Evidence-Based Medicine Conference

Department of Neurology
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個案病例摘要

- A 21-year-old male who presented to our emergency department with twisted face and difficulty with left eye closure. No gait disturbances, weakness, numbness, tingling and taste disturbances were noted.
- Past medical history was unremarkable. After initial evaluation, idiopathic Bell's palsy was impressed.

個案病例摘要

- We informed the patient that the management was predominantly supportive and most patients would recover within 1 month or two.
- However, he asked that whether there's any medical treatment beneficial to him.

提出可回答的臨床問題(Asking)

- Problem: What is the treatment (medicine) strategy ?
- Intervention: medicine use
- Comparison intervention: placebo
- Outcome: facial motor function recovery/ length of absence from work were evaluated

搜尋最有用的資料(Acquire)

- Key word: therapy, treatment; Bell’s palsy
- Database:

Cochrane Library(3/3)

Cochrane central register of controlled trials(2/6)

Cochrane database of systemic reviews(2/4)

ACP Journal club(2/6)

PubMed(10/22)

Database of Abstracts of Reviews of Effectiveness(1/4)

:::FlyERMG v1.0::: - Microsoft Internet Explorer

http://er.lib.kmu.edu.tw/cgi-bin/er/browse.cgi

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主頁 跳至 第 筆

檢索結果 26 筆 每頁筆數 50

1		ACP Journal Club (Journal) American College of Physicians, 1997- UC WebOPAC
2		Bandolier (Journal) Bandolier UC WebOPAC
3	T	Clinical Evidence 實證醫學資料庫(試用版) (Database) 金珊資訊有限公司
4		CMDT (Book) AccessMedicine, 2005-
5		Cochrane Library實證醫學資料庫 (Database) Wiley InterScience
6	F	Critical Care (Journal) BioMed Central UC WebOPAC
7	T N	DynaMed即時實證醫學及臨床醫療資訊資料庫(試用版) (Database) EBSCO
8		EBMR: ACP Journal Club 實證醫學資料庫 (Database) OVID, 1991-2003/10
9		EBMR: Cochrane Central Register of Controlled Trials 實證醫學資料庫 (Database) OVID, 1991-2003/Q4
10		EBMR: Cochrane Database of Systematic Reviews 實證醫學資料庫 (Database) OVID, 1991-2003/Q4
11		EBMR: Database of Abstracts of Reviews of Effectiveness 實證醫學資料庫 (Database) OVID, 1991-2003/Q4
12		Evidence-Based Dentistry (Journal) Nature Publishing Group, 1998- UC WebOPAC
13		Evidence-Based Medicine (Journal) HighWire, 2000-(限1年前) UC WebOPAC
14	F	Evidence-Based Mental Health (Journal) HighWire, 限1年前 UC WebOPAC
15	F	Evidence-Based Nursing (Journal) HighWire, 限1年前 UC WebOPAC
16		InfoPOEMs資料庫 (Database) 金珊資訊有限公司

謹慎的文獻選讀(Appraisal)

CEBM - Centre for Evidence Based Medicine - Microsoft Internet Explorer

檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

上一頁 搜尋 我的最愛

網址(D) http://www.cebm.net/levels_of_evidence.asp 移至 連結

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Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

完成

Worksheet

Are the results of this single preventive or therapeutic trial valid?	
Was the assignment of patients to treatments randomised? -and was the randomisation list concealed?	
Were all patients who entered the trial accounted for at its conclusion? -and were they analysed in the groups to which they were randomised?	
Were patients and clinicians kept "blind" to which treatment was being received?	
Aside from the experimental treatment, were the groups treated equally?	
Were the groups similar at the start of the trial?	

是否可應用到此臨床個案(Apply)..
steroid

(1) Review: Corticosteroids for Bell's palsy (idiopathic facial paralysis)--Ia

- *The Cochrane Database of Systematic Reviews* **2006 Issue 2**
- **Search strategy**
  - the Cochrane Neuromuscular Disease Group register (searched December 2003) for randomised trials
  - MEDLINE (January 1966 to April 2003)
  - EMBASE (January 1980 to April 2003)
  - LILACS (January 1982 to April 2003)
- **Selection criteria:** RCTs
- **Main results**
- 4 trials, 179 patients.
  - One trial compared cortisone acetate with placebo;
  - one compared prednisone plus vitamins, with vitamins alone;
  - one compared high-dose prednisone administered intravenously against saline solution,
  - and one, not-placebo controlled, tested the efficacy of methylprednisolone.

- meta-analyse
- incomplete recovery of facial motor function six months after randomisation
  - 13/59 (22%) of the patients allocated to steroid therapy
  - 15/58 (26%) in the control group.
- This reduction was not significant (relative risk 0.86, 95% confidence interval 0.47 to 1.59).
- **Conclusions:**
  - The available evidence from randomised controlled trials does not show significant benefit from treating Bell's palsy with corticosteroids.
  - More randomised controlled trials with a greater number of patients are needed to determine reliably whether there is real benefit (or harm) from the use of corticosteroid therapy in patients with Bell's palsy.

(2) Influence of early high-dose steroid treatment on Bell's palsy evolution--Ib

- Neurol Sci. 2002 Sep;23(3):107-12.
- double-blind, randomized, placebo-controlled study
- 62 patients, enrolled within 72 hours of facial palsy onset, assigned to
  - Gr. A: high dose i.v. prednisone in combination with i.m. polyvitaminic therapy
  - Gr.B: polyvitaminic therapy alone
- Clinical grading of facial muscle strength and length of absence from work were evaluated.
- Results:
  - an early worsening of facial muscle strength was observed in controls
  - treated patients returned to work earlier than controls.
- Conclusion: early treatment based on high-dose corticosteroids slightly accelerates spontaneous improvement in Bell's palsy.

Acyclovir

(1) Review: Acyclovir or valacyclovir for Bell's palsy (idiopathic facial paralysis) -- Ia

- ***The Cochrane Database of Systematic Reviews* 2006 Issue 4**
- **Search strategy**
  - the Cochrane Neuromuscular Disease Group register (searched April 2003),
  - MEDLINE (from January 1966 to April 2003),
  - EMBASE (from January 1980 to April 2003)
  - LILACS (from January 1982 to April 2003).
- **Selection criteria:** Randomised trials
- **Main results**
- 3 studies, 246 patients.
  - One study evaluated acyclovir with corticosteroid versus corticosteroid alone,
  - another study evaluated acyclovir alone versus corticosteroid
  - a further study evaluated valacyclovir with corticosteroid versus corticosteroid alone or versus placebo alone.

- Motor synkinesis (ex: crocodile tears) one year after start of treatment

  -- one study reported a significant difference between the treatment groups in favor of the acyclovir plus corticosteroid group over corticosteroid alone

  - another demonstrated an inconclusive result with no difference between the acyclovir and corticosteroid.

- **Conclusions:**
  - More data are needed from a large multicentre randomised controlled and blinded study with at least 12 months' follow up before a definitive recommendation can be made regarding the effect of acyclovir or valacyclovir on Bell's palsy.

(2) Idiopathic facial paralysis: a randomized, prospective, and controlled study using single-dose prednisone versus acyclovir three times daily-level Ib

- Laryngoscope. 1998 Apr;108(4 Pt 1):573-5.
- prospective, controlled, and randomized study
  - 101 patients, treated with acyclovir (54 patients) or prednisone (47 patients).
  - acyclovir dosage:2400 mg (800 mg tid) for 10 days,
  - prednisone: a single daily dose of 1 mg/kg, for 10 days and tapered to 0 over the next 6 days.
- follow-up: 3 months in all patients
- Result:
  - Patients in the prednisone group had better clinical recovery than those treated with acyclovir.
  - Less degree of neural degeneration was observed in the prednisone group compared with acyclovir patients.
  - The incidence of sequelae was the same in both groups.
- According to these results, in a 10-day treatment cycle acyclovir given 800 mg three times is not as useful as prednisone given 1 mg/kg of body weight once a day in patients with idiopathic facial nerve paralysis.

(3) Bell's palsy treatment with acyclovir and prednisone compared with prednisone alone: a double-blind, randomized, controlled trial – level Ib

- Ann Otol Rhinol Laryngol. 1996 May;105(5):371-8.
- a double-blind, randomized, controlled trial.
- 99 patients, treated with
  - 53 p't: acyclovir-prednisone: acyclovir: 2,000 mg (400 mg 5 times daily) for 10 days
  - 46 p't: placebo-prednisone
- Electrical tests included electroneurography and the maximal stimulation test.
- Result:
  - Treatment with acyclovir-prednisone was statistically more effective in returning volitional muscle motion (recovery profile of 10; p = .02) and in preventing partial nerve degeneration (p = .05) than placebo-prednisone treatment.
- Conclusion: acyclovir-prednisone is superior to prednisone alone in treating Bell's palsy patients and suggest that herpes simplex is the probable cause of Bell's palsy.

Methylcobalamin

Methylcobalamin treatment of Bell's palsy – level Ib

- Methods Find Exp Clin Pharmacol. 1995 Oct;17(8):539-44.
- Randomized Controlled Trial
- 60 patients, assigned into three treatment groups:
  - steroid (group 1),
  - methylcobalamin (group 2)
  - methylcobalamin + steroid (group 3).
- Comparison
  - the number of days needed to attain full recovery,
  - facial nerve scores,
  - and improvement of concomitant symptoms.
- The time required for complete recovery of facial nerve function was significantly shorter ($p < 0.001$) in the methylcobalamin (mean of 1.95 +/- 0.51 weeks) and methylcobalamin plus steroid groups (mean of 2.05 +/- 1.23 weeks) than in the steroid group (mean of 9.60 +/- 7.79 weeks).
- The facial nerve score after 1-3 weeks of treatment was significantly more severe ($p < 0.001$) in the steroid group compared to the methylcobalamin and methylcobalamin plus steroid groups.
- Conclusion: the improvement of concomitant symptoms was better in the methylcobalamin treated groups than the group treated with steroid alone.

Summary (I)

- **1.** Corticosteroids :
  - More randomised controlled trials with a greater number of patients are needed to determine reliably whether there is real benefit (or harm) (Ia)
  - early treatment of corticosteroids slightly accelerates spontaneous improvement in Bell's palsy (Ib)

Summary (II)

- 2. Acyclovir or valacyclovir
  - More data are needed from a large multicentre randomised controlled and blinded study (Ia)
  - acyclovir-prednisone combination is effective in improving facial functional outcomes (Ib)

Summary (III)

- 3. Methylcobalamin
  - revealed the improvement of concomitant symptoms (Ib)

Thanks for your attention~