

PERSPECTIVES
ON IBD
QUALITY
OF CARE



PRESS KIT

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European
Crohn's and Colitis
Organisation

PERSPECTIVES ON IBD QUALITY OF CARE



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PERSPECTIVES ON IBD QUALITY OF CARE



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PRESS RELEASE

Improving quality of care for IBD

(Copenhagen, February 19, 2014) Inflammatory Bowel Disease (IBD) affects more than 3 million people in Europe, usually starting at a young age. There is no known cure and care is variable despite European (ECCO) Guidelines.

“**Perspectives on IBD Quality of Care**” is a campaign by the European Crohn’s and Colitis Organisation (ECCO) to raise public awareness during the world’s largest meeting on IBD to

- Present the patients’ perspective
- Report a 5,000 patient survey
- Describe the IBD2020 Aspirations
- Highlight the newest research
- Outline ways to improve quality of care
- Open a unique Art Exhibition that captures the physical, psychological and socio-economic challenges for patients

The patient’s perspective

More than 3 million people in Europe are affected by Ulcerative Colitis or Crohn’s Disease. They and their families have no choice but to live with the consequences daily and learn to cope with IBD. One of those 3 million, Irish citizen Gerald Nash, has been invited to tell his story. He was 14 when he was first diagnosed with Crohn’s Disease. “We have to get more comfortable with talking about conditions such as Crohn’s and Colitis. I find it invaluable talking to other people with IBD about how they manage their own condition as well”, says Gerald Nash.

Dr. Marco Greco from the European Federation of Crohn’s and Colitis Associations (EFCCA) confirms: “Quality of care often concentrates on quality of services, therapy, desired health outcomes, effectiveness and timeliness of care. Even though these are important aspects we feel that an important outcome, namely the patient’s quality of life, can sometimes be forgotten. Instead of concentrating on therapy alone, we should be concentrating on the individual with his or her personal needs.”

The IBD2020 survey

IBD2020 is a global forum created to discuss initiatives to improve the quality of care for patients with IBD. A survey (2013) attracting responses from over 5000 patients from 6 countries found that

- A quarter had to wait more than a year for diagnosis
- A third had emergency admissions in the last 12 months

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- One in five described “continuous” symptoms in the last 12 months
- Less than half had a discussion on goals of treatment
- A minority had a consultation with a specialist nurse
- Perceived quality of care was closely related to involvement in treatment decisions

“Thinking about their care in the previous 12 months, only 44% of all respondents said that a healthcare professional had discussed with them the main goals or priorities for their care and only 20 % said that a healthcare professional had helped them make a plan for their daily life with IBD”, says Richard Driscoll, co-chair of IBD2020. Driscoll continues, “One of the key principles of good IBD care is access to a multidisciplinary team that includes a gastroenterologist, a surgeon, a specialist nurse, a dietitian and a psychologist or counsellor. There have been improvements over time in IBD care but it varies enormously between countries and the process has been slow”.

IBD2020 Aspirations for better quality of care

In a collective effort, patients, patient associations, physicians and industry established so-called “Aspirations for Quality of Care” at IBD2020. In summary:

- Patients with IBD should
 - Be treated with the goal of controlling inflammation to prevent progression (IBD2020 Delphi Consensus: 96.6%)
 - Have access to specialist IBD multidisciplinary care (IBD2020 Delphi Consensus: 100%)
 - Have access to all therapeutic options (IBD2020 Delphi Consensus: 89.7%)
 - Have rapid access to specialist care to enable accurate diagnosis (IBD2020 Delphi Consensus: 100%)
 - Be provided with easy access to educational resources (IBD2020 Delphi Consensus: 100%)
 - Be informed about research for which they might be eligible and should be enabled to participate if they wish to do so (IBD2020 Delphi Consensus: 96.4%)
- Health professionals and healthcare administrations should value and support the role of patient associations (IBD2020 Delphi Consensus: 96.6%)
- Government and healthcare administrations should ensure that IBD care is adequately resourced and researched (IBD2020 Delphi Consensus: 100%)

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“The survey findings and aspirations remind healthcare administrations and governments of their responsibility to ensure that IBD care and research should be adequately resourced,” says Driscoll.

Newest research on IBD at ECCO

The ECCO Congress 2014 has attracted a record number of over 4700 specialists from all disciplines, patients and industry, as well as almost 1000 original papers (abstracts) presenting the newest research.

Professors Michael Kamm, Melbourne and Brian Feagan London, Ontario, present their pick. One highlight is the POCER study “While new drugs and discoveries about disease causation are important, most patients with Crohn’s Disease require surgery at some stage in their life and in most the disease will recur. The Post-operative Crohn’s Endoscopic Recurrence study (POCER) is a treat-to-target study which evaluated the value of endoscopic monitoring after surgery, the timing and best use of drug therapy, the risks for recurrence and whether marker measurement (calprotectin) can substitute for endoscopic monitoring” says Kamm. “Management is increasingly focused on patient involvement, to the extent that patients can self-monitor or manage their disease at home. New means of measuring faecal calprotectin at home transmit results to a central nurse who can rationalise patient care and indicate when a change of therapy is required.” Kamm continues: “The most effective current therapy for IBD is anti-TNF therapy. Many new drugs are under development, but those most likely to have an impact in the near future are those that inhibit homing of inflammatory cells to sites of inflammation”. Professor Feagan takes up the narrative to describe the REACT study, presented for the first time at ECCO: “The REACT study in Canada compared a structured approach to treatment with conventional care. It showed the potential to reduce hospitalisation and surgery very significantly using a structured approach to care.” Other highlights being presented include the TOSCA study on a new drug that stops immune cells homing into exacerbate inflammation in Crohn’s Disease that may have a particular role when patients lose response to anti-TNF therapy and encouraging results on tralokinumab, targeting IL-13.

Improving care for IBD

“To know that you are improving care for IBD, first you have to measure care. The aim is to provide added value”, says Professor Daniel Hommes, Los Angeles. POLARIS is a study that has evaluated clinical practice patterns for patients with IBD using health care assessment questionnaires to assess treatment patterns and quality of care from the perspective of patients with

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Crohn's Disease and their healthcare providers in Canada and Germany. "Only by improving quality will we be able to add value and contain the costs of care," outlines Hommes.

Next steps

"Our aim is to seek common ground and identify differences, so that the territory of quality assessment and improvement in IBD can be defined" said Dr. Simon Travis at the IBD2020 Forum in Oxford in September 2013. Next steps include

- Sharing current examples of best practice
- Defining a vision for global quality of care, incorporating clinician and patient perspectives
- Acknowledging the need for standards to change the healthcare landscape in IBD
- Establishing practical approaches to measure improvement in the quality of care
- Mobilising strategies to ensure that delivering high quality IBD care becomes a focus in all countries

You can help. Describe the patient experience, report the research at ECCO, promote the Perspectives in IBD exhibition and give IBD a voice.

Perspectives on IBD Quality of Care has been made possible through support of sponsors. ECCO is grateful for this generosity and will continue to make tireless efforts to be a strong voice for each and every one suffering from IBD.

Contact the ECCO Office for further information

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SPEAKERS



Séverine Vermeire, MD PhD

University Hospital of Leuven, Leuven, Belgium



Daniel W. Hommes, MD PhD

UCLA Center for Inflammatory Bowel Diseases, Los Angeles
United States



Gerald Nash, TD

IBD Patient, Parliamentarian, Drogheda, Ireland



Marco Greco, PhD

Chairperson of EFCCA, Milan, Italy



Richard Driscoll

Independent Healthcare Consultant, St. Albans, United Kingdom



Michael Kamm, MB BS MD FRCP FRACP

St Vincent's Hospital and University Of Melbourne, Australia &
Imperial College, London, United Kingdom



Brian G. Feagan, MD FRCPC

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London Health Sciences Centre University of Ontario, Western
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Simon Travis, DPhil FRCP

John Radcliffe Hospital, Oxford, United Kingdom

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STATEMENTS

Today's press conference in perspective

Séverine Vermeire, MD PhD

University Hospital of Leuven, Leuven, Belgium
President-Elect of ECCO

In an era of economic crisis and financial challenges in Europe, healthcare has been put under considerable pressure in many countries. Patients suffering from chronic diseases such as Inflammatory Bowel Disease are very vulnerable to these recesses.

Moreover, the fact that disease onset shows a shift to younger ages causing biological therapies – which are associated with considerable expenses - to be applied earlier in the disease and continued for many years, should push healthcare providers to critically revise standards and quality of care throughout the EU countries.

For this, the unmet needs should be clearly defined, both from the patient's perspective as from the medical experts and both should seek where and how care can be improved. Optimising care does not necessarily mean cutting down on the healthcare budget as room for innovation needs to be guaranteed, something which ECCO has always put high up on the priority list.

It is only by critical self-reflection and an open mind that one can always do better in order for this to be achieved! I would also invite all stakeholders in this mission to join forces!

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Current situation and unmet needs

Daniel W. Hommes, MD PhD

UCLA Center for Inflammatory Bowel Diseases, Los Angeles,
United States

Seen in a global perspective the health expenditure is uncontrolled. There is significant waste in the way healthcare is provided. Only a minor part, 3%, of the money spent is used for prevention, 75% is spent on treatment.

70% of healthcare expenditures is spent on chronic diseases. A comparison conducted by the Agency for Healthcare Research and Quality's (AHRQ) shows that Inflammatory Bowel Diseases is among the most expensive diseases.

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The patient's perspective

Gerald Nash, TD

IBD Patient, Parliamentarian, Drogheda, Ireland

Gerald Nash will discuss what it was like, as a fit and active 14 year old, to be diagnosed with Crohn's Disease. He will refer to the sense of loneliness and confusion which the diagnosis first aroused, and the search for understanding by him and his family in terms of how their lives would change and adapt.

Gerald will discuss how he has learned to live with IBD; what he feels works (and doesn't work); and how a diagnoses of Crohn's should not mean any limitations on your life experiences. He will also speak about how services and social attitudes to IBD need to change.

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The patient's perspective

Marco Greco, PhD

Chairperson of EFCCA, Milan, Italy

Recent results of the IBD2020 survey involving patient associations have highlighted that the aims of care are rarely discussed between patients and doctors. 50% of respondents said that no healthcare professional discussed with them main goals or priorities in caring for their condition(s). Even more alarming 72% of respondents said that no healthcare professional helped make a plan that could be carried out in daily life. These results clearly show a need for improving the quality of care in IBD!

Similar results and ...not...

The IBD2020 survey shows that there are not enough discussions amongst patients and doctors and it reveals that care is therapy-oriented and the overall impact of IBD on patient's life is often forgotten. The message emerging from the IMPACT survey remains the same: more efforts need to be made to ensure that the quality of life for people living with IBD is improved in all domains including social life, relationships, work and education.

"Quality of care" often concentrates on quality of services, therapy, desired health outcomes, effectiveness and timeliness of care. Even though these are important aspects we feel that an important outcome, namely the patient's quality of life, can sometimes be forgotten. Instead of concentrating on therapy alone, we should be concentrating on the individual with his or her personal needs.

We are aware that factors such as the economy, structure of trials and drug-development, guidelines, lack of time, lack of resources (also human) and the patient themselves can lead to the risk of a "therapeutic-focused" approach.

From "therapeutic-focused" approach to "patient-focused" approach

We believe that care should not only be evidence-based but also patient-based. We need to "think outside the bowel"...the patient is more than just his/her illness. Of course not only healthcare personnel but also patients must be more aware of their role.

Therefore we recommend that patients are the ones to refer to when you need "first-hand" information. A patient with a long history of IBD has a lot of experience and knowledge; theoretical knowledge is not the equivalent of a patient's subjective feelings and long experience with IBD.

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The involvement of patients

Decisions must be made in cooperation with patients and healthcare professionals, both must listen to one another. If this is based on a real cooperation built on trust, the patients will be more compliant if there is a trusting environment with the healthcare professionals.

What can be done to improve the quality of care for patients?

We think it is important that the medical profession cooperates with us and that we together can develop new strategies. We also believe it is valuable that newly diagnosed (but not only) patients and their families are informed about the existence of patient associations and the work we do. On a political level we think it is essential to lobby together in order to achieve our common aims.

To conclude: patients should come back to the centre of OUR common work. This approach could lead to a better allocation of the actual limited resources. This approach would work only in the contact of an open, honest and mutual cooperation.

UNITED WE STAND

About EFCCA

The European Federation of Crohn's & Ulcerative Colitis Associations is an umbrella organisation representing 28 national patients' associations from 27 European countries and 3 associate members from outside Europe. EFCCA aims to work to improve life for people with IBD and give them a louder voice and higher visibility across Europe.

For more information please visit our website at: www.efcca.org

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Aspirations for better quality of care

Richard Driscoll

Independent Healthcare Consultant, St. Albans, United Kingdom

The IBD2020 Forum held in Oxford in September 2013 brought together representatives of 13 IBD patient organisations and 38 clinicians from 18 countries. The aims of the meeting were to promote quality improvement in Inflammatory Bowel Disease (IBD) care by

- Sharing ideas and experiences across countries, share current examples of best practice and future perspectives for improving the quality of IBD care
- Defining a vision ('aspirations') for global quality of care, incorporating clinician and patient perspectives
- Discussing practical approaches to enable improvement in quality of care.

To form a basis for discussion at the meeting, with the help of six IBD patient organisations, we undertook a survey of IBD patients' perspectives on their healthcare. Over 5,000 patients completed the survey from Canada, France, Italy, Spain, Sweden and the UK. The questions asked about the person's IBD, medication, healthcare and their IBD-related online activity.

As is often the case with health surveys, more women than men participated, however there was a good representation of a range of ages, both with Crohn's Disease (CD) and Ulcerative Colitis (UC).

The impact of IBD on people's lives was illustrated by the fact that in the previous 12 months 52% had had 1-3 flares of disease, 19% said their disease was active continuously, 29% had had one or more emergency admissions to hospital; 57% of those in employment had had some time off work due to IBD and 35% had lost 5 days or more.

About 50% of patients rated their care over the last 12 months as excellent or very good, 30% as good and 20% as only fair or poor.

Other key findings were:

- More than 1 in 3 patients with CD waited more than a year for diagnosis from the time they first went to their doctor with symptoms. Disappointingly this time interval had not improved over the last 25 years
- Two-thirds of patients with CD and 42% of those with UC had at least one emergency visit to hospital before being diagnosed

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- A third of patients with CD and 15% of those with UC had three or more emergency visits.

We asked patients about the care they received in the first 12 months after diagnosis:

- Apart from the UK, only 20% of patients or fewer had a consultation with an IBD specialist nurse
- In France, Italy and Spain only about 20% of patients were given leaflets about IBD; Canada, Sweden and the UK only achieved 54-61%
- Only 10% were offered group education to help them understand their disease
- Less than 40% in all countries were told about their national patient organisation.
- There has been a trend to improvement over the past 25 years, but the figures clearly show that many patients are not receiving even basic information from their healthcare team.

Survey findings indicate there is a failure consistently to involve patients in the management of their disease and their life with IBD. Thinking about their care in the previous 12 months, only 44% of all respondents said that a healthcare professional had discussed with them the main goals or priorities for their care and only 20% said that a healthcare professional had helped them make a plan for their daily life with IBD. Canada, France and Italy seemed a little better at this than the other countries.

One of the key principles of good IBD care is access to a multidisciplinary team (MDT) that includes a gastroenterologist, a surgeon, a specialist nurse, dietician and a psychologist or counsellor. Our survey showed that there was a significant unmet need among patients for access to dietary advice and psychological support and only 33% had access to a specialist nurse. Interestingly, when we looked at those patients who did or did not have access to a full MDT, we found that only 48% of those who did not have access rated their care excellent or very good, compared with 76% of those that could access a nurse, dietician and a psychologist or counsellor.

These findings underpinned all the discussions at the IBD2020 Forum. Everyone recognised that whilst there have been improvements over time in IBD care, this varies enormously between countries and progress is slow. One of the aims of the meeting was to develop a set of shared aspirations between patients and healthcare professionals that would express what

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good quality IBD care should look like. They also remind healthcare administrations and governments of their responsibility to ensure that IBD is not neglected, and that IBD care and research should be adequately resourced.

This is a summary of the aspirations:

- Patients with IBD should
 - Be treated with the goal of controlling inflammation to prevent progression
 - Have access to specialist IBD multidisciplinary care
 - Have access to all therapeutic options
 - Have rapid access to specialist care to enable accurate diagnosis
 - Be provided with easy access to educational resources
 - Be informed about research for which they might be eligible and should be enabled to participate if they wish to do so
- Health professionals and healthcare administrations should value and support the role of patient associations
- Government and healthcare administrations should ensure that IBD care is adequately resourced.

More information about the IBD2020 Forum can be found at www.ibd2020.org and in the published report.

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Newest research on IBD at ECCO

Michael Kamm, MB BS MD FRCP FRACP

St Vincent's Hospital and University of Melbourne, Melbourne, Australia & Imperial College, London, United Kingdom

Some of the research highlights at this year's ECCO meeting include:

Improving disease management

While new drugs and discoveries about disease pathogenesis are important, care for patients with Inflammatory Bowel Disease can be improved now by testing and adopting proven beneficial management strategies.

A key example relates to the management of Crohn's Disease patients in relation to surgery. Most patients with Crohn's Disease require an intestinal resection at some stage in their life, but in most the disease will recur. The Post-Operative Crohn's Endoscopic Recurrence (POCER) study, presented and awarded at ECCO this year, was a treat-to-target study which aimed to maintain mucosal healing after surgical resection. It evaluated the value of endoscopic monitoring after surgery, the timing and best use of drug therapy, the identification of risks for recurrence, and whether marker measurement (calprotectin) can substitute for endoscopic monitoring.

The POCER study demonstrated that treating according to a patient's risk of recurrence, with early colonoscopy and treatment step-up for recurrence, is superior to optimal drug therapy alone in preventing post-op disease recurrence. Faecal calprotectin can be used to monitor for recurrence and is superior to established serologic markers and clinical indices. This study has established a management paradigm for patients undergoing surgical resection.

Management is becoming increasingly focused on patient involvement, to the extent that patients can self-monitor or manage disease at home. Biomarkers such as faecal calprotectin have gained an increasingly prominent role in identifying active disease. New means of measuring faecal calprotectin at home have been developed. Collection, processing, and transmitting the result to a central physician or nurse can now streamline patient care, and indicate early when a change of therapy is required.

New drug therapies

Anti-TNF therapy is the most effective therapy for IBD currently available. While many new drugs are under development, those

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that are most likely to have a big impact in the near future are those that inhibit homing of inflammatory cells to sites of inflammation, or their entry to sites of inflammation. Several presentations at ECCO will consider the safety of these drugs in relation to ongoing immune surveillance, their efficacy, and their role in contrast to established anti-TNF therapy.

What causes IBD? - Investigating the microbiome

Organisms in the gut lumen are central to driving the inflammatory process in IBD, or protecting against it. At ECCO this year an organism that may be central to maintaining mucous integrity, *Akkermansia muciniphila*, has been demonstrated to be deficient in ulcerative colitis.

Faecalibacterium prauznitzii has been shown to be deficient in Crohn's Disease. A protein derived from this bacterium that may play an important anti-inflammatory role has been characterised. Such translational research opens up the possibility of new gut - derived therapies. Details will be presented in oral abstract presentations as part of the scientific programme at the 9th Congress of ECCO.

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Newest research on IBD at ECCO

Brian G. Feagan, MD FRCPC

Division of Gastroenterology Department of Epidemiology and Biostatistics. CEO Robarts Clinical Trials Inc. Robarts Research Institute London Health Sciences Centre University of Western Ontario London, Ontario, Canada.

REACT- Randomized Evaluation of an Algorithm for Crohn's Treatment

The primary objective of the REACT study was to determine if the implementation of a treatment algorithm for Crohn's Disease featuring early combined immunosuppression would increase rates of symptomatic remission compared to conventional management at community based gastroenterology practices.

The secondary objective was to assess impact of implementation of a treatment algorithm on hospitalisations, complications, medication use, and quality of life.

40 practices were recruited for this study, 34 from Canada and 6 from Belgium.

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Next steps

Simon Travis, DPhil FRCP

John Radcliffe Hospital, Oxford, United Kingdom
President of ECCO

The aim of IBD2020 was to seek common ground across countries and identify differences between initiatives, so that the territory of quality assessment and improvement in IBD could be defined. The IBD2020 meeting was simply the start: the momentum to improve the quality of care is unstoppable, with everyone now recognizing the need to address quality to improve the lives of patients, ensure that treatment is used for the right reasons, at the right time, and yes, to contain costs that often arise from complications of inappropriate care.

Next steps include

- Sharing current examples of best practice
- Defining a vision for global quality of care, incorporating clinician and patient perspectives
- Acknowledging the need for standards to change the healthcare landscape in IBD
- Establishing practical approaches to measure improvement in the quality of care
- Mobilising strategies to ensure that delivering high quality IBD care becomes a focus in all countries

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CURRICULUM VITAE

Séverine Vermeire, MD PhD

University Hospital of Leuven, Leuven, Belgium

Séverine Vermeire is a full-time staff member of the Gastroenterology department at the University Hospital of Leuven, Belgium, and is currently Associate Professor at the Catholic University of Leuven.

She received her medical degree from the Catholic University of Leuven and undertook further training at the Universidad Nacional de Asuncion, Paraguay, and at the Montreal General Hospital (McGill University) in Canada. Dr. Vermeire spent time at the University of Oxford, UK, while working towards her PhD. Dr Vermeire is President-Elect of ECCO. Her scientific work has contributed to more than 250 peer-reviewed papers. Dr. Vermeire is an associate editor for the *Journal of Crohn's and Colitis*.

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CURRICULUM VITAE

Daniel W. Hommes, MD PhD

UCLA Center for Inflammatory Bowel Diseases, Los Angeles,
United States

Daniel is a certified internist & gastroenterologist specialised in Inflammatory Bowel Diseases (IBD). After completing medical school at the University of Amsterdam, he spent many years working in the Academic Medical Center (Amsterdam) where he qualified as an internist (2000) and later as a gastroenterologist (2002). His PhD thesis (1994) dealt with novel drug targets for IBD, supervised by *Prof Dr Sander van Deventer* and *Prof Dr Guido Tytgat*. In 2001, he was appointed Head of the IBD department in the Academic Medical Center in Amsterdam.

In 2006 he moved to Leiden, the Netherlands, to become Chair of the department of Gastroenterology and Hepatology at the Leiden University Medical Center (LUMC). In 2007 he was appointed full professor of Gastroenterology and Hepatology at the University of Leiden. He successfully reorganised the department, focusing on IBD, liver diseases (incl. liver transplantation) and colorectal cancer. He established a clinical trial center as well as a basic research lab with 4 post-docs and 12 PhD students. In addition, he designed 'CuraRata' (www.curarata.com), a platform for personalised medicine successfully piloted in IBD patients and officially launched by the Dutch Minister of Health.

Nationally, Daniel was one of the founders of the Dutch Academic IBD Society ICC which he chaired from 2003 until 2007. Also, he initiated the Pearl String Initiative (PSI) in 2006, a national academic biobanking infrastructure between the eight Dutch University Medical Centers for eight disease areas, supported by a € 35 million Dutch Government funding program.

Internationally, Daniel served as primary investigator in numerous IBD programs and studies since 2001 and was invited to act as both a consultant and member of advisory boards on many occasions for a wide variety of biomedical industry. He has authored well over 190 peer-reviewed papers and has lectured all around the globe. His interest and expertise in integrating biobanking into healthcare led to a number of consultancies in Europe and the US. In addition, he serves as reviewer and editor for medical journals. From 2004 to 2008 he chaired the Scientific Committee of the European Crohn's and Colitis Organisation ECCO, and from 2010 until 2012 he served as ECCO President.

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In 2011 Daniel moved to Los Angeles where he was appointed as professor of Medicine at the Division of Digestive Diseases of UCLA. He serves as director of the Center for Inflammatory Bowel Diseases, being responsible for both the clinical programmes as translational research. In addition, he will implement a quality programme across the entire division.

Together with his UCLA team, he has now successfully piloted a value-based healthcare delivery programme in over 830 IBD patients. This programme integrates a number of different aspects of modern healthcare, like home care, biobanking, a mental reinforcement programme, patient education and much more. This is demonstrated in two YouTube videos: Vision <http://youtu.be/da7dRLSQPEI>; Operations: <http://youtu.be/HdmsL7GVmMg>). This programme has further expanded from September 1, 2012 and on. UCLA leadership has endorsed his pioneering programmes on value-based healthcare and a combined effort between the UCLA Health Innovation Council and the UCLA Growth Strategy Committee resulted in a recent Value Summit (September 2013) during which his IBD model has been chosen as a model to be rolled out across a wide range of diseases in the UCLA Health System. He will coordinate this project with a UCLA team of experts and aim to design and test multiple value-based models over the next year.

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CURRICULUM VITAE

Gerald Nash, TD

IBD Patient, Parliamentarian, Drogheda, Ireland

Gerald Nash is a member of the Irish Parliament (Dáil Eireann). First elected in 2011, he was formerly Mayor of his home city, Drogheda, and formerly worked in the public relations field with the not-for-profit sector. Now 38, he was diagnosed with Crohn's Disease in 1990. As a public figure, Gerald has worked with the Irish Society for Crohn's & Colitis to raise awareness of IBD, speaking publicly about the challenges of living with Crohn's and advocating for improved services and a wider public understanding of IBD.

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CURRICULUM VITAE

Marco Greco, PhD

Chairperson of EFCCA, Milan, Italy

Marco Greco is chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) since 2008. He has also been the founder of the EFCCA Youth Group, and was its leader from 2003 till 2007.

He is also board member of the European Patients' Forum (EPF) and member (alternate patients' representative) of the Pharmacovigilance Risk Assessment Committee at European Medicines Agency (PRAC-EMA).

He works as attorney at law. He has a PhD in Law and Religion, Religious Freedom and Discrimination and a master degree in law both earned at Università Cattolica del Sacro Cuore in Milano, where he still cooperates on several projects.

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CURRICULUM VITAE

Richard Driscoll

Independent Healthcare Consultant, St. Albans, United Kingdom

Richard Driscoll works as an independent healthcare specialist with a particular interest in patient engagement and quality improvement in health services for long term conditions. He has substantial experience in bringing together patients, health professionals, pharmaceutical companies and National Health Service organisations to collaborate in projects designed to deliver high quality patient-centred care. Within IBD in the UK he has a continuing part-time role as Director of Development for the UK IBD Registry, and he recently co-chaired the IBD2020 Global Forum with Simon Travis in Oxford in September 2013.

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CURRICULUM VITAE

Michael Kamm, MB BS MD FRCP FRACP

St Vincent's Hospital and University of Melbourne, Melbourne, Australia & Imperial College, London, United Kingdom

Michael Kamm is Professor of Gastroenterology at St Vincent's Hospital Melbourne, University of Melbourne, and Imperial College London.

From 1986 until 2008 he was Professor of Gastroenterology (Imperial College), Chairman of Medicine, and Director of the Inflammatory Bowel Disease and Physiology Units at St Mark's Hospital, the London specialist hospital for intestinal diseases.

His special interests are in Inflammatory Bowel Diseases and functional gut and pelvic floor disorders. He spends half his time in clinical practice and half in research and teaching. Michael Kamm publishes and lectures widely.

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CURRICULUM VITAE

Brian G. Feagan, MD FRCPC

Division of Gastroenterology Department of Epidemiology and Biostatistics. CEO Robarts Clinical Trials Inc. Robarts Research Institute London Health Sciences Centre University of Western Ontario London, Ontario, Canada.

Brian G. Feagan, MD, is CEO of Robarts Clinical Trials Inc. at the Robarts Research Institute and Professor of Medicine at the University of Western Ontario in London, Ontario, Canada.

Brian G. Feagan completed a medical degree at the University of Western Ontario in London, Ontario, Canada. His postdoctoral training included residency in the Department of Medicine and a clinical fellowship in the Division of Gastroenterology at the University of Western Ontario. A Fellow of the Royal College of Physicians and Surgeons of Canada, Dr. Feagan holds membership in the Canadian and American Association of Gastroenterology, the American College of Gastroenterology, the College of Physicians and Surgeons of Ontario and Crohn's and Colitis Foundation of Canada. Dr. Feagan has authored over 100 articles, book chapters, and monographs and over 200 abstracts. He has also given over 800 invited presentations and national and international scientific meetings.

In 1997, Dr. Feagan became Director of Robarts Clinical Trials at the University of Western Ontario. His research efforts focus on the design and implementation of randomized controlled trials of therapy for Inflammatory Bowel Disease and he has been the principal investigator on numerous large-scale randomized clinical trials.

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CURRICULUM VITAE

Simon Travis, DPhil FRCP

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Simon Travis is President of the European Crohn's and Colitis Organisation (ECCO, 2012–2014), Fellow of Linacre College at the University of Oxford and Consultant Gastroenterologist at the John Radcliffe Hospital in Oxford. He qualified from St Thomas' Hospital London in 1981 and trained in Gastroenterology both in London and in Oxford, where he did his PhD on colonic epithelial electrophysiology. He was formerly Chair of the IBD Section of the BSG (2002–2005), Member of Council of the British Society of Gastroenterology (2004–2007) and Chair of the scientific committee of ECCO (2007–2010). Research interests focus on inflammatory bowel disease, clinical prediction, endoscopy and outcomes in clinical trials. He is the author of 6 books, 30 chapters and over 200 papers including many peer-reviewed international guidelines.

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FACT SHEET ECCO

What is ECCO?

The European Crohn's and Colitis Organisation (ECCO) is a fast growing and highly active non-profit association focusing on Inflammatory Bowel Disease (IBD). ECCO acts mainly in Europe and encourages collaboration beyond Europe's borders allowing anyone around the globe interested in IBD to benefit from our programme and services.

Mission

ECCO's mission is to improve the care of patients with IBD in all aspects through international guidelines for practice, education, research and collaboration in the area of IBD.

Aims

A key goal of ECCO is to promote, sponsor and steer national and international IBD research efforts. ECCO successfully influences IBD management through the development, publication, dissemination and teaching of IBD guidelines and other educational materials such as workshops and the e-CCO learning platform. ECCO facilitates and promotes the education of healthcare professionals in the field of IBD. It enhances the quality of research in the field of IBD, both in basic and clinical science.

ECCO takes a political voice in Europe and collaborates with organisations sharing an interest in IBD, including medical societies, patient organisations and industries. Furthermore ECCO participates in the activities of the United European Gastroenterology (UEG) and in the organisation of the annual United European Gastroenterology Week (UEG Week).

Country Members

Since the foundation in 2001, ECCO has embraced 33 Country Members who are the driving force and are considered as ambassadors spreading the ECCO Spirit, such as Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey, Ukraine, United Kingdom.

History

ECCO was founded in Vienna, Austria, in 2001 as an umbrella organisation for national Inflammatory Bowel Diseases (IBD) study groups in Europe. It expanded from an organisation with 14

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Country Members to an association comprising 33 affiliated countries in 2014.

More information: <http://www.ecco-ibd.eu>



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ABSTRACTS

OP004 Early combined immunosuppression for the management of Crohn's Disease: A community-based cluster randomized trial

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Background: Conventional management (CM) of Crohn's Disease (CD) consists of sequential use of corticosteroids, antimetabolites, and tumor necrosis factor (TNF)-antagonists. Recent evidence indicates that early combined immunosuppression (ECI) with a TNF-antagonist and an antimetabolite may be more effective than CM. We compared the effectiveness of ECI (Figure 1) to CM in community gastroenterology practices.

Methods: In this cluster randomization trial (Randomized Evaluation of an Algorithm for Crohn's Treatment or REACT; Clinicaltrials.gov NCT01030809; partial support AbbVie), practices in Canada (n = 34) or Belgium (n = 5) were randomly assigned in a 1:1 ratio to ECI or CM. Up to 60 consecutive adult patients (<18 years of age) with a documented diagnosis of CD in each practice were evaluated for 24 months. The primary outcome was the proportion of patients in remission (Harvey Bradshaw Score (HBS) <4 in the absence of steroids) at 12 months, evaluated at the practice level. Secondary measures were the rates of

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complications, hospitalizations, and surgeries over the entire follow-up period, based on patient level analyses.

Therapeutic Algorithm for Crohn's Disease

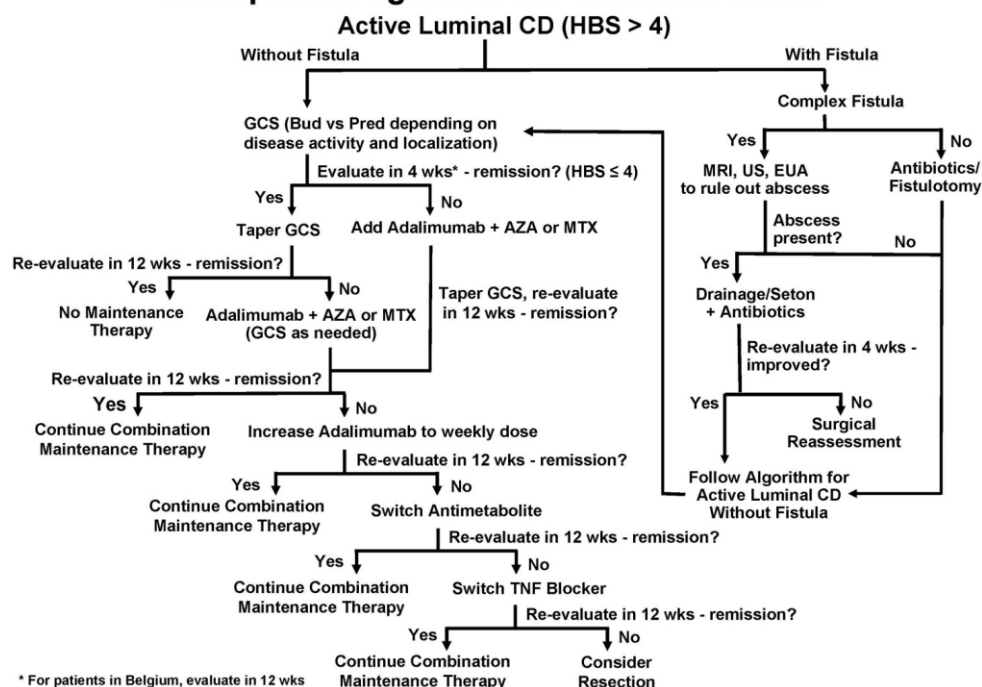


Figure 1. Therapeutic algorithm utilized for patients in the ECI group.

Results: Twenty-one centers (1084 patients) were assigned to ECI and 18 (898 patients) to CM. The mean age of the patients was 44.2 in the ECI group and 44.1 in the CM group. Mean HBS scores were 4.1 in both groups. The proportion of patients in the ECI and CM groups who received combination of antimetabolite/TNF-antagonist by 12 months was 15.1% and 6.5% ($P < 0.001$) and 19.7% and 9.6% by 24 months ($P < 0.001$). Mean % (SD) remission rates in the ECI and CM groups were 66 (14) and 62 (17) at 12 months ($P = 0.65$) and 73 (8) and 65 (17) at 24 months ($P = 0.35$). However, highly significant and clinically important differences in the rates of complications, surgeries, and the combined outcome of hospitalizations, complications, and surgeries were observed in favor of ECI over 24 months (Figure 2). The 24 month actuarial estimates for the combined outcome were 27.7% and 35.1% in the ECI and CM groups, respectively (hazard ratio adjusted for CD caseload and country: 0.74 [0.62, 0.87, $P < 0.001$]).

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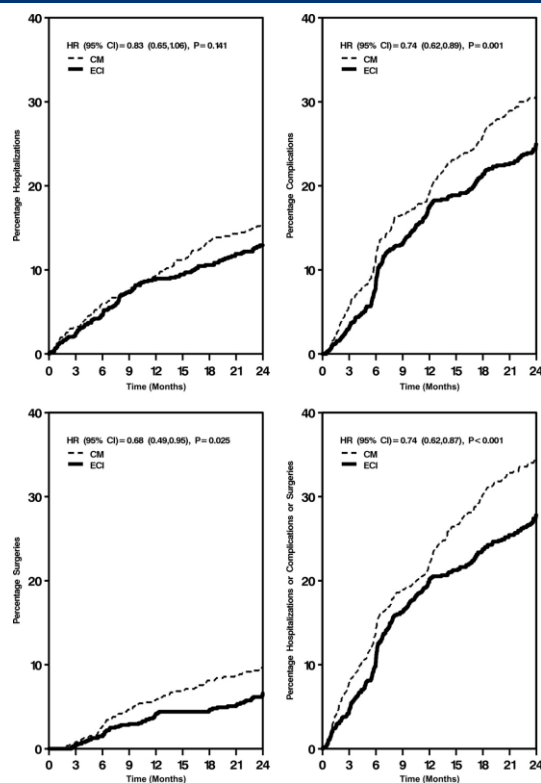


Figure 2. Hospitalizations, complications*, and surgeries for patients in the ECI and CM groups over 24 months. *Abscess, new fistula, extra-intestinal manifestations of CD and serious AEs.

Conclusions: Community-based data indicate that (1) a symptom based conventional approach to CD management may not be optimal and (2) ECI may be more effective in preventing CD-related complications.



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OP007

Anti-MAdCAM monoclonal antibody PF-00547659 does not affect immune surveillance in the central nervous system of anti-TNF and immunosuppressant experienced Crohn's Disease patients who are anti-TNF inadequate responders: Results from the TOSCA study

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Background: Therapy that inhibits white blood cell (WBC) trafficking from the bloodstream to the gut has shown promising results in the treatment of inflammatory bowel disease. Its use, however, has been limited by the risk of progressive multifocal leukoencephalopathy (PML) in patients treated with the nonselective anti- α 4 integrin antibody natalizumab. PML is an opportunistic infection caused by the highly prevalent JC virus that attacks the central nervous system (CNS) in immunocompromised hosts. Reduced CNS immune surveillance from inhibition of immune cell trafficking is a likely element in the pathogenic cascade. PF-00547659 is a human monoclonal antibody that binds to MAdCAM on endothelial cells and blocks its interaction with a α 4 β 7-bearing WBC, preventing their entry into gut tissue while sparing the CNS, which is constitutively devoid of MAdCAM. This report is the first to describe effects of an anti-MAdCAM antibody on cellular elements of the CSF.

Methods: In 8 European centers, patients with moderate to severe Crohn's Disease (CD) (ie, Harvey Bradshaw Index (HBI) >8 + highly sensitive C-reactive protein (hsCRP) >5.0 mg/L or active lesions on endoscopy or imaging) and prior treatment with both anti-TNF and immunosuppressants (azathioprine, 6-MP or methotrexate), underwent a lumbar puncture (LP) followed by

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subcutaneous injections of 225 mg PF-00547659 every 4 weeks for 3 doses. 2 weeks after the last dose of PF-00547659 a 2nd LP was performed. CSF was analyzed by flow cytometry in a central laboratory adjusting with TruCount beads for enumeration of lymphocytes and T cell subsets. Results: 24 subjects were enrolled (16F/8M). Baseline characteristics mean (sd) were: age: 38.0 (9.7) years; duration of CD: 11.7 (6.1) years; HBI (16 pts without stoma): 8.6 (1.4); and hsCRP: 12.0 (18.7) mg/L. 12 subjects had a 2nd LP after treatment. Cell counts by flow cytometry were not available for 1 subject, and data from another were excluded due to a traumatic tap. Results of flow cytometry are shown in Table 1.

Table 1. Lymphocytes (cells per mL) before and after treatment [Geometric Mean (CV%)]

| | N | Lymphocytes | CD3+ | CD3+/CD4+ | CD3+/CD8+ | CD4:CD8 |
|-----|----|-------------|------------|------------|------------|------------|
| LP1 | 24 | 471 (132%) | 435 (132%) | 294 (141%) | 122 (119%) | 2.40 (50%) |
| LP2 | 12 | 626 (185%) | 595 (188%) | 409 (197%) | 160 (171%) | 2.52 (52%) |

Conclusions: In anti-TNF and immunosuppressant experienced patients with moderate to severe CD, a full induction course of the highest clinical dose of PF-00547659 did not affect CSF lymphocytes. The results of the TOSCA study support the gut selectivity and the CNS-sparing mechanism proposed for PF-00547659.



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OP011

Tralokinumab (CAT-354), an interleukin 13 antibody, in moderate to severe ulcerative colitis: A phase 2 randomized placebo-controlled study

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Background: Interleukin 13 (IL-13) is a central cytokine effector in the Th2 immune response and potentially a key player in Ulcerative Colitis (UC) pathogenesis. Tralokinumab (CAT-354) is a humanized IgG4 antibody that binds and inhibits IL-13. The purpose of this study was to evaluate the efficacy and safety of tralokinumab in subjects with moderate to severe active UC. Methods: Subjects (18-75 yrs) with UC and total Mayo score 6-12 received tralokinumab or placebo as add-on therapy in this European multicenter, randomized, double-blind, placebo-controlled study sponsored by AstraZeneca (ClinicalTrials.gov #NCT01482884). Subjects received subcutaneous tralokinumab (300 mg) or placebo every 2 wks during a 12-wk treatment phase followed by a 12-wk safety follow-up. The primary endpoint was clinical response at wk 8 defined as a reduction of 3 points and 30% or more from baseline total Mayo score. Secondary endpoints included clinical remission (Mayo score \leq 2 with no subscore $>$ 1 point), mucosal healing (endoscopic Mayo score 0), improvement in Mayo score at wk 8, partial Mayo score, and safety. Allowed background medications included stable doses of 5-ASA, prednisolone (\leq 20 mg daily), and thiopurines. Results: 111 subjects were randomized (tralokinumab n = 56; placebo n = 55). Baseline subject and disease characteristics were similar in both arms. The median baseline Mayo score was 8 in both arms; 23% and 31%, respectively, had received prior TNF- α therapies; 43 (77%) tralokinumab subjects and 37 (67%) placebo subjects, respectively, completed the study. Improvements in

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mean partial Mayo scores were greater in the tralokinumab subjects (1.8 vs. 0.8, $p = 0.04$).

| Results at week 8 | Tralokinumab | Placebo | P value |
|--------------------------------|--------------|---------|---------|
| Clinical response (%) | 38 | 33 | 0.41 |
| Clinical remission (%) | 18 | 6 | 0.03 |
| Mucosal healing (%) | 32 | 20 | 0.10 |
| Mean improvement in Mayo Score | -3.2 | -2.6 | 0.39 |

Serum eosinophil counts and total IL-13 levels increased during therapy with tralokinumab. Symptoms of UC were the most frequently reported adverse events (AEs). The number of subjects experiencing AEs and AEs leading to discontinuation of drug were similar in both groups. There were no clinically relevant changes in laboratory variables, vital signs, and electrocardiograms. No new safety signals were identified for tralokinumab.

Conclusions: Multiple efficacy measures were numerically higher in the tralokinumab arm. However, the difference in clinical response at week 8 (primary endpoint) between the tralokinumab and placebo groups was not statistically significant. Safety and tolerability were acceptable and consistent with previous tralokinumab trials.

OP023

Optimising post-operative Crohn's disease management: Best drug therapy alone versus endoscopic monitoring, disease evolution, and faecal calprotectin monitoring. The POCER study

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Background: Disease recurs in most Crohn's Disease patients after intestinal resection, with endoscopic recurrence preceding clinical recurrence. We investigated (i) whether early endoscopic monitoring with treatment step-up for endoscopic recurrence is superior to standard drug therapy alone; (ii) disease evolution under optimal drug therapy is it possible to regain remission after endoscopic recurrence and is ongoing monitoring needed after early remission? (iii) whether faecal calprotectin (FC) can substitute for endoscopic monitoring.

Methods: This IIS Post-Operative Crohn's Endoscopic Recurrence (POCER) treat-to-target study aimed for mucosal healing. All patients received 3 months metronidazole. High risk patients (smoker, perforating disease, >2nd operation) also received daily thiopurine, or adalimumab if thiopurine intolerant. Patients were randomised 2:1 to colonoscopy at 6 months ("active care") or no colonoscopy ("standard care"). Endoscopic remission was defined as Rutgeerts score i0 or i1 and recurrence as ≥i2. For endoscopic recurrence at 6 months low risk patients stepped up to thiopurine, high risk patients stepped up to adalimumab fortnightly, and high risk thiopurine-intolerant patients stepped up to weekly adalimumab. All patients were colonoscoped at 18 months, scored centrally blind to treatment, with primary end-point endoscopic recurrence at 18 months. FC (319 samples) CRP and CDAI were measured pre-operatively, and at 6, 12, & 18 months.

Results: 174 patients (83% high risk) in 21 hospitals enrolled. Of 122 active care patients 39% underwent 6 month treatment step-up. 18 months endoscopic recurrence occurred in 49% active care v 67% standard care patients (P = 0.028). Step up at 6 months brought 38% of patients with endoscopic recurrence into remission 1 year later; conversely endoscopic disease recurred 1 year later in 41% of patients who were in remission at 6 months. FC correlated with endoscopic recurrence (r = 0.42, p < 0.001) and

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score ($r = 0.44$, $p < 0.001$); CRP and CDAI did not. FC $>100\text{mcg/g}$ indicated endoscopic recurrence with a sensitivity 0.89 and NPV 91%, potentially allowing avoidance of colonoscopy in 41% of patients.

Conclusions: Treating according to risk of recurrence, with early colonoscopy and treatment step-up for recurrence, is superior to optimal drug therapy alone in preventing postop disease recurrence. Selective immunosuppression, with colonoscopy-based adjustment, rather than its use in all high risk patients, leads to effective disease control in a majority. Early endoscopic remission requires ongoing monitoring. FC can be used to monitor for recurrence and is superior to CRP and CDAI.



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P514

Disease-specific health-related quality of life in adult patients with mild to moderate ulcerative colitis receiving short-term and long-term daily treatment with MMX mesalazine

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Background: Symptoms (eg, rectal bleeding, stool frequency) experienced by mild-to-moderate Ulcerative Colitis (UC) patients, negatively affect health-related quality of life (HRQL). These analyses examine the magnitude of improvements in UC patients' HRQL following short-term and long-term treatment with MMX mesalazine. Methods: Data were from a completed, open-label, prospective, multi-country trial of mild-to-moderate UC patients (NCT01124149). In the acute phase, adults with active UC received 8 weeks MMX mesalazine 4.8 g/d once daily (QD). Patients achieving complete remission (CR; modified UC Disease Activity Index [UCDAI] ≤ 1 ; rectal bleeding and stool frequency scores of 0; ≥ 1 -point reduction in endoscopy score) or partial remission (PR; modified UCDAI ≤ 3 ; combined stool frequency and rectal bleeding score ≤ 1 ; not in CR) by week 8 subsequently received 12 mos of maintenance with MMX mesalazine 2.4 g/d QD. Patients' HRQL (a tertiary endpoint), as impacted by UC symptoms, was assessed with the Shortened Inflammatory Bowel Disease Questionnaire (SIBDQ), a 10-item survey measuring Inflammatory Bowel Disease (IBD)-specific HRQL over a 2-week recall period. The SIBDQ has 4 domains: Bowel Symptoms (BS), Systemic Symptoms (SS), Emotional Function (EF), and Social Function (SF). Total score is used to assess overall IBD related HRQL. Higher SIBDQ scores indicate better HRQL. Changes over time were tested using paired-samples t-tests or repeated-measures analysis of variance models. Multiplicity was controlled using Bonferroni-adjusted P values. Cohen's *d* effect sizes for standardised differences in means for paired samples were calculated to interpret magnitude of change. Results: Patients who completed the 8 week acute phase showed significant improvement in all SIBDQ scores, with mean increases of 4.5 points for BS (n = 425), 2.1 for SS (n = 442), 3.6 for EF (n = 439), 3.0 for SF (n = 446), and 13.2 for total score (n = 413; all *P*s <0.0001). Effect sizes for change were all ≥ 0.77 , with BS showing the largest improvement (*d* = 1.16). Patients completing maintenance showed significant increases in all SIBDQ scores from baseline to Mo 12, with mean increases of 5.0 points for BS (n = 209), 2.6 for SS (n = 221), 4.6 for EF (n = 215), 3.6 for SF (n =

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221), and 15.7 for total score (n = 198; all Ps <0.0001). There were no significant changes in any scores from the end of the acute phase to the Mo 12 visit (all changes \leq 0.5 points; all Ps >0.24). Conclusions: Patients with active mild-to-moderate UC showed significant, medium to large improvements in disease-specific HRQL following 8 weeks of MMX mesalazine 4.8 g/d QD. These improvements were maintained among patients in CR or PR who subsequently received 12 mos of MMX mesalazine 2.4 g/d QD.

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