#### **EVIDENCE-BASED SURGERY**

This month, the *Journal* presents four abstracts from the Cochrane Collaboration, representing work in several surgical specialties. The Cochrane Collaboration is an international organization that provides systematic reviews to help readers make well informed decisions about healthcare; Cochrane prepares, maintains, and promotes the accessibility of systematic reviews of the effects of healthcare interventions.

The first abstract reviews evidence concerning bioresorbable fixation devices for adult fractures. Although somewhat counterintuitive, implants to stabilize adult fractures that are absorbed over time, are as effective for some fractures as are metal fixation devices.

The next abstract reviews the evidence, pro and con, for the use of the immunosuppressive drug cyclosporine

for Crohn's Disease. These results are disappointing. Toxicity of the drug outweighs its potential benefits.

The third abstract is bound to be controversial, but its conclusions are irrefutable. Although abdominal ultrasonography is potentially a very useful tool in evaluating patients with blunt abdominal trauma, there are insufficient well-designed, multi-center clinical trials to prove its worth. Randomized clinical trials are a must in trauma, where dogma often prevails.

Finally, the Cochrane collaborators take issue with the tendency of clinical researchers to publish positive, but not always negative results of their trials. Trial registries, mandated by September 15, 2005 by prestigious journals, may help to encourage full disclosure of these costly trials, positive or negative.

Editor

#### **ABSTRACT**

# Bioresorbable fixation devices for musculoskeletal injuries in adults

Jainandunsing JS, van der Elst M, van der Werken CC

**Summary:** Use of implants made of materials that slowly dissolve over time theoretically offer benefits over metal implants to fixate bone fractures and to reattach ligaments to bone. Once inserted, there would be no need to remove the bioresorbable implants and mechanical load would be gradually transferred onto the healing bone. Thirty one randomised trials show that there are no significant differences in functional outcome, incidence of infections and other complications with the two types of implant devices. Reoperation rates are lower in the bioresorbable group because the devices do not have to be removed.

**Background:** Bioresorbable implants for musculoskeletal injuries involving bone and ligaments in adults might have significant advantages compared to the conventionally used non-resorbable metal implants because they lead to a gradual transfer of the mechanical load from the implant to the healing bone and do not require a secondary removal operation. Tissue reactions may present a problem and bioresorbable screws are mechanically not as strong as their metal counterparts.

**Objectives:** To compare bioresorbable implants to non-resorbable implants with respect to functional outcome, wound infections, other complications and reop-

eration rate, in the fixation of bone fractures or reattachment of soft tissue to bone.

**Search Strategy:** We searched the Cochrane Musculoskeletal Injuries Group Specialised Register (March 2004), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 1, 2004), MEDLINE (1966 to February 2004), EMBASE (1988 to February 2004), BL Inside (to February 2004), SIGLE (to February 2004), the metaRegister of Controlled Trials at http://controlled-trials.com/, and reference lists of articles.

**Selection Criteria:** Randomised controlled trials (RCTs) and quasi-randomised trials, comparing bioresorbable osteosynthesis with metal osteosynthesis (including titanium and stainless steel implants) were included.

**Data Collection and Analysis:** Review authors independently assessed trial quality and extracted data. Data were pooled where relevant and possible. Subanalyses for specific type of fractures and for specific type of tissue reactions were performed. Requests for more information were sent to trialists.

**Main Results:** No significant difference between the bioresorbable and other implants could be demonstrated with respect to functional outcome, infections and other complications. Reoperation rates were lower in some of the groups of people treated with bioresorbable implants.

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**Authors' Conclusions:** In a selected group of compliant patients with simple fractures, the use of bioresorbable fixation devices might be advantageous.

**Citation:** Jainandunsing JS, van der Elst M, van der Werken CC. The use of bioresorbable fixation devices compared with metal implants for musculoskeletal injuries involving bone and ligaments in adults. In: *The Cochrane Database of Systematic Reviews*, Issue 2, 2005. The Cochrane Collaboration. Chichester, UK: John Wiley & Sons, Ltd.

#### **ABSTRACT**

## Cyclosporine for induction of remission in Crohn's disease

McDonald JWD, Feagan BG, Jewell D, Brynskov J, Stange EF, MacDonald JK

**Summary:** The results of this review demonstrate that low dose oral cyclosporine is not effective for treatment of active Crohn's disease. Studies indicate that Crohn's patients treated with low dose (5 mg/kg/day) oral cyclosporine could experience side effects including kidney problems. Therefore the use of this medication for the treatment of chronic active Crohn's disease is not advisable. Higher oral doses and injections of cyclosporine have not been sufficiently evaluated. Larger doses of cyclosporine are not likely to be useful for the long-term management of Crohn's disease due to the risk of kidney damage and the availability of other proven medications.

**Background:** Cyclosporine was first found to be an effective and well-tolerated immunosuppressive agent in organ transplant recipients, and subsequently in several autoimmune diseases. It was reported in open studies that cyclosporine is effective for induction of remission in Crohn's disease. Four randomized controlled trials have been performed to determine whether the results observed in these open studies were valid. This systematic review summarizes the evidence on the use of oral cyclosporine for the induction of remission in Crohn's disease.

**Objectives:** To evaluate the effectiveness of oral cyclosporine for induction of remission in patients with active Crohn's disease in the presence and absence of concomitant steroid therapy. Secondary objectives were to evaluate clinical response rates and adverse events associated with cyclosporine.

**Search Strategy:** Computer-assisted searches of the online bibliographic databases MEDLINE and EMBASE were performed to identify potentially relevant publications between 1980 and July 2004. The MeSH terms "Crohn Disease" or "Inflammatory Bowel disease" and "Cyclosporin" (exploded) were used to perform key word searches of the databases. Manual searches of reference lists from potentially relevant papers were performed in order to identify additional studies that may have been missed. Abstracts from major gastroenterological meetings, The Cochrane Central Register of Controlled Trials and the Cochrane Inflammatory Bowel Disease Group Specialized Trials Register were also searched for relevant studies. Appropriate officials at Sandoz Corporation were contacted to seek information on any unpublished trials.

**Selection Criteria:** Prospective, randomized, double-blinded, placebo-controlled trials of parallel design with treatment duration of a minimum 12 weeks comparing oral cyclosporine therapy with placebo for treatment of patients with active Crohn's disease were eligible for inclusion.

Data Collection and Analysis: All data were analyzed on an intention-to-treat basis. Data were extracted from the original research articles and converted into  $2 \times 2$  tables (cyclosporine vs. placebo). Where available, individual  $2 \times 2$  tables for strata within studies were also used. Heterogeneity was assessed using the chi-square test (p < 0.10 was regarded as statistically significant). For non-pooled data, p-values were derived using the chi-square test. For pooled data, summary test statistics were derived using the Peto odds ratio and 95% confidence intervals. A fixed effects model was used for pooling of data. For continuous data, summary test statistics were derived using the weighted mean difference and 95% confidence intervals. The definitions of treatment success, remission and clinical improvement were set by the authors of each paper, and the data were combined for analysis only if these definitions were sufficiently similar.

**Main Results:** Brynskov 1989a found that patients receiving high dose cyclosporine (median 7.6 mg/kg/day) had statistically significant clinical improvement at 12 weeks compared to placebo patients. None of the other studies found any statistically significant benefit for clinical improvement or induction of remission for

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