放射腫瘤科
實證醫學月會報告

報告者： 陳建宏 醫師

指導者： 黃志仁 主任
黃鈞民 醫師

Clinical Scenario

Patient Profile

- Name：楊x成
- Chart Number：27022925
- Gender：male
- Age：55
- Date of Birth：1957/4/7

Chief Complaint

- Bilateral neck mass noted in 2012/8.

Present Illness

- This 55 y/o male patient sufferred from bilateral neck mass in 2012/8. He came to local clinic for help and was referred to KMUH ENT OPD on 101.10.12.
- Physical examination showed bilateral neck mass(left 2.5x2cm;right 3x2cm) and fiberscopy revealed nasopharyngeal bulging mass.
- Pathology of biopsy revealed nonkeratinizing carcinoma,differentiated. on 101.10.13.

Present Illness

- Other associated symptoms and signs include: tinnitus(+,right).
- Under the impression of nasopharyngeal carcinoma, cT1N2M0, stage III, the patient received 2 course of neoadjuvant chemotherapy with Platinol 70mg/㎡+5-FU 600mg /㎡ and CCRT with 7000cGy/35fx during 2012/12/17 - 2013/1/16.

實證醫學五大步驟

- Asking
  - 將病人的問題寫成PICOT
- Acquire
  - 找資料來回答問題
- Appraisal
  - 嚴格評讀文獻
- Apply
  - 是否可應用到病人身上
- Audit
  - 自我評估

Asking

提出臨床問題

Clarifying the Problem Using PICOT Model

Patient	A 55-year-old man with nasopharyngeal carcinoma, cT1N2M0, stage III
Intervention	CCRT
Comparison	Definitive RT
Outcome	Over-all survival
Time frame	Nil

Acquire

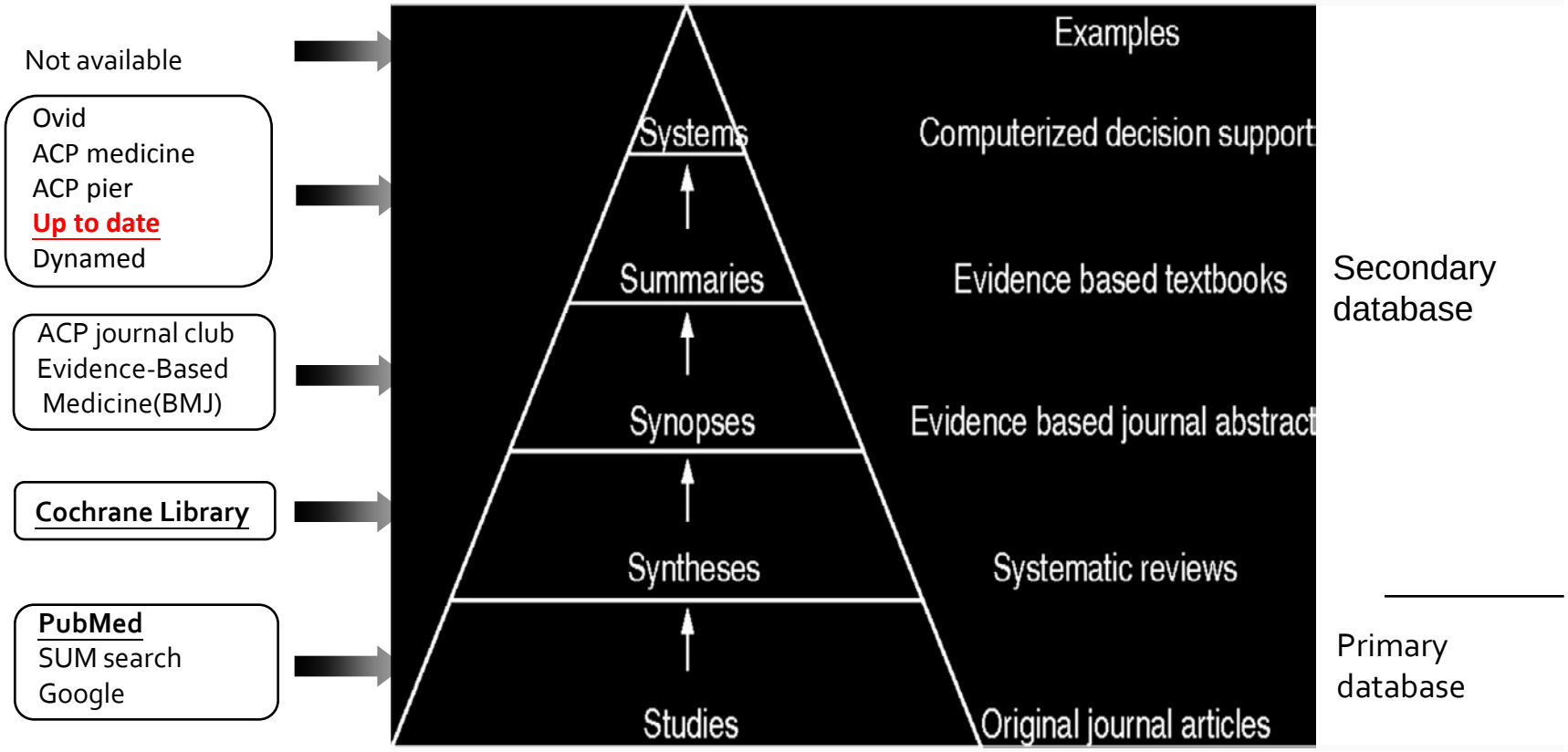
搜尋最有用的資料

先從已經過評讀的database開始找起
(system,synopses,synthesis)

最後再找尚未經過嚴格評讀的study

The "5S" levels of organisation of evidence from healthcare research

Brian Haynes, R Evid Based Med 2006;11:162-164



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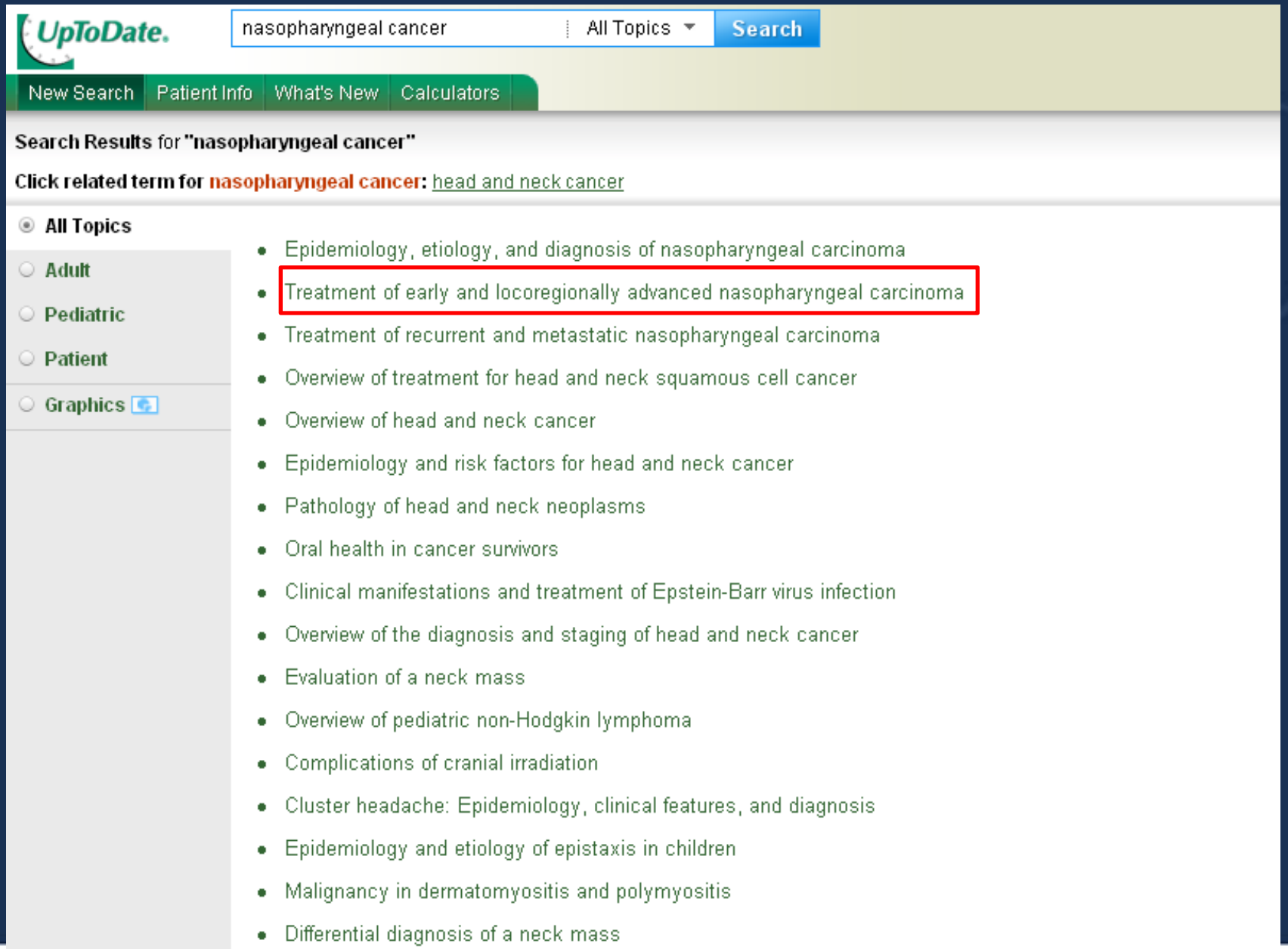
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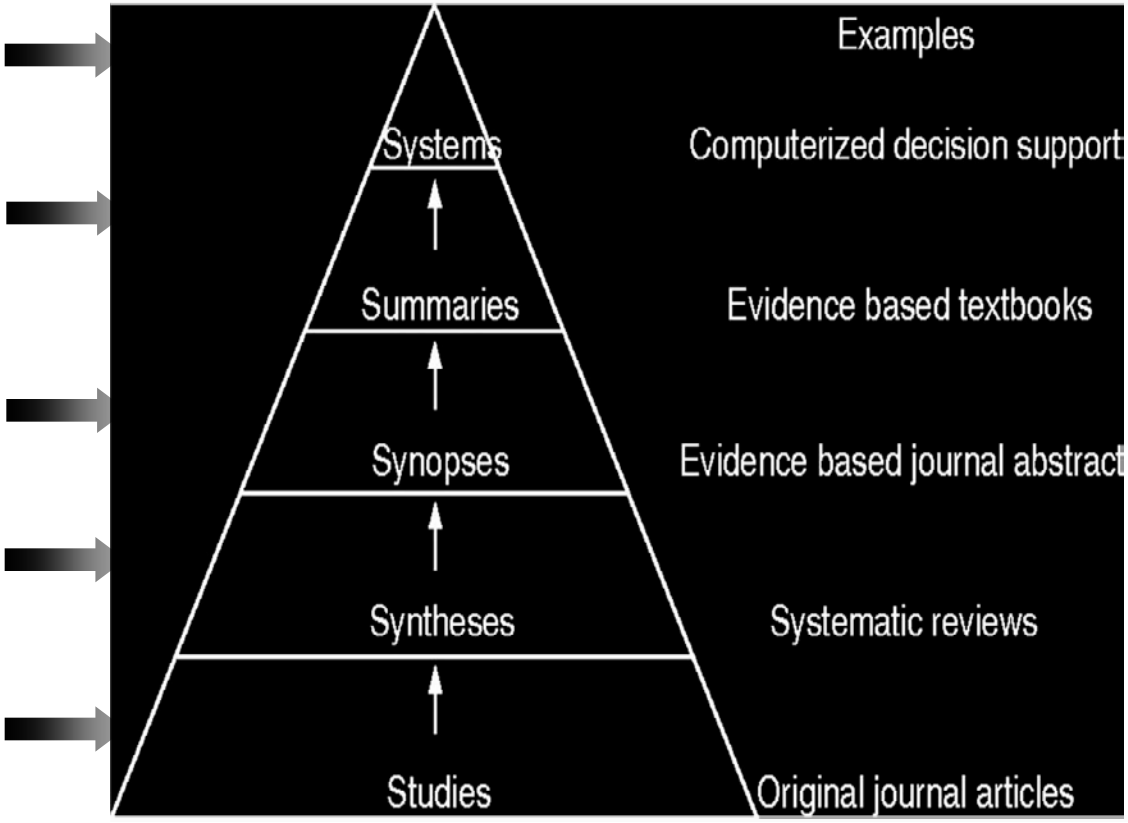
Treatment of early and locoregionally advanced nasopharyngeal carcinoma
Treatment of recurrent and metastatic nasopharyngeal carcinoma
Overview of treatment for head and neck squamous cell cancer
Overview of head and neck cancer
Epidemiology and risk factors for head and neck cancer
Pathology of head and neck neoplasms
Oral health in cancer survivors
Clinical manifestations and treatment of Epstein-Barr virus infection
Overview of the diagnosis and staging of head and neck cancer
Evaluation of a neck mass
Overview of pediatric non-Hodgkin lymphoma
Complications of cranial irradiation
Cluster headache: Epidemiology, clinical features, and diagnosis
Epidemiology and etiology of epistaxis in children
Malignancy in dermatomyositis and polymyositis
Differential diagnosis of a neck mass

SUMMARY AND RECOMMENDATIONS — Because of the anatomical location of the nasopharynx and its proximity to critical neurovascular structures, radiation therapy (RT), rather than surgery, is the mainstay of first-line treatment for early stage nasopharyngeal carcinoma. For more advanced disease, concurrent chemoradiation reduces the rate of distant metastasis and improves local control and overall survival compared to RT alone.

- Treatment approaches are based upon the stage of the disease. Despite differences in prognosis, there is insufficient evidence to suggest that treatment should differ based upon WHO histopathologic classification. (See 'Prognostic risk groups' above.)
- For patients with early (stage I, (table 1)) disease, we recommend RT alone rather than a combined modality approach (**Grade 1B**). (See 'Early (stage I) disease' above.)
- For patients with intermediate (stage II) disease, we recommend concurrent chemoradiation rather than RT alone (**Grade 1B**). Concurrent weekly cisplatin significantly increased acute but not late toxicity. (See 'Intermediate (stage II) disease' above.)
- For patients with advanced (stage III, IVA, and IVB) disease, we recommend concurrent chemoradiotherapy (**Grade 1A**). While adjuvant chemotherapy has been a standard part of many concurrent chemoradiotherapy regimens, its benefit is uncertain and toxicity is substantial. Adjuvant chemotherapy may be a reasonable option for patients with high-risk disease and a good performance status. (See 'Advanced (stage III and IV) disease' above.)
- For eligible patients being treated with concurrent chemoradiotherapy, cisplatin (100 mg/m^2 on days 1, 22, and 43) concurrent with RT is a standard option for patients with good performance status. (See 'Concurrent chemotherapy regimen' above.)
    - Low dose cisplatin (30 to 40 mg/m^2 weekly) concurrent with RT or the substitution of carboplatin for cisplatin are options for patients with a poor performance status or comorbidities. (See 'Concurrent chemotherapy regimen' above.)
- Until more data in support of sequential therapy are available, we suggest not using sequential therapy for most patients with advanced nasopharyngeal carcinoma (**Grade 2C**). However, some experts do choose sequential therapy for large or extensive primary tumors or advanced nodal disease. (See 'Sequential therapy' above.)

The "5S" levels of organisation of evidence from healthcare research

Brian Haynes, R Evid Based Med 2006;11:162-164



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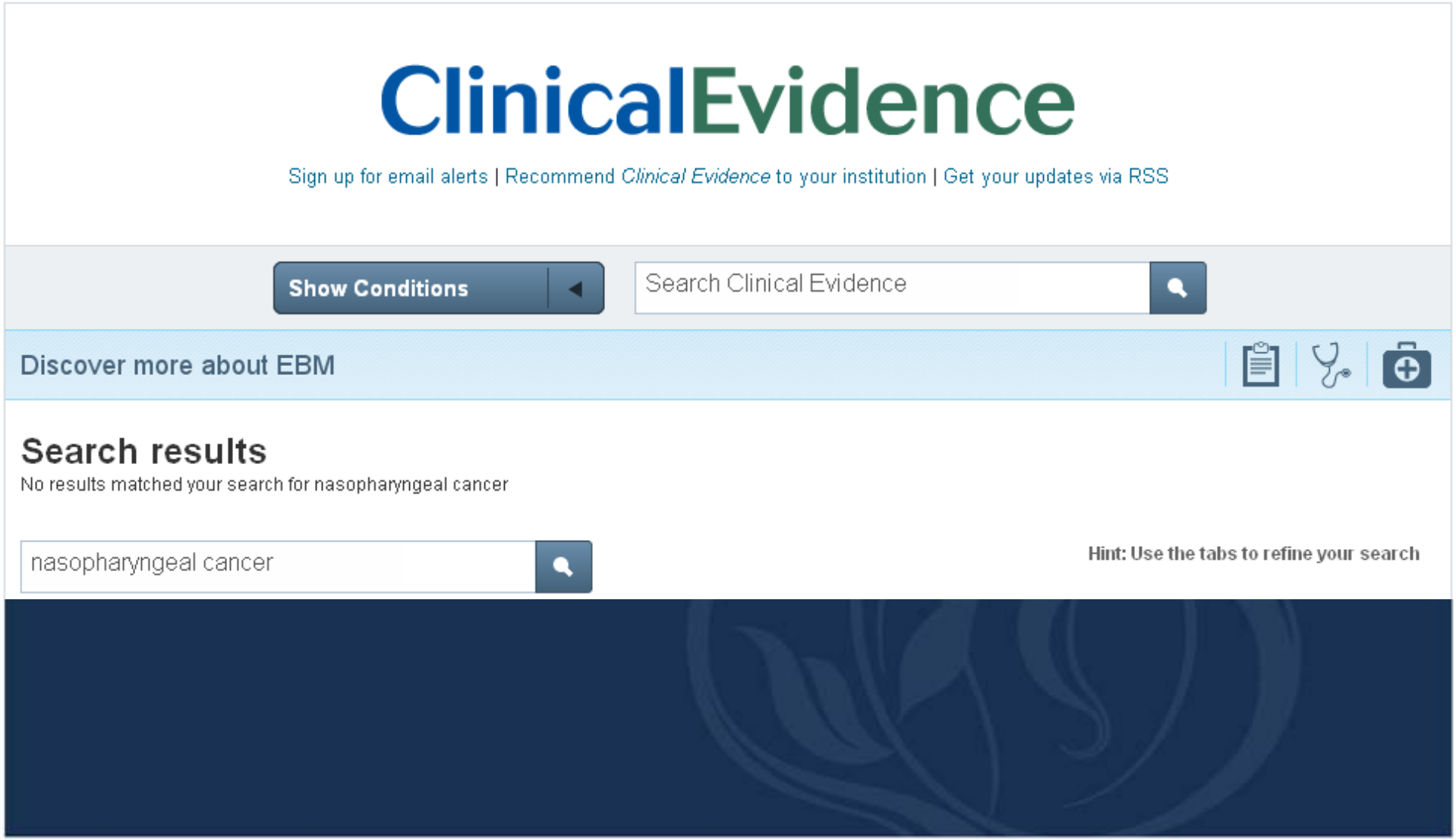

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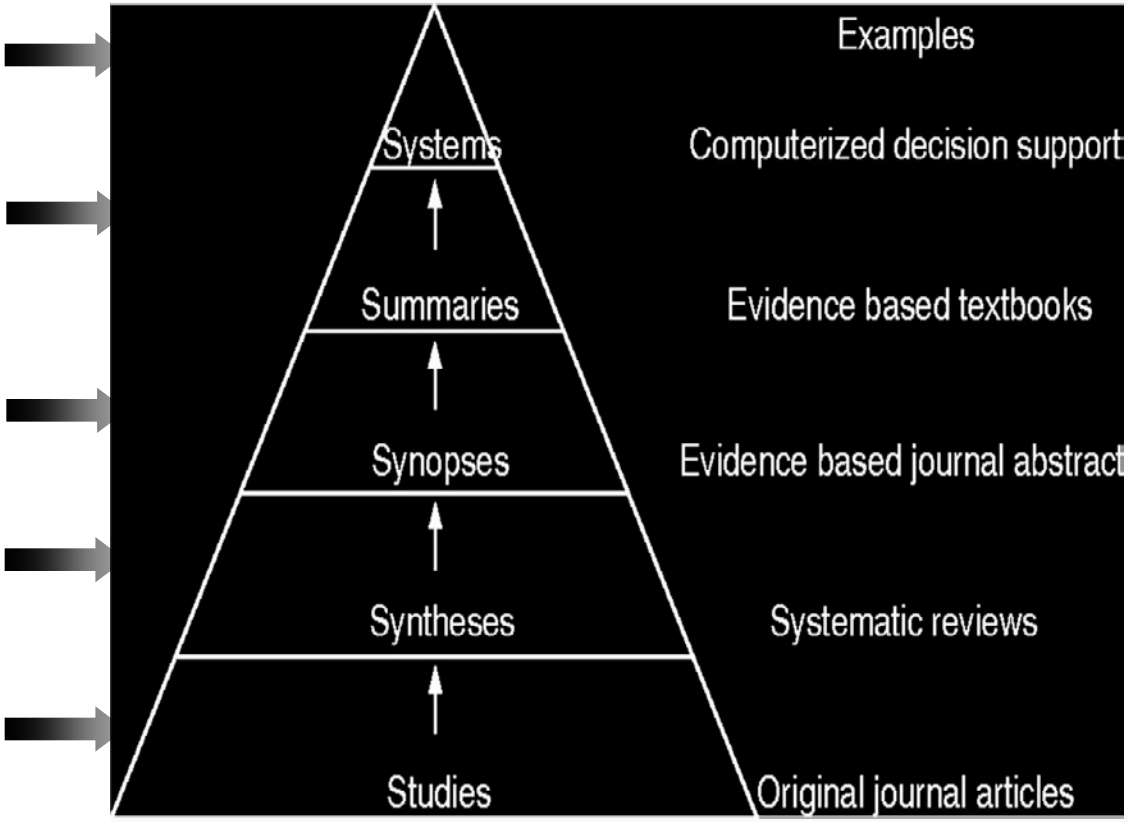

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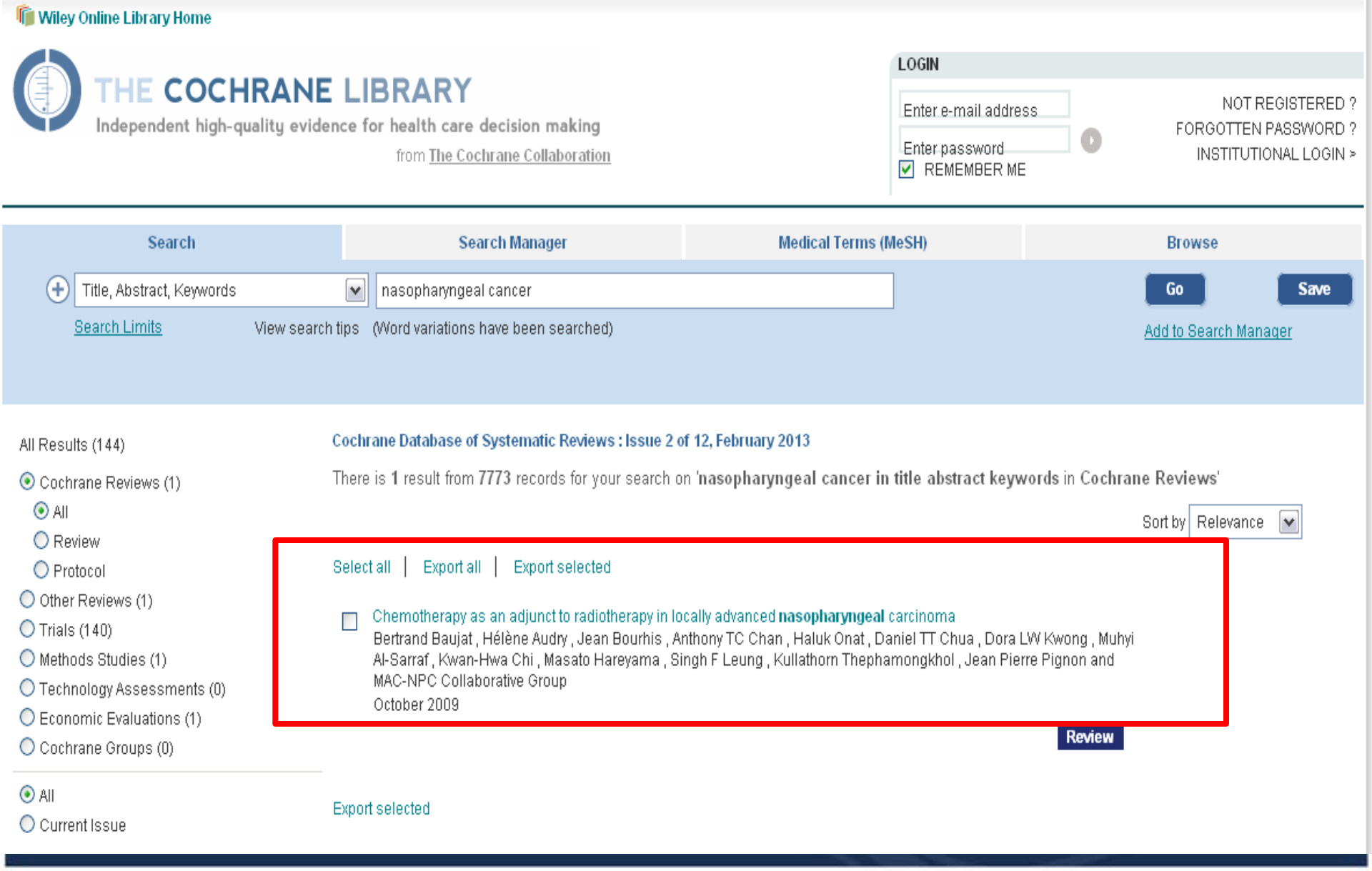

Chemotherapy as an adjunct to radiotherapy in locally advanced nasopharyngeal carcinoma

Bertrand Baujat[1,*], Hélène Audry[2], Jean Bourhis[3], Anthony TC Chan[4], Haluk Onat[5], Daniel TT Chua[6], Dora LW Kwong[6], Muhyi Al-Sarraf[7], Kwan-Hwa Chi[8], Masato Hareyama[9], Singh F Leung[4], Kullathorn Thephamongkhol[10], Jean Pierre Pignon[11], MAC-NPC Collaborative Group[1]

Editorial Group: Cochrane Ear, Nose and Throat Disorders Group

Published Online: 7 OCT 2009

Assessed as up-to-date: 22 AUG 2006

DOI: 10.1002/14651858.CD004329.pub2

Database Title

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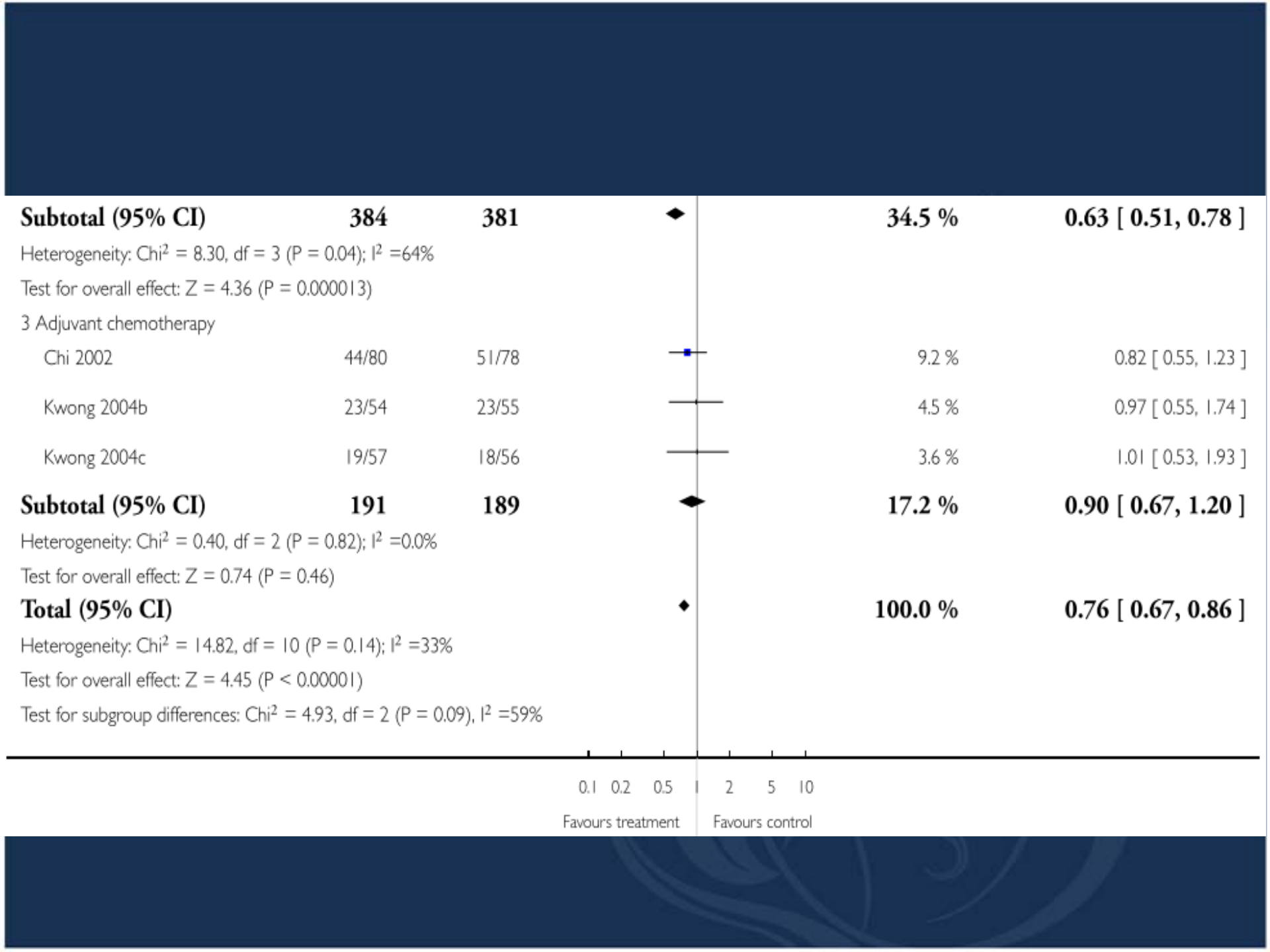
Analysis 1.2. Comparison 1 Radiotherapy versus radiotherapy + chemotherapy, Outcome 2 Effect of chemotherapy on event-free survival, hazard ratio of tumour failure or death by timing of chemo..

Review: Chemotherapy as an adjunct to radiotherapy in locally advanced nasopharyngeal carcinoma

Comparison: 1 Radiotherapy versus radiotherapy + chemotherapy

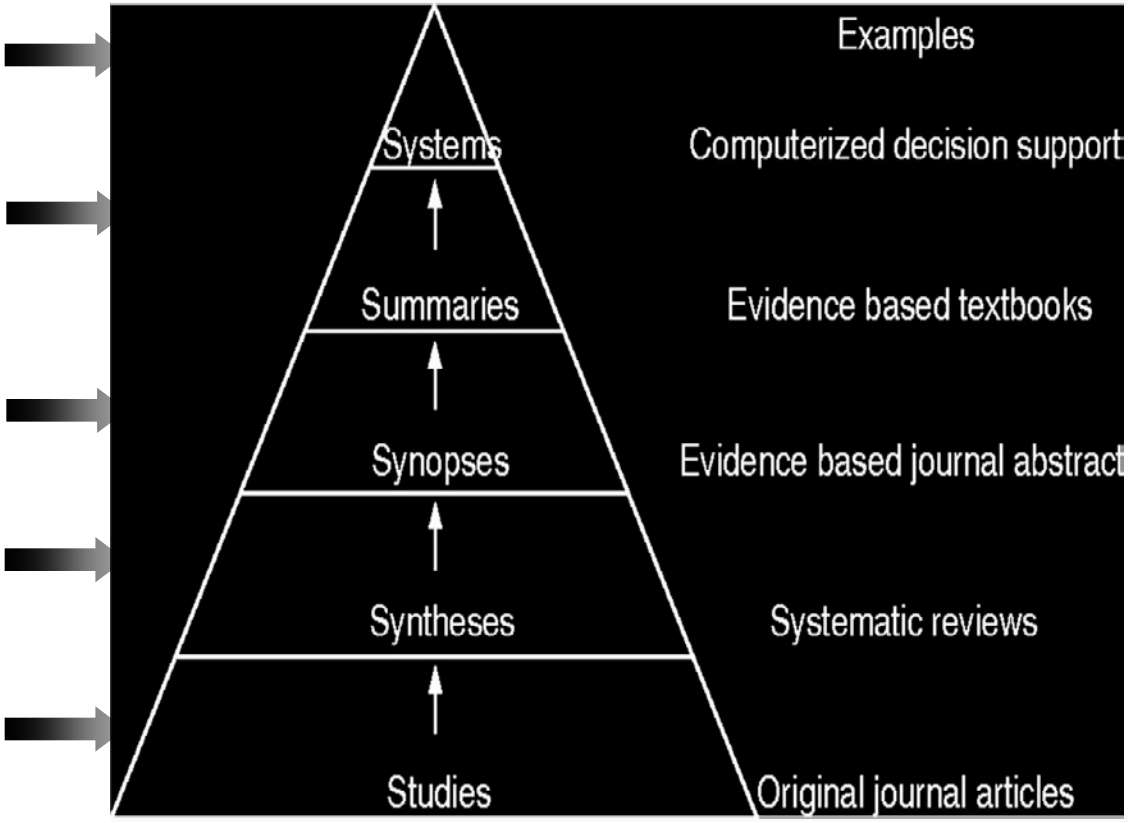
Outcome: 2 Effect of chemotherapy on event-free survival, hazard ratio of tumour failure or death by timing of chemo.

Study or subgroup	Chemotherapy n/N	Control n/N	Peto Odds Ratio Exp[(O-E)/V],Fixed,95% CI	Weight	Peto Odds Ratio Exp[(O-E)/V],Fixed,95% CI
1 Induction +/- adjuvant chemotherapy					
Chan 1995	17/37	17/40		3.3 %	0.99 [0.50, 1.94]
Chua 1998	100/167	108/167		20.1 %	0.88 [0.67, 1.16]
Cvitkovic 1996	102/171	114/168		20.7 %	0.76 [0.58, 0.99]
Hareyama 2002	19/40	24/40		4.2 %	0.70 [0.39, 1.28]
Subtotal (95% CI)	**415**	**415**		**48.3 %**	**0.82 [0.68, 0.97]**
Heterogeneity: Chi^2 = 1.19, df = 3 (P = 0.75); I^2 =0.0%					
Test for overall effect: Z = 2.28 (P = 0.023)					
2 Concomitant +/-adjuvant chemotherapy					
Al-Sarraf 1998	47/97	71/96		10.7 %	0.40 [0.28, 0.58]
Chan 2002	77/174	87/176		15.8 %	0.80 [0.59, 1.09]
Kwong 2004a	18/56	23/55		4.0 %	0.72 [0.39, 1.32]
Kwong 2004d	19/57	23/54		4.0 %	0.72 [0.39, 1.32]


Subtotal (95% CI) 384 381 34.5 % 0.63 [0.51, 0.78]
Heterogeneity: Chi² = 8.30, df = 3 (P = 0.04); I² =64%
Test for overall effect: Z = 4.36 (P = 0.000013)
3 Adjuvant chemotherapy
Chi 2002 44/80 51/78 9.2 % 0.82 [0.55, 1.23]
Kwong 2004b 23/54 23/55 4.5 % 0.97 [0.55, 1.74]
Kwong 2004c 19/57 18/56 3.6 % 1.01 [0.53, 1.93]
Subtotal (95% CI) 191 189 17.2 % 0.90 [0.67, 1.20]
Heterogeneity: Chi² = 0.40, df = 2 (P = 0.82); I² =0.0%
Test for overall effect: Z = 0.74 (P = 0.46)
Total (95% CI) 100.0 % 0.76 [0.67, 0.86]
Heterogeneity: Chi² = 14.82, df = 10 (P = 0.14); I² =33%
Test for overall effect: Z = 4.45 (P < 0.00001)
Test for subgroup differences: Chi² = 4.93, df = 2 (P = 0.09), I² =59%
0.1 0.2 0.5 1 2 5 10
Favours treatment
Favours control

The "5S" levels of organisation of evidence from healthcare research

Brian Haynes, R Evid Based Med 2006;11:162-164



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1. Concurrent chemoradiotherapy with or without adjuvant chemotherapy in intermediate and locoregionally advanced **nasopharyngeal** carcinoma.
   Zhang W, Dou H, Lam C, Liu J, Zhou J, Liu Y, Wang X.
   Tumour Biol. 2013 Feb 23. [Epub ahead of print]
   PMID: 23436047 [PubMed - as supplied by publisher]
   Related citations

2. Positive effect of high RKIP expression on reduced distant metastasis by chemotherapy when combined with radiotherapy in locoregionally advanced **nasopharyngeal** carcinoma: a prospective study.
   Li SW, Wang H, Liu ML, Zhang HB, Xiang YQ, Lv X, Xia WX, Zeng MS, Mai HQ, Hong MH, Guo X.
   Med Oncol. 2013 Mar;30(1):322. doi: 10.1007/s12032-012-0322-9. Epub 2012 Dec 15.
   PMID: 23254962 [PubMed - in process]
   Related citations

3. A randomized trial of induction chemotherapy plus concurrent chemoradiotherapy versus induction chemotherapy plus radiotherapy for locoregionally advanced **nasopharyngeal** carcinoma.
   Huang PY, Cao KJ, Guo X, Mo HY, Guo L, Xiang YQ, Deng MQ, Qiu F, Cao SM, Guo Y, Zhang L, Li NW, Sun R, Chen QY, Luo DH, Hua YJ, Mai HQ, Hong MH.
   Oral Oncol. 2012 Oct;48(10):1038-44. doi: 10.1016/j.oraloncology.2012.04.006. Epub 2012 May 14.
   PMID: 22591726 [PubMed - in process]
   Related citations

4. Comparison of concurrent chemoradiotherapy versus induction chemotherapy followed by radiation in patients with **nasopharyngeal** carcinoma.
   Komatsu M, Tsukuda M, Matsuda H, Horiuchi C, Taguch T, Takahashi M, Nishimura G, Mori M, Niho T, Ishitoya J, Sakuma Y, Hirama M, Shiono O.
   Anticancer Res. 2012 Feb;32(2):681-6.
   PMID: 22287763 [PubMed - indexed for MEDLINE]
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The role of concurrent chemoradiotherapy in the treatment of locoregionally a [BMC Cancer. 2010]

Validation of bidimensional measurement in **nasopharyngeal** carcinom [Radiat Oncol. 2010]

Radiation therapy combined with (or without) cisplatin-based chemotl [Cancer Res Treat. 2008]

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1. A **randomized** trial of induction chemotherapy plus concurrent chemoradiotherapy versus induction chemotherapy plus radiotherapy for locoregionally **advanced nasopharyngeal** carcinoma.
Huang PY, Cao KJ, Guo X, Mo HY, Guo L, Xiang YQ, Deng MQ, Qiu F, Cao SM, Guo Y, Zhang L, Li NW, Sun R, Chen QY, Luo DH, Hua YJ, Mai HQ, Hong MH.
Oral Oncol. 2012 Oct;48(10):1038-44. doi: 10.1016/j.oraloncology.2012.04.006. Epub 2012 May 14.
PMID: 22591726 [PubMed - in process]
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2. Induction chemotherapy followed by concomitant radiotherapy and weekly cisplatin versus the same concomitant chemoradiotherapy in patients with **nasopharyngeal** carcinoma: a **randomized** phase II study conducted by the Hellenic Cooperative Oncology Group (HeCOG) with biomarker evaluation.
Fountzilas G, Ciuleanu E, Bobos M, Kalogera-Fountzila A, Eleftheraki AG, Karayannopoulou G, Zaramboukas T, Nikolaou A, Markou K, Resiga L, Dionysopoulos D, Samantas E, Athanassiou H, Misailidou D, Skarlos D, Ciuleanu T.
Ann Oncol. 2012 Feb;23(2):427-35. doi: 10.1093/annonc/mdr116. Epub 2011 Apr 27.
PMID: 21525406 [PubMed - indexed for MEDLINE] **Free Article**
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3. Preliminary results of a phase III **randomized** study comparing chemotherapy neoadjuvantly or concurrently with radiotherapy for locoregionally **advanced nasopharyngeal** carcinoma.
Xu T, Hu C, Zhu G, He X, Wu Y, Ying H.
Med Oncol. 2012 Mar;29(1):272-8. doi: 10.1007/s12032-010-9803-x. Epub 2011 Jan 30.
PMID: 21279704 [PubMed - indexed for MEDLINE]
Related citations

4. The role of concurrent chemoradiotherapy in the treatment of locoregionally **advanced nasopharyngeal** carcinoma among endemic population: a meta-analysis of the phase III **randomized** trials.
Zhang L, Zhao C, Ghimire B, Hong MH, Liu Q, Zhang Y, Guo Y, Huang YJ, Guan ZZ.
BMC **Cancer**. 2010 Oct 15;10:558. doi: 10.1186/1471-2407-10-558.
PMID: 20950416 [PubMed - indexed for MEDLINE] **Free PMC Article**
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The role of concurrent chemoradiotherapy in the treatment of locoregionally **a** [BMC Cancer. 2010]

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Zhang et al. BMC Cancer 2010, 10:558
http://www.biomedcentral.com/1471-2407/10/558

BMC Cancer

RESEARCH ARTICLE Open Access

The role of concurrent chemoradiotherapy in the treatment of locoregionally advanced nasopharyngeal carcinoma among endemic population: a meta-analysis of the phase iii randomized trials

Li Zhang[1†], Chong Zhao[2†], Bijesh Ghimire[1], Ming-Huang Hong[3], Qing Liu[3], Yang Zhang[3], Ying Guo[3*], Yi-Jun Huang[4*], Zhong-Zhen Guan[1]

Background

- The main objective of this meta-analysis was to determine the clinical benefit of concurrent chemoradiotherapy (CCRT) compared with radiation alone (RT) in the treatment of nasopharyngeal carcinoma (NPC) patients in endemic geographic areas.

Methods

- Using a prospective meta-analysis protocol, two independent investigators reviewed the publications and extracted the data. Published randomized controlled trials (RCTs) in which patients with NPC in endemic areas were randomly assigned to receive CCRT or RT alone were included.

Results

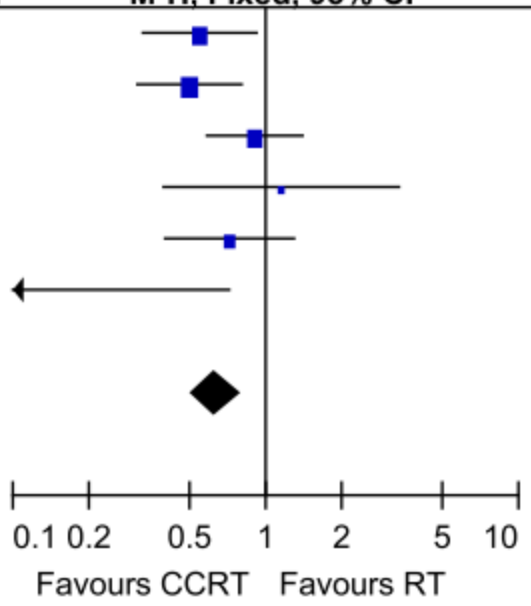
- Seven trials (totally 1608 patients) were eligible. Risk ratios (RRs) of 0.63 (95% CI, 0.50 to 0.80), 0.76 (95% CI, 0.61 to 0.93) and 0.74 (95% CI, 0.62 to 0.89) were observed for 2, 3 and 5 years OS respectively in favor of the CCRT group. The RRs were larger than that detected in the previously reported meta-analyses (including both endemic and non-endemic), indicating that the relative benefit of survival was smaller than what considered before

A 2 years Overall Survival

Study or Subgroup	CCRT Events	CCRT Total	RT Events	RT Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chan (11,25)	19	174	35	176	23.3%	0.55 [0.33, 0.92]
Chen (16)	21	158	42	158	28.1%	0.50 [0.31, 0.80]
Lee 9901 (13,18)	31	172	35	176	23.2%	0.91 [0.59, 1.40]
Lee 9902 (15,17)	7	51	5	42	3.7%	1.15 [0.39, 3.37]
Wee (12)	16	111	22	110	14.8%	0.72 [0.40, 1.30]
Zhang (14)	1	59	10	56	6.9%	0.09 [0.01, 0.72]
Total (95% CI)		**725**		**718**	**100.0%**	**0.63 [0.50, 0.80]**
Total events	95		149			

Heterogeneity: $Chi^2 = 8.60$, $df = 5$ ($P = 0.13$); $I^2 = 42\%$

Test for overall effect: $Z = 3.78$ ($P = 0.0002$)

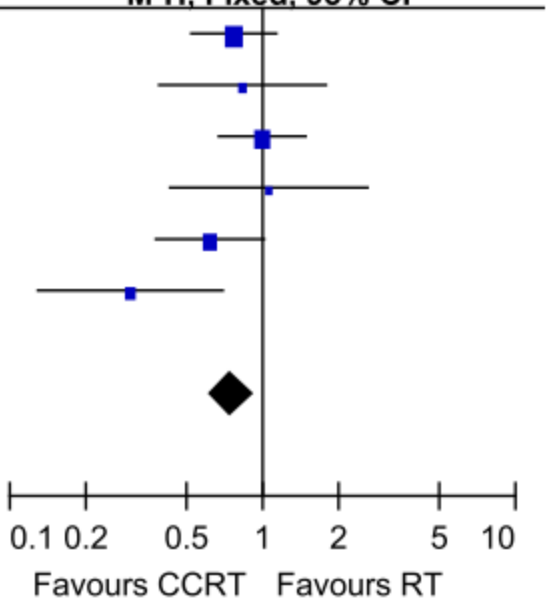


B 3 years Overall Survival

Study or Subgroup	CCRT Events	CCRT Total	RT Events	RT Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chan (11,25)	35	174	46	176	29.4%	0.77 [0.52, 1.13]
Kwong (10)	15	110	9	55	7.7%	0.83 [0.39, 1.78]
Lee 9901 (13,18)	38	172	39	176	24.8%	1.00 [0.67, 1.48]
Lee 9902 (15,17)	9	51	7	42	4.9%	1.06 [0.43, 2.60]
Wee (12)	20	111	32	110	20.7%	0.62 [0.38, 1.01]
Zhang (14)	6	59	19	56	12.5%	0.30 [0.13, 0.70]
Total (95% CI)		**677**		**615**	**100.0%**	**0.76 [0.61, 0.93]**
Total events	123		152			

Heterogeneity: $Chi^2 = 7.77$, df = 5 (P = 0.17); $I^2 = 36\%$

Test for overall effect: Z = 2.59 (P = 0.010)

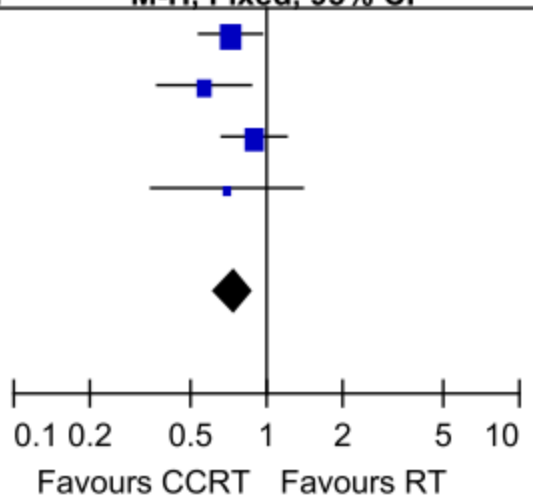


C 5 years Overall Survival

Study or Subgroup	CCRT Events	CCRT Total	RT Events	RT Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chan (11,25)	52	174	73	176	37.9%	0.72 [0.54, 0.96]
Wee (12)	24	111	42	110	22.1%	0.57 [0.37, 0.87]
Lee 9901 (13,18)	55	172	63	176	32.6%	0.89 [0.67, 1.20]
Lee 9902 (15,17)	11	51	13	42	7.5%	0.70 [0.35, 1.39]
Total (95% CI)		**508**		**504**	**100.0%**	**0.74 [0.62, 0.89]**
Total events	142		191			

Heterogeneity: $Chi^2 = 3.14$, $df = 3$ ($P = 0.37$); $I^2 = 5\%$

Test for overall effect: $Z = 3.29$ ($P = 0.001$)



Conclusions

- This is the first meta-analysis of CCRT vs. RT alone in NPC treatment which included studies only done in endemic area. The results confirmed that CCRT was more beneficial compared with RT alone. However, the relative benefit of CCRT in endemic population might be less than that from previous meta-analyses.

Appraisal (嚴格評讀）

對找到的文章
進行critical appraisal

證據等級

Level	與[治療/預防/病因/危害]有關的文獻
1a	用多篇RCT所做成的綜合性分析(SR of RCTs)
1b	單篇RCT(有較窄的信賴區間)
1c	All or none
2a	用多篇世代研究所做成的綜合性分析
2b	單篇cohort及低品質的RCT
2c	Outcome research / ecological studies
3a	SR of case-control studies
3b	Individual case-control studies
4	Case-series(poor quality :cohort / case-control studies)
5	沒有經過完整評讀醫學文獻的專家意見

Grades of Recommendation

A	**consistent level 1 studies**
B	consistent level 2 or 3 studies ***or*** extrapolations from level 1 studies
C	level 4 studies ***or*** extrapolations from level 2 or 3 studies
D	level 5 evidence ***or*** troublingly inconsistent or inconclusive studies of any level

Item	AAMPICOT for therapy- Criteria	Comments
Answer	此文獻有沒有回答我的問題	有
Authors	作者群是這領域的專家嗎？	是
	有沒有利益衝突？	沒有
Method	本文獻研究設計是屬於以下那一類SR, RCT, Cohort, Case-control, Case series or report, Expert opinion	RCT
Population	取樣是否為隨機取樣？	是
	取的樣本是否具代表性？其特性是否接近我的病人	是，取樣標準與本病人不盡相同
	分組是否是隨機分組？	是
	分組是否採用盲法？	否
Intervention	給予實驗組的處置是否描述清楚，並且是臨床可行的？	是
Comparison	給予對照組的處置是否描述清楚，並且是臨床可行的？各種可能比較皆有了？	是
Outcome	測量了那些結果？是否用客觀的方式測量？	2, 3 and 5 years OS 是
	這些結果是否有統計學上的重要性？	是
	這些結果是否有臨床上的重要性？	是
	是否呈現結果的「數值」，「p值」，「信賴區間」，「檢力」？	是
Time	測量結果的時間點是否合宜？	是
	追蹤時間是否夠長？	是
	文獻發表時間？	2010

Apply

結合醫學倫理方法

將study的結果應用在病人身上

醫療現況	病人意願
55歲男性，鼻咽癌第三期合併頸部淋巴轉移。	病人願意配合治療。
生活品質	**社會脈絡**
使用影像導引強度調控放射線治療有助於降低急性及長期副作用。	此病人家庭支持度夠 未提及經濟問題

Audit

自我評估

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？有
- 我是否明確的陳述了我的問題？
  - 我的是否可以清楚的寫成PICO？是
- 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？是
- 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？是

在「搜尋最佳證據」方面的自我評估

- 我是否已盡全力搜尋？是
- 我是否知道我的問題的最佳證據來源？是
- 我是否從大量的資料庫來搜尋答案？是
- 我工作環境的軟硬體設備是否能支援我在遇到問題時進行立即的搜尋？是
- 我是否在搜尋上愈來愈熟練了？是
- 我會使用「斷字」、布林邏輯、同義詞、MeSH term，限制（limiters)等方法來搜尋？大致上會

關於「嚴格評讀文獻」方面的自我評估

- 我是否盡全力做評讀了？是
- 我是否了解Number need to treat 的意義？大致了解
- 我是否了解Likelihood Ratios的意義？大致了解
- 我是否了解worksheet每一項的意義？大致了解
- 評讀後，我是否做出了結論？是

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？盡量
- 我是否能將搜尋到的結論用病人聽得懂的方式解釋給病人聽？是
- 當搜尋到的最佳證據與實際臨床作為不同時，我如何解釋？臨床還是以病人的實際狀況為主

關於「改變醫療行為」的自我評估

- 當最佳證據顯示目前臨床策略需改變時，我是否遭遇任何阻止改變的阻力？否
- 我是否因此搜尋結果而改變了原來的治療策略？做了那些改變？否

關於「效率」的自我評估

- 這篇報告，我總共花了多少時間？大約十五個小時
- 我是否覺得這個進行實證醫學的過程是值得的？是

~THANK YOU~