



The Cochrane Library ... the best single source of reliable evidence about the effects of health care

Strictly Embargoed until 00:01 hours (BST), 18th October 2006

This alert highlights some of the key health care conclusions and their implications for practice as published this week in The Cochrane Library, 2006, Issue 4.

To receive a full copy of the Reviews highlighted in this newsletter, or to arrange an interview with an author, contact Polly Young +44 (0)1243 770633 or by email, pyoung@wiley.co.uk.

Reviews highlighted in this newsletter:

- **Home-based teeth whitening products can work – but watch out for sensitivity and gum damage.**

An increasing number of home-use teeth whitening products are entering the consumer market. A Cochrane Review shows that, although there is considerable variation between products, they do work – at least in the short term. The research also showed that some products can cause mild to moderate tooth sensitivity and irritation of the gums.

- **Obesity: Rimonabant can give modest weight loss after one year**

Rimonabant is a selective cannabinoid-1 receptor antagonist that is currently undergoing phase III trials to investigate whether it can help obese people lose weight. A Cochrane Review of the preliminary research shows that it can produce a 5% reduction in weight after one year.

- **Treating haemorrhoids - warn of risks before offering ‘staples’**

A relatively new surgical technique for haemorrhoids, stapled hemorrhoidopexy was introduced in 1998. While it is less painful and has a quicker recovery rate than conventional surgery, a Cochrane Review of current research shows that it is associated with a higher risk of haemorrhoid recurrence and prolapse compared to the ‘gold standard’ “Milligan-Morgan” technique of open hemorrhoidectomy.

- **General or regional anaesthesia for Caesarean sections? Let mother choose, while considering costs**

A Cochrane Review finds there is not enough evidence to show whether general anaesthesia or regional anaesthesia (spinal or epidural) for Caesarean sections is better for the mother or baby. Both produce different types of mild side effects. In high-income countries the choice should rest with the mother.

- **No evidence that soy formula milk is better than cow's milk formulas for infants at high risk of allergy or food intolerance**

The authors of a Cochrane Review analysed research in infants at risk of allergy or food intolerance who received at least part of their diet as soy formula milk. Infants showed no differences in allergic conditions such as asthma, eczema and rhinitis when compared with others who received formulas based on cow's milk.

- **Occupational therapy benefits patients with strokes**

A Cochrane Review finds that people with strokes who get help from an occupational therapist have higher levels of independence than those who do not see an occupational therapist. They are better at feeding themselves, dressing, bathing, toileting and moving around.

- **For cyclists and pedestrians: bright clothing and lights lets you be seen better, but does it make you any safer?**

A Cochrane Review brings together the growing body of evidence that bright clothing, particularly fluorescent yellow, red and orange clothing, or flashing lights or reflectors, helps drivers see cyclists and pedestrians. However, the existing research is unable to prove that this makes them safer.

- **Can progesterone treat premenstrual syndrome? Poor research methods leaves question unanswered**

Progesterone may help some women with premenstrual syndrome (PMS), but flaws in many of the trials that set out to test this therapy mean that we still don't know for sure, finds a Cochrane Review published this week in The Cochrane Library.

Home-based teeth whitening products can work – but watch out for sensitivity and gum damage.

An increasing number of teeth whitening products designed for home use are entering the consumer market. A new analysis of published data shows that, although there is considerable variation between products, they do work – at least in the short term. The data also showed that some products can cause mild to moderate tooth sensitivity and cause irritation of the gums.

The Authors of this Cochrane systematic Review note that amidst more than 400 articles that looked at teeth whitening agents, only 25 met their inclusion criteria. All looked at the effect after using the whitener for two weeks, but only 13 studies reported outcome data one week after this two-week application period. Of these, only 6 reported outcome data after one month or longer.

“People should be aware that there is no available long term data on the effect or safety of these products,” says lead author Dr Hana Hasson.

The Review Authors also noted that all of the trials were either sponsored or carried out by the manufacturers of the products.

“There is an urgent need for independent long-term studies evaluating the effectiveness and harms associated with home teeth-whitening products,” says Hasson.

Hasson H, Ismail AI, Neiva G. Home-based chemically-induced whitening of teeth in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD006202. DOI: 10.1002/14651858.CD006202.

Obesity: Rimonabant can give modest weight loss after one year

Rimonabant is a selective cannabinoid-1 receptor antagonist that is currently undergoing phase III trials to investigate whether it can help obese people lose weight. A review of the early research shows that it can produce a 5% reduction in weight after one year.

The increasing worldwide prevalence of obesity is creating a growing demand for effective treatments. One possible option is rimonabant. Cochrane Review Authors analysed data from four randomized controlled studies in which people were either given 20 mg rimonabant, 5 mg rimonabant or a placebo. At the same time they all followed a low calorie diet. Each of the trials ran for 1 year.

Over the year, people taking 20 mg rimonabant lost 4.9 kg more than those given the placebo. Those taking 5 mg only lost 1.3 kg more when compared with placebo.

Taking the higher dose of 20 mg rimonabant did, however, cause significantly more adverse effects, which may account for the fact that 40% of people **overall** dropped out of the trials early

“Even modest amounts of weight loss may be beneficial, though drug therapy in obesity should always be considered in connection with non-pharmacological interventions,” says lead author, Cintia Curioni who works at the Instituto de Medicina Social, in Rio de Janeiro, Brazil.

The Authors also comment that preventing non-obese individuals becoming obese, and using non-pharmacological interventions should remain the cornerstones of obesity therapy. Better quality studies with longer follow-up and outcomes which are important for patients, such as health-related quality of life, are needed to establish the place of rimonabant in the treatment of obesity.

Curioni C, André C. Rimonabant for overweight or obesity. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD006162. DOI: 10.1002/14651858.CD006162.pub2.

Treating haemorrhoids - warn of risks before offering ‘staples’

A relatively new surgical technique for treating haemorrhoids, stapled hemorrhoidopexy, was introduced in 1998. While it is less painful and has a quicker recovery rate than conventional surgery, a systematic Review of the research shows that it is associated with a higher risk that the haemorrhoids will return or prolapsed compared to the ‘gold standard’ “Milligan-Morgan” technique of open haemorrhoidectomy.

Haemorrhoids are a common form of anorectal disorder, affecting around half of the population at some point in their lives. When they are severe, the person may be offered surgery. Conventional surgery is effective, but is associated with complications such as urinary retention, haemorrhage and pain. The newer Circular stapled technique reduces the patient’s pain, and initial reports suggested that it was preferred by patients. It was also found to work well in day-case surgery, which makes it economical to perform.

By gathering together all data from randomised trials, Cochrane Review Authors found that haemorrhoids recurred in 23 out of 269 patients who had staples, compared with 4 out of 268 who had conventional surgery. They also found a greater number of prolapses after one year and after five years in the stapled group.

“Patients should be informed of the risks when being offered stapled technique, particularly if they are worried about the chance of recurrence or prolapse,” says lead researcher Dr Shiva Jayaraman who works in the Department of Surgery at the University of Western Ontario, London, Canada.

The Review does confirm, though, that both methods are safe and serious complications are rare with either technique.

Jayaraman S, Colquhoun PHD, Malthaner RA. Stapled versus conventional surgery for hemorrhoids. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD005393. DOI: 10.1002/14651858.CD005393.pub2.

General or regional anaesthesia for Caesarean sections? Let mother choose, while considering costs

There is not enough evidence to show whether general anaesthesia or regional anaesthesia (spinal or epidural) for Caesarean sections are better for the mother or baby. Both lead to different types of mild side effects. In high-income countries the choice should rest with the mother. In low-income countries, doctors may seek to use the technique that costs less

Some form of anaesthesia is vital before a surgeon can deliver a baby by Caesarean section. Deciding whether to offer general or regional anaesthesia is complicated by the different advantages and disadvantages offered by each.

Regional anaesthesia has the advantage that the mother is awake, and it is associated with lower blood loss during the procedure than general anaesthesia. General anaesthesia is easier to perform and leads to less pain during the operation as the mother is unconscious, but the women tend to need additional pain killers sooner after the operation than those who had regional anaesthesia. They also tended to shiver more. Nausea and vomiting are more likely to occur in women who had regional anaesthesia.

The research data on the health of the babies delivered following general or regional anaesthesia also showed no consistent difference between the techniques.

“With no evidence of one method being superior to the other, the choice then falls to a combination of the mother’s wishes and what is technically feasible or affordable in the hospital, “ says Lead Review Author Dr Bosede Afolabi, who works in the Department of Obstetrics & Gynaecology at the University of Lagos, Nigeria.

Afolabi BB, Lesi FEA, Merah NA. Regional versus general anaesthesia for caesarean section. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD004350. DOI: 10.1002/14651858.CD004350.pub2.

No evidence that soy formula milk is better than cow’s milk formulas for infants at high risk of allergy or food intolerance

Many infants are fed at least some formula milk early in life. Soy formula is often recommended for infants who are at particular risk of allergy or intolerance, because research has shown that while around 1.8% of children have an allergy to cow's milk, only 0.5% have allergic responses to soy.

Cochrane Review Authors analysed data from trials in which some of the at risk infants received at least part of their diet as soy formula milk. The infants in these trials showed no differences in allergic conditions such as asthma, eczema and rhinitis between those receiving soy formula milk and those receiving formulas based on cow's milk.

The researchers looked for studies that compared soy formula with human breast milk or hydrolysed cow's milk, but found none that met their criteria for the quality of the design of the trial and the proportion of infants who completed the trial.

"Current evidence suggests that using a soy formula instead of cow's milk does not reduce allergies in infants and children," says co-author Dr John Sinn, who works in the Neonatal Unit at Westmead Hospital, Westmead, New South Wales, Australia.

"This Review should also be viewed alongside one we published in 2003 which found limited evidence of benefit from hydrolysed protein formula when compared to cow's milk formula," says co-author Dr David Osborn, from the Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia.

Osborn DA, Sinn J. Soy formula for prevention of allergy and food intolerance in infants. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD003741. DOI: 10.1002/14651858.CD003741.pub4.

Occupational therapy benefits patients with strokes

People with strokes who get help from an occupational therapist have higher levels of independence than those with strokes who do not see an occupational therapist. They are better at feeding themselves, dressing, bathing, using the toilet and moving around.

Stroke is one of the major causes of death and disability in the Western world. Around a third of people who survive a stroke will remain dependent on others for care. While much research has shown that rehabilitation after stroke can help, it has not been clear what benefit came specifically from receiving occupational therapy. Occupational therapists aim to help people reach their maximum level of function and independence in all aspects of daily life.

A systematic Review that drew data from ten studies involving 1348 participants showed that occupational therapy significantly reduced the chance of a person having a poor outcome. In particular the Review showed occupational therapy significantly increased people's ability to look after themselves.

For every 11 people who received occupational therapy, 1 fewer will experience a deterioration in their ability to look after themselves.

"What we need to do now is to find out which aspects of an occupational therapist's intervention helps people most in their recovery after a stroke," says lead author Lynn Legg, Project Manager for the Stroke Therapy Evaluation Programme at Glasgow Royal Infirmary in Scotland.

Legg LA, Drummond AE, Langhorne P. Occupational therapy for patients with problems in activities of daily living after stroke. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD003585. DOI: 10.1002/14651858.CD003585.pub2.

For cyclists and pedestrians: bright clothing and lights lets you be seen better, but does it make you any safer?

There is a growing body of evidence that bright clothing, particularly fluorescent yellow, red and orange clothing, or flashing lights or reflectors, helps drivers see cyclists and pedestrians.

There is, however, no evidence that this necessarily makes cyclists or pedestrians any safer. The problem is that no one has done the research needed to test this.

“To get meaningful data will require large trials, and they will be difficult to conduct, but it is important that we discover whether being seen is necessarily the same as being safe,” says Lead Review Author Irene Kwan, who works at the National Collaborating Centre for Women’s and Children’s Health at the Royal College of Obstetricians and Gynaecologists, in London.

The statistics show why this is such an important issue globally as well as in the UK, at a time when walking and cycling are being actively promoted for their environmental, economic and health benefits. Worldwide, road crashes account for over a million deaths and some ten million permanent disabilities a year. Nearly three-quarters of road deaths are in low and middle-income countries, and most of the injured people were pedestrians or cyclists, for whom walking and cycling are essential modes of travel.

In the UK in 2000 42,033 pedestrians and 20,612 cyclists were injured. (Figures from the former Department for Environment, Transport and the Regions)

A frequent cause of accidents is drivers not noticing other road users until it is too late. This issue is particularly important at night when a high proportion of accidents occur.

Kwan I, Mapstone J. Interventions for increasing pedestrian and cyclist visibility for the prevention of death and injuries. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD003438. DOI: 10.1002/14651858.CD003438.pub2.

Can progesterone treat premenstrual syndrome? Poor research methods leaves important question unanswered

Progesterone may help some women with premenstrual syndrome (PMS), but flaws in many of the trials that set out to test this therapy mean that we still don’t know.

Five in every one hundred women suffer premenstrual symptoms at some time in their lives that are severe enough to interfere with their lives. One possible cause of the symptoms is the drop in progesterone that comes before menstruation. A suggested treatment, therefore, is to give women extra progesterone. But many health professionals doubt whether this treatment works.

To see if the research evidence can help resolve this, Cochrane Review Authors examined 17 different studies before performing a more detailed analysis of the

data from the two trials which met their eligibility criteria. Of these, one trial of 'better quality' concluded that progesterone was more effective than placebo.

The main problem with assessing the benefit of progesterone is that 15 of the 17 trials had to be excluded for one or more important reasons. Some did not screen women for psychiatric disorders or persistence of symptoms after their menstrual periods, and others had to be excluded because the diagnosis of PMS was based on less than two cycles of symptom records. Probably because they needed to be run over many months, many trials also had a high drop out rate.

"The Review has revealed more about the difficulties inherent in the study of PMS and consequent deficiencies in method, than about the efficacy of progesterone in treating it," says Lead Review Author Olive Ford former honorary Research Officer for the National Association for Premenstrual Syndrome.

Knowing whether progesterone is a useful treatment is complicated by the fact that treatments for PMS generally show large placebo effects. The Review Authors describe how some trials involving other therapies have found the placebo to have more effect than the treatment.

The Review points out that any women who do use progesterone need to be told of the mild side effects. These can include changes in menstrual cycle length and a tendency to become drowsy. In addition one woman who had believed herself to be infertile, conceived when taking progesterone, out of a total of about 650 women in all the trials examined.

Ford O, Lethaby A, Mol B, Roberts H. Progesterone for premenstrual syndrome. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD003415. DOI: 10.1002/14651858.CD003415.pub2.

- Ends -

Notes for editors

1. The Cochrane Library contains high quality health care information, including Systematic Reviews from The Cochrane Collaboration. These Reviews bring together research on the effects of health care and are considered the gold standard for determining the relative effectiveness of different interventions. The Cochrane Collaboration (<http://www.cochrane.org>) is a UK registered international charity and the world's leading producer of systematic Reviews. It has been demonstrated that Cochrane Systematic Reviews are of comparable or better quality and are updated more often than the Reviews published in print journals .
2. The Cochrane Library can be accessed at <http://www.thecochranelibrary.com>. Guest users may access abstracts for all Reviews in the database, and members of the media may request full access to the contents of the Library. For further information, see contact details below.
3. A number of countries have national provisions by which some or all of their residents are able to access The Cochrane Library for free. These include:

Australia	www.nicsl.com.au/Cochrane
New Zealand	http://www.moh.govt.nz/cochranelibrary or http://www.nzgg.org.nz/ or http://www.cochrane.org.nz/
Denmark	www.vifab.dk or www.sundhedsportalen.dk or www.deff.dk or www.cochrane.dk
England	www.nelh.nhs.uk/cochrane.asp
Finland	www.terveysportti.fi
Ireland	All residents within the Island of Ireland can access The Cochrane Library for free, thanks to funding for a national provision by The Health Research Board in Dublin and The Research and Development Office in Belfast.

Norway www.cochrane.no
Scotland <http://www.nes.scot.nhs.uk/>
Spain <http://www.update-software.com/Clibplus/ClibPlus.asp>
South Africa <http://www.sahealthinfo.org/evidence/databases.htm>
Sweden www.sbu.se
Wales All residents of Wales with access to the Internet can access The Cochrane Library for free, thanks to funding provided by The Welsh Assembly Government.
The Canadian Province of Saskatchewan www.thecochranelibrary.com
The US State of Wyoming www.thecochranelibrary.com

4. There are also several programmes, such as the Health InterNetwork Access to Research Initiative (HINARI) that provide access in developing countries. To find out whether your country is included in any of these programmes/provisions, or to learn how to get access if you don't already have it, please visit: <http://www.thecochranelibrary.com>.

If you would like to see a full list of Reviews published in the new issue of The Cochrane Library, or would like to request full access to the contents of The Library, please contact.

Contact: Julia Lampam
Tel: +44 (0)1243 770668
Email: jlampam@wiley.co.uk

^a Jadad AR, Cook DJ, Jones A, Klassen TP, Tugwell P, Moher M, et al. Methodology and reports of systematic Reviews and meta-analyses: a comparison of Cochrane Reviews with articles published in paper-based journal.