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Cochrane Column: Best Evidence from the Cochrane Library

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Usage of Azathioprine for Primary Biliary Cirrhosis is not Supported by Evidence

Primary biliary cirrhosis (PBC) is a chronic disease of the liver with annual incidence of two to 24 patients per million population, and prevalence estimate of 19 to 240 patients per million population. It primarily affects middle-aged women. The forecast for the symptomatic patient after diagnosis is between 10 and 15 years. The cause of PBC is unknown, but the dynamics of the disease resemble the group 'autoimmune disease'. Therefore, one may expect a noticeable effect by administering an immunosuppressant.

Azathioprine is used for patients with PBC, but the therapeutic responses in randomized clinical trials (RCTs) have been conflicting. The authors’ aim was to assess the benefits and harms of azathioprine for patients with PBC.

RCTs comparing azathioprine versus placebo, no intervention, or another drug were included irrespective of blinding, language, year of publication, and publication status.

Two RCTs with 293 patients were included in the review. Only one of the trials was regarded as having low- bias risk. Azathioprine did not significantly decrease mortality (relative risk RR=0.80, 95% CI: 0.49 to 1.31, two trials). Azathioprine did not improve pruritus at one-year (RR=0.71, 95%CI: 0.28 to 1.84, one trial), cirrhosis development, or quality of life. Patients given azathioprine experienced significantly more adverse events than patients given no intervention or placebo (RR=2.44, 95%CI: 1.14 to 5.20, two trials). The common adverse events were rash, severe diarrhea, and bone marrow depression.

The primary findings of the review are that azathioprine has no effect on survival, itching, progression of the disease (cirrhosis development), or quality of life. Patients given azathioprine experienced more adverse events than patients given placebo.

Gong et al. believe that there is no evidence to support the use of azathioprine for patients with PBC and researchers who are interested in performing further RCTs should be aware of the risks of adverse events.


Music and Video Can Reduce the Anxiety during Colposcopy

Colposcopy, the visualization of the cervix using a stereoscopic binocular microscope of low magnification, facilitates the performance of a diagnostic biopsy or treatment of abnormal cervix. It is a part of the cervical screening program that aims to prevent cancer in women by detecting precursor lesions which if left untreated could lead to the development of cancer and is performed after abnormal cervical smear.

Women experience high levels of anxiety and negative emotional responses at all stages of cervical screening. This is even higher than anxiety levels in women before surgery and similar to the anxiety levels in women following an abnormal screening test for fetal abnormalities. High levels of anxiety before and during colposcopy can have adverse consequences, including pain and discomfort during the procedure and high loss to follow-up rates. This review evaluates interventions designed to reduce anxiety levels during colposcopic examination.

Eleven trials examining 1,441 women's anxiety levels after different types of intervention were included. Several methods were included such as: information leaflets: proved not to be associated
with anxiety reduction; counseling: pre-colposcopic counseling was not associated with anxiety reduction; information leaflets and information video and precolposcopy counseling: was not associated with a reduction in anxiety levels; listening to music during colposcopy: this intervention was associated with reduction in anxiety levels (P<0.002); video colposcopy was associated with reduction in anxiety levels, and the reduction in anxiety was significant (P<0.0002); information using graphs and verbal information and information video versus information only when sought: there was no significant reduction in the level of anxiety in the intervention group; and information leaflets and information video versus information leaflets only: there was a reduction in anxiety levels in the intervention group compared to the control group (P=0.00001).

Regarding the mentioned studies, anxiety can be reduced by playing music during colposcopy, showing information video prior to colposcopy and viewing video colposcopy during the procedure. Although information leaflets did not reduce anxiety levels, they did increase knowledge levels; so, are useful in obtaining clinical consent to the colposcopic procedure.


**Anticoagulation for Thrombosis Prophylaxis in Cancer Patients with Central Venous Catheters**

Central venous catheter (CVC) placement increases the risk of thrombosis in cancer patients and it often necessitates the removal of the CVC resulting in treatment delays and thrombosis-related morbidity and mortality. The efficacy and safety of anticoagulation in reducing venous thromboembolic (VTE) events in cancer patients with CVC were the aims of present review. Of 3,986 identified citations, nine RCTs were included in the meta-analysis including one published as an abstract and one focusing on pediatric patients not included in the meta-analysis. The use of heparin in cancer patients with CVC was associated with a trend towards a reduction in symptomatic DVT (RR=0.43; 95% CI: 0.18 to 1.06), but the data did not show any statistically significant effect on mortality (RR=0.74; 95%CI: 0.40 to 1.36), infection rate (RR=0.91; 95%CI: 0.36 to 2.28), major bleeding (RR=0.68; 95%CI: 0.10 to 4.78), or thrombocytopenia (RR=0.85; 95%CI: 0.49 to 1.46). The effect of warfarin on symptomatic DVT was not statistically significant (RR=0.62; 95%CI: 0.30 to 1.27). When studies assessing different types of anticoagulants were pooled, symptomatic DVT rates were significantly reduced (RR=0.56; 95%CI: 0.34 to 0.92).

The authors concluded that cancer patients with CVC considering anticoagulation, should consider the possible benefit of reduced incidence of thromboembolic complications with the burden and harms of anticoagulation. Future studies should be adequately powered to evaluate the effects of newer anticoagulants such as fondaparinux and ximelagatran in cancer patients with CVC.


**Antibiotic Prophylaxis for Elective Inguinal Hernia Repair Can not be Universally Recommended**

Although elective hernia repair is considered a clean procedure, the rate of postoperative wound infection in many countries exceeds the one expected for clean surgery, increasing discomfort in patients, and healthcare expenses. In addition, antibiotic administration is not exempt of potential risks.

Regarding the disparity among results of studies considering antibiotic prophylaxis for hernia repair, the present review focused to clarify the effectiveness of antibiotic prophylaxis in reducing postoperative wound infection rates in elective open inguinal hernia repair. The present review is the second update of previous reports (first published in the Cochrane Library 2003 Issue 2 and the first update was published in Cochrane Library 2004 Issue 4).

Twelve RCTs with 6,705 participants (treatment group: 4,128, control group: 2,577) were identified. Six of them used prosthetic material for hernia repair (hernioplasty) whereas the remaining studies did not (herniorraphy). Pooled and subgroup analyses were conducted depending on whether prosthetic material was used or not.

Overall infection rates were 2.9% and 3.9% in...
The prophylaxis and control groups, respectively (OR=0.64, 95%CI: 0.48 to 0.85). The subgroup of patients with herniorrhaphy had infection rates of 3.5% and 4.9% in the prophylaxis and control groups, respectively (OR=0.71, 95%CI: 0.51 to 1.00). The subgroup of patients with hernioplasty had infection rates of 1.4% and 2.9% in the prophylaxis and control groups, respectively (OR=0.48, 95%CI: 0.27 to 0.85).

Based on the results of this meta-analysis, the administration of antibiotic prophylaxis for elective inguinal hernia repair can not be universally recommended. Nevertheless, its administration seems to be useful when high rates of wound infection are expected.