實證醫學 病例討論報告 Evidence-Based Medicine

職級:R1

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Outline

- Clinical scenario-臨床場景
- Asking-提出問題
- Acquire- 搜尋資料
- Appraisal-嚴格評讀
- Apply-臨床應用
- · Audit-自我評估

Clinical scenario

PATIENT'S PROFILE

- The 43 year-old male had no any underlying disease.
- This time, he suffered from sudden hearing loss of right ear for 2 days. Tinnitus and fullness of right ear were also complaint. He denied other discomfortable such like vertigo, fullness and otalgia.
- The conventional therapy with oral steroid and intravenous dextran were prescribed after admission.

ASKING Background question

Q1: What is Sudden sensorineural hearing loss?

Q2: What is the current therapy?

Q3: The prognosis of Sudden sensorineural hearing loss?

Q1: What is Sudden sensorineural hearing loss?

- 資料出處:Uptodate
- Answer:
 - The US National Institute for Deafness and Communication Disorders (NICDC) specifies the following criteria for the diagnosis of SSNHL:
 - idiopathic hearing loss of at least 30 dB over at least three test frequencies occurring over a 72-hour period.

Q1: What is Sudden sensorineural hearing loss?

- 資料出處:Uptodate
- Answer:

Main causes of sudden sensorineural hearing loss (SSNHL)*

Infections

Viral cochleitis associated with herpesviruses, parainfluenza virus, influenza, mumps, measles, rubella, or HIV; bacterial meningitis; Mycoplasma pneumoniae infection; Lyme disease; tuberculosis, syphilis, or fungal infection

Ototoxic drugs

Aminoglycosides, vancomycin, erythromycin, loop diuretics, antimalarials, cisplatin, sildenafil, cocaine

Neoplasms

Acoustic neurinoma; meningeal carcinomatosis; lymphoma, leukemia, or plasma cell dyscrasia

Trauma

Head injury, barotraumas; noise exposure

Autoimmune disease

Autoimmune inner ear disease; Cogan's syndrome; Susac syndrome; systemic lupus erythematosus; antiphospholipid antibody sydrome; rheumatoid arthritis; Sjögren's syndrome; relapsing polychondritis; vasculitides (polyarteritis nodosa, Behçet's disease, Kawasaki disease, granulomatosis with polyangiitis (Wegener's), temporal arteritis, or primary central nervous system vasculititis)

Vascular disorder

Vertebrobasilar cerebrovascular accident or transient ischemic attack; cerebellar infarction; inner ear hemorrhage

Varied causes

Meniere disease, otosclerosis; Paget's disease; multiple sclerosis; sarcoidosis; hypothroidism; idiopathic SSNHL

^{*} In many of the conditions listed, SSNHL can be the presenting manifestation of the disease. Sometimes, both ears may be affected simultaneously. Reproduced with permission from: Schattner A, Halperin D, Wolf D, Zimhony O. Enteroviruses and sudden deafness. CMAJ 2003; 168:1421. Copyright © 2003 Canadia Medical Association.

Question 2~ What is the current therapy??

資料出處:Uptodate

• Answer:

Oral glucocorticoids

• The recommended dose for <u>prednisone</u> is 1 mg/kg/day (to 60 mg maximum) given as a single dose for 10 to 14 days. Some have advised that treatment be extended another 10 days if a partial response is found at the end of the initial course.

Intratympanic glucocorticoids

• Dosing regimens for intratympanic glucocorticoids vary between studies, but include dexamethasone 10 to 24 mg/mL or methylprednisolone 30 to 40 mg/mL; dosing frequency ranges from a few times a day through a pressure-equalizing tube to several days consecutively or once weekly.

Question 2~ What is the current therapy??

- 資料出處:Uptodate
- Answer:

Antiviral agents

• In the absence of larger trials of antivirals, we typically treat SSNHL of unknown origin with a 7- to 10-day course of an anti-HSV antiviral such as <u>valacyclovir</u> 1 g three times daily or <u>famciclovir</u> 500 mg three times daily, in addition to high-dose <u>prednisone</u>.

Other

- Hyperbaric oxygen
- Apheresis of fibrinogen and low density lipoprotein (LDL)
- Oral magnesium and Zinc
- Intravenous Hypaque and dextran
- Tympanotomy and sealing of the round window membrane

Question 3~

The prognosis of Sudden sensorineural hearing loss?

- 資料出處:Uptodate
- Answer:
- The prognosis for sudden sensorineural hearing loss (SSNHL) is reasonably good, especially if it is a high- or low-frequency hearing loss pattern and not flat across all frequencies.
- The prognosis is poor in patients with profound hearing loss across all frequencies: approximately three-quarters of such patients have no recovery of hearing [25].

Question 3~

The prognosis of Sudden sensorineural hearing loss?

- 資料出處:Uptodate
- Answer:
- Among patients who recovered at least partially, 54.5 percent showed improvement within 10 days.
- Approximately two-thirds of patients with idiopathic SSNHL will experience recovery, although this recovery is often not complete.
- Prognosis is worse in patients who are older and may be worse in those with vertigo, although this is not a consistent finding.
- Patients who have not improved within three months will generally not recover significantly.

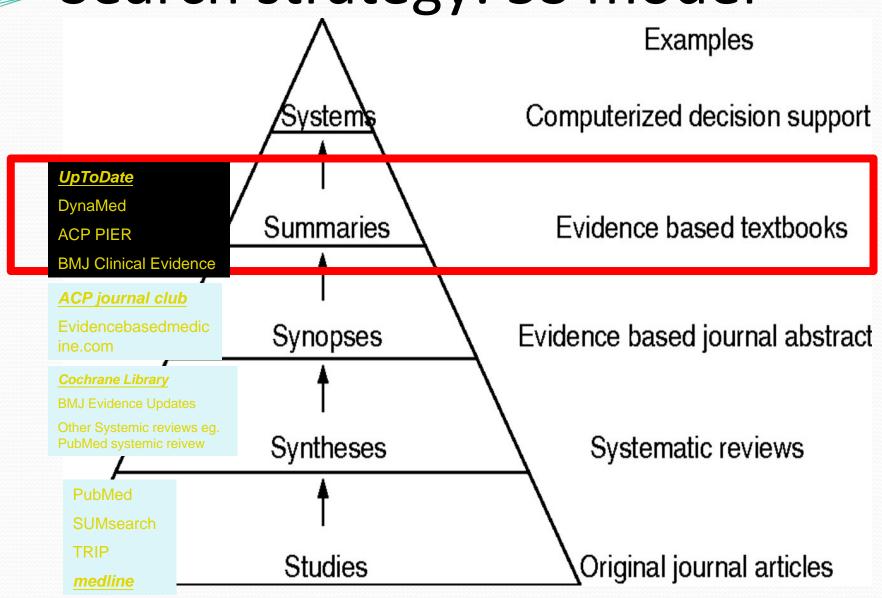
Foreground questions

Hyperbaric oxygen是否能有效改善Sudden sensorineural hearing loss預後

PICO

Patient	43 year old male present with sudden hearing loss, tinnitus and fullness of right ear for 2 days
Intervention	Hyperbaric oxygen
Comparison	Conventional therapy with oral steroid and intravenous dextran
Outcome	Pure tone audiometry (PTA)

Search strategy: 55 model





搜尋Summaries

- Key word:
 - Sudden hearing loss
- 搜尋到的文章標題:
 - Sudden sensorineural hearing loss
 - Peter C Weber, MD, FACS
 - This topic last updated:十月 24, 2012.

搜尋到的文章內容

Hyperbaric oxygen

- A systematic review concluded that hyperbaric oxygen therapy may be of some benefit when administered early in the course of SSNHL, although the clinical significance of the benefit was unclear and the underlying studies had methodologic shortcomings.
- In one institution, patients seen between 2002 and 2009 were treated with intravenous glucocorticoids and hyperbaric oxygen, and those seen between 2009 and 2011 were treated with systemic plus intratympanic glucocorticoids; patients who received intratympanic steroids were more likely to recover hearing.

將Summaries搜尋的結果應用到我的病人

• 根據Summaries的結果,目前對於Hyperbaric oxygen無明確改善PTA證據。

Search strategy: 55 model Examples System**** Computerized decision support **UpToDate** DynaMed **ACP PIER** Evidence based textbooks Summaries **BMJ Clinical Evidence** ACP journal club Synopses Evidence based journal abstract **Cochrane Library** Syntheses Systematic reviews **PubMed SUMsearch TRIP** Original journal articles Studies medline

搜尋Synopses, ACP Journal Club



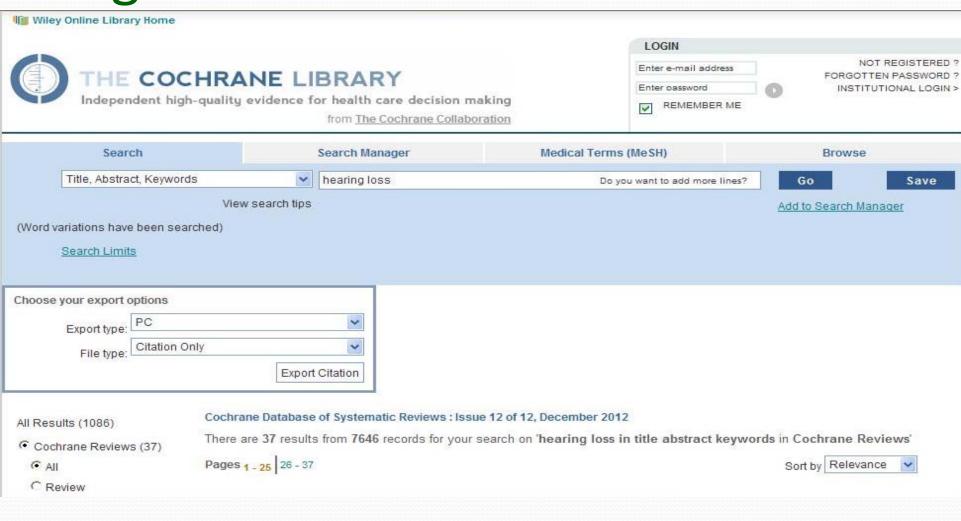
將Synopses搜尋的結果應用到我的 病人

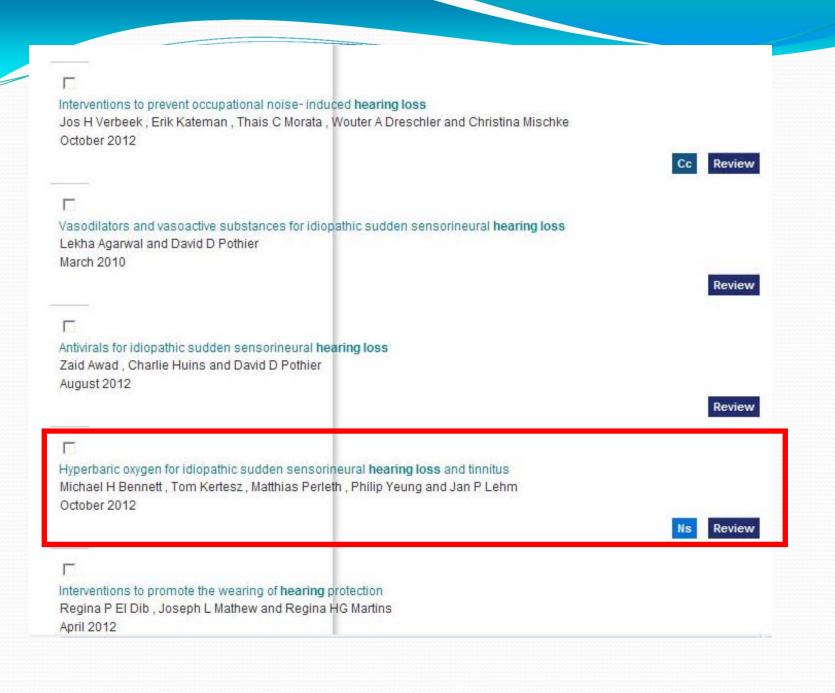
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Search strategy: 55 model Examples System**** Computerized decision support **UpToDate** DynaMed **ACP PIER** Summaries Evidence based textbooks **BMJ Clinical Evidence** ACP journal club Synopses Evidence based journal abstract **Cochrane Library Syntheses** Systematic reviews PubMed **SUMsearch TRIP** Original journal articles **Studies**

medline

搜尋 syntheses, Cochrane Central Register of Controlled Trials





Bennett MH, Kertesz T, Perleth M, Yeung P, Lehm JP



Objectives

• To assess the benefits and harms of HBOT for treating ISSHL and/or tinnitus.

Search methods

- We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; Database of Randomised Trials in HyperbaricMedicine (DORCTHIM); CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials.
- The date of the most recent search was 2 May 2012, following previous searches in 2009, 2007 and 2004.

Selection criteria

 Randomised studies comparing the effect on ISSHL and tinnitus of HBOT and alternative therapies.

- Data collection and analysis
 - Three authors evaluated the quality of trials using the 'Risk of bias' tool and extracted data from the included trials.

Main results

- Seven trials contributed to this review (392 participants). The studies were small and of generally poor quality.
- Pooled data from two trials did not show any significant improvement in the chance of a 50% increase in hearing threshold on pure-tone average with HBOT (risk ratio (RR) with HBOT 1.53, 95% confidence interval (CI) 0.85 to 2.78, P = 0.16), but did show a significantly increased chance of a 25% increase in pure-tone average (RR 1.39, 95% CI 1.05 to 1.84, P = 0.02).
 - There was a 22% greater chance of improvement with HBOT
 - the number needed to treat (NNT) to achieve one extra good outcome was 5 (95% CI 3 to 20).
 - There was also an absolute improvement in average pure-tone audiometric threshold following HBOT (mean difference (MD) 15.6 dB greater with HBOT, 95% CI 1.5 to 29.8, P = 0.03).
- The significance of any improvement in tinnitus could not be assessed.
- There were no significant improvements in hearing or tinnitus reported for chronic presentation (sixmonths) of ISSHL and/or tinnitus.

Comparison 1. Acute presentation - recovery of hearing as measured by audiometry

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Greater than 50% return of	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
hearing				
1.1 Mild hearing loss	1	17	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.79, 2.55]
1.2 Moderate hearing loss	1	20	Risk Ratio (M-H, Random, 95% CI)	1.2 [0.54, 2.67]
1.3 Severe hearing loss	1	27	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.29, 3.88]
1.4 Over all grades	2	114	Risk Ratio (M-H, Random, 95% CI)	1.53 [0.85, 2.78]
2 Greater than 25% return of hearing	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Mild hearing loss	1	17	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.86, 2.02]
2.2 Moderate hearing loss	1	20	Risk Ratio (M-H, Fixed, 95% CI)	1.33 [0.74, 2.41]
2.3 Severe hearing loss	1	27	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.56, 2.91]
2.4 Over all grades	2	114	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [1.05, 1.84]
3 Mean improvement in PTA (% baseline)	1	50	Mean Difference (IV, Fixed, 95% CI)	37.3 [21.75, 52.85]
4 Mean absolute improvement in PTA > 20 dB	1	20	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.14, 65.90]
5 Mean hearing improvement over all frequencies (dB)	4	169	Mean Difference (IV, Random, 95% CI)	15.64 [1.45, 29.83]
5.1 Mild hearing loss	1	19	Mean Difference (IV, Random, 95% CI)	0.20 [-9.95, 10.35]
5.2 Moderate hearing loss	1	22	Mean Difference (IV, Random, 95% CI)	19.27 [5.17, 33.37]
5.3 Severe hearing loss	1	14	Mean Difference (IV, Random, 95% CI)	37.7 [22.87, 52.53]
5.4 Over all grades	3	114	Mean Difference (IV, Random, 95% CI)	9.0 [0.44, 17.56]

Analysis I.I. Comparison I Acute presentation - recovery of hearing as measured by audiometry, Outcome I Greater than 50% return of hearing.

Review: Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus

Comparison: I Acute presentation - recovery of hearing as measured by audiometry

Outcome: I Greater than 50% return of hearing

Study or subgroup	HBOT	Control	Risk Ratio M-	Weight	Risk Ratio M-
	n/N	n/N	H,Random,95% CI		H,Random,95% Cl
I Mild hearing loss					
Cavallazzi 1996	8/9	5/8	 	100.0 %	1.42 [0.79, 2.55]
Subtotal (95% CI)	9	8	-	100.0 %	1.42 [0.79, 2.55]
Total events: 8 (HBOT), 5 (Co	ontrol)				
Heterogeneity: not applicable					
Test for overall effect: Z = 1.18	8 (P = 0.24)				
2 Moderate hearing loss					
Cavallazzi 1996	6/10	5/10	-	100.0 %	1.20 [0.54, 2.67]
Subtotal (95% CI)	10	10		100.0 %	1.20 [0.54, 2.67]
Study or subarrup	НВОТ	Control	Risk Ratio	Weight	(Continued) Risk Ratio
Study or subgroup	HBOI	Control	M- H,Random,95%	vveignt	M- H,Random,95%
	n/N	n/N	CI		CI CI
Test for overall effect: $Z = 0.45$	5 (P = 0.66)				
3 Severe hearing loss Cavallazzi 1996	4/15	3/12		100.0 %	1.07 [0.29, 3.88]
Subtotal (95% CI)	15	12		100.0 %	1.07 [0.29, 3.88]
Total events: 4 (HBOT), 3 (Co					,
Heterogeneity: not applicable					
Test for overall effect: $Z = 0.10$ 4 Over all grades	0 (P = 0.92)				
Cavallazzi 1996	18/34	13/30	- -	63.3 %	1.22 [0.73, 2.05]
Fattori 2001	17/30	5/20		36.7 %	2.27 [1.00, 5.15]
Subtotal (95% CI)	64	50		100.0 %	1.53 [0.85, 2.78]
Total events: 35 (HBOT), 18 (Control)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		10010 ,0	133 [3.33, 2.73]
Heterogeneity: Tau ² = 0.08; C		$P = 0.20$); $I^2 = 38\%$			
Test for overall effect: $Z = 1.4$	I (P = 0.16)				
			0.1 0.2 0.5 1 2 5 10		
			0.1 0.2 0.5 1 2 5 10 Favours control Favours HBOT		

Analysis 1.2. Comparison I Acute presentation - recovery of hearing as measured by audiometry, Outcome 2 Greater than 25% return of hearing.

Review. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus

Comparison: I Acute presentation - recovery of hearing as measured by audiometry

Outcome: 2 Greater than 25% return of hearing

Study or subgroup	HBOT	Control	Risk Ratio	Weight	Risk Ratio			
	n/N	n/N	M-H,Fixed,95% CI		M-H,Fixed,95% CI			
I Mild hearing loss								
Cavallazzi 1996	9/9	6/8	-	100.0 %	1.32 [0.86, 2.02]			
Subtotal (95% CI)	9	8	-	100.0 %	1.32 [0.86, 2.02]			
Total events: 9 (HBOT), 6 (Co	ntrol)							
Heterogeneity: not applicable								
Test for overall effect: Z = 1.25	5 (P = 0.21)							
2 Moderate hearing loss								
Cavallazzi 1996	8/10	6/10		100.0 %	1.33 [0.74, 2.41]			
Subtotal (95% CI)	10	10	-	100.0 %	1.33 [0.74, 2.41]			
Total events: 8 (HBOT), 6 (Co	ntrol)							
Heterogeneity: not applicable								
Test for overall effect: $Z = 0.95$	5 (P = 0.34)							
3 Severe hearing loss								
Cavallazzi 1996	8/15	5/12	-	100.0 %	1.28 [0.56, 2.91]			
Subtotal (95% CI)	15	12	-	100.0 %	1.28 [0.56, 2.91]			
Total events: 8 (HBOT), 5 (Co	ntrol)							
Heterogeneity: not applicable								
Test for overall effect: $Z = 0.59$	9 (P = 0.56)							
4 Over all grades								
Cavallazzi 1996	25/34	17/30	-	57.8 %	1.30 [0.89, 1.88]			
Fattori 2001	25/30	11/20	-	42.2 %	1.52 [0.99, 2.32]			
Subtotal (95% CI)	64	50	•	100.0 %	1.39 [1.05, 1.84]			
Total events: 50 (HBOT), 28 (Control)								
	Heterogeneity: $Chi^2 = 0.29$, $df = 1$ ($P = 0.59$); $I^2 = 0.0\%$							
Test for overall effect: $Z = 2.30$) (P = 0.022)							

Analysis I.3. Comparison I Acute presentation - recovery of hearing as measured by audiometry, Outcome 3 Mean improvement in PTA (% baseline).

Review: Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus

Comparison: I Acute presentation - recovery of hearing as measured by audiometry

Outcome: 3 Mean improvement in PTA (% baseline)

Study or subgroup	HBOT		Control		Diff	Mean Terence	Weight	Mean Difference	
	N	Mean(SD)	N	Mean(SD)	IV,Fixe	ed,95% CI		IV,Fixed,95% CI	
Fattori 2001	30	61.3 (33.6)	20	24 (22.5)		-	100.0 %	37.30 [21.75, 52.85]	
Total (95% CI)	30		20			•	100.0 %	37.30 [21.75, 52.85]	
Heterogeneity: not app	Heterogeneity: not applicable								
Test for overall effect: $Z = 4.70 (P < 0.00001)$									
Test for subgroup differences: Not applicable									
						ı	L		
				-	100 -50	0 50	00		
				F	avours control	Favours HB0	DT)		

Analysis I.4. Comparison I Acute presentation - recovery of hearing as measured by audiometry, Outcome 4 Mean absolute improvement in PTA > 20 dB.

Review: Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus

Comparison: I Acute presentation - recovery of hearing as measured by audiometry

Outcome: 4 Mean absolute improvement in PTA > 20 dB

Study or subgroup	HBOT	Control	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,95% CI		M-H,Fixed,95% CI
Hoffmann 1995b	1/10	0/10		100.0 %	3.00 [0.14, 65.90]
Total (95% CI)	10	10	-	100.0 %	3.00 [0.14, 65.90]
Total events: I (HBOT), 0	(Control)				
Heterogeneity: not applica	ible				
Test for overall effect: Z =	0.70 (P = 0.49)				
Test for subgroup differen	ces: Not applicable				
			0.001 0.01 0.1 1 10 100 1000		
			Favours control Favours HBOT		

Analysis 1.5. Comparison I Acute presentation - recovery of hearing as measured by audiometry, Outcome 5 Mean hearing improvement over all frequencies (dB).

Review: Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus

Comparison: I Acute presentation - recovery of hearing as measured by audiometry

Outcome: 5 Mean hearing improvement over all frequencies (dB)

Study or subgroup	HBOT N	Mean(SD)	Control	Mean(SD)	Mean Difference IV.Random.95% CI	Mean Difference IV,Random,95% CI
		11001(50)		1 (55)	Try sales in party sales	THE METHOD IN COLUMN
I Mild hearing loss	13	22.52.712.70	,	22.22 (0.21)	<u> </u>	0201 005 10351
Topuz 2004	13	22.53 (12.68)	6	22.33 (9.31)	Ţ	0.20 [-9.95, 10.35]
Subtotal (95% CI)	13		6		†	0.20 [-9.95, 10.35]
Heterogeneity: not applicabl						
Test for overall effect: $Z = 0$.04 (P = 0.97)				
2 Moderate hearing loss		75 45 47 47			-	
Topuz 2004	Ш	35.45 (22.09)	11	16.18 (9)	_	19.27 [5.17, 33.37]
Subtotal (95% CI)	11		11		•	19.27 [5.17, 33.37]
Heterogeneity: not applicabl	le					
Test for overall effect: $Z = 2$.68 (P = 0.00	74)				
3 Severe hearing loss						
Topuz 2004	10	50.7 (21.54)	4	13 (6.58)	-	37.70 [22.87, 52.53]
Subtotal (95% CI)	10		4		•	37.70 [22.87, 52.53]
Heterogeneity: not applicabl	le					
Test for overall effect: $Z = 4$.98 (P < 0.00	001)				
4 Over all grades						
Hoffmann 1995b	10	7.5 (0)	10	-0.7 (0)	1	0.0 [0.0, 0.0]
Pilgramm 1985	18	29.2 (14.7)	19	20.2 (11.6)	=	9.00 [0.44, 17.56]
Schwab 1998	24	15.6 (0)	33	10.7 (0)	+	0.0 [0.0, 0.0]
Subtotal (95% CI)	52		62		•	9.00 [0.44, 17.56]
Heterogeneity: Tau ² = 0.0; ($Chi^2 = 0.0, df$	= 0 (P = 1.00); l ² =	0.0%			
Test for overall effects 7 = 2	04 (B = 0.03	9)				
Total (95% CI)	86		83		•	15.64 [1.45, 29.83]
Heterogeneity: Tau ² = 172.2	21; $Chi^2 = 18$.23, $df = 3$ (P = 0.00	039); I ² =84%			
Test for overall effect: Z = 2						
Test for subgroup difference	$cs Chi^2 = 18.2$	23, $df = 3 (P = 0.00)$, I ² =84%			

0 50 100

Favours HBOT

Favours Control

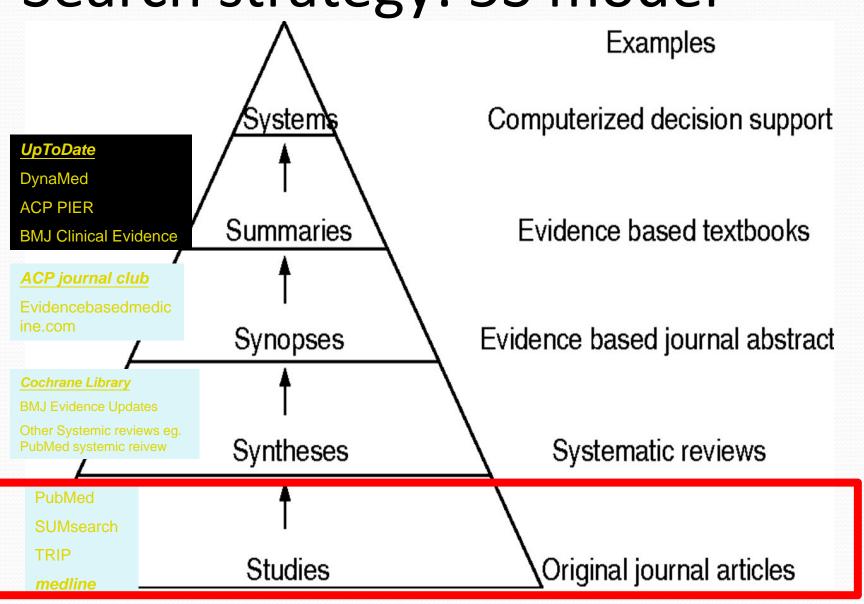
Authors' conclusions

- For people with acute ISSHL, the application of HBOT significantly improved hearing, but the clinical significance remains unclear.
- We could not assess the effect of HBOT on tinnitus by pooled analysis. In view of the modest number of patients, methodological shortcomings and poor reporting, this result should be interpreted cautiously.
- An appropriately powered trial is justified to define those patients (if any) who can be expected to derive most benefit from HBOT.
- There is no evidence of a beneficial effect of HBOT on chronic ISSHL or tinnitus and we do not recommend the use of HBOT for this purpose.

将SYNTHESIS的搜尋結果應用到我病人身上

• 根據synthesis的結果, Hyperbaric oxygen對聽 力是有程度上的改善。

Search strategy: 55 model



搜尋 PubMed

- Key words
 - Hyperbaric oxygen
 - Sudden sensorineural hearing loss

sudden hearing loss.

Filipo R, Attanasio G, Viccaro M, Russo FY, Mancini P, Rocco M, Pietropaoli P, Covelli E.

Acta Otolaryngol. 2012 May;132(5):475-81. doi: 10.3109/00016489.2011.647360. Epub 2012 Jan 31.

PMID: 22292673 [PubMed - indexed for MEDLINE]

Related citations

- Re: Comparison of therapeutic results in sudden sensorineural hearing loss
- 8. with/without additional hyperbaric oxygen therapy: a retrospective review of 465 audiologically controlled cases.

Bhutta MF.

Clin Otolaryngol. 2011 Aug;36(4):397-8; author reply 398-9. doi: 10.1111/j.1749-4486.2011.02349.x. No abstract available.

PMID: 21848560 [PubMed - indexed for MEDLINE]

Related citations

- Re: Comparison of therapeutic results in sudden sensorineural hearing loss
- with/without additional hyperbaric oxygen therapy: a retrospective review of 465 audiologically controlled cases.

Lee DH.

Clin Otolaryngol. 2011 Aug;36(4):395-6; author reply 396-7. doi: 10.1111/j.1749-4486.2011.02338.x. No abstract available.

PMID: 21848558 [PubMed - indexed for MEDLINE]

Related citations

- Hyperbaric oxygen therapy in idiopathic sudden sensorineural hearing loss
- 10. (ISSNHL) in association with combined treatment.

Holy R, Navara M, Dosel P, Fundova P, Prazenica P, Hahn A.

Officersea Hyperb Ivied, 2011 Iviar-Apr,30(2), 131-42

PMID: 21510273 [PubMed - indexed for MEDLINE]

Related citations

- Efficacy comparison of oral steroid, intratympanic steroid, hyperbaric oxygen and
- oral steroid + hyperbaric oxygen treatments in idiopathic sudden sensorineural hearing loss cases.

Alimoglu Y, Inci E, Edizer DT, Ozdilek A, Aslan M.

Eur Arch Otorhinolaryngol. 2011 Dec;268(12):1735-41. doi: 10.1007/s00405-011-1563-5. Epub 201

Mar 23.

PMID: 21431435 [PubMed - indexed for MEDLINE]

Eur Arch Otorhinolaryngol (2011) 268:1735–1741 DOI 10.1007/s00405-011-1563-5

OTOLOGY

Efficacy comparison of oral steroid, intratympanic steroid, hyperbaric oxygen and oral steroid + hyperbaric oxygen treatments in idiopathic sudden sensorineural hearing loss cases

Yalcin Alimoglu · Ender Inci · Deniz Tuna Edizer · Alper Ozdilek · Mehmet Aslan

Received: 26 September 2010 / Accepted: 3 March 2011 / Published online: 23 March 2011 © Springer-Verlag 2011

BACKGROUND

- Idiopathic sudden sensorineural hearing loss is a rare disorder of unknown pathogenesis in which hearing is lost partially or totally.
- About 60 treatment modalities have been described.
- We aimed to compare the efficacy of hyperbaric oxygen, oral steroid, intratympanic steroid therapy and their combinations in idiopathic sudden sensorineural hearing loss patients.

- Files of patients who were followed up between 2004 and 2010 in our clinic were examined retrospectively.
- Patients were divided into four groups according to the therapy received:
 - Oral steroid,
 - oral steroid + hyperbaric oxygen
 - intratympanic steroid
 - hyperbaric oxygen.
- Treatment success was assessed by Siegel criteria and mean gains using pre-treatment and posttreatment audiograms.

- Pretreatment PTA (mean of thresholds at 500, 1,000, and 2,000 Hz) of all patients was 66.08 ± 24.61 dB.
 - group A was 72.12 ± 20.68 dB
 - group B was 63.68 ± 22.97 dB
 - group C was 61.08 ± 22.97 dB
 - group D was 66.28 ± 28.20 dB
- There was no statistically significant difference between groups in terms of pretreatment PTA (p > 0.05).

- There was no statistically significant difference between groups in terms of time of therapy start (p > 0.05).
- Totally and in each study group, there was no statistically significant difference between mean gains of cases in whom therapy was started in the first 3 days and thereafter(*p* > 0.05).

- Group A(oral steroid)
 - 1 mg/kg prednisolone or equivalent and a 10 mg taper every 3 days. Oral steroid therapy lasted about 3 weeks.
- Group B(oral steroid + hyperbaric oxygen)
 - Group A+D
- Group C(Intratympanic steroid)
 - o.5 ml of o.4% dexamethasone is injected through anteroinferior quadrant into the middle ear
 - 2 days/week to the affected side for 3 weeks, with a total of six times.
- Group D(hyperbaric oxygen)
 - two sessions per day in the first 3 days and one session per day in the following days for a total of 20 sessions at 2.5 ATA with 120 min per session.

Result

- 217 patients and 219 ears were examined.
- The proportion of patients responding to therapy
 - oral steroid + hyperbaric oxygen group with 86.88% (53/61)
 - oral steroid group with 63.79% (37/58),
 - intratympanic steroid group with 46,51% (20/43)
 - hyperbaric oxygen group with 43.85% (25/57).

Result

- The proportion of patients who had complete recovery
 - oral steroid + hyperbaric oxygen group with 42.6% (26/61)
 - oral steroid group with 19.0% (11/58)
 - hyperbaric oxygen group with 17.5% (10/57)
 - intratympanic steroid group with 11.6% (5/43)
- The oral steroid + hyperbaric oxygen group has the highest mean hearing gain among all groups (p < 0.05).

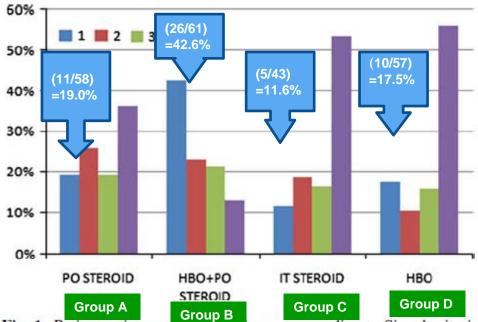


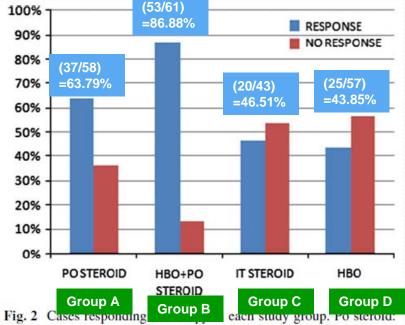
Fig. 1 Patient ratio responding to therapy according to Siegel criteria in each study group. Po steroid: Group receiving oral steroid (group A). HBO + po steroid: Group receiving hyperbaric oxygen + oral steroid (group B). IT steroid: Group receiving intratympanic steroid (group C). HBO: Group receiving only hyperbaric oxygen (group D). I Complete recovery, 2 Partial recovery, 3 Slight improvement, 4 No improvement

Table 1 Patient numbers responding to therapy according to Siegel criteria in each study group

		Group			Total	
		A	В	С	D	
1	Complete recovery	11	26	5	10	52
2	Partial recovery	15	14	8	6	43
3	Slight improvement	11	13	7	9	40
4	No improvement	21	8	23	32	84
	Total	58	61	43	57	219

A Oral steroid group, B Hyperbaric oxygen + oral steroid group, C Intratympanic steroid group, D Hyperbaric oxygen group

=1/23.6%=4.24



Group receiving oral steroid (group A). HBO + po steroid: Group receiving hyperbaric oxygen + oral steroid (group B). IT steroid: Group receiving intratympanic steroid (group C). HBO: Group receiving only hyperbaric oxygen (group D). Response: Cases responding to therapy (cases with more than 15 dB gain of mean gains at thresholds 500, 1,000, 2,000 and 4,000 Hz or cases cured). No response: Cases not responding to therapy (cases with less than 15 dB gain of mean gains at thresholds 500, 1,000, 2,000 and 4,000 or worsening cases)

ARR =86.88%-63.79% =23.09% NNT =1/23.09%=4.33

Result

- Mean gain of
 - group A was statistically significantly better than group C (Z = -2.232; p = 0.026)

 group D (Z = -2.486; p = 0.013).
 - Group B was statistically signifficantly better than group A (Z = -2.049; p = 0.040) group C (Z = -4.569; p = 0.0) group D (Z = -4.275; p = 0.0).
 - No difference was found between C and D groups (p > 0. 05).

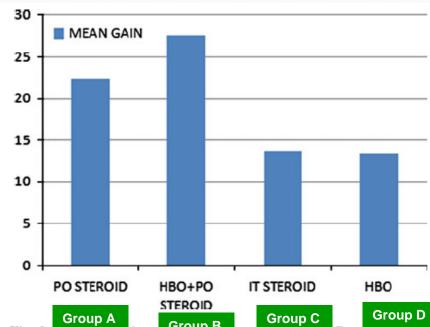


Fig. 3 Wean gams in ea Group B pup. Fo steroid: Group receiving oral steroid (group A). HBO + po steroid: Group receiving hyperbaric oxygen + oral steroid (group B). IT steroid: Group receiving intratympanic steroid (group C). HBO: Group receiving only hyperbaric oxygen (group D). Mean gain: Means of gains at 500, 1,000, 2,000 and 4,000 Hz thresholds in dB

Conclusion

 Idiopathic sudden sensorineural hearing loss patients receiving oral steroid + hyperbaric oxygen combination therapy have a higher likelihood of recovery than patients receiving oral steroids, hyperbaric oxygen or intratympanic steroids alone.

Appraisal

使用worksheet進一步評讀文獻

比文獻有沒有回答我的問題	有
作者群是這領域的專家嗎?	是
	Cerrahpasa Medical Faculty,
	Otolaryngology Department, Istanbul University, Istanbul, Turkey
有沒有利益衝突?	無法評估
	, m. 1 1 1 2
contro, Case series or report, Expert opinion	
取樣是否為隨機取樣?	否
取的樣本是否具代表性?其特性是否接近我的病人?	無法評估
分組是否是隨機分組?	無法評估
分組是否採用盲法?	否
合予實驗組的處置是否描述清楚,並且是臨床可行的?	是
合予對照組的處置是否描述清楚,並且是臨床可行的?各	是
重可能比較皆有了?	
則量了那些結果?是否用客觀的方式測量?	PTA
這些結果是否有統計學上的重要性?	有
這些結果是否有臨床上的重要性?	有
是否呈現結果的「數值」,「p值」,「信賴區間」,「檢	是
h \downarrow ?	
則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?	March 23, 2011
一有一体 (1)	E者群是這領域的專家嗎? 「沒有利益衝突? 「文獻研究設計是屬於以下那一類SR, RCT, Cohort, Case-contro, Case series or report, Expert opinion 「意樣是否為隨機取樣? 」 「我是否為隨機取樣?」 」 「如是否是隨機分組? 」 「如是否是隨機分組? 」 「如是否採用盲法? 」 「一个子對照組的處置是否描述清楚,並且是臨床可行的?各一方式,並且是臨床可行的?各一方式,以上,其上,其上,其一,其一。 「一个子對照組的處置是否描述清楚,並且是臨床可行的?各一方式,其一。」 「一个子對照組的處置是否描述清楚,並且是臨床可行的?各一方式,其一。」 「一個」,「信賴區間」,「檢」」。 「一個」,「「信賴區間」,「檢」」。 「一個」,「「信賴區間」,「檢」」。 「一個」,「「信賴區間」,「檢」」。 「一個」,「自賴區間」,「檢」」。 「一個」,「自賴區間」,「檢」」。 「一個」,「自賴區間」,「檢」。 「一個」,「自賴區間」,「檢」。 「一個」,「自賴區間」,「檢」。 「一個」,「自賴區間」,「檢」。 「一個」,「自賴區間」,「檢」。

Item	AAMPICOT for therapy- Criteria	Comments(評論並說明你的根據)
Answer	此文獻有沒有回答我的問題	有 Idiopathic sudden sensorineural hearing loss patients receiving oral steroid + hyperbaric oxygen combination therapy have a higher likelihood of recovery
Authors	作者群是這領域的專家嗎?	是
	有沒有利益衝突?	無法評估
Method	本文獻研究設計是屬於以下那一類SR, RCT, Cohort, Case-contro, Case series or report, Expert opinion	

Item	AAMPICOT for therapy- Criteria	Comments(評論並說明你的根據)
Population	取樣是否為隨機取樣?	否
	取的樣本是否具代表性?其特性是否接近我的病人?	無法評估
	分組是否是隨機分組?	無法評估
	分組是否採用盲法?	否

Item	AAMPICOT for therapy- Criteria	Comments(評論並說明你的根據)
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?	足
Outcome	测量了那些結果?是否用客觀的方式測量?	Pure tone audiometry (PTA)
	這些結果是否有統計學上的重要性?	具統計意義
	這些結果是否有臨床上的重要性分	有

Item	AAMPICOT for therapy- Criteria	Comments(評論並說明你的根據)
Time	測量結果的時間點是否合宜?	足
	追蹤時間是否夠長?	足
	文獻發表時間?	March 23, 2011

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

醫療現況	病人意願		
目前主流為口服steroid為主,而 hyperbaric oxygen則為治療無效時 ,才會進一步考慮	病人配合度高,病視感高,及經濟上許可,推測會有意願		
生活品質	社會脈絡		
若能大幅改善聽力,對於生活品質定能大幅提昇	合併使用hyperbaric oxygen是可以相當程度改善聽力回復比例		

總結與討論

此病人除了口服steroid外,因經濟上許可,是可以建議病人接受hyperbaric oxygen來提昇聽力回復比例。

AUDIT (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?有
- 我的foreground question 是否可清楚的寫成PICO?可以
- 我的background question是否包括what, when, how, who等 字根?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?知道,屬於治療上的
- 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?有

- 我是否已盡全力搜尋?盡力了...
- 我是否知道我的問題的最佳證據來源?知道
- 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?尚待練習
- 我會使用「斷字」、布林邏輯、同義詞、MeSH term,限制 (limiters)等方法來搜尋?不全然能夠熟練~
- 我的搜尋比起圖書館人員或其他對於提供病人最新最好醫療有熱情的同事如何?仍需更主動積極一些

- 我是否盡全力做評讀了?盡力了
- 我是否了解Number need to treat 的意義?了解
- 我是否了解worksheet每一項的意義?多能瞭解
- 評讀後,我是否做出了結論?是

- 我是否將搜尋到的最佳證據應用到我的臨床工作中?是
- 我是否能將搜尋到的結論如NNT,LR用病人聽得懂的方式解釋給病人聽?大致上可以
- 當搜尋到的最佳證據與實際臨床作為不同時,我如何解釋? 瞭解不同國家的醫療現況以及病人能配合治療的實際情形。

- 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?目前無
- 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?沒有

- 這篇報告,我總共花了多少時間?兩個多晚上
- 我是否覺得這個進行實證醫學的過程是值得的?值得,雖然累,但搜尋資料的過程比以前上手,也有很多收穫。
- 我還有那些問題或建議?有關study統計分析的結果評讀, 以及文獻的選擇,實驗的設計優劣評估等等都是將來要再 加強的地方。

Thanks for your attention!