

Department of Traditional Chinese Medicine 報告:R1曾碩平 指導:VS 林宏隆 時間:2012/02/06

臨床場景(Clinical scenario)分析

臨床情境 (Clinical Scenario)

- 56歲陳小姐於民國100年7月發現右側乳癌stage II,並於9/19施行手術
- 於10/27施行第二次化療後,由於化療後有
- 1.頭面部紅疹會癢會痛
- 2.吃東西後易腹悶感、嘔吐
- 3. 貧血和白血球低下

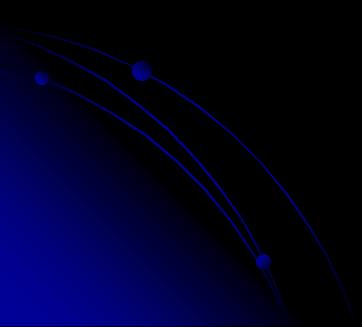
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(12/28:WBC:3.3 x1000/uL; Hgb:11.2 g/dL)

 等上述情形,10/29開始來中醫部門診就診,希望中藥 能改善其化療副作用

Patient's Concerns

• Whether traditional chinese medicine (TCM) may reduce the sideeffects of chemotherapy in breast cancer patients?



Background question

- There are some short term side effects that occur during the course of treatment and generally resolve within months of completion of therapy.
- They include fatigue, phlebitis, alopecia, nausea, vomiting, mucositis, anemia, and myelosuppression or neutropenia.

Background question

- The prevalence of cancer-related fatigue increases to 80 to 96% in patients undergoing chemotherapy.
- Chemotherapy-induced nausea and vomiting can be either acute (commencing shortly after administration and most severe during the next 6 to 8 hours) or delayed (occurring after 24 hours).
- Chemotherapy-induced mucositis is an important, doselimiting, and costly side effect of cancer therapy. It occurs in approximately 40% of patients who receive cancer chemotherapy.

Foreground question

• Do Chinese medicinal herbs treat the side-effects of chemotherapy in breast cancer patients?

EBM的五項步驟

• Asking

- 將病人的問題寫成PICO

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

PICO

P Patient	breast cancer patients receive chemotherapy
Intervention	Chinese medicinal herbs
Comparison	Nil
Outcome	reduce side-effects of chemotherapy

EBM的五項步驟

• Asking

- 將病人的問題寫成PICO
- 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

Search Strategy Design

Keywords:

Chinese medicinal herbs
Chemotherapy side effects
Breast cancer

Search Secondary Database

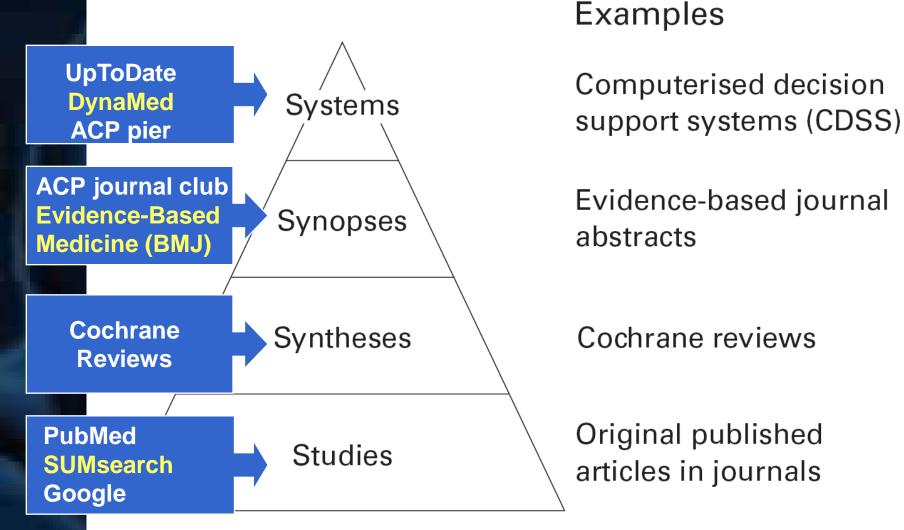


Figure "4S" levels of organisation of evidence from research.

Search Strategy Design

-Key words Chinese medicinal herbs Chemotherapy side effects Breast cancer

Database Sources : UpToDate : 1 results ACP Journal Club : 1 results DynaMed : 1 results The Cochrane Library : 1 results Pubmed : 4 results

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Pediatric	 Adjuvant chemotherapy for early stage HER2-negative breast cancer 		SHORT-TERM SIDE EFFECTS						
Patient	 Clinical features and management of locally advanced breast cancer 		Magnitude of the problem						
Graphics 💽	• Systemic treatment for metastatic breast cancer: Single agent chemotherapy		 Myelosuppression Gastrointestinal side effects 						
	Male breast cancer		Neurologic and musculoskeletal						
	 Systemic treatment for metastatic breast cancer: Selection of chemotherapy regimen 		toxicity • Weight gain						
	Neoadjuvant systemic therapy for breast cancer: Neoadjuvant chemotherapy		 Fatigue and anemia Use of epoetin and darbepoetin 						
	Systemic treatment for metastatic breast cancer: General principles		- Other therapies for fatigue						
	 Breast cancer during pregnancy and lactation: Treatment 		Vasomotor symptoms LONG-TERM SIDE EFFECTS						
	 Adjuvant medical therapy for HER2-positive early stage breast cancer 		Cognitive dysfunction						
	 Inflammatory breast cancer: Clinical features and treatment 		Ovarian failure						
	Systemic treatment for metastatic breast cancer: Combination chemotherapy		 Risk factors Amenorrhea and impact on 						
	 Neoadjuvant systemic therapy for breast cancer: Locoregional and adjuvant treatment 		prognosis - Use of aromatase inhibitors in						
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Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients (Review)

- Search methods
- We searched The Cochrane Breast Cancer Specialised Register (15/02/2007), The Cochrane Central Register of Controlled Trials (CENTRAL); (The Cochrane Library 2006, Issue 4); MEDLINE (1966 to December 2006); EMBASE (1990 to December 2006); and Chinese Biomedical Literature (2006, Issue 4).
- A number of journals were hand searched.
- Selection criteria
- Randomised controlled trials comparing chemotherapy with or without Chinese herbs in women with breast cancer.
- Data collection and analysis
- Two authors independently extracted the data, which were analysed using RevMan 4.2. For dichotomous data, we estimated the relative risk. For continuous data, we calculated the weighted mean difference.

Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients (Review)

Main results

- We identified seven randomised controlled trials involving 542 breast cancer patients undergoing or having recently undergone chemotherapy.
- All studies were conducted and published in China.
- We did not pool the results because few studies were identified and no more than two used the same intervention.
- All were of low quality and used CMH plus chemotherapy compared with chemotherapy alone.
- CMH combined with chemotherapy showed no statistically significant difference for the outcomes of phlebitis and alopecia. Only one study showed an improvement in nausea and vomiting, and in fatigue. Three indicated an improvement in white blood cells in the group receiving CMH. Two showed an increase in percentage changes in T-lymphocyte subsets CD4 and CD8. One study showed a statistically significant difference for CMH in percentage changes in T-lymphocyte subsets CD4. Two herbal compounds may have improved quality of life. One study reported that CMH may have some effect on reducing toxicity in liver and kidney, but differences were not statistically significant.

Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients (Review)

- Authors' conclusions
- This review provides limited evidence about the effectiveness and safety of Chinese medicinal herbs in alleviating chemotherapy induced short term side effects.
- Chinese medicinal herbs, when used together with chemotherapy, may offer some benefit to breast cancer patients in terms of bone marrow improvement and quality of life, but the evidence is too limited to make any confident conclusions.
- Well designed clinical trials are required before any conclusions can be drawn about the effectiveness and safety of CHM in the management of breast cancer patients.

Analysis 1.1. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 1 Nausea and vomiting.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

- Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone
- Outcome: I Nausea and vomiting

Study or subgroup	Treatment	Control	Risk Ratio	Risk Ratio
	n/N	r/N	M-H,Fixed,95% CI	M-H,Fixed,95% Cl
l Shenqi fuzheng injections p	plus chemotherapy versus cher	notherapy alone		
Li 2002	19/40	24/35		0.69 [0.47, 1.03]
2 Aidi injections plus chemo	therapy versus chemotherapy	alone		
Yang 2004	19/31	23/28		0.75 [0.54, 1.04]
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Analysis 1.2. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 2 Nausea and vomiting improved.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 2 Nausea and vomiting improved

Study or subgroup	Treatment		Control		Mean Difference					Mean Difference		
	Ν	Mean(SD)	Ν	Mean(SD)		IV,F	ixed,95	% CI		IV,Fixed,95% CI		
I Aifukang capsules plu	us chemotherapy vers	sus chemotherapy alone										
Situ 2005	61	7.21 (0.64)	59	6.37 (0.87)			+			0.84 [0.57, 1.11]		
									1			
					-10	-5	0	5	10			
					Favours	control		Favours	treatment			

Analysis 1.3. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 3 Alopecia.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 3 Alopecia

Study or subgroup	Treatment r/N	Control n/N	Risk Ratio M-H,Fixed,95% CI						Risk Ratio M-H,Fixed,95% Cl	
l Shenqi fuzheng injections p	plus chemotherapy versus cher	motherapy alone								
Li 2002	10/40	10/35			_	┽				0.88 [0.41, 1.85]
			1							
			QI	0.2	0.5	I	2	5	10	
			Favou	rs trea	atmeni	t	Favou	rs cor	ntrol	



Analysis 1.4. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 4 Fatigue.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 4 Fatigue

Study or subgroup	Treatment				Mean Difference					
	Ν	Mean(SD)	Ν	Mean(SD)		IV,F	fixed,95		IV,Fixed,95% CI	
I Aifukang capules plus	s chemotherapy ver	rsus chemotherapy alone								
Situ 2005	61	10.11 (1.08)	59	9.31 (1.29)			+			0.80 [0.37, 1.23]
					-10	-5	0	5	10	
						control		Favours	treatment	

Analysis 1.5. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 5 Phlebitis.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 5 Phlebitis

Study or subgroup	Treatment	Control	Risk Ratio	Risk Ratio		
	n/N	n/N	M-H,Fixed,95% CI	M-H,Fixed,95% Cl		
I Aidi injections plus chemo	otherapy versus chemotherapy	/ alone				
Yang 2004	17/31	15/28		1.02 [0.64, 1.64]		
2 Shenqi fuzheng injection p	olus chemotherapy versus cher	motherapy alone				
Li 2002	4/40	7/35		0.50 [0.16, 1.57]		
			0.1 0.2 0.5 1 2 5 10			
			Favours treatment Favours control			

Analysis 1.6. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 6 White blood cell reduction.

Review. Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

- Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone
- Outcome: 6 White blood cell reduction

Study or subgroup	Treatment	Control	Risk Ratio	Risk Ratio
	n/N	n/N	M-H,Fixed,95% CI	M-H,Fixed,95% Cl
I Aidi injections plus chemo	otherapy versus chemotherapy	alone		
Yang 2004	27/31	25/28	+	0.98 [0.81, 1.18]
2 Shenqi fuzheng injections	plus chemotherapy versus cher	motherapy alone		
Li 2002	12/40	18/35		0.58 [0.33, 1.03]
3 Shenmai injections plus ch	nemotherapy versus chemother	rapy alone		
Huo 2003	6/26	20/22	———	0.25 [0.12, 0.52]
				L
			Favours treatment Favours contro	k

Analysis 1.7. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 7 White blood cell change after treatment.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

- Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone
- Outcome: 7 White blood cell change after treatment

Study or subgroup	Treatment		Control					Mean Difference						
	Ν	Mean(SD)	Mean(SD)		IV,F	IV,Fixed,95% CI								
I Chinese herbs decoo	tion plus chemother.	apy versus chemotherap	oy alone											
Fang 1995	30	7.2 (1.2)	38	5(1)			+			2.20 [1.67, 2.73]				
2 Shenmai injections pl	lus chemotherapy ver	rsus chemotherapy alon	e											
Liu 2000	40	5.3 (1.3)	40	4.7 (1.2)			+			0.60 [0.05, 1.15]				
3 Jiawei Guilu Erxian D	an plus chemotherap	y versus chemotherapy	plus batilol alor	e										
Hong 2005	62	4.86 (2.37)	30	3.95 (1.71)		+				0.91 [0.06, 1.76]				
					-10	-5	0	5	10					
					Favours	control	I	Favours	treatment					

Analysis 1.8. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 8 Percentage change of CD3-positive cells (Tlymphocyte subsets).

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 8 Percentage change of CD3-positive cells (Tlymphocyte subsets)

Study or subgroup	Treatment			D	M Viffere	Mean Difference				
	Ν	Mean(SD) N		Mean(SD)		IV,F	IV,Fixed,95% CI			
I Shenqi fuzheng inject	ions plus chemothe	rapy versus chemother	apy alone							
Li 2002	40	53.9 (9.6)	35	52.4 (10.9)		_	+	·		1.50 [-3.18, 6.18]
2 Aidi injections plus d	nemotherapy versus	chemotherapy alone								
Yang 2004	31	52.4 (6.9)	28	42.2 (5.9)						10.20 [6.93, 13.47]
3 Shenmai injections pl	us chemotherapy ve	ersus chemotherapy alo	me							
Liu 2000	40	61.11 (9.79)	40	61.71 (7.76)			-+	_		-0.60 [-4.47, 3.27]
					-10	-5	0	5	10	
					Favours	s control		Favours	s treatment	

Analysis 1.9. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 9 Percentage change of CD4-positive cells (Tlymphocyte subsets).

Review. Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 9 Percentage change of CD4-positive cells (Tlymphocyte subsets)

Study or subgroup	Treatment	Control				Di		Mean Difference		
	Ν	Mean(SD) N		Mean(SD)		IV,Fid	IV,Fixed,95% CI			
l Shenqi fuzheng injecti	on plus chemother	apy versus chemotherap	oy alone							
Li 2002	40	38 (8)	35	35 (7.3)			+			3.00 [-0.46, 6.46]
2 Aidi injection plus che	motherapy versus	chemotherapy alone								
Yang 2004	31	46.7 (6.5)	28	35.1 (5.4)					-	1.60 [8.56, 14.64]
3 Shenmai injection plu:	s chemotherapy ve	rsus chemotherapy alon	e							
Liu 2000	40	35.15 (5.21)	40	29.49 (3.92)					-	5.66 [3.64, 7.68]
					-10	-5	0	5	10	
					Favours o	ontrol		Favours	treatment	

Analysis 1.10. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 10 Percentage change of CD8-positive cells (Tlymphocyte subsets).

Review. Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 10 Percentage change of CD8-positive cells (Tlymphocyte subsets)

Study or subgroup	Treatment		Control				Mean Difference						
	Ν	Mean(SD)	Ν	Mean(SD)		IV,Fi×	ed,95	5% CI		IV,Fixed,95% CI			
I Shenqi fuzheng injectio	on plus chemother	apy versus chemotherap	y alone										
Li 2002	40	25.6 (5.3)	35	27.8 (6.2)			+			-2.20 [-4.83, 0.43]			
2 Aidi injection plus cher	motherapy versus o	chemotherapy alone											
Yang 2004	31	27.1 (3.5)	28	21.4 (3.1)				— —		5.70 [4.02, 7.38]			
3 Shenmai injection plus	chemotherapy ver	rsus chemotherapy alon	e										
Liu 2000	40	21.42 (4.38)	40	19.34 (2.04)						2.08 [0.58, 3.58]			
						-	<u> </u>		10				
					-10	-5	0	5	10				
					Favours	control		Favours	treatment				

Analysis 1.11. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 11 Thrombocytopenia.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 11 Thrombocytopenia

Study or subgroup	Treatment	Control	Risk Ratio							Risk Ratio
	n/N	r/N	M-H,Fixed,95% CI						M-H,Fixed,95% Cl	
l Shenqi fuzheng injections plu	us chemotherapy versus chen	notherapy alone								
Li 2002	2/40	3/35	_			+				0.58 [0.10, 3.29]
			I							
			QI	0.2	0.5	I	2	5	10	
			Favour	rs trea	atment		Favou	rs cor	ntrol	



Analysis 1.12. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 12 Quality of life: EuroQLQ-BR23 symptoms scores.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 12 Quality of life: EuroQLQ-BR23 symptoms scores

Study or subgroup	Treatment	Control				C	M Differe	Mean Difference		
	Ν	Mean(SD) N Mean(SD)			IV,F	ïxed,	IV,Fixed,95% CI			
l Aifukang capules plus	s chemotherapy ve	rsus chemotherapy alon	e							
Situ 2005	61	198.23 (7.25)	59	183.76 (10.46)					•	4.47 [1.24, 7.70]
						1				
					-10	-5	0	5	10	
					Favours	control		Favours	treatment	



Analysis 1.13. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 13 Quality of life: improvement in Karnofsky performance status.

Review. Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 13 Quality of life: improvement in Karnofsky performance status

Study or subgroup	Treatment r/N	Control r/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI		
I Shenqi fuzheng injections p	plus chemotherapy versus che	emotherapy alone				
Li 2002	20/40	8/35		2,19 [1.10, 4.33]		
2 Aidi injections plus chemo	therapy versus chemotherapy	/ alone				
Yang 2004	17/31	8/28		1.92 [0.98, 3.74]		
			0.1 0.2 0.5 1 2 5 10			
			Favours control Favours treatment			

Analysis 1.14. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 14 Liver toxicity.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 14 Liver toxicity

Study or subgroup	Treatment	Control	Risk Ratio	Risk Ratio M-H,Fixed,95% CI
	n/N	n/N	M-H,Fixed,95% CI	
l Shenqi fuzheng injections	plus chemotherapy verse chem	notherapy alone		
Li 2002	3/40	3/35		0.88 [0.19, 4.06]
			0.1 0.2 0.5 1 2 5 10	
			Favours treatment Favours control	
		2		

Analysis 1.15. Comparison 1 Chinese medicinal herbs plus chemotherapy versus chemotherapy alone, Outcome 15 Kidney toxicity.

Review: Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients

Comparison: I Chinese medicinal herbs plus chemotherapy versus chemotherapy alone

Outcome: 15 Kidney toxicity

Study or subgroup	Treatment	Control n/N				Risk	Risk Ratio			
	n/N		M-H,Fixed,95% Cl						M-H,Fixed,95% CI	
l Shenqi fuzheng injection p	olus chemotherapy verses chem	notherapy alone								
Li 2002	1/40	1/35	-			+			-	0.88 [0.06, 13.48]
			0.1	0.2	0.5	Т	2	5	10	
			Favours	treat	ment		Favou	rs cor	ntrol	



EBM的步驟

Asking

- 將病人的問題寫成PICO

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

Appraisal

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



- Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients (Review)
 - Level of evidence: 1a
 - Source: Cochrane Database Systematic Review, 2009
 - Authors: Zhang M, Liu X, Li J, He L, Tripathy D

1. Did the review ask a clearly-focused question?

Consider if the question is 'focused' in terms of:

- the population studied
- the intervention given or exposure
- the outcomes considered

Yes Can't tell No

- Aim: find whether traditional chinese medicine(TCM) may improve the side-effects of chemotherapy in breast cancer patients
- This review identified seven studies of six different herbal remedies to treat the side effects of chemotherapy in breast cancer patients.
- All studies compared CMH plus chemotherapy versus chemotherapy alone.
- All the reported outcomes were measured at the end of treatment.

2. Did the review include the right type of study?

Consider if the included studies:

- address the review's question
- have an appropriate study design



- Types of studies: RCTs, regardless of blinding, language or publication status.
- Types of participants: Female breast cancer patients receiving chemotherapy and experiencing chemotherapy-induced side effects.
- Types of interventions: traditional chinese medicine
 TCM with conventional therapy vs. conventional therapy

3. Did the reviewers try to identify all relevant studies?

Consider:

- which bibliographic databases were used
- if there was follow-up from reference lists
- if there was personal contact with experts
- if the reviewers searched for unpublished studies
- if the reviewers searched for non-English-language studies
 - Authors of the review searched the following electronic databases regardless of language and publication status
 - Database: Cochrane Stroke Group Trials, CENTRAL, MEDLINE, EMBASE, CINAHL, AMED, ISI Science Citation Index

🛛 Yes

Can't tell

No

- Search reference lists of all relevant papers
- Authors of relevant studies were contacted to elicit any unpublished or on-going studies

4. Did the reviewers assess the quality of the included studies?

Consider:

- if a clear, pre-determined strategy was used to determine which studies were included. Look for:
 - a scoring system
 - more than one assessor
- Two authors independently allocated each trial to one of the three quality categories described in the Cochrane Reviewers' Handbook (Alderson 2004). When disputes arose about category allocation, again we attempted resolution by discussion or by consulting a third author.

Yes

Can't tell

🗆 No

- We assessed trial quality according to the following criteria (Schulz 1995).
- 1. Minimisation of selection bias.
 - a) Was the randomisation procedure adequate?
 - b) Was allocation concealment adequate?
- 2. Minimisation of performance bias were the patients and individuals administering treatment blind to group allocation?
- 3. Minimisation of attrition bias.
 - a) Were withdrawals and dropouts completely described?
 - b) Was analysis by intention to treat?
- 4. Minimisation of detection bias were outcome assessors blind to the intervention?

5. If the results of the studies have been combined, was it reasonable to do so?

Consider whether:

- the results of each study are clearly displayed
- the results were similar from study to study (look for tests of heterogeneity)
- the reasons for any variations in results are discussed

🛾 Yes 🛛 Can't tell



- The results of each study are clearly displayed.
- The results are not similar from study to study.
- The reasons for the variations in results are not discussed.

6. How are the results presented and what is the main result?

Consider:

- how the results are expressed (e.g. odds ratio, relative risk, etc.)
- how large this size of result is and how meaningful it is
- how you would sum up the bottom-line result of the review in one sentence
- CMH combined with chemotherapy showed no statistically significant difference for the outcomes of phlebitis and alopecia.
- Only one study showed an improvement in nausea and vomiting, and in fatigue.
- Three indicated an improvement in white blood cells in the group receiving CMH.
- Two showed an increase in percentage changes in T-lymphocyte subsets CD4 and CD8.
- One study showed a statistically significant difference for CMH in percentage changes in T-lymphocyte subsets CD3, CD4 and CD8.
- Two herbal compounds may have improved quality of life.
- One study reported that CMH may have some effect on reducing toxicity in liver and kidney, but differences were not statistically significant.
- A total of 542 participants were included in the seven studies.

7. How precise are these results?

Consider:

- if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?
- if a p-value is reported where confidence intervals are unavailable
- Chinese medicinal herbs, when used together with chemotherapy, may offer some benefit to breast cancer patients in terms of bone marrow improvement and quality of life, but the evidence is too limited to make any confident conclusions.
- Well designed clinical trials are required before any conclusions can be drawn about the effectiveness and safety of CHM in the management of breast cancer patients.

8. Can the results be applied to the local population?



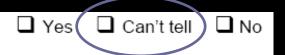
Consider whether:

- the population sample covered by the review could be different from your population in ways that would produce different results
- your local setting differs much from that of the review
- you can provide the same intervention in your setting
- The population sample covered by the review is not different from my population.
- My local setting doesn't differ from that of the review.
- I can provide the same intervention in my setting.

9. Were all important outcomes considered?

Consider outcomes from the point of view of the:

- individual
- policy makers and professionals
- family/carers
- wider community



- Breast cancer patients treated with chemotherapy
- Chinese herbal medicine, when used together with chemotherapy, may have the potential to offer benefits in terms of improvements in marrow suppression and the immune system, and in the overall status of quality of life, but the evidence is too limited to make any conclusions with confidence.
- Clinicians
- There are currently no data to make specific recommendations on whether herbal therapy should be used, and which specific regimens would be suited to specific conditions.
- Funders and policy makers
- This review does not provide sufficient evidence to either support or refute the use of TCM or CMH combined with chemotherapy for alleviation of the side effects of chemotherapy in breast cancer patients.

Yes Can't tell No

10. Should policy or practice change as a result of the evidence contained in this review?

Consider:

- whether any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?
- This intervention seems to have enough supporting evidence from both ancient practice and modern studies to be worth further investigation in some areas.
- This review does not provide sufficient evidence to either support or refute the use of TCM or CMH combined with chemotherapy for alleviation of the side effects of chemotherapy in breast cancer patients.
- There has been only limited assessment of the safety of herbal therapy.

結合實證醫學的結果、臨床專業經驗給予病人建議

醫療現況	病人意願					
中藥對於化療中的乳癌患者應	接受化療的乳癌病患,其化療					
有改善其化療副作用的效果,	副作用明顯者希望嘗試以傳統					
但其研究結果仍未有一制性。	中藥來減緩化療副作用。					
生活品質	社會脈絡					
若能使疲勞、骨髓抑制、噁心	化療中副作用減輕,可使病人					
嘔吐等症狀減緩,可改善病人	日常生活依賴程度減少及社交					
生活品質。	活動參與度增加。					

Audit

Self-Evaluation

- 能提出結構完整的臨床問題
- 能更有效率地搜尋臨床問題的相關研究
- 了解系統性文獻的評讀重點
- 可將審慎評估之結果融入臨床診療中,適當應用於
 病人身上

Thanks for your attention