

IBD Research Review™

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Issue 32 – 2016

In this issue:

- *Vedolizumab induction therapy in CD and UC*
- *Faecal calprotectin and postop recurrence of paediatric CD*
- *Comparison of faecal inflammatory markers in CD*
- *Anaemia in IBD: A nationwide cross-sectional study*
- *Infection risk associated with ADA/IFX in mothers and newborns*
- *Epithelial changes and colorectal dysplasia in IBD*
- *Maternal IBD: not a risk factor for offspring morbidity*
- *POCER study: thiopurines/ADA and CD recurrence in high-risk patients*
- *IFX reduces endoscopic recurrence of CD post resection*
- *Mobile phone apps for IBD self-management*
- *QoL in IBD: adolescents and their parents*

Abbreviations used in this issue

ADA = adalimumab
ARR = absolute risk reduction
CD = Crohn's disease
CDAI = Crohn's Disease Activity Index
CRP = C-reactive protein
HBI = Harvey-Bradshaw Index
IBD = inflammatory bowel disease
IFX = infliximab
OR = odds ratio
QoL = quality of life
RR = relative risk
SCCAI = Simple Clinical Colitis Activity Index
SEC = serrated epithelial changes
TNF = tumour necrosis factor
UC = ulcerative colitis

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Welcome to the thirty-second issue of IBD Research Review.

We would like to take this opportunity to thank Professor Richard Geary, who will be standing down from his role as an expert commentator for this review. Richard has provided outstanding, meaningful and illuminating commentary for this review over the past 8 years. We would like to welcome Dr Srikantaiah Manjunatha (Manju), who will be taking over from Richard. Manju is a consultant gastroenterologist at Southern District Health Board and an Honorary Clinical Senior Lecturer at the University of Otago. We are very pleased to have Manju as part of the IBD Research Review team.

In this issue we focus on a range of topics covering both CD and UC, including two studies looking at maternal IBD and risks to offspring. Our research nurse, Merrilee Williams, has also reviewed an interesting article looking at quality of life in adolescents with IBD and the impact of their disease on their parents.

Research Review is ten!! The first ever issues of Research Review were delivered to inboxes in February 2006. Fast forward ten years and we now publish 48 regular reviews to which there are over 160,000 subscriptions. We're grateful to each and every one of you for your support and are looking forward to even bigger and better things over the coming years.

We hope you enjoy the latest issue of IBD Research Review and welcome your comments and feedback.

Kind regards,

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Vedolizumab induction therapy for inflammatory bowel disease in clinical practice – a nationwide consecutive German cohort study

Authors: Baumgart DC et al.

Summary: A multicentre consecutive cohort study was conducted to examine the use of vedolizumab, the humanised monoclonal IgG1 antibody targeting $\alpha 4\beta 7$ integrin, for the treatment of CD ($n = 97$; 71.1% female) and UC ($n = 115$, 42.6% female). After 14 weeks, clinical remission (CD Harvey-Bradshaw index [HBI] ≤ 4 , UC partial Mayo [pMayo] score ≤ 1) was achieved by 23.7% of CD patients and 23.5% of UC patients. Steroid-free remission was achieved by 19.6% and 19.1% and a clinical response (HBI/pMayo score reduction ≥ 3) by 60.8% and 57.4%. Clinical remission among CD patients was associated with absence of prior extraintestinal manifestations ($p = 0.019$), no previous use of adalimumab ($p = 0.011$), absence of hospitalisation in the past 12 months ($p = 0.015$) and a low HBI score ($p = 0.02$). In UC patients, clinical remission was associated with active or prior smoking ($p = 0.044/0.028$) and no previous anti-TNF- α use ($p = 0.023$). In CD patients, a low HBI score ($p = 0.019$) and absence of hospitalisation in the past 12 months ($p = 0.01$) were predictive of clinical remission.

Comment (MS): Many New Zealand sites participated in the GEMINI program evaluating the effect of vedolizumab in CD. The results were published in the NEJM reporting remission rates of 14.5% at week 6 (see Sandborn WJ et al. *N Engl J Med.* 2013; 369:711-721). Among patients who had a response to induction therapy, 39.0% and 36.4% of those assigned to vedolizumab every 8 weeks and every 4 weeks, were in clinical remission at week 52. Unfortunately, the Baumgart et al. study chose time points not comparable to the original study, but at week 14, 23.7% of CD patients achieved clinical remission and 19.6% steroid-free remission. The numbers were similar in UC. For most patients included in this trial, vedolizumab was used as a second-line treatment after the failure of a previous biological agent. Vedolizumab has recently been funded in Australia as a second-line treatment in IBD.

Reference: *Aliment Pharmacol Ther.* 2016;43(10):1090-102

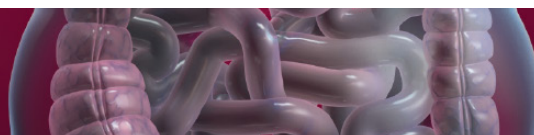
[Abstract](#)



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Faecal calprotectin in the prediction of postoperative recurrence of Crohn's disease in children and adolescents

Authors: Hukkinen M et al.

Summary: This study in 22 patients tested whether faecal calprotectin levels were associated with postoperative CD recurrence in children (median age 15.1 years) who underwent surgery for CD. After surgery faecal calprotectin levels decreased from 659 to 103 µg/g ($p = 0.001$). Over a median 5.7 years of follow-up, endoscopic or histological recurrence occurred in 17 (77%) patients. Faecal calprotectin >139 µg/g at the time of endoscopy, or a faecal calprotectin increase of 79 µg/g over the initial postoperative level predicted endoscopic recurrence (Rutgeerts score ≥ 2), while a faecal calprotectin level of >101 µg/g or an increase of 21 µg/g predicted histological recurrence. The greatest accuracy of recurrence prediction combined faecal calprotectin level at endoscopy and the postoperative increase of faecal calprotectin. The area under the receiver operating characteristic value for endoscopic recurrence was 0.74 (95% CI 0.58-0.89) while that for histological recurrence was 0.81 (95% CI 0.67-0.95).

Comment (SM): see below

Reference: *J Pediatr Surg.* 2016;Feb 4 [Epub ahead of print]

[Abstract](#)

Comparison of fecal inflammatory markers in Crohn's disease

Authors: Wright EK et al.

Summary: In a prospective randomised controlled trial, data from 135 participants were used to test the use of faecal calprotectin, lactoferrin and S100A12 as biomarkers for the progression of CD after intestinal resection as assessed by endoscopic recurrence (Rutgeerts score). Preoperatively, median faecal calprotectin (1347 µg/g), lactoferrin (40.9 µg/g) and S100A12 (8.4 µg/g) levels were all elevated. Six months postoperatively, these biomarker concentrations were reduced (166, 3.0 and 0.9 µg/g) and were higher in recurrent disease versus remission (275 vs 72 µg/g, $p < 0.001$; 5.7 vs 1.6 µg/g, $p = 0.007$; 2.0 vs 0.8 µg/g, $p = 0.188$). Faecal calprotectin >135 µg/g, lactoferrin >3.4 µg/g and S100A12 >10.5 µg/g were indicative of endoscopic recurrence (Rutgeerts score ≥ 2) with sensitivity, specificity, and negative predictive values of 0.87, 0.66 and 91% for calprotectin, 0.70, 0.68 and 81% for lactoferrin, and 0.91, 0.12 and 71% for S100A12. Faecal calprotectin and lactoferrin levels were correlated with the presence and severity of endoscopic recurrence.

Comment (SM): Though faecal biomarkers have the potential to play a major role in the postoperative monitoring of CD patients for sustained remission or relapse, no single marker has shown the consistency to be considered a gold standard. Faecal calprotectin has attracted most attention so far, but is yet to show the high predictive value required for a universal screening test. The emergence of new faecal markers like S100A12, alpha1 antitrypsin, eosinophil-derived proteins etc., may provide additional tools for assessing the potential for relapse. Both the studies showed faecal calprotectin to be an effective marker for monitoring the disease activity in postoperative CD. The second study also showed faecal calprotectin to be an optimal marker in comparison to other markers like lactoferrin and S100A12, and also CRP and CDAI. It is interesting that S100A12 was sensitive but had low specificity and negative predictive value though it is neutrophil specific unlike calprotectin, which is also found in cells other than neutrophils! It is suggested that combining faecal markers does not seem to be of greater diagnostic value than using one alone. More accurate prediction of relapse may need an optimum combination of faecal and serum markers aided by non-invasive imaging like ultrasound.

Reference: *Inflamm Bowel Dis.* 2016;22(5):1086-1094

[Abstract](#)

Anaemia in patients with inflammatory bowel disease – A nationwide cross-sectional study

Authors: Portela F et al.

Summary: This Nationwide Portuguese observational cross-sectional multicentre study examined the prevalence of anaemia in 1313 IBD patients (54.8% female, mean age 42.8 years, 59% CD, 39% UC and 2% IBD unclassified) and sought to define its relationship to the main IBD clinical features. Over a median follow-up of 7 years, anaemia occurred in 244 patients (prevalence 18.6%; 95% CI 16.6-20.9). Most cases (90%) were mild or moderate anaemia (mean haemoglobin 11.3 g/dL) and the incidence was higher in females ($p = 0.006$). Differences between patients with CD (19.1%) and UC (17.7%) were not significant. Anaemia occurred more frequently (33.6 vs. 15.6%, $p < 0.001$) in patients with active disease (HBI >4 ; SCCAI >2) than in those in clinical remission and was more common in patients receiving steroids (36.8%) versus other treatments ($p < 0.001$). Only 47% of anaemia patients received specific treatment (oral iron 67%; intravenous iron 41%).

Comment (SM): This Portuguese observational study highlights the importance of anaemia in IBD and the need for improvement in management. The association between anaemia and increased clinical activity is well known and the association with increased use of corticosteroids and immunomodulators in this study indirectly echoes the same message. There was no association between anaemia and type of IBD in contrast to earlier studies, which have suggested anaemia to be more common in CD. The investigations done are very limited in this study and it is assumed that all patients with anaemia had iron deficiency, without measuring even the basic iron indices like ferritin. The relative merits of parenteral over oral iron are mentioned. The under treatment of anaemia highlighted in this study is a concern echoed in other studies previously. Even though iron deficiency and anaemia of chronic disease are the common causes, the aetiology of anaemia in IBD is diverse. The latest ECCO guidelines/consensus paper (Dignass AU et al. 2015 *J Crohns Colitis.* 2015;9(3):211-22) on anaemia in IBD is comprehensive and highly recommended.

Reference: *Digestion* 2016;93(3):214-20

[Abstract](#)

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1. Danese S et al. *Aliment Pharmacol Ther* 2011; 33:857-69. 2. Fidder H et al. *Gut* 2009;58(4):501-8. 3. Lichtenstein GR et al. *Am J Gastroenterol* 2012; 107:1409-22. 4. Rutgeerts P et al. *N Engl J Med* 2005; 353:2462-76. 5. Reinisch W et al. *Inflamm Bowel Dis* 2012;18(2):201-11. 6. Remicade Data Sheet 11 June 2015. Available at www.medsafe.govt.nz. 7. Janssen Data on File (JC141208).

For more information, please go to <http://www.medsafe.govt.nz>

Concentrations of adalimumab and infliximab in mothers and newborns, and effects on infection

Authors: Julsgaard M et al.

Summary: In a prospective study of 80 pregnant women with IBD, researchers in this multinational trial examined adalimumab (n = 36) and infliximab (n = 44) concentrations in umbilical cord blood, the rate of clearance in newborns after birth, and correlations with maternal drug concentrations and the infection risk during the first year of life. Time from last exposure inversely correlated with cord blood drug concentration (adalimumab $r = -0.64$, $p = 0.000$; infliximab $r = -0.77$, $p < 0.0001$) and mothers blood concentration at the time of birth (adalimumab $r = -0.80$; infliximab $r = -0.80$; both $p < 0.0001$). Median infant:mother drug concentration ratio at birth for adalimumab was 1.21 (95% CI 0.94-1.49) while for infliximab it was 1.97 (95% CI 1.50-2.43). Mean infant drug clearance time was 4.0 months (95% CI 2.9-5.0) for adalimumab and 7.3 months (95% CI 6.2-8.3; $p < 0.0001$) for infliximab; drugs were undetectable in infants by 12 months. A total of 4 (5%) infants developed bacterial infections and 16 (20%) developed viral infections. Where mothers had received the combination of an anti-TNF agent and thiopurine, the relative infection risk was 2.7 (95% CI 1.09-6.78; $p = 0.02$) versus anti-TNF monotherapy.

Comment (MS): IBD is common during younger years and therefore during reproductive years. To optimise pregnancy outcome it is generally recommended to conceive during times of remission and often treatment has to continue during pregnancy. Adalimumab and infliximab cross the placenta in clinically relevant concentrations during the third trimester leading to exposure of the infant. In this prospective study, with participation from New Zealand centres, 80 pregnant women with IBD receiving an anti-TNF- α blocker were recruited and blood from the umbilical cord was taken at the time of delivery to measure drug concentrations. Drug levels correlated with the time of last exposure and clearance was achieved after a mean of 4 months for adalimumab and 7.3 months for infliximab. It is noteworthy, however, that the majority of exposed infants had drug levels exceeding those of their mothers, due to accumulation. An increased risk of postnatal infections was seen in infants from mothers treated with a combination of thiopurine and anti-TNF agents.

Reference: *Gastroenterol.* 2016;Apr 7 [Epub ahead of print]

[Abstract](#)

Association between serrated epithelial changes and colorectal dysplasia in inflammatory bowel disease

Authors: Parian A et al.

Summary: In this retrograde, observational study, pathology data at a tertiary referral centre were analysed to evaluate the relationship between serrated epithelial changes (SEC), dysplasia and colorectal neoplasia in 187 patients with IBD. Mean IBD duration was 16 years and median follow up was 28 months. The rate of high-grade dysplasia or colorectal neoplasia was 17 per 1000 patient-years in patients with SEC and 21% had synchronous or metachronous dysplasia or colorectal neoplasia with 68% local concordance. Dysplasia in patients with SEC was associated with SEC on follow up endoscopies, older age at time of IBD diagnosis, male gender and having a first-degree relative with colorectal neoplasia. The authors conclude that SEC is associated with high incidence of dysplasia and that SEC on endoscopy further increases the risk of dysplasia or colorectal neoplasia.

Comment (SM): SEC is a more recently defined histological abnormality identified in patients with IBD characterised by bland non-hyperchromatic appearance and identified histologically by "saw tooth" epithelial architecture extending all the way down to the crypts. Early observations in the natural history of SEC in IBD are conflicting in their estimates of subsequent colorectal neoplasia risk. However, with the recognition of serrated pathway in the pathogenesis of colorectal neoplasia, accurate diagnosis and prognostic assessment of serrated lesions in IBD patients has important clinical relevance. This makes surveillance colonoscopies even more challenging; diligently looking for SEC with additional targeted biopsies. If future controlled studies support the clinical relevance of SEC, the inclusion of presence or absence of SEC in the histology reports may become obligatory, along with dysplasia.

Reference: *Gastrointest Endosc.* 2015;Dec 18 [Epub ahead of print]

[Abstract](#)

Independent commentary by Associate Professor Michael Schultz,

Consultant Gastroenterologist for the Southern District Health Board and Associate Professor in Medicine (Gastroenterology) at the University of Otago, Dunedin School of Medicine. **FOR FULL BIO** [CLICK HERE](#).



Independent commentary by Dr Srikantaiah Manjunatha (Manju) FRACP,

Consultant Gastroenterologist at Southern DHB, Dunedin and Honorary Senior Clinical Lecturer at the University of Otago. **FOR FULL BIO** [CLICK HERE](#).



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Maternal inflammatory bowel disease during pregnancy is not a risk factor for long-term morbidity of the offspring

Authors: Freud A et al.

Summary: This population-based cohort study (n = 255,352 deliveries from 1991-2014) examined whether offspring of women with IBD during gestation have an increased risk of long-term (≤ 18 years) paediatric morbidity (hospitalisation for cardiovascular, endocrine, neurological, haematological, respiratory, gastrointestinal, or urinary conditions). Among 278 children there was no increased risk for long-term morbidity versus a comparison group.

Comment (MS): Many patients ask questions not only about their own prognosis following a diagnosis of IBD but also about fertility and potential health risks future children might face. This study is important, as it looked long-term at the offspring of mothers with IBD. A family history of IBD, especially affecting a first-degree relative is the greatest risk factor for developing IBD, in some cases exceeding 30%. Conflicting data exists with regards to general pregnancy outcome in IBD patients. Some studies have shown no differences while others found higher rates of small for gestational age, preterm labour and low birth weight, caesarean delivery and fertility treatments. Of 255,352 deliveries, 278 were born by mothers with IBD. In the short-term, newborns were born a few days earlier, weighed slightly less, and there was a significantly higher rate of low birth weight. However, regarding long-term outcome, there was no difference in hospitalisation rates in all health related categories, including gastrointestinal IBD, assessed up to 18 years of age.

Reference: *J Crohn Col* 2016;Apr 16 [Epub ahead of print]

[Abstract](#)

Efficacy of thiopurines and adalimumab in preventing Crohn's disease recurrence in high-risk patients – a POCER study analysis

Authors: De Cruz P et al.

Summary: This sub-analysis of the POCER study compared the relative efficacy of thiopurines (azathioprine 2 mg/kg/day or mercaptopurine 1.5 mg/kg/day) and anti-TNF therapy (adalimumab induction then 40 mg fortnightly) in 101 patients (50% male; median age 36 years) at high risk of disease recurrence (smoker, perforating disease, $\geq 2^{\text{nd}}$ operation). Fifteen patients withdrew prior to 6-month follow-up. Endoscopic recurrence (Rutgeerts score ≥ 2) occurred in 33 (45%) of 73 thiopurine recipients versus 6 (21%) of 28 adalimumab-recipients (intent-to-treat [ITT] analysis $p = 0.028$). In per-protocol analysis, recurrence occurred in 24 (39%) of 62 thiopurine recipients versus three (13%) of 24 adalimumab-recipients ($p = 0.020$). Complete mucosal endoscopic normality (Rutgeerts i0) was observed in 23% of thiopurine recipients versus 54% of adalimumab-recipients (ITT; $p = 0.003$). In per-protocol analysis the proportions were 27% versus 63% ($p = 0.002$). Advanced disease (Rutgeerts i3 and i4) occurred in 8% of thiopurine versus 4% of adalimumab recipients.

Comment (SM): see right

Reference: *Aliment Pharmacol Ther.* 2015;42(7):867-79

[Abstract](#)

Infliximab reduces endoscopic, but not clinical, recurrence of Crohn's disease following ileocolonic resection

Authors: Reguiero M et al – PREVENT study group

Summary: This randomised trial in 297 patients compared infliximab 5 mg/kg versus placebo every 8 weeks for 200 weeks to prevent CD recurrence following resection. Numerically fewer infliximab than placebo recipients had a clinical recurrence (CD Activity Index score >200 and a ≥ 70 point increase from baseline, and endoscopic recurrence [Rutgeerts score ≥ 2], or development of a new or re-draining fistula or abscess) by week 76 (12.9% vs 20.0%), but this difference was not statistically significant (absolute risk reduction 7.1%; 95% CI -1.3 to 15.5; $p = 0.097$). Fewer infliximab than placebo recipients had endoscopic recurrence (30.6% vs 60.0%; ARR 29.4%; 95% CI 18.6-40.2; $p < 0.001$). Fewer infliximab recipients had endoscopic recurrence based only on Rutgeerts scores ≥ 2 (22.4% vs 51.3%; ARR 28.9%; 95% CI 18.4-39.4; $p < 0.001$). Previous anti-TNF recipients or those with >1 resection had a greater risk for clinical recurrence.

Comment (SM): Most patients with CD need intestinal resection, but a majority will also subsequently have recurrence needing further surgery. Various strategies have been tried to address this issue, but none has stood the test of time as ideal. The aim of the POCER study (De Cruz P et al. 2015. *Lancet.* 2015;385(9976):1406-17) was to define the optimal strategy to prevent postoperative CD recurrence and treatment according to clinical risk of recurrence, with early endoscopy and treatment intensification. The paper by De Cruz et al. is a part of the POCER study analysis comparing the efficacy of thiopurines and anti-TNF therapy in patients at high risk of recurrence. Adalimumab treatment showed significantly lesser recurrence rates and increased mucosal healing rates compared to thiopurines.

The second study, PREVENT, compared the efficacy of infliximab with placebo to prevent CD recurrence. Infliximab was not superior to placebo in preventing clinical recurrence, although there was significant reduction in endoscopic recurrence. The different outcome in this study could be due to limitations admitted by the authors: a) infliximab was started 45 days after resection by which time there could have been endoscopic recurrence and hence not 'preventive'; b) the primary end point of clinical recurrence may be influenced by CDAI which is subjective and has no correlation to endoscopic recurrence; c) Even though the intent was to recruit high-risk patients as in POCER, nearly 70% had only one risk factor and 57% were undergoing first resection. It is reasonable to monitor all patients and to approach low-risk patients with first resection conservatively. Treatment is initiated only if there is endoscopic recurrence at 6 months. High-risk patients need treatment and further intensification at 6 months if needed, and anti TNF agents seem to be superior to thiopurines in this group.

Reference: *Gastroenterology* 2016;Mar 2 [Epub ahead of print]

[Abstract](#)

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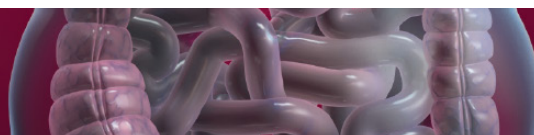


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Mobile phone apps for inflammatory bowel disease self-management: A systematic assessment of content and tools

Authors: Con D & De Cruz P

Summary: This study systematically assessed the content and tools of IBD mobile phone apps to identify functionalities that may facilitate self-management in patients. In total, 26 apps were assessed, including 10 for Android, eight for iOS platforms, and eight for both platforms. 54% of the apps provided diary functions and 39% provided health information about IBD; however, none offered decision support to facilitate self-initiation of medical therapy. 19% of the apps had professional medical involvement in their design. The apps covered only 38% of the international consensus statements examined (European Crohn's and Colitis Organisation, American College of Gastroenterology and Gastroenterology Society of Australia). Average price was AUD\$1.37.

Comment (MS): A recent study found 56% of the world's population owned a smartphone and although enthusiasm for mHealth is strong, the level of evidence does not match the level of excitement, as more than 90% of apps are reported as being of low quality. It is unknown whether IBD-related apps follow this trend and a recent comprehensive systematic review uncovered 50 trials pertaining to a range of diseases, none of which were IBD. It has been shown that a Web-based approach to IBD management improves patient engagement, quality of life and reduces the duration of relapse. The purpose of this paper, therefore, was to study the content and functions of commercially available apps for IBD patients in relation to their utility in assisting patients with self-management of IBD. From 238 apps initially identified, only 26 were included in this analysis. Unfortunately, no app offered decision support and no apps were identified that were specifically developed for self-management of IBD. This is not to say, though, that the available apps are not useful, as evidence from other chronic diseases suggests that educational and diary apps may have a role in improving self-efficacy, knowledge, and understanding, and enhance adherence to prescribed therapy.

Reference: *JMIR Mhealth Uhealth* 2016;4(1):e13
[Abstract](#)

Merrilee Williams,
Clinical nurse specialist in endoscopy, Mercy Hospital, Dunedin.

Quality of life and parental styles assessed by adolescents suffering from inflammatory bowel diseases and their parents

Authors: Jelenova D et al.

Summary: This cross-sectional study assessed the impact of adolescent IBD on adolescent patients and their parents. Twenty-seven adolescents with IBD and 39 healthy controls completed the questionnaires ADOR (parenting styles), KidScreen-10 (QoL), SAD (The Scale of Anxiety in Children), and CDI (Children's Depression Inventory), while their parents completed the BAI (Beck Anxiety Inventory), BDI-II (Beck Depression Inventory, second version), and PedsQL (Pediatrics Quality of Life) Family Impact Module. Generally, no significant differences were seen in the parental styles of the parents of the IBD adolescents and controls, except that the fathers' positive parental style was significantly higher in the fathers of the controls. The parents of adolescents with IBD exhibited a significantly lower QoL than the parents of the controls (PedsQL total scores in mothers 66.84±14.78 vs 76.17±14.65 and in fathers 68.86±16.35 vs 81.74±12.89, respectively). The mothers of adolescents with IBD were significantly more anxious (BAI scores 9.50±10.38 vs 5.26±4.75) and the fathers more depressed (BDI-II scores 7.23±6.50 vs 3.64±3.51) than the parents of the controls. There were no statistically significant differences between the adolescents with IBD and controls in QoL assessed using KidScreen-10, nor in the levels of anxiety or depression. A positive correlation was seen between the positive parental style of both the parents of the adolescents suffering from IBD and the QoL of the adolescents (evaluated by KidScreen-10). A negative correlation was seen between the positive parental style of the fathers and the adolescent's state and trait anxiety and the severity of childhood depression.

Comment (MW): It is to be expected that parents of a child with a chronic illness such as IBD are likely to have periods of anxiety or depression in response to the feeling of helplessness as they support their children through times of illness. This interesting study looks at how these emotional traits affect parents of children with IBD compared to children without chronic disease. As parents, they are responsible for the most part, for their children's success, ensuring they are well established within the healthcare setting, receiving optimal care, teaching them the benefits of managing their medication regime carefully and supporting them through difficult times, while empowering their children to live life to the fullest. Parents too need our support, through education, positive feedback and provision of information to support them in the role of parenting a youngster through the challenges of having IBD.

Reference: *Neuropsychiatr Dis Treat.* 2016;12:665-72

[Abstract](#)

Merrilee Williams is a clinical nurse specialist in endoscopy at Mercy Hospital in Dunedin and a study coordinator for clinical trials in gastroenterology, primarily IBD and hepatitis C, at the University of Otago. She previously worked for many years as a registered nurse in the Gastroenterology Unit, Dunedin Hospital. Merrilee is currently completing a Postgraduate Diploma in Health Sciences (Nursing) at the University of Otago.

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ASACOL™ ABRIDGED DATA SHEET - ASACOL 800mg enteric coated/gastro-resistant tablets. QUALITATIVE & QUANTITATIVE COMPOSITION: ASACOL 800mg enteric coated/gastro-resistant Tablets: Each gastro-resistant tablet contains 800mg mesalazine. Excipient with known effect: 152.8mg lactose. Therapeutic Indications **Gastro-resistant Tablets** Ulcerative Colitis: Induction of remission of mild to moderate episodes. Maintenance of remission. Crohn's ileo-colitis: Maintenance of remission. **Suppositories** Treatment of mild to moderate distal (proctitis and proctosigmoiditis) ulcerative colitis and maintenance of remission of distal ulcerative colitis. POSOLOGY & METHOD OF ADMINISTRATION **Gastro-resistant Tablets** **Ulcerative colitis** Induction of remission: 2.4 to 4.8g (6 to 12 of the 400mg tablets, or 3 to 6 of the 800mg tablets) a day in divided doses. The dosage can be adjusted in accordance with the response to the treatment. Maintenance of remission: 1.2 to 2.4g (3 to 6 of the 400mg tablets, or up to 3 of the 800mg tablets) a day taken once daily or in divided doses **Crohn's ileo-colitis** Maintenance of remission: 2.4g (6 of the 400mg tablets, or 3 of the 800mg tablets) in divided doses. **Older People:** The normal adult dose can be taken unless liver or renal function is severely impaired (see Data Sheet). No studies have been carried out in older people. **Paediatric Population:** **Asacol 400mg and 800mg Tablets:** There is only limited documentation for an effect in children (age 6 - 18 years). **Children 6 years of age and older** Active disease: To be determined individually, starting with 30-50mg/kg/day in divided doses. Maximum dose: 75mg/kg/day in divided doses. The total dose should not exceed 4.0 g/day. Maintenance treatment: To be determined individually, starting with 15-30mg/kg/day in divided doses. The total dose should not exceed 2.0 g/day. It is generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg. Asacol tablets must be swallowed whole preferably with some liquid before food intake. They must not be chewed, crushed or broken before swallowing. If one or more doses have been missed, the next dose is to be taken as usual. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Known hypersensitivity to salicylates. Severe liver impairment. Severe renal impairment (GRF < 30mL per minute/1.73m²). Children under 2 years of age. **SPECIAL WARNINGS & SPECIAL PRECAUTIONS** **FOR USE** Renal Impairment Urinary status (dip sticks) should be determined prior to and during treatment, at the discretion of the treating physician. Caution should be exercised in patients with raised serum creatinine or proteinuria. The possibility of mesalazine-induced nephrotoxicity should be suspected in patients developing impairment of renal function during treatment. Treatment with ASACOL should be stopped immediately if there is evidence of renal impairment and patients should seek immediate medical advice. Blood Dyscrasia Serious blood dyscrasia has very rarely been reported. ASACOL therapy should be stopped immediately if there is a suspicion or evidence of blood dyscrasia (signs of unexplained bleeding, bruising, purpura, anaemia, persistent fever or sore throat), and patients should seek immediate medical advice. **UNDESIRABLE EFFECTS** **Gastrointestinal disorders** Common: dyspepsia. Skin and subcutaneous tissue disorders Common: rash. **Prescription Medicine.** Asacol is a fully funded medicine on the Pharmaceutical Schedule. DATE OF PREPARATION 22 May 2014 Based on ASACOL 400mg tablets, ASACOL 800mg tablets & ASACOL 500mg suppositories SPC revised February 2014. Please refer to the Medsafe website (www.medsafe.govt.nz) for full approved data sheet. ASACOL is a registered trademark of Tillotts Pharma AG. TAPS 4711MM ANZ/167/16-0001.

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USING RESEARCH REVIEW ABSTRACTS FOR CNE POINTS

Time spent reading this publication has been approved for Continuing Nursing Education (CNE) by The College of Nurses Aotearoa (NZ) for RNs and NPs. All you have to do is to have a record of the activity and a few sentences about what you learnt and how this impacts your practice as a RN & NP on the CNE Template. **Available by clicking [HERE](#).**

We have used some of the recent Diabetes & Obesity Research Review abstracts as examples to show how you can easily record such activity if you would like this to contribute to your requirement for CNE. This example template can be used as a guide for completing the reflection form across all Research Reviews.

See the College of Nurses website for more information on Continuing Nursing Education (CNE) <http://www.nurse.org.nz/continuing-nursing-education-cne-template.html>



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This template is designed as a permanent record of a continuing nursing education (CNE) or professional development activity. Complete one template for each research review.

Name:

Practice area:

Details of the research review chosen for this activity:

Diabetes & Obesity Research Review Issue 104

Key points from the review:

- Need to encourage all adolescents to exercise regularly due to long-term risk of obesity and lack of fitness & CV risk later in life.
- Reducing weight gain (even modest weight loss) in high-risk individuals (including rural women) does reduce rates of type 2 diabetes.
- Structured self-management education programmes are an important part of a quality diabetes service and help to reduce emergency diabetes-related incidences.

Application to my practice:

Making time to work with people towards manageable, realistic and incremental lifestyle adjustments has considerable benefits in terms of managing diabetes and reducing CV risk.

Length of time given to each review: 30 minutes

For CNE purposes allow 30 minutes per Research Review publication for reflective reading and follow-up.