inclusione e di esclusione ai full text
- Selezionare gli studi eleggibili finali

# Processo per condurre una revisione sistemática (4)

## Valutazione

- Valutare la qualità metodologica degli studi (validity assessment)
- Estrarre i dati da ogni studio rispetto i partecipanti, esposizione o intervento, disegno dello studio
- Estrarre i risultati

# Processo per condurre una revisione sistemática (5)

## Condurre l'analisi

- Esplorare l'eterogeneità
- Determinare metodi per riassumere i risultati
- Combinare i risultati (se appropriato)

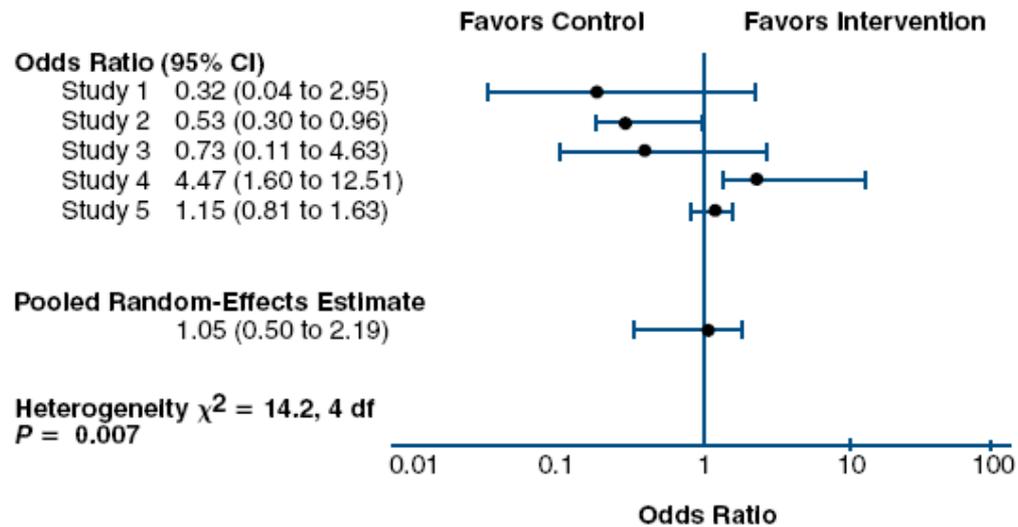


Figure 24-1. Results of meta-analysis A

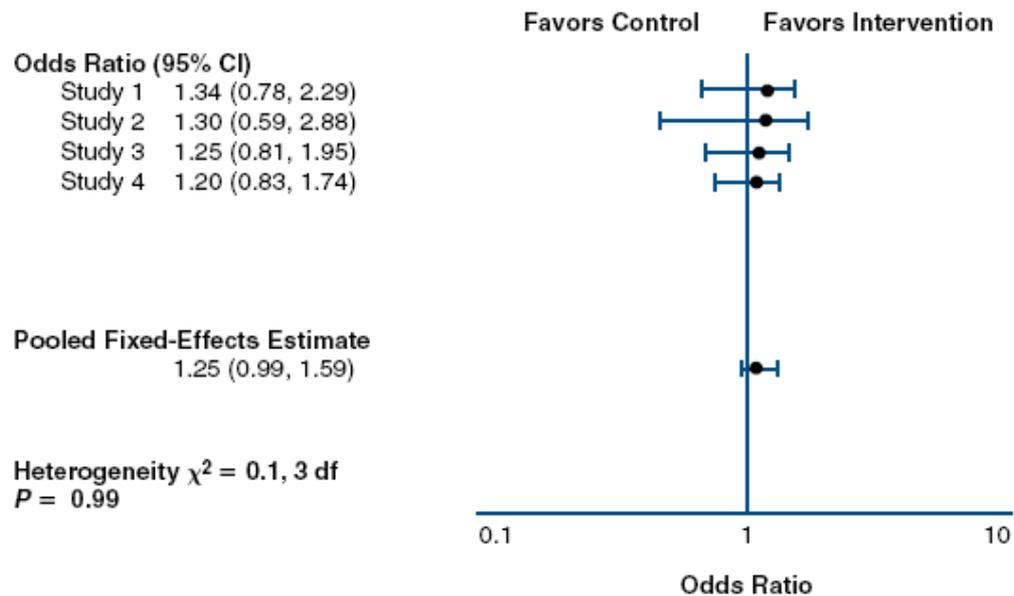


Figure 24-2. Results of meta-analysis B

**VALUTARE UNA REVISIONE**

# Come valutare una revisione? (1)

## I risultati sono validi?

- La revisione esplicita un quesito clinico sensibile?
- La ricerca bibliografica è avvenuta in dettaglio e in modo esaustivo?
  - Quali database?
  - Abstract di recenti congressi/meeting
  - esperti (identificare studi non inclusi per errore e per evitare publication bias)
  - [publication bias]

# Come valutare una revisione? (2)

## I risultati sono validi?

- Gli studi inclusi sono stati condotti con una metodologia adeguata e di qualità?
  - Studi di bassa qualità tendono a sovrastimare l'efficacia terapeutica/preventiva di un intervento [Guyatt GH, 2000]

## Randomized trials versus observational studies in adolescent pregnancy prevention

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### Abstract

The objective of this study is to compare the results of randomized trials and observational studies of interventions to prevent adolescent pregnancy. We identified published and unpublished reports through computerized searches of CATLINE, CINAHL, CONFERENCE PAPERS INDEX, DISSERTATION ABSTRACTS ONLINE, EMBASE, ERIC, MEDLINE, NTIS, POPLINE, PsycINFO, and SOCIOLOGICAL ABSTRACTS; manual searches of eight relevant journals; reference lists from primary articles; and contact with content experts. We included randomized trials and observational studies that evaluated the impact of primary prevention interventions including sex education classes, school-based clinics, free-standing clinics, physician/nurse practitioner practice-based service, improved access, and community-based programs on four outcomes: sexual intercourse, birth control use, responsible sexual behavior, or pregnancy in adolescents. One investigator abstracted the data and a second conducted a detailed review of the abstraction. We identified 13 randomized trials and 17 observational studies. We generated estimates of the impact of the interventions separately for males and females for all four outcomes for both observational studies and randomized trials. For six of the eight outcomes the summary odds ratios for the observational studies showed a significant intervention benefit ( $P < 0.05$ ) while the randomized trials did not show a benefit for any outcome in either females or males. The difference between the results of the observational studies and randomized trials was statistically significant in two of the eight outcomes ( $P < 0.05$  for initiation of intercourse and pregnancy in females). Observational studies yield systematically greater estimates of treatment effects than randomized trials of adolescent pregnancy prevention interventions. Public policy or individual patient treatment decisions should be based on observational studies only when randomized trials are unavailable and only with careful consideration of possible biases. © 2000 Elsevier Science Inc. All rights reserved.

**Keywords:** Randomized trials; Observational studies; Adolescent pregnancy; Prevention strategies

# Come valutare una revisione? (3)

## **I risultati sono validi?**

- La valutazione degli studi è riproducibile

# Come valutare una revisione? (3)

## Quali sono i risultati

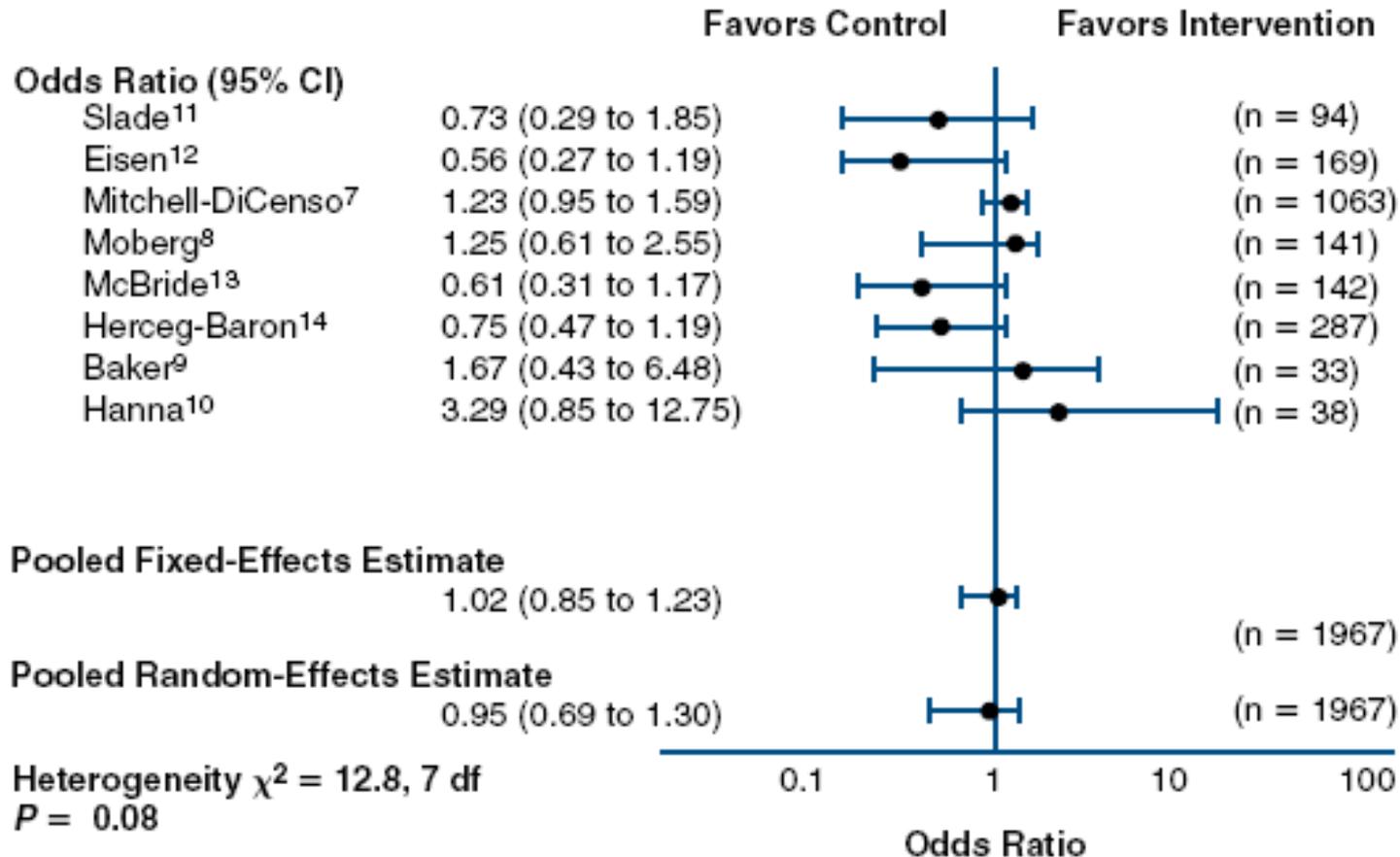
- I risultati degli studi sono simili tra loro?
  - Valutazione degli intervalli di confidenza dei vari studi coincidono
  - Test of heterogeneity (solitamente chi-square test)
    - Attenzione se il numero di studi e i campioni sono piccoli

# Come valutare una revisione? (4)

## Quali sono i risultati

- Qual è il risultato della revisione?
  - La semplice comparazione tra studi positivi e studi negativi non è sufficiente
  - Attraverso la meta – analisi si pesano i vari studi tenendo in considerazione il loro campione, in modo tale che studi con una numerosità campionaria grande abbiano un peso maggiore
  - Sensibility analysis
  - Fixed – effects model vs Random – effects model
- Come sono precisi i risultati?

# Fixed – effects model vs Random – effects model



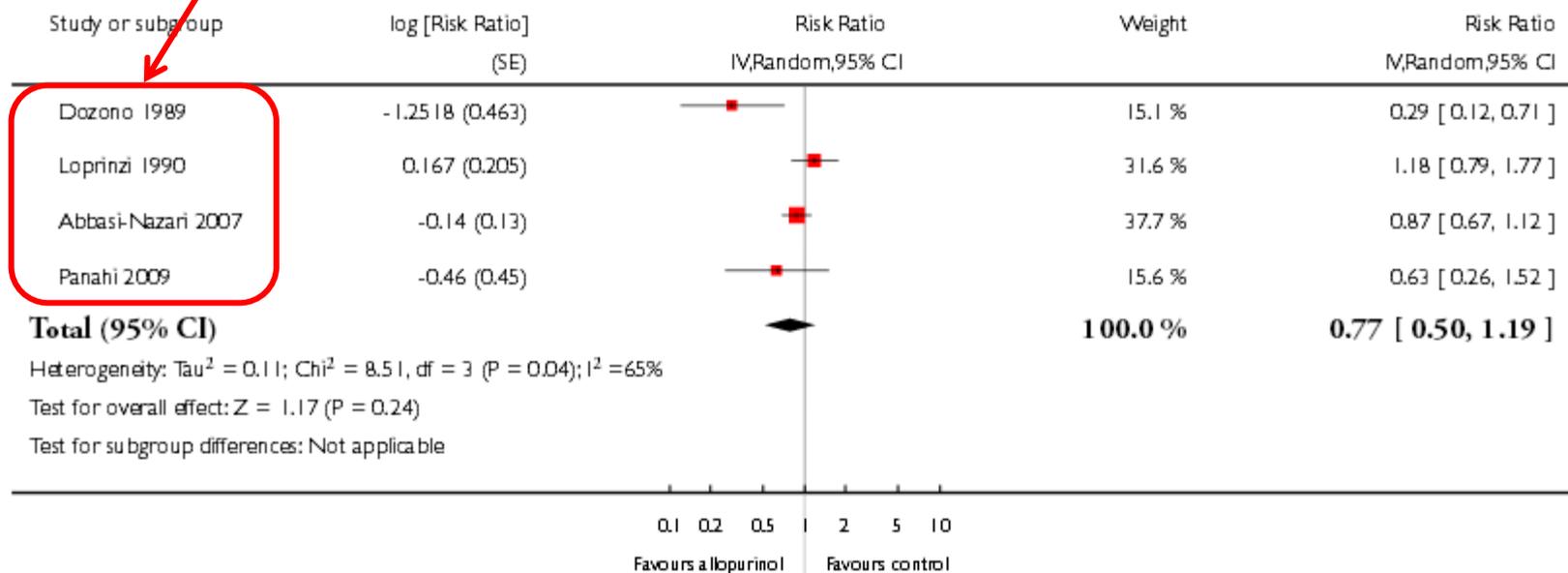
## Primo autore e anno di pubblicazione degli studi inclusi nell'analisi

### Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



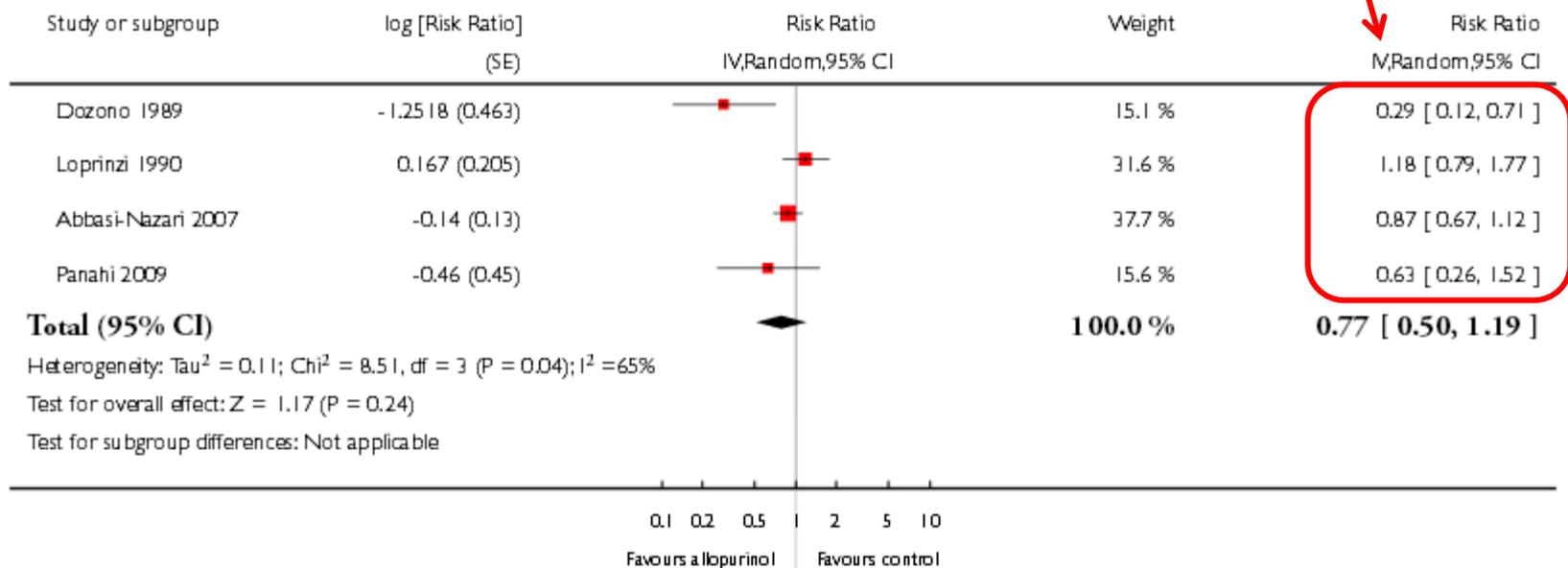
## Tasso di rischio con relativo intervallo di confidenza di ogni studio

### Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



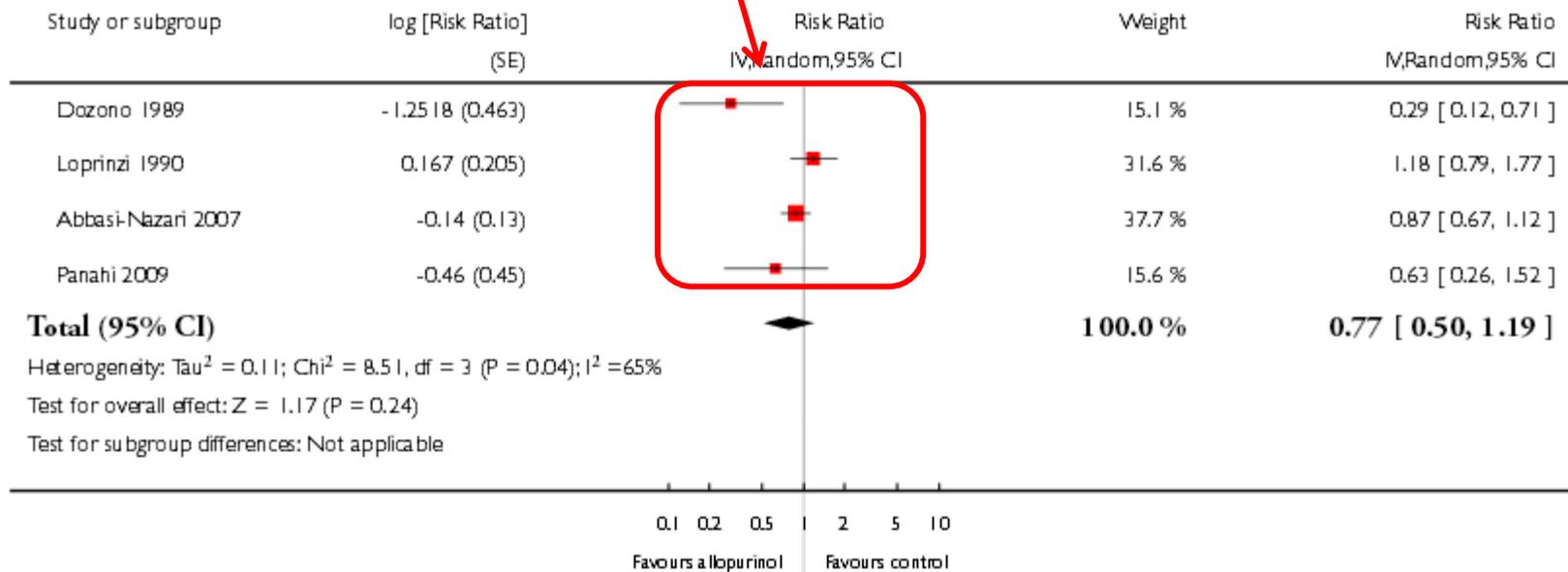
## Risultato di ogni singolo studio: RR e IC

### Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



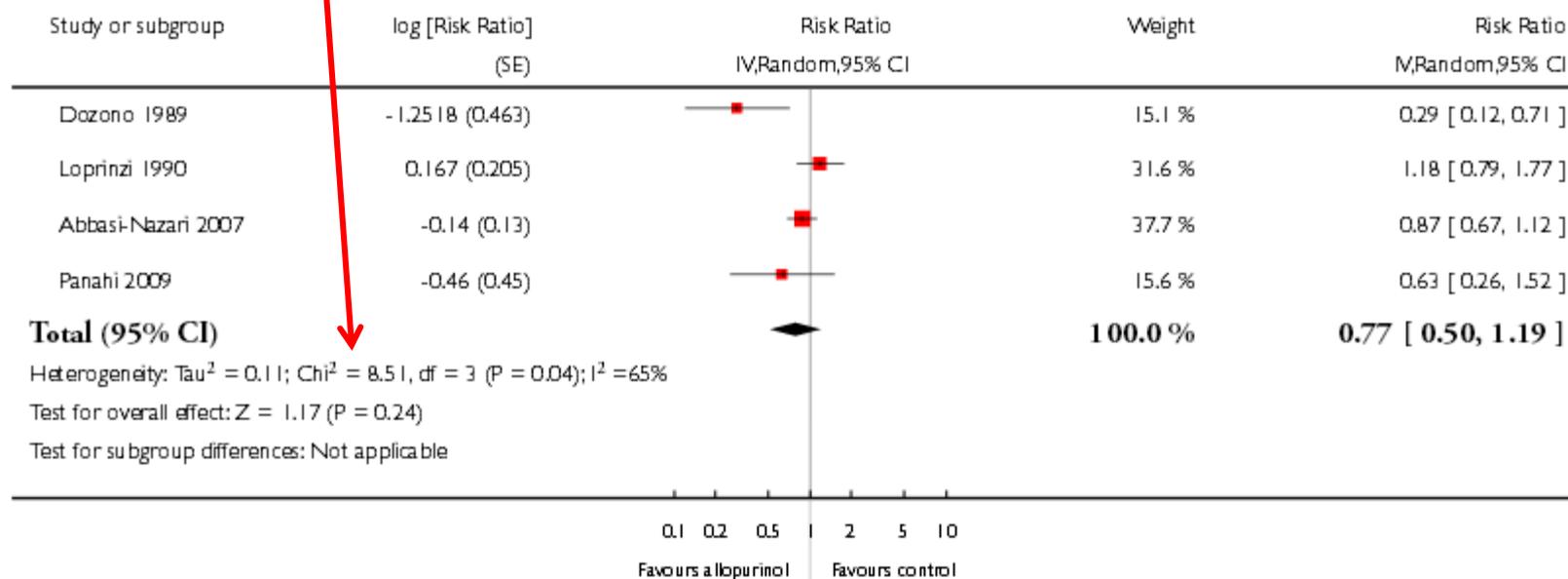
# Test of homogeneity

## Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



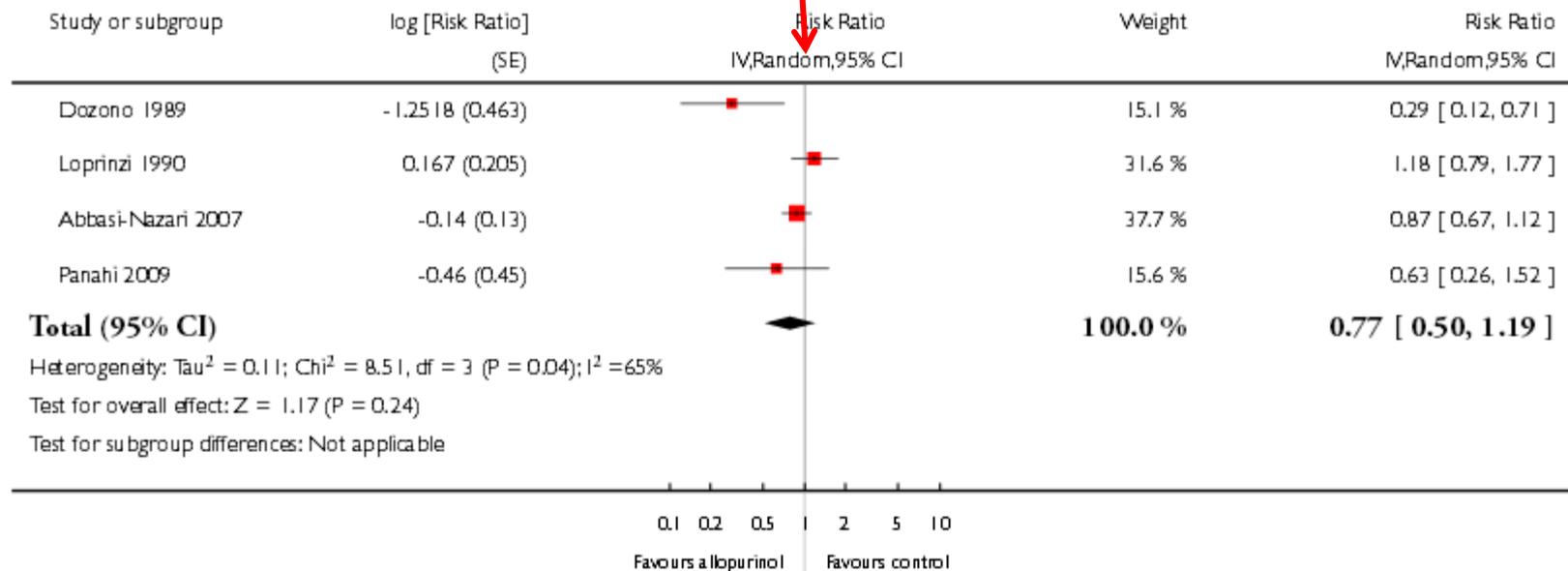
## Modello utilizzato per combinare i risultati

### Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



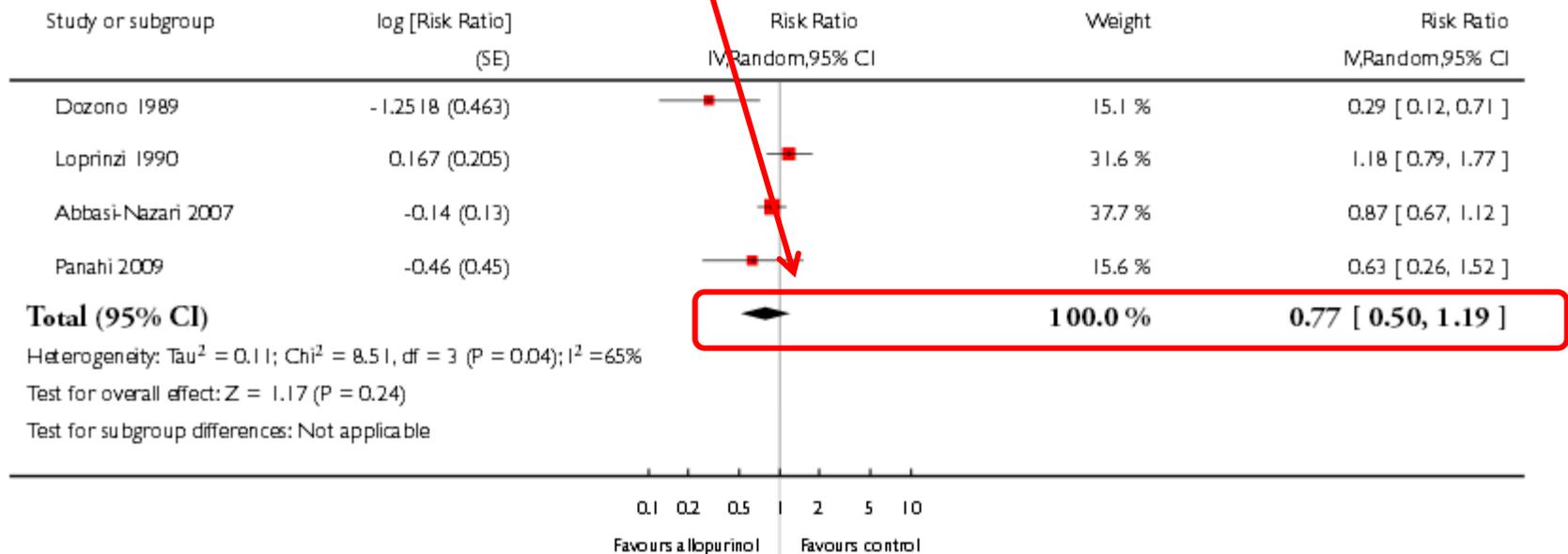
# Risultato conclusivo della revisione

## Analysis 1.1. Comparison 1 Allopurinol versus placebo/no treatment, Outcome 1 Mucositis (any).

Review: Interventions for preventing oral mucositis for patients with cancer receiving treatment

Comparison: 1 Allopurinol versus placebo/no treatment

Outcome: 1 Mucositis (any)



# Come valutare una revisione? (5)

## Come si possono applicare i risultati nella cura dei pazienti

- Come si possono interpretare al meglio i risultati per applicarli nella pratica?
- Tutti i “Patient-Important Outcomes” sono stati considerati?
  - Sono valutati tutti gli effetti positivi e negati del trattamento (esempio: terapia ormonale: riportato l’aumento del rischio di cancro della mammella)
  - Costi
- I benefici sono bilanciati con i rischi potenziali

# **PERCHE' UTILIZZARE LE REVISIONI SISTEMATICHE NELLA PRATICA CLINICA ASSISTENZIALE**

# Cos'è l'Evidence Based Practice?



# Cosa è l'evidenza?

- Impiego attento, esplicito e ragionevole delle migliori prove di efficacia disponibili per prendere decisioni sull'assistenza di singoli pazienti (Sackett et al., 1996)
- L'EBM è l'integrazione delle migliori prove di efficacia fondate sulla ricerca con le abilità cliniche e i valori dei pazienti (Sackett et al., 2000)

# Evidence – Based Nursing

Il termine EBN compare per la prima volta nel 1996 sulla banca dati di Medline

# Evidence-Based Nursing

*“L'EBN è un processo per mezzo del quale le infermiere e gli infermieri assumono le decisioni cliniche utilizzando le migliori ricerche disponibili, la loro esperienza clinica e le preferenze del paziente ...”*

(DiCenso A, Cullum N, Ciliska D. Implementing evidence based nursing: some misconceptions [Editorial]. Evidence Based Nursing 1998; 1:38-40)

# Un processo a 5 fasi

1. I **bisogni di informazioni** originano dalla **pratica** e sono **convertiti in domande**
2. Le **domande** sono utilizzate come **base** per ricercare nella letteratura al fine di identificare le prove di efficacia rilevanti
3. Le **prove di efficacia** vengono valutate criticamente per provarne la **validità** e **generalizzabilità**
4. Le **migliori prove** vengono utilizzate insieme **all'abilità clinica** e alle **preferenze del paziente**
5. Il **risultato** è valutato attraverso un processo di **auto riflessione, audit o valutazione fra pari**.

(Flemming, 1998)

Porre domande cliniche  
cui si può rispondere

Trovare le prove migliori

Valutare le prove

Prendere una decisione

Valutare la vostra prestazione

# Formulazione Domanda di Ricerca

- Origine del “problema”
  - Riflessioni, pratica clinica, discussioni, audit,...
- Formulazione della domanda di ricerca
  - È il **collegamento** più importante tra **ricerca** e **pratica**
  - Spesso le domande sono imprecise, ampie,...

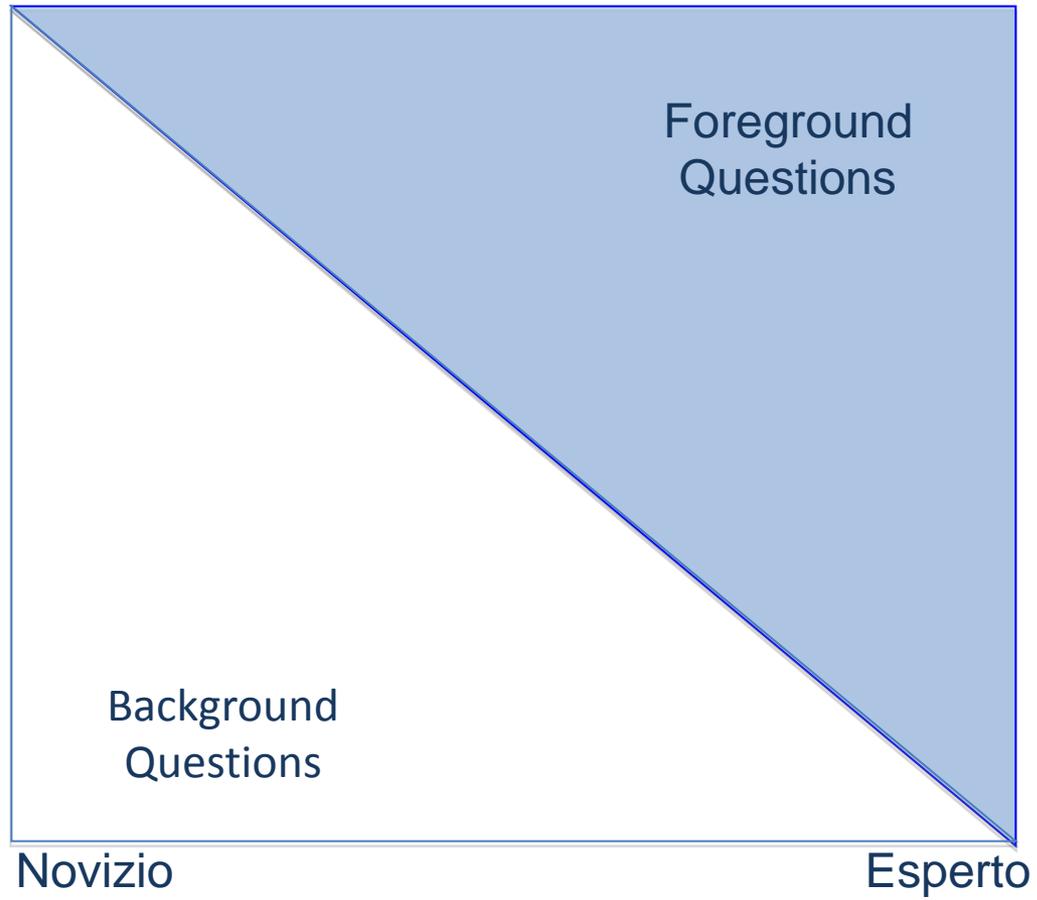
Il **dubbio scientifico** è  
l'elemento fondamentale dei sanitari

In realtà non è proprio così!

Sicurezza di massa



Incapacità a farsi domande.



# Quale differenza tra queste domande?

- Come si deve realizzare l'assistenza al paziente con ictus?
- In un paziente con ictus il posizionamento dei liquidi sull'arto plegico *versus* il posizionamento sull'arto non plegico può determinare modifiche sugli esiti funzionali?

# Quale differenza tra queste domande?

- Quali terapie riducono il dolore post operatorio?
- In pazienti adulti sottoposti ad intervento chirurgico, l'immaginazione guidata rispetto alla musica terapia influisce sull'uso degli analgesici nelle prime 24 ore successive al post-operatorio?

# Domanda sulla terapia

INTERVENTO



OUTCOME



l'acupressione è efficace nel trattare la nausea?

PAZIENTE/PROBLEMA



INTERVENTO



Nei pazienti oncologici con nausea è l'acupressione efficace nel ridurre la nausea rispetto al trattamento X?



OUTCOME



CONFRONTO

**+RCT**

# Domanda sull'eziologia

ESPOSIZIONE



OUTCOME



L'educazione terapeutica genera ansia

PAZIENTE/PROBLEMA



ESPOSIZIONE



I pazienti che ricevono un intervento educativo sono esposti a > rischio di ansia rispetto a non riceverlo?



OUTCOME



CONFRONTO

**+studio di coorte/caso-controllo**

# Domanda sulla diagnosi

(TEST)  
INTERVENTO



La digitopressione è un buon test per le lesioni stadio I

OUTCOME



(TEST)  
INTERVENTO



la digitopressione rispetto alla distensione della cute è più accurata per la diagnosi di lesione allo stadio 1?

CONFRONTO



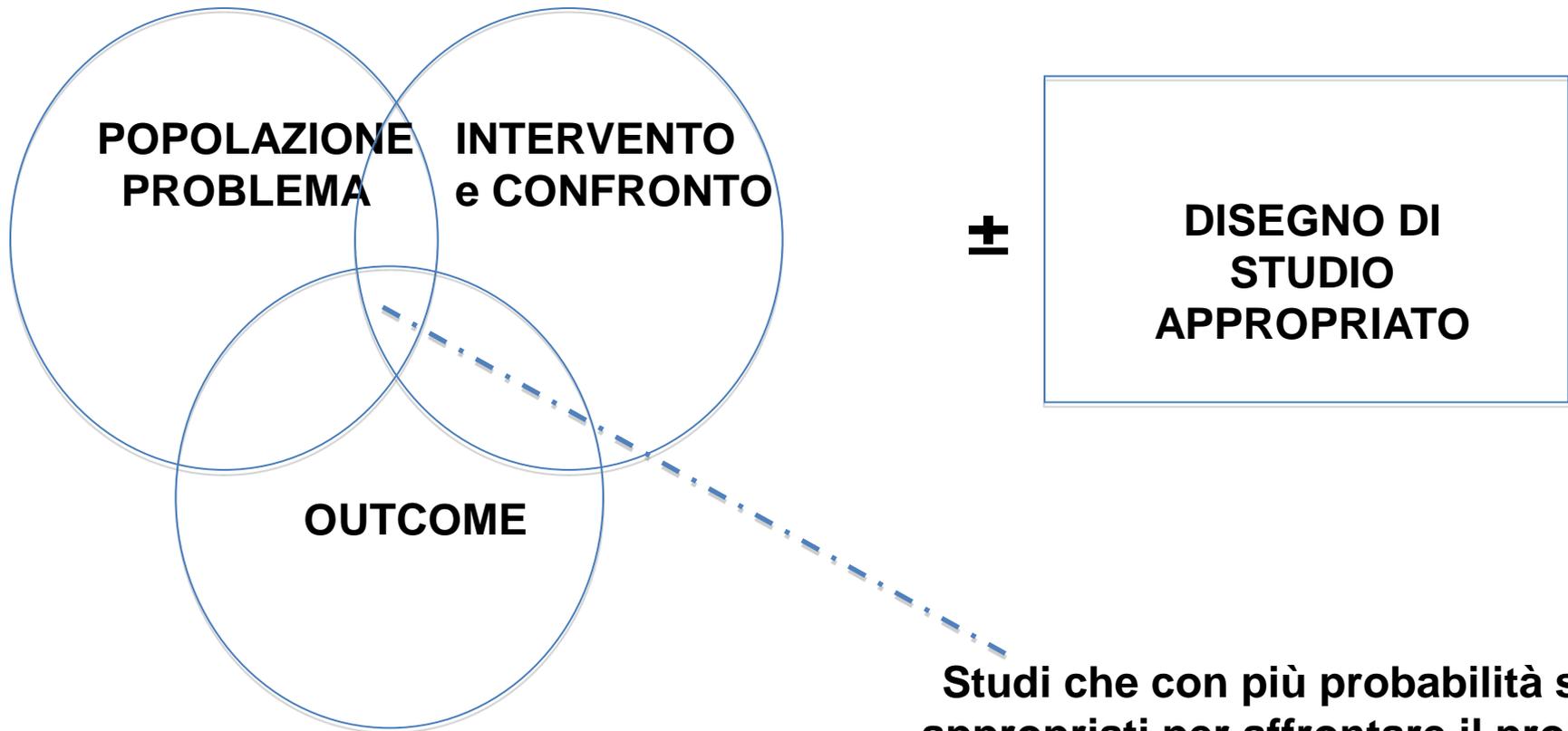
PROBLEMA



OUTCOME

**+studio trasversale/cross sectional**

# PICO + Disegno di Studio



<b>POPULATION</b>	<b>INTERVENTION</b>	<b>COMPARISON</b>	<b>OUTCOME</b>
Include: 1. Malattia/Condizione (es. cancro/ictus) 2. Popolazione (es. età) 3. Setting (es. territorio)	1. Attività 2. Procedura 3. Trattamento (es. uso tool valutazione; scelta medicazione; scelta di un metodo;...)	Alternativa (es. il trattamento standard)	Risultato di una specifica azione

**TROVARE LE MIGLIORI EVIDENZE**

## Dove ricercare le evidenze scientifiche:

- Libro di testo
- Internet
- Riviste (riviste con referee)
- Database bibliografici
- Pubblicazioni secondarie
- Revisioni sistematiche (Cochrane collaboration)
- Le linee guida

# FONTI DELLA LETTERATURA

## **Risorse primarie**

Scritta dall'autore che ha condotto la ricerca, sono quelle che dovrebbero essere tenute principalmente in considerazione

## **Risorse secondarie**

Descrizione di uno studio effettuato da altri autori, spesso presentate come risposta, sintesi o critica dei lavori originali

# Pubblicazioni secondarie

Riviste Evidence Based:

Si tratta di riviste che pubblicano riassunti strutturati che sintetizzano la ricerca recente di migliore qualità e clinicamente più utile pubblicata in letteratura.

# Le Linee Guida

Sono documenti sviluppati con una metodologia sistematica allo scopo di assistere il personale sanitario nella decisione relativa ad una specifica circostanza

# Revisioni sistematiche

Una revisione sistematica è “una revisione di un quesito chiaramente formulato la quale usa metodi sistematici e espliciti per identificare, selezionare e valutare criticamente la ricerca in questione e per raccogliere e analizzare i dati degli studi che sono stati inclusi nella revisione. Possono essere usati o meno metodi statistici per analizzare e sintetizzare i risultati degli studi inclusi” [Cochrane Library 1998, Glossary]

# LE BANCHE DATI

- MEDLINE
- CINAHL

# Le banche dati biomediche

PubMed

<http://www.ncbi.nlm.nih.gov/pubmed/>

- Interfaccia di Medline
- Sviluppata dal National Center for Biotechnology Information (NCBI)
- National Library of Medicine (NLM)
- Oltre 21 milioni di citazioni bibliografiche (dal 1946 al 5 Maggio 2012)
- PubMed è parte dell'Entrez Retrieval System

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Publication dates 5 years 10 years Custom range...

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Article types Clinical Trial Meta-Analysis Practice Guideline Randomized Controlled Trial Review Systematic Reviews more ...

Languages English more ...

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Results: 1 to 20 of 495883

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Should neck pain in a patient with Hashimoto's thyroiditis be underestimated? A case and review of the literature.

Mousa U, Cunejd A, Alptekin G. Indian J Endocrinol Metab. 2012 May;16(3):444-6. PMID: 22629517 [PubMed - in process] Related citations

Pulmonary function tests in patients with primary hyperparathyroidism.

Bhadada SK, Agrawal A, Shah V. Indian J Endocrinol Metab. 2012 May; PMID: 22629510 [PubMed - in process] Related citations

Delay in diagnosis of primary int

Segal D, Lidar Z, Corn A, Const Surg Neurol Int. 2012;3:52. Epub 201 PMID: 22629489 [PubMed - in process] Related citations

Trigeminal neuralgia: Assessment steady-state acquisition and 3D resonance imaging.

Prieto R, Pascual JM, Yus M, Jor Surg Neurol Int. 2012;3:50. Epub 201 PMID: 22629487 [PubMed - in process] Related citations

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Article types Clinical Trial Meta-Analysis Practice Guideline Randomized Controlled Trial Review Systematic Reviews more ...

Languages English more ...

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Effectiveness of the gaze direction recognition task for chronic neck pain and cervical range of motion: a randomized controlled pilot study.

Nobusako S, Matsuo A, Morioka S. Rehabil Res Pract. 2012;2012:570387. Epub 2012 May 7. PMID: 22645685 [PubMed - in process]

A Quantitative Examination of Extreme Facial Pain Expression in Neonates: The Primal Face of Pain across Time.

Schiavenato M, von Baeyer CL. Pain Res Treat. 2012;2012:251625. Epub 2012 May 7. PMID: 22645679 [PubMed - in process]

Single-port laparoscopic cholecystectomy: scarless cholecystectomy.

Zubaidi AM. Minim Invasive Surg. 2012;2012:204380. Epub 2012 May 7. PMID: 22645675 [PubMed - in process]

The association of obesity with walking independent of knee pain: the multicenter osteoarthritis study.

White DK, Neogi T, Zhang Y, Felson D, Lavalley M, Niu J, Nevitt M, Lewis CE, Torner J, Douglas Gross K. J Obes. 2012;2012:261974. Epub 2012 May 7. PMID: 22645666 [PubMed - in process]

Greater omentum gastrointestinal stromal tumor with PDGFRA-mutation and hemoperitoneum.

Murayama Y, Yamamoto M, Iwasaki R, Miyazaki T, Saji Y, Doi Y, Fukuda H, Hirota S, Hiratsuka M. World J Gastrointest Oncol. 2012 May 15;4(5):119-24. PMID: 22645683 [PubMed - in process]

Ricerca fatta il 31 maggio 2012

Related searches low back pain neuropathic pain chronic pain pain management pain syndrome

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34899 free full-t PubMed Centr Should neck pain thyroiditis be ut [In Pulmonary functio hyperparathyroi [In Delay in diagnosis cord tumors.

# Cos'è Medline?

- Medline è tra le più diffuse banche dati
- PubMed è la sua interfaccia gratuita dal 1996
- Medline indicizza 5500 riviste (US + altri paesi)
- Settori: medicina, infermieristica, odontoiatria, organizzazione sanitaria, vet
- Il 90% sono fonti di lingua inglese
- L'83% delle citazioni presenta un abstract

# Cos'è Cinahl?

database generale per infermieri ed altre professioni sanitarie correlate. Nacque nel 1940 e la sua versione computerizzata iniziò nel 1983 e include citazioni di più di 250.000 articoli. Il contenuto è concentrato sull'assistenza infermieristica, fisioterapia, terapia occupazionale, assistenza d'emergenza e trattamenti alternativi.

(Indirizzo internet: *<http://www.cinahl.com/>*).

# **COME INTERROGARE LE BANCHE DATI**

# Key word

- Le key word (= parole chiave): termini con cui interrogare le banche dati.
  - Termine libero vs termine controllato
  - Gli operatori booleani

# Termine libero vs Termine controllato

- Termine libero (Free-Text): parola/e presente nei campi del record bibliografico. Termine inserito liberamente.
- Termine controllato: parola/e estratti da un dizionario controllato, assegnate da un esperto previa lettura dell'articolo per esteso. Termine presente nel *thesaurus*.

# Termine libero vs Termine controllato

## USANDO UN TERMINE LIBERO CONSIDERARE:

- Sinonimi
- Plurali
- Inglese/americano

Esempio:

- PAIN or PAIN(FUL) or BACK PAIN or BACKACHE
- CANCER or CANCERS or TUMOR or TUMOUR or NEOPLASM\*

# Termine libero vs Termine controllato

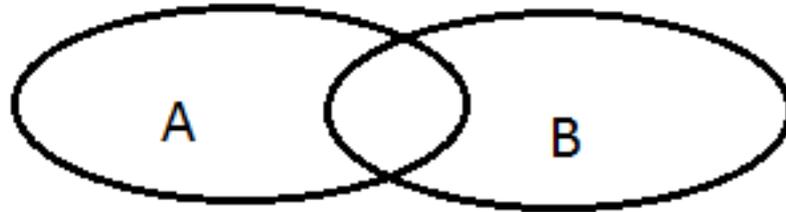
- Thesaurus: vocabolario controllato realizzato ad hoc per quel database, che abolisce i sinonimi.
- Thesaurus garantisce univocità nei termini di ricerca.
- Il Thesaurus ha una struttura ad albero permettendo maggiore specificità nella ricerca.

# Gli operatori booleani

- Gli operatori booleani permettono di combinare tra loro le parole chiave.
- Operatori booleani:
  - OR
  - AND
  - NOT

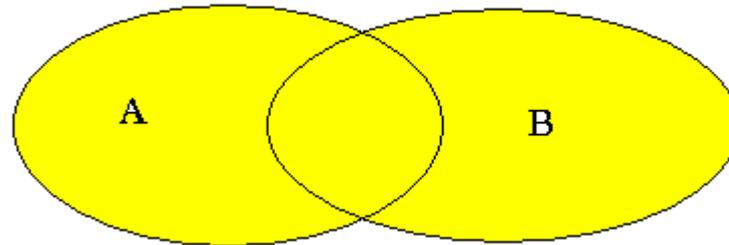
# L'operatore booleano OR

a **OR** b



# L'operatore booleano OR

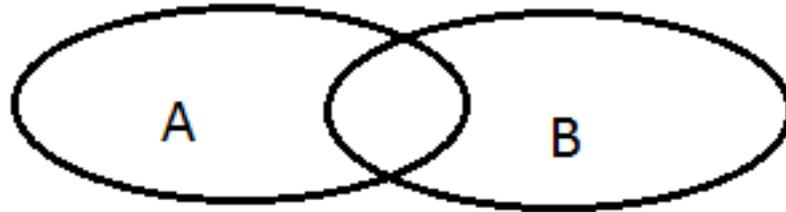
a **OR** b



Utilizzando l'operatore booleano OR si recuperano tutte le risorse bibliografiche che contengono almeno uno delle parole chiave indicate

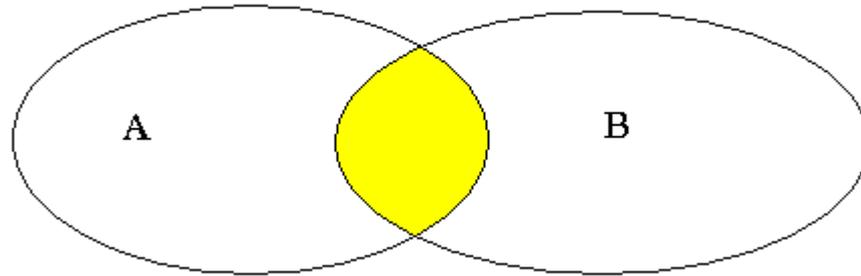
# L'operatore booleano AND

a **AND** b



# L'operatore booleano AND

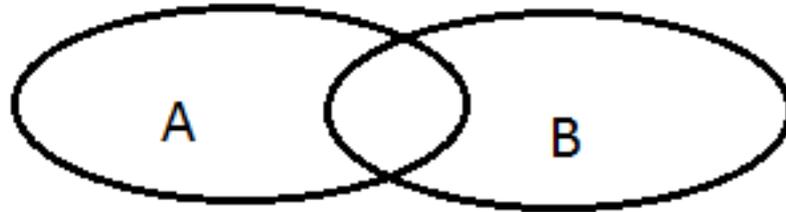
a **AND** b



Utilizzando l'operatore booleano AND si recuperano tutte le risorse bibliografiche che contengono tutte le parole chiave inserite. Con l'operatore AND si restringe la ricerca.

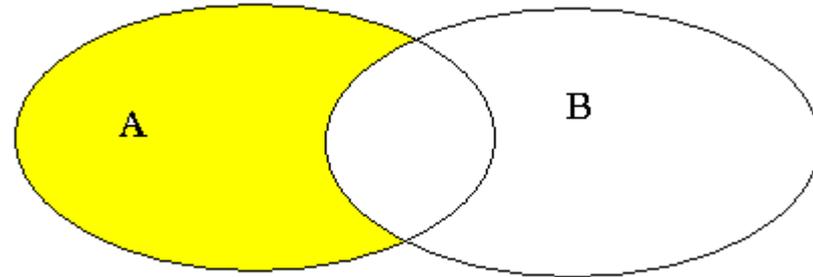
# L'operatore booleano NOT

a **NOT** b



# L'operatore booleano NOT

a **NOT** b



Utilizzando l'operatore booleano NOT si recuperano tutte le risorse bibliografiche che contengono una parola chiave e NON l'altra. Con l'operatore NOT si limita la ricerca.

# Gli operatori booleani

RIASSUMENDO ...

**OR:** deve essere presente almeno una della parole;

**AND:** devono essere presenti tutte le parole chiave introdotte;

**NOT:** deve essere presente solo la prima e non la seconda parole chiave

# La stringa di ricerca

- **Stringa di ricerca:** Termine o insieme di termini inseriti in un database per ricercare materiale bibliografico
- Esempio:
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  3. ["Copeptin Helps "Copeptin Helps in the Early Detection Of Patients with Acute Myocardial Infarction": the primary results of the CHOPIN Trial.](#) Maisel A, Mueller C, Neath SX, Christenson RH, Morgenthaler NG, Nowak RM, Vilke G, Daniels LB, Hollander JE, Apple FS, Cannon C, Nagurney JT, Schreiber D, Defilippi C, Hogan C, Diercks DB, Stein JC, Headden G, Limkakeng AT Jr, Anand I, Wu AH, Papassotiriou J, Hartmann O, Ebmeyer S, Clopton P, Jaffe AS, Frank Peacock W. J Am Coll Cardiol. 2013 Apr 30. doi:pii: S0735-1097(13)01729-4. 10.1016/j.jacc.2013.04.011. [Epub ahead of print] PMID: 23643595 [PubMed - as supplied by publisher] [Related citations](#)

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- [Acute Insulin Resistance Assessed by the Homeostatic Model Assessment in Acute Coronary Syndromes Without Previously Known Diabetes.](#)  
1. Lazzeri C, Valente S, Chiostrì M, Attanà P, Mattesini A, Gensini GF.  
Angiology. 2013 May 6. [Epub ahead of print]  
PMID: 23650645 [PubMed - as supplied by publisher]
- [Advances in antiplatelet technologies to improve cardiovascular disease morbidity and mortality: a review of ticagrelor.](#)  
2. Davis EM, Knezevich JT, Teply RM.  
Clin Pharmacol. 2013 Apr 19;5:67-83. doi: 10.2147/CPAA.S41859. Print 2013.  
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3. Golenia A, Chrzanowska-Wasko J, Jagiella J, Wrnk M, Ferens A, Klimkowicz-Mrowiec A, Adamski M, Ciecko-Michalska I, Slowik A.  
Neurol Neurochir Pol. 2013 Mar-Apr;47(2):152-6. Polish.  
PMID: 23650004 [PubMed - in process]
- [Mild Therapeutic Hypothermia After Out-Of-Hospital Cardiac Arrest Complicating ST-Elevation Myocardial Infarction: Long-term Results in Clinical Practice.](#)  
4. Zimmermann S, Flachskampf FA, Schneider R, Dechant K, Alff A, Klinghammer L, Rittger H,

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*[DiCenso – Guyatt – Ciliaska, Evidence Based Nursing: A guide to Clinical Practice. Elsevier Mosby, 2005: pp 33]*

Efficacia della crioterapia nella  
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[The effect of cryotherapy on oral mucosa: a study in healthy volunteers.](#)

1. Svanberg A, Ohrn K, Broström H, Birgegård G.  
Med Oncol. 2012 Apr 5. [Epub ahead of print]  
PMID: 22476810 [PubMed - as supplied by publisher]  
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2. Katrancı N, Ovayolu N, Ovayolu O, Sevinc A.  
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[\[Treatment and prevention of cancer treatment related oral mucositis\].](#)

3. Ruiz-Esquide G, Nervi B, Vargas A, Maíz A.  
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[Ice ball cryotherapy for chemotherapy-induced mucositis]. [Gan To Kagaku Ryoho. 1994]

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[Cancer](#). 2008 Apr 1;112(7):1600-6.

## **Double-blind, placebo-controlled, randomized study of chlorhexidine prophylaxis for 5-fluorouracil-based chemotherapy-induced oral mucositis with nonblinded randomized comparison to oral cooling (cryotherapy) in gastrointestinal malignancies.**

[Sorensen JB](#), [Skovsgaard T](#), [Bork E](#), [Damstrup L](#), [Ingeberg S](#).

Department Oncology, Finsen Centre/National University Hospital, Copenhagen, Denmark. jens.benn.soerensen@rh.regionh.dk

### **Abstract**

**BACKGROUND:** The purpose was to evaluate prevention of oral mucositis (OM) using chlorhexidine compared with placebo and with oral cooling (cryotherapy) during fluorouracil (5-FU)-based chemotherapy in gastrointestinal (GI) cancer.

**METHODS:** Patients with previously untreated GI cancer receiving bolus 5-FU/leucovorin chemotherapy were randomized to chlorhexidine mouthrinse 3 times a day for 3 weeks (Arm A), double-blind placebo (normal saline) with the same dose and frequency (Arm B), or cryotherapy with crushed ice 45 minutes during chemotherapy (Arm C). Patients self-reported on severity (CTC-grading) and duration of OM.

**RESULTS:** Among 225 patients randomized, 206 answered the questionnaire (70, 64, and 63 patients in Arms A, B, and C, respectively) and were well balanced with respect to diagnoses, stage, age, sex, smoking habits, and performance status. Mucositis grade 3-4 occurred more frequently in Arm B (33%) than in **A (13%,  $P < .01$ ) and C (11%,  $P < .005$ )**. Duration was significantly longer in B than in both A ( $P = .035$ ) and C ( $P = .003$ ).

**CONCLUSIONS:** The frequency and duration of OM are significantly improved by prophylactic chlorhexidine and by cryotherapy. The latter is easy and inexpensive but has limited use, as it is drug- and schedule-dependent. The current study is the first double-blind randomized evaluation of prophylactic chlorhexidine in a large adult patient population with solid tumors receiving highly OM-inducing chemotherapy. A role for chlorhexidine in the prevention of OM is suggested, which should be evaluated further.

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[Bone Marrow Transplant](#). 2007 Mar;39(6):347-52. Epub 2007 Feb 5.

## **Cryotherapy in the prevention of oral mucositis in patients receiving low-dose methotrexate following myeloablative allogeneic stem cell transplantation: a prospective randomized study of the Gruppo Italiano Trapianto di Midollo Osseo nurses group.**

[Gori E](#), [Arpinati M](#), [Bonifazi F](#), [Errico A](#), [Mega A](#), [Alberani F](#), [Sabbi V](#), [Costazza G](#), [Leanza S](#), [Borrelli C](#), [Berni M](#), [Feraut C](#), [Polato E](#), [Altieri MC](#), [Pirola E](#), [Loddo MC](#), [Banfi M](#), [Barzetti L](#), [Calza S](#), [Brignoli C](#), [Bandini G](#), [De Vivo A](#), [Bosi A](#), [Baccarani M](#).

Department of Hematology and Medical Oncology Seragnoli, University of Bologna, Bologna, Italy.

### **Abstract**

Severe oral mucositis is a major cause of morbidity following allogeneic hematopoietic stem cell transplantation (AHSCT). Cryotherapy, that is, the application of ice chips on the mucosa of the oral cavity during the administration of antineoplastic agents, may reduce the incidence and severity of chemotherapy-related oral mucositis. In this multicenter randomized study, we addressed whether cryotherapy during MTX administration is effective in the prevention of severe oral mucositis in patients undergoing myeloablative AHSCT. One hundred and thirty patients undergoing myeloablative AHSCT and MTX-containing GVHD prophylaxis were enrolled and randomized to receive or not receive cryotherapy during MTX administration. The incidence of severe (grade 3-4) oral mucositis, the primary end point of the study, was comparable in patients receiving or not cryotherapy. Moreover, no difference was observed in the incidence of oral mucositis grade 2-4 and the duration of oral mucositis grade 3-4 or 2-4, or in the kinetics of mucositis over time. In univariate and multivariate analysis, severe oral mucositis correlated with TBI in the conditioning regimen and lack of folinic acid rescue following MTX administration. Thus, cryotherapy during MTX administration does not reduce severe oral mucositis in patients undergoing myeloablative allogeneic HSCT. Future studies will assess cryotherapy before allogeneic HSCT.

Quindi ....

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Intervention Review

## Interventions for preventing oral mucositis for patients with cancer receiving treatment

Helen V Worthington<sup>1,\*</sup>, Jan E Clarkson<sup>2</sup>, Gemma Bryan<sup>1</sup>, Susan Furness<sup>1</sup>, Anne-Marie Glenny<sup>1</sup>, Anne Littlewood<sup>1</sup>, Martin G McCabe<sup>3</sup>, Stefan Meyer<sup>4</sup>, Tasneem Khalid<sup>5</sup>

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Helen V Worthington<sup>1\*</sup>, Jan E Clarkson<sup>2</sup>, Gemma Bryan<sup>1</sup>, Susan Furness<sup>1</sup>, Anne-Marie Glenny<sup>1</sup>, Anne Littlewood<sup>1</sup>, Martin G McCabe<sup>3</sup>, Stefan Meyer<sup>4</sup>, Tasneem Khalid<sup>5</sup>

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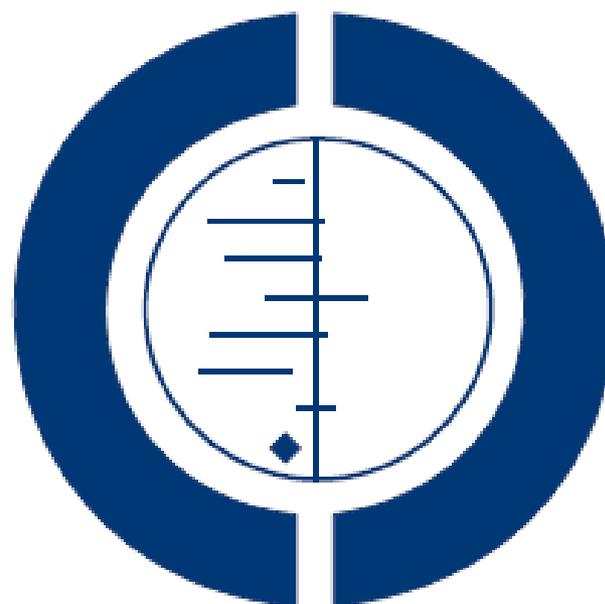
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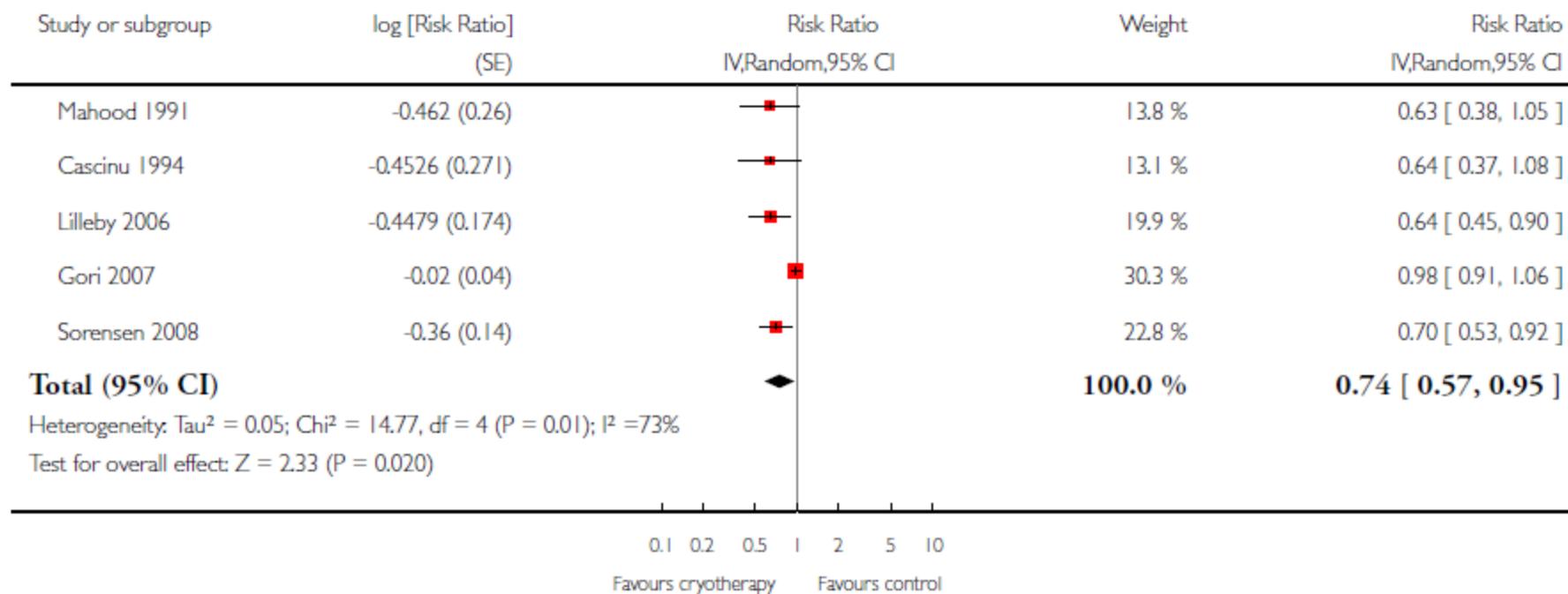
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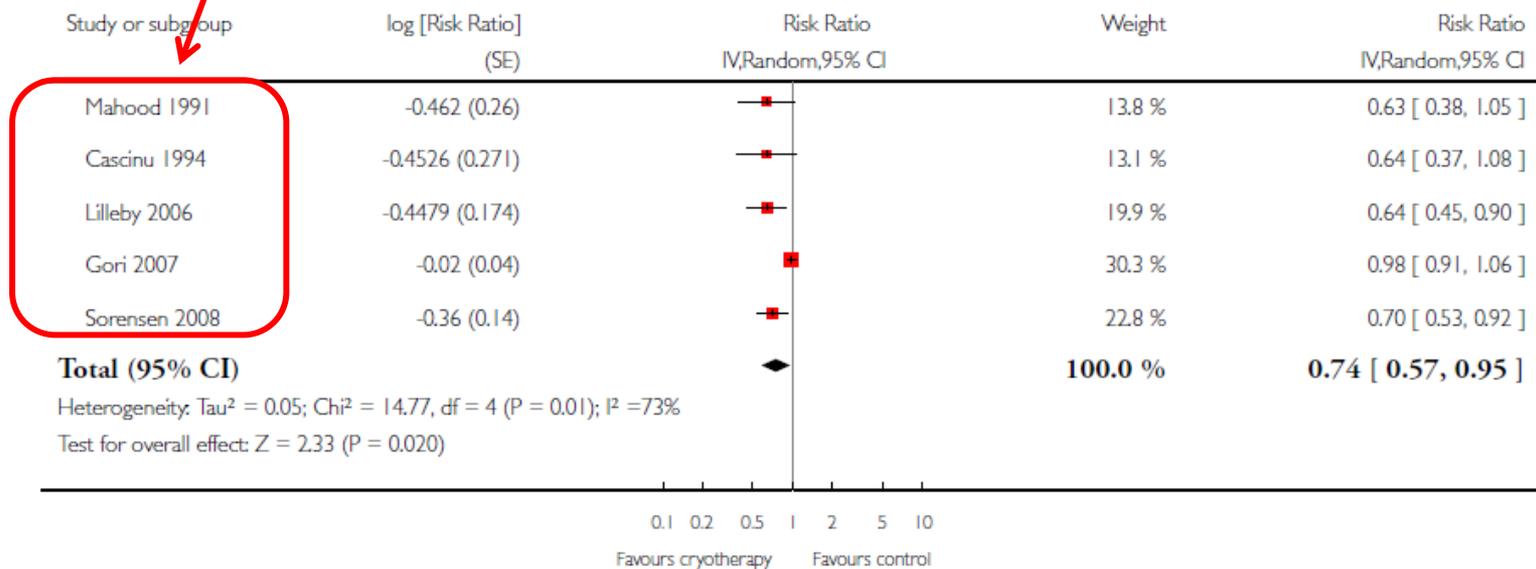
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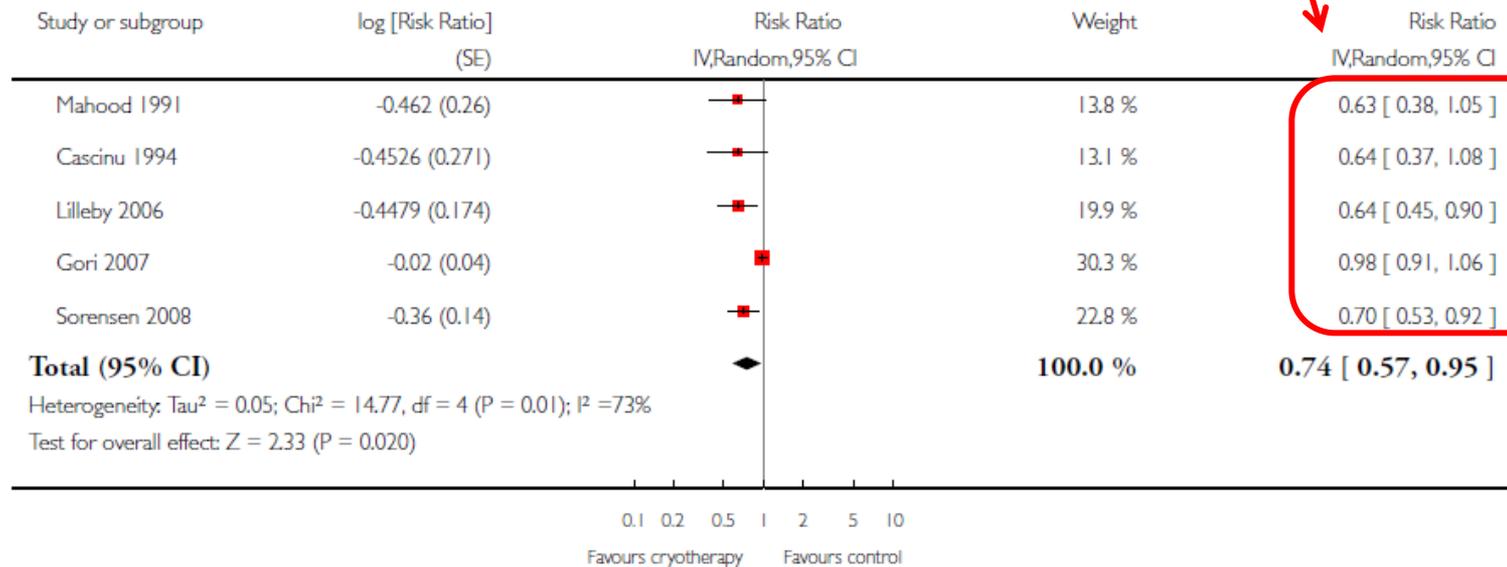
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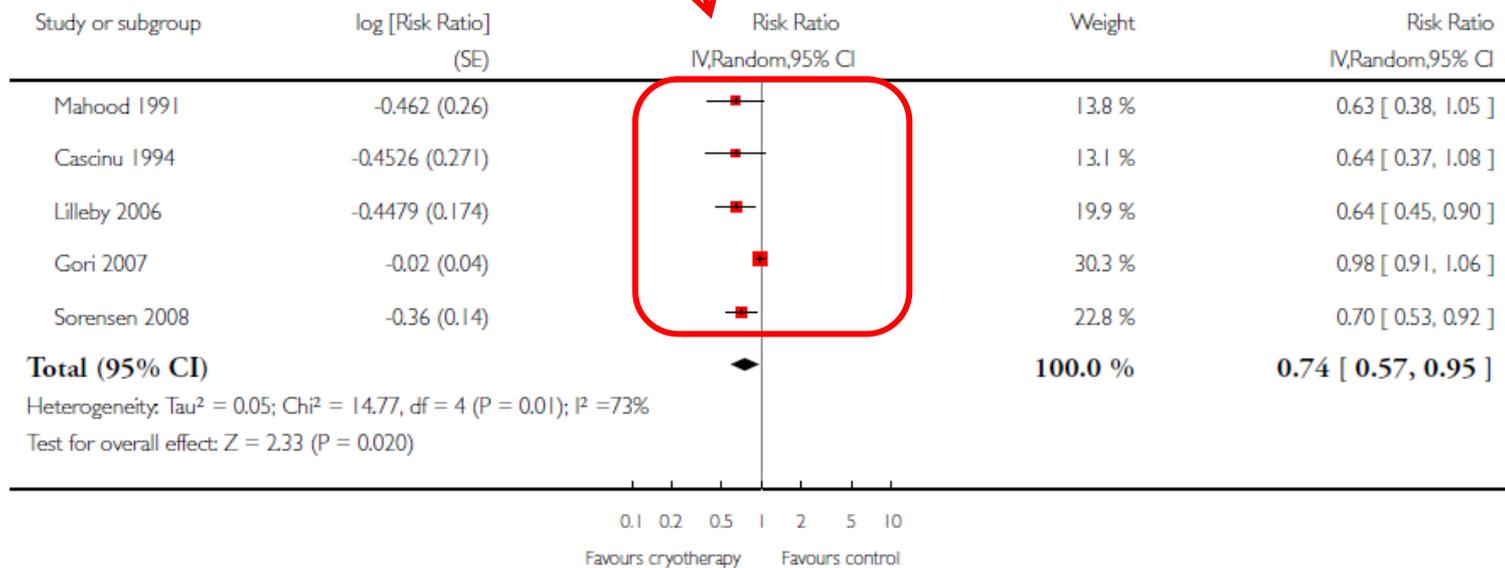
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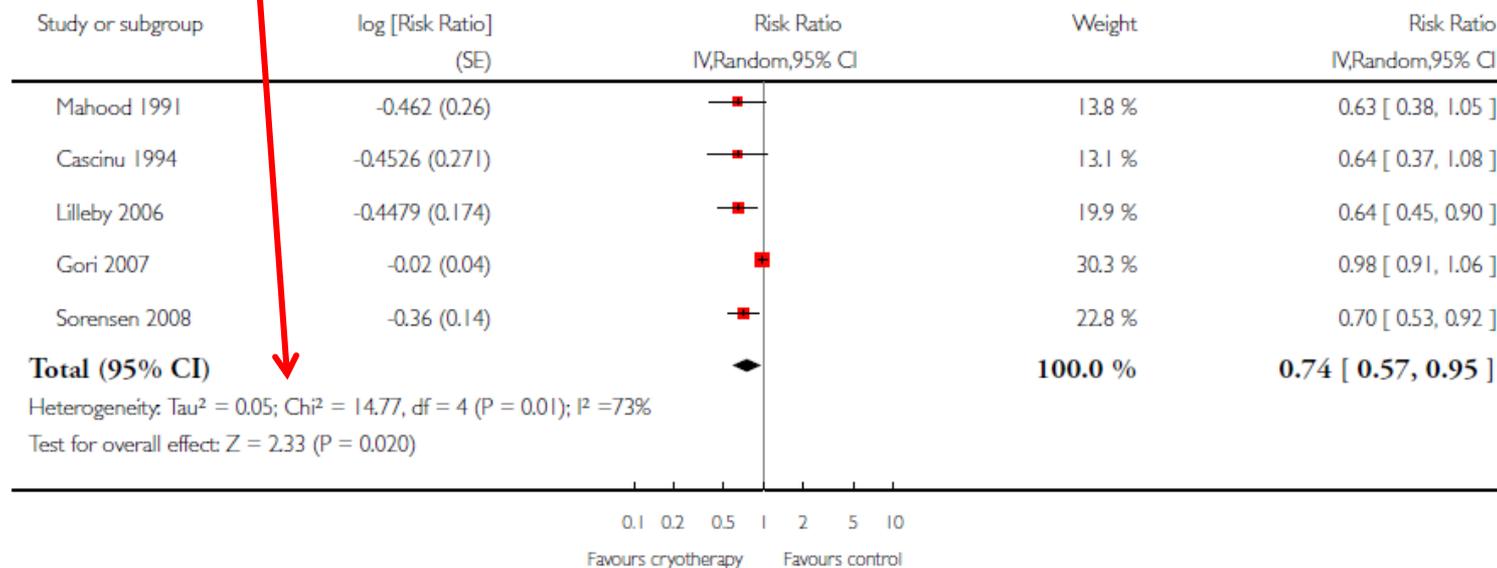
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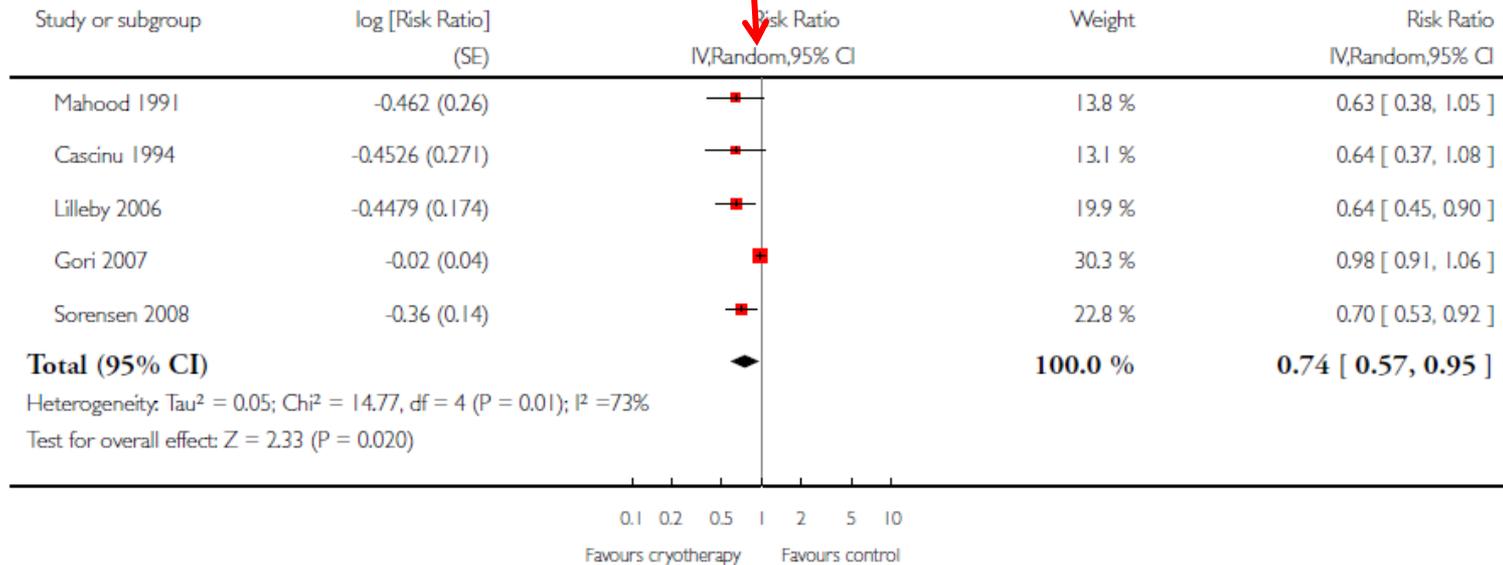
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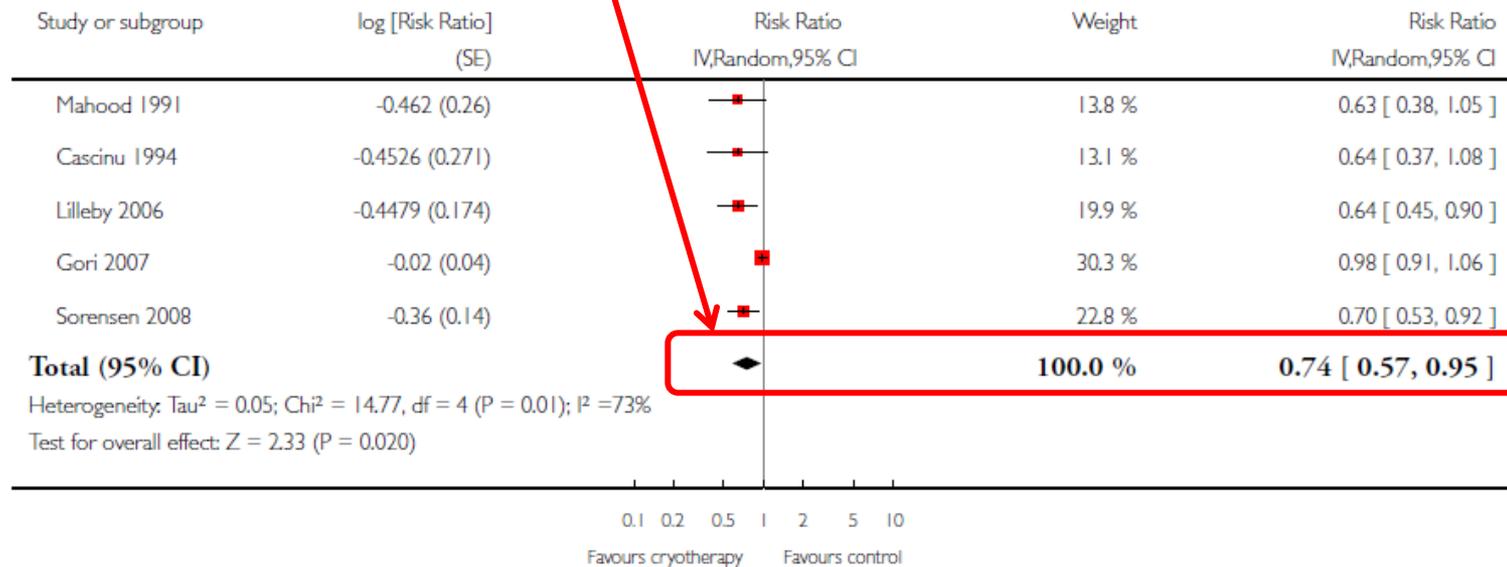
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Outcome: 1 Mucositis (any)



# DISCUSSION

## Summary of main results

This update has identified a further 42 included trials which have been published in less than 3 years, bringing the total number of included studies up to 131. The trials included in this review have evaluated 43 different interventions and recruited a total of 10,514 patients.

There is some evidence of a benefit for cryotherapy (ice chips) and keratinocyte growth factor based on a body of evidence comprising at least 6 trials and at least 550 participants for each of these interventions. However all these trials were assessed as being at either high or unclear risk of bias.

- Cryotherapy was found to be beneficial in the prevention of all the outcome categories of mucositis. Specifically the prevention of any mucositis RR = 0.74 (95% CI 0.57 to 0.95, P = 0.02), moderate plus severe mucositis RR = 0.53 (95% CI 0.31 to 0.91, P = 0.02), and severe mucositis RR = 0.36 (95% CI 0.17 to 0.77, P = 0.008).

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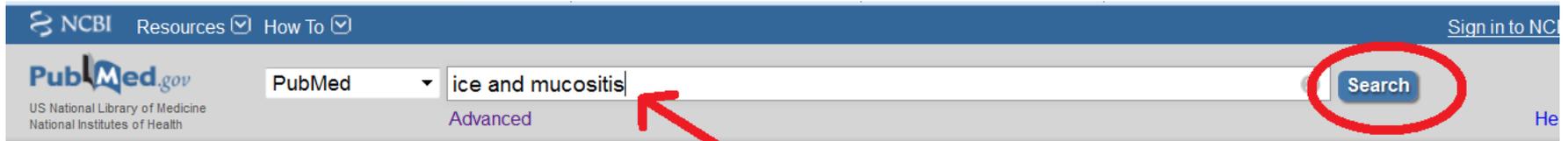
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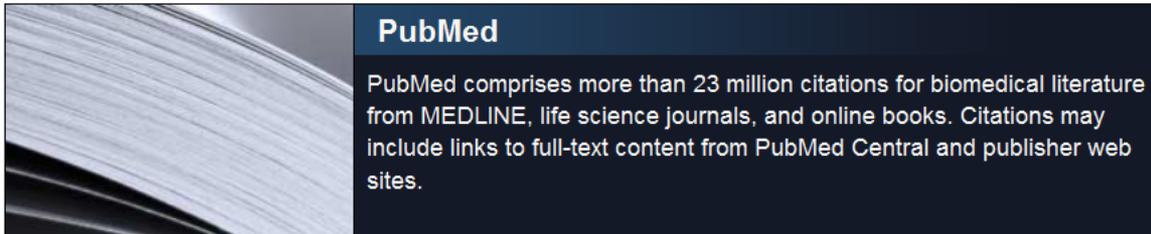
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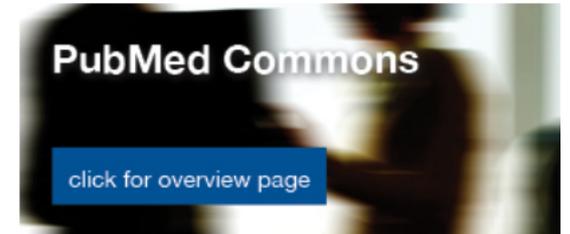


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- [\[Application of Cochrane systematic reviews in diagnosis and treatment for oral mucosal diseases\].](#)  
1. Li QH, Chen QM, Zeng X.  
Hua Xi Kou Qiang Yi Xue Za Zhi. 2010 Oct;28(5):573-5. Chinese.  
PMID: 21179702 [PubMed - in process] **Free Article**  
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- [Interventions for preventing oral mucositis for patients with cancer receiving treatment.](#)  
2. Worthington HV, Clarkson JE, Eden OB.  
Cochrane Database Syst Rev. 2007 Oct 17;(4):CD000978. Review. Update in: [Cochrane Database Syst Rev. 2010;\(12\):CD000978.](#)

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# Esercitazione

## **I risultati sono validi?**

- La revisione esplicita un quesito clinico sensibile?
- La ricerca bibliografica è avvenuta in dettaglio e in modo esaustivo?
- Gli studi inclusi sono stati condotti con una metodologia adeguata e di qualità?
- La valutazione degli studi è riproducibile?

## **Quali sono i risultati**

- I risultati degli studi sono simili tra loro?
- Qual è il risultato della revisione?
- Come sono precisi i risultati?

## **Come si possono applicare i risultati nella cura dei pazienti**

- Come si possono interpretare al meglio i risultati per applicarli nella pratica?
- Tutti i “Patient-Important Outcomes” sono stati considerati?
- I benefici sono bilanciati con i rischi potenziali