Two-thirds of the world’s population live in Asia – China, India, Korea, Japan, and the Southeast Asian countries – and it follows that most patients with Functional Gastrointestinal Disorders (FGIDs) are Asians. In the last 5 years Asian physicians have become increasingly aware of the importance of the FGIDs in their countries and are asking whether Western explanatory models fit their patients and their circumstances. This article is a brief summary of some of this activity.

Role of the Rome criteria. In the West, the concept of functional gastrointestinal disorders emerged gradually over a period of 150 years from clinical observations that psychological stress has a strong influence on GI function and that many patients have chronic disabling GI symptoms without any infectious or structural cause. The Rome diagnostic criteria developed out of a need for a consensus on research diagnostic criteria and are used in many tertiary care GI clinics, but they continue to be ignored by the majority of primary care physicians. In Asia, the evolution has been quite different: Many Asian physicians became aware of the FGIDs through research and other publications based on the Rome criteria. A major milestone for Asians was the decision by a group of Chinese physicians headed by Dr. Meiyun Ke to translate the book, “Rome III: The Functional Gastrointestinal Disorders” into Mandarin Chinese, and the Rome criteria are used in the clinical diagnosis and management of IBS throughout Asia.

Consensus documents on IBS and FD. Publication of Rome III into Chinese was soon followed by the establishment of the Asian Neurogastroenterology and Motility Association (ANMA) in 2005, which has become a focus for clinical research on the FGIDs. Under the leadership of Kok Ann Gwee of Singapore, the ANMA sponsored working teams to review the published data on the FGIDs in Asia, published an Asian Consensus on IBS (J Gastroenterol Hepatol 2010;25:1189-1205) and is preparing a separate Asian Consensus on Functional Dyspepsia for publication as well. These working teams concluded that the pathophysiology of IBS and FD is identical to what has been reported in the West. However, they also concluded that there are important differences in the symptoms with which Asian patients present for care. Most notably, they concluded that psychological comorbidity is less common and less important in Asian patients compared to Western patients, that reactions to eating play a more important role in Asia, and that bloating rather than pain is the cardinal symptom of Asian IBS. They also concluded that normal ranges for stool frequency and stool form differ for Asians compared to Western populations, probably as a consequence of differences in diet.

Rome Asian Working Team (RAWT). Based on the conclusions of their systematic review of IBS and FD, the leaders of the ANMA considered discarding the Rome criteria and developing uniquely Asian diagnostic criteria for the FGIDs. However, through a series of meetings between Kok Ann Gwee, Doug Drossman, John Kellow, and Bill Whitehead, the decision was to conduct a survey of symptoms associated with FGIDs in Asian countries to determine whether different diagnostic criteria are required or whether modifications to the Rome criteria would meet the needs of physicians caring for Asian patients. This resulted in an agreement to form a Rome-Asian Working Team chaired by Kok Ann Gwee and co-chaired by Bill Whitehead, to design and carry out the survey. Members of the working team are: Andrew Chua (Malaysia), Uday Ghoshal and Nitesh Pratap (India), Sutep Gonlachnavit (Thailand), Minhu Chen and Hou Xiao-Hua (China), Bak Young-Tae (Korea), Hiroto Miwa (Japan), and Reuben Wong (Singapore).

Translation and validation of Diagnostic Questionnaire. The first task undertaken by the RAWT was to develop
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The Center’s co-directors are: Douglas A. Drossman, MD, Professor of Medicine and Psychiatry, and William E. Whitehead, PhD, Professor of Medicine and Gynecology.

For more information about the Center, please visit our website at www.med.unc.edu/ibs

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Over the past decade, the UNC Center for Functional GI and Motility Disorders has enjoyed significant grant support from a number of private foundations and corporations. These grants have ranged from unrestricted grants in support of fellowships and the Center’s education and training effort. Support for the Digest Newsletter is provided by Takeda Pharmaceuticals North America, Inc.

and validate a common survey instrument. The working team first adapted the Rome Diagnostic Questionnaire by adding supplemental questions while preserving all the questions in the standard Rome questionnaire. The supplemental questions addressed additional symptoms the committee believed would be important to Asian patients. The next step was to translate and validate the questionnaire into 7 languages: Mandarin Chinese, Indian Hindi, Indian Telugu, Indian and Pakistani Bengali, Thai, Korean, Malaysian, and possibly Japanese. The translations were done by the technique recommended by Ami Sperber (Gastroenterology 2004;126(Suppl 1):S124-8), which includes two forward translations from English to the target language by independent translators, review by a bilingual physician and resolution of differences between the target language translations, backwards translation into English, and review of differences between the backwards translation and the original English version. The translations were validated for understandability by administering them to small groups of patients with FGIDs and for content validity by comparing questionnaire responses to independent clinical diagnoses. Test-retest reliability was assessed by comparing questionnaire responses to independent physicians which could contribute to East-West differences and these are not addressed by the study. However, this survey will inform the Rome working teams who are tasked with revising the Rome criteria by 2016, and it will provide a foundation for an anticipated multinational survey of FGIDs that the Rome Foundation will undertake. It may also provide some initial insights into the remarkable observation that there has been a 2-3 fold increase in the prevalence of IBS and FD in Asian countries in the past decade.

Survey design. The investigators from each of the 6 participating countries have been asked to enroll at least 200 FGID patients from two different sites and to administer the new enhanced Asian FGID diagnostic questionnaire. Data will be transferred to a statistical core at the National University of Singapore for analysis. An interim report on the progress of the study will be presented at the Asian Digestive Disease Week held in Singapore in October, 2011. Sponsors of the survey, in addition to the Rome Foundation, are Abbott and Janssen-Cilag pharmaceutical companies.

There are limitations to the survey being conducted by the RAWT: For example, there is no concurrent comparison group of patients form North America and Europe, and the patients will be clinic attendees rather than representative of the population. Moreover, there are important confounders such as diet and exposure to enteric pathogens which could contribute to East-West differences and these are not addressed by the study. There are limitations between the backwards translation and the forwards translation into English, and review of differences between the target language translations, forwards translation into English, and review of differences between the target language translations.

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Dear Friends and Colleagues,

I would like to take this opportunity to inform you of a major transition in my career. As of December 31, I will be leaving full-time employment at UNC and the UNC Center for Functional GI and Motility Disorders in order to expand my mission to help physicians and patients on a larger scale. Although leaving UNC may come as a surprise to some, it is something I have considered carefully over the last year and I believe it is the best choice at this time. I plan to broaden my educational and clinical activities from a successful 35 year career in academic medicine to apply my knowledge and skills at a national and global level. While my career path is not fully worked out, there are some things I can share with you at this time.

- I will continue as adjunct Professor of Medicine and Psychiatry at UNC and will be advising and teaching at the UNC Center of Functional GI and Motility Disorders where as you know I am currently co-director.
- I will enhance my international activities as President of the Rome Foundation in order to further develop the Foundation and the Rome IV initiative.
- I will continue to consult in the health care field. This will include:
  - academic programs in medicine, psychiatry and digestive diseases
  - Federal (NIH) or pharmaceutical grants where I will serve as a mentor or consultant
  - gastrointestinal medical practices
  - pharmaceutical advisory boards
  - health care foundations
  - medico legal groups
  - non-profit health care and educational and media companies

Finally, I am seeking advice and assistance in developing a non-profit organization that would focus on the education of clinicians and patients in biopsychosocial research, education and patient-centered care. I am looking to discuss this further with experts in business development and potential individuals and organizations that might seek to support such an endeavor.

My 35 years at UNC have been enjoyable and productive; now I look forward to the future with anticipation and enthusiasm. I want to thank you for our association over all these years and am hopeful this will continue in the future.

Douglas A. Drossman, MD
Professor of Medicine and Psychiatry
Co-Director UNC Center for Functional GI and Motility Disorders
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Psychologists working at the intersection of medicine and psychology often have a sub specialization in the field of “Behavioral Medicine”. This area of psychological training examines the role of behaviors, thoughts (cognitions) and emotions as they contribute to the predisposition, onset and perpetuation of illness. While including psychologists into gastroenterology clinics is still in its infancy, this type of integration has been happening in other areas of medicine (cardiology, pain management, diabetes management and cancer care) for some time.

In partnering with medical doctors, psychologists bring a broad understanding of human behavior and a skill set that can inform the medical interaction. In the Functional GI disorders clinic, the psychologist has five important roles.

- Education – of patients and physicians on how the patient can make changes in their behavior to help improve the clinical response
- Assessment – the evaluation of coping and symptom management strategies and the detection of psychological diagnoses
- Treatment – using psychological interventions that complement or enhance the medical care given
- Communication – within and among the treatment team and patients
- Research – on the role of psychological factors in illness experience

Psychologists Foster Understanding of FGIDs and Treatments

For patients, the symptom experiences of Irritable Bowel Syndrome and other FGIDs are very real. Often, patients have an underlying understanding of the relationship between experience and their symptom presentation, but know only limited ways of dealing with or managing their symptoms. Physicians will use the Rome criteria to help diagnose FGIDs, but patients may have difficulty understanding how and why their bodies are reacting with symptoms the way they are. These are areas in which education of both patients and physicians on mind body relationship principles can be particularly effective. Helping patients to develop a grounded understanding of how their symptoms have developed over time, as well as how their clinician is assessing and treating the condition can help patients feel more in control of their symptoms. Positive self-care strategies and implementing behavioral changes can have a positive impact on symptom experience and thereby increase the patients’ abilities to engage in effective symptom management. Psychologists are experienced at educating individuals on what it takes to engage in effective symptom management.

Assessing Patient Coping and Symptom Management

Psychologists complete evaluations (assessments) to learn about which psychosocial factors contribute to functional GI diagnoses and how these factors can affect patients. Sometimes a regular length physician appointment is not enough time to understand the contributing factors to a patient’s symptom experience. Psychologists have more frequent and longer availability to develop this type of understanding with the patient. We know that GI symptoms often have a considerable impact on moods and behaviors. Psychologists are trained in assessing these effects, and providing recommendations for reducing their adversity. Assessment of coping skills and symptom management strategies are also useful in developing a comprehensive treatment plan.

Conducting Therapy

Dealing with FGID symptoms for a prolonged period of time can have lasting effects on mood. Psychologists are trained to help patients develop clearer strategies for managing those feelings as well. Treatments such as cognitive behavioral therapy (CBT), hypnosis, mindfulness based stress reduction, biofeedback and interpersonal psychotherapy have been shown to be effective in treating functional GI disorders. Not all psychologists will be trained in each modality, but many will have a good understanding of how each may help ameliorate symptom experience. Working with a psychologist can help patients learn to effectively treat the co-occurring mood and behavioral difficulties that can be associated with the illness.

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Facilitating Communication

While therapy discussions with psychologists are confidential, often times treatment relevant factors are brought up during the course of therapy. The psychologist works with the patient to determine how best to communicate treatment relevant information to the treatment team while maintaining patient confidentiality. In this way the psychologist can act as a treatment facilitator. Additionally, the psychologist can serve as another point of contact for the patient while on their own outside of the clinic, facilitating communication on the topic of how treatment is progressing and how symptom experiences change over time.

Engaging in Research

The influence of psychosocial factors in symptom development and management is an important factor in conducting research on FGIDs. With their understanding of how cognitions, behaviors and emotions can influence symptoms, psychologists are able to inform the conduct of research in FGIDs. Current research topics that our center is examining relate to psychological correlates of FGIDs. Any treatment modalities will be agreed upon and discussed with the patient in order to collaboratively develop a plan to improve symptom management strategies.

Follow up appointments will always start with a discussion of present symptom experience and then move to the active therapeutic modality being worked with at that time (CBT, hypnosis, relaxation training, etc.) The psychologist will communicate relevant treatment issues to the treating clinician – often only in general terms so that the clinician can be aware of contributing factors to care. As members of the same treatment team working to help the patient, these communications are helpful, however confidentiality rules are always observed.

The number of sessions one works with a psychologist is determined by a multitude of factors but is always communicated and established collaboratively with the patient. Typical visit numbers will vary with the degree of symptom experience and typically range from one to twelve sessions. Most insurance plans will cover a portion of or a certain number of psychotherapy sessions.

Evaluation will include: current symptom experience and the process of symptom onset, exacerbating or ameliorating factors, engagement in self care, sleep/ diet and exercise habits. Additional topics of traumatic stressors and substance use history will likely also be discussed. Towards the end of the visit, the psychologist will work with the patient to develop a treatment plan moving forwards. The plan will include either referral to a clinician close to the patient, setting up of follow up appointments and services with the assessing psychologist and engagement in psychoeducation on the topic of FGIDs. Any treatment modalities will be agreed upon and discussed with the patient in order to collaboratively develop a plan to improve symptom management strategies.

Putting it all together

Working with a licensed psychologist or mental health practitioner in a gastroenterology clinic need not be distressing, rather, they are often effective members of the treatment team who can help clinicians provide the most comprehensive and effective care to patients. Patients should know that when coming to an initial visit, topics discussed during this evaluation will include: current symptom experience and the process of symptom onset, exacerbating or ameliorating factors, engagement in self care, sleep/ diet and exercise habits. Additional topics of traumatic stressors and substance use history will likely also be discussed. Towards the end of the visit, the psychologist will work with the patient to develop a treatment plan moving forwards. The plan will include either referral to a clinician close to the patient, setting up of follow up appointments and services with the assessing psychologist and engagement in psychoeducation on the topic of FGIDs. Any treatment modalities will be agreed upon and discussed with the patient in order to collaboratively develop a plan to improve symptom management strategies.

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History and Physical Examination

In addition to trying to establish a cause and formulate management, the history should attempt to ascertain the frequency, severity and nature of incontinence, and the impact of incontinence on quality of life. This includes the ability to leave the house for work and social activities. Patients are particularly affected by the unpredictability of episodes of incontinence and often alter both social and professional activities.

Understanding anorectal structure and function provides a road map to the directed physical examination. The technique of performing a digital exam has not been sufficiently emphasized and its assessment has been dismissed by some investigators as inaccurate. As with any test, accuracy depends upon the skill of the examiner. When performed by an experienced and knowledgeable examiner, the following features can be assessed: anal canal tone, external anal sphincter contraction, puborectalis muscle contraction, the presence of a fecal impactor or mass, and large disruptions of the anal sphincter complex.

Fecal incontinence is one of the most devastating of all nonfatal illnesses, resulting in considerable embarrassment and anxiety to those who suffer from it. It affects 2% to 17% of people living in the community and almost half of all nursing home residents. Many individuals with fecal incontinence are so embarrassed that they do not volunteer this complaint to their physicians and must be asked directly.

The prevalence of fecal incontinence is increased in (1) women; (2) older age groups; (3) those with poor health status or physical limitations, and (4) individuals residing in nursing homes.

The causes of fecal incontinence may be classified into a number of broad categories that occur alone or in combination. Many of these are suggested by a careful history and directed physical examination, including perianal inspection and a digital rectal examination. Such an examination is heavily dependent upon the experience and skills of the examining physician. In selected patients, especially when there is diagnostic uncertainty, tests to assess anorectal structure and function may be performed.

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Ask the Expert

has largely replaced EMG mapping of the external anal anatomically disrupted anal sphincter complex. The use important factors associated with improvement. Many believe that improvement of perception of to intra-rectal stimuli such as balloon distension. are directed exclusively at re-educating weakened or strengthening exercises such as Kegel exercises which and external anal sphincter. In contrast to pelvic floor Biofeedback has been reported to be effective in abnormalities are characterized by decreased anal canal effective. Patients with isolated internal anal sphincter colostomy may provide dramatic improvement. For those with severe refractory incontinence, a diverting colostomy may provide dramatic improvement.

Biofeedback has been reported to be effective in many patients with fecal incontinence associated with impaired functioning of the puborectalis muscle and external anal sphincter. In contrast to pelvic floor strengthening exercises such as Kegel exercises which are directed exclusively at re-educating weakened or impaired muscles, biofeedback attempts to improve rectal sensation and sphincter muscle responsiveness to intra-rectal balloon distension. Many believe that improvement of perception of rectal sensation and the synchronization of external anal sphincter contractions to rectal stimulation are important factors associated with improvement.

Surgical Approaches

Anal sphincteroplasty is based on repairing an anatomically disrupted anal sphincter complex. The use of anal sonography to demonstrate sphincter disruptions has largely replaced EMG mapping of the external anal sphincter. Although many studies have reported short term improvement of fecal incontinence in up to 85% of patients, failure rates of approximately 50% are noted after 40-60 months. In a number of representative series, full continence after sphincteroplasty was maintained in only 28% of patients after a mean follow-up of 40 months, and in only 11-14% of patients followed for over 69 months.

Antegrade colonic irrigation via appendicostomy or cecostomy was initially developed to treat fecal incontinence in children and later was applied to fecal incontinence in adults. The premise of antegrade colonic irrigation is that regularly administered large volume enemas delivered into the cecum produce complete colonic emptying to prevent fecal soiling. The procedure can be helpful in appropriately selected children and adults.

Other surgical approaches

Replacement of a damaged or non-functioning anal sphincter complex involves using nearby muscles (dynamic graciloplasty) or an artificial implanted sphincter. Improved continence occurs in over 50% of patients on intention-to-treat analyses, but with significant morbidity, including infections, device malfunctions, and in the case of the artificial sphincter, a high percentage of explantation of the device. Such procedures are best performed by surgical teams with considerable experience. For those with severe refractory incontinence, a diverting colostomy may provide dramatic improvement.

Sacral spinal nerve stimulation for fecal incontinence was developed as an extension of its successful use for disorders of urinary voiding and continence. The procedure involves three phases: (i) location of the sacral spinal nerves by percutaneous probing with a needle electrode to identify the nerve root which maximally stimulates anal sphincter contraction; (ii) temporary placement of an electrode to chronically stimulate the nerve root identified as the most efficient during acute testing; (iii) permanent implantation of a neurostimulator for chronic therapeutic stimulation. Many believe that improvement of perception of rectal sensation and the synchronization of external anal sphincter contractions to rectal stimulation are important factors associated with improvement.

In ancient times, clinicians have recognized that the physician – patient relationship based on trust and compassion has considerable healing power and in modern terms “therapeutic effect.” In order for the physician to make accurate diagnosis and provide optimal treatment recommendations, the patient must be able to communicate all relevant information about an illness. Physicians are obliged to honor the special nature of the medical relationship and to refrain from revealing confidential information. The traditional, paternalistic model for the physician-patient relationship involved patient dependence on the physician’s professional authority. Believing that patient would benefit from the physician’s actions, patient’s preferences were generally overridden or ignored. During the second half of the twentieth century, the physician-patient relationship has evolved towards shared decision making. This model respects the patients’ rights to hold views, to make choices, and to take actions based on personal values and beliefs. Patients have been increasingly entitled to weigh the benefits and risks of different treatments options, and to select the treatment that best promotes their own values: “Nothing about me without me.” (1)

Because of its therapeutic potential, the relationship physicians have with their patients is arguably one of the most powerful, sensitive, and versatile "remedies" they can offer to their patients. However, in the western medical tradition, aside from for mental health professionals, clinicians seldom think of their relationships with patents as a therapeutic tool or even as a placebo. This is not surprising, given that the nature of this relationship today appears to be far more complex than ever before. Varieties of factors within and outside the health care system are constantly molding patient and physician behavior. Among the most important is the prevalence of chronic illnesses, new medical technologies, shifting reimbursement practices, the Internet, government regulations, rising costs, medical litigation and changing social norms. Unfortunately, the once-respected doctor-patient relationship is in great danger. Increasingly, research and anecdotal reports
I had a brief but very helpful visit at the UNC Center for Functional GI and Motility Disorders last month. It was a great opportunity for me to learn about the treatment of FGID’s in the US. I will never forget the practical training in the biopsychosocial approach to the most common disabling functional disorders in medicine that I received at UNC.

During my stay, I observed wonderful humanistic interviews in clinic, as well as the integration of psychotherapy into GI services. It was fascinating and I feel it would be useful for all medical students of different sectors, and subspecialties to experience these observations as part of their education.

I have been practicing with FGIDs, mainly IBS patients, since 2006, and our most important practical and educational materials came from the UNC Center for Functional GI & Motility Disorders. Although professor Drossman and professor Whithead were main sources of practice and education for our group, I still had a lot of questions in mind about working with these patients. Questions like - How much education is necessary for the patient? When should we prescribe medication? When is it possible to taper medications?

My first impressions of Chapel Hill were how wonderfully “foresty” the town was. It seemed like everyone built their buildings around the trees as not to disturb the forest, and that was so deliciously refreshing and unlike London where even the gardens can be sculpted. The second thing that really impressed me was how friendly everybody was. From the street vendor all the way up to the company director there was a genuine friendliness and consideration for you.

Upon meeting the UNC team for the first time I was struck at how both the Drossman and Whitehead teams were compared to the teams that I am used to in Europe. I also appreciated the integrated way pharmacological, preclinical and clinical aspects were dealt with, at all stages of research, from concept to post-analysis. Another thing I envied was the high level of multi-disciplinary team work that you do during actual clinics. It was glad to see that you have similar problems to what we have in London, in that the managers are always complaining about us taking too long with our out-patient consultations, and that our clinics are always overbooked, with long waiting lists. One thing I do covet is the very high level of multi-disciplinary team work that you do during actual clinics and the time you take to consider each patient from different angles even before giving feedback the patient.

I had a sense that with a consultation of this intensity, the highest level of patient care was assured. I had a chance to join and observe Dr. Drossman and his physician assistant Christine Dalton in their clinic and I found many answers to my questions. Sometimes refractoriness of disorders, stubbornness or difficult problems, limitation of medications in these groups, slowness of responses and patients’ severe suffering makes practicing very hard and challenging. It can therefore cause disappointment in physicians working with FGIDs. This issue was difficult for me before visiting UNC.

Pharmacotherapy for FGIDs is a dilemma. The majority of patients could benefit from antidepressants but many have negative attitude toward pharmacotherapy or medication intolerances. The integration of different skills for education and managing the patients requires a holistic attitude and biopsychosocial approach. I think medical practitioners can find an excellent example of an integrative care model of the biopsychosocial approach by working in Dr. Drossman clinic.

Another valuable experience in UNC clinic was taking part in psychotherapy observation sessions with Dr. Weinland. I observed professional, classic sessions of therapies, which are very helpful for all psychotherapists. To be honest, I would have loved to have video tapes to teach others how to conduct psychotherapy as well!

Two important research projects attracted me, during my observation. The first one was about Narcotic Bowel Syndrome (NBS) that is likely a common FGID in my country because of a high prevalence of opioid abuse and dependency. The other research project was a Sensouq study for refractory IBS cases that was very interesting for me because we have had experience with...
I cannot begin to describe my experience at the University of North Carolina Center for Functional Gastrointestinal & Motility Disorders without mentioning the humility that embraces all the faculty and staff. I am truly thankful for your instruction and hospitality. Our program director highly recommended a rotation with Dr. Drossman and having an interest in functional GI disease, I had hoped to visit UNC.

During my two weeks, I identified the readings from Rome III with my observation of patient interviews and their clinical assessment. I also participated in the following: watching the recorded interview simulation videos by Dr. Drossman, observing the Psychology clinics, and observing manometry procedures. I also attended the research lab meeting, and the biology research meeting.

Each aspect of my experience was educational. With this foundation, I hope to advance my understanding of management and employment of functional GI disorders as a part of my patient evaluation. Thank you for the opportunity to visit UNC.

Olanzapine in a randomized clinical trial for IBS patient in our clinic in Esfahan. Both of these inspired me to perform some more research in our clinical research centers. I wish I could have conducted a research project under the supervision of UNC.

I will never forget the fascinating lecture Dr. Drossman gave at Duke University about FAPS (functional abdominal pain syndrome). It contained the fundamental and advanced discussion about one of the most difficult functional disorders for patients and physicians. I found it beneficial and well laid out.

Finally, my short experience at UNC was very stimulating and informative. I would like to thank everybody for their help in making my visit interesting and educational. In particular, I am grateful to Sarah Barrett, Jennifer Layton and Dr. Stephan Weinland for their kind supports, which made me feel like a member of the UNC FGID Center Family.

Thank you to everyone who was involved in my visit.

Health care providers often harbor negative attitudes towards IBS patients (4) thus diminishing their ability to form therapeutic relationships with patients who feel embarrassed by the presence of bowel symptoms, stigmatized, isolated and perhaps worst of all often dismissed by their family members and health care providers (5-7). The impacts of IBS-related isolation and impairment on daily life are far greater than physicians can imagine. Physicians generally trained “to cure” report feeling frustrated with lack of definitive treatment options, time constrains and may even feel emotionally drained from their interactions with IBS patients (8). The communication gap between physicians and patients with functional bowel disorders is further broadened by patients’ reluctance to accept the “functional” diagnosis. In a recent study, strikingly, only 1 of 13 patients agreed with or accepted the functional diagnosis, despite all being diagnosed by a specialist as having such (9).

The communication gap between patients and physicians seems to be expanding. There is a tragic irony in this phenomenon in that physicians and patients want the same thing: the best care possible. There is no simple remedy for protecting and restoring the physician-patient bond. It will have to be a mixture of many “potions” among which will be expanded training and assessment of physicians communication skills; joint physician-patient advocacy on behalf of the relationship as well as changing the reimbursement structure so it rewards and incentivizes the relationship aspects of medical care. It is not an easy task to change today’s health care system, but there is one thing every one can do - begin the conversation.

REFERENCES
**GENETIC AND ENVIRONMENTAL FACTORS THAT CAUSE OR INFLUENCE IBS:**
Contact: Lenore Keck, RN
(919) 966-8329
http://ibsstudy.com

This study involves measuring the relationship between genes, the environment, and various psychological and health factors in men and women with IBS. Individuals who participate will spend one overnight visit in the General Clinical Research Center at UNC Hospital. No additional visits are required.

**TIOGA:**
Contact Renuka Kelapure
(919) 843-7892

Patients who are eligible for this study should have an IBS-D diagnosis with a minimum of 4 BMs a day. These patients should also have had a recent flex sig or colonoscopy.

This is a double blind, placebo controlled study with anasamodamine, which is a kappa opioid agonist, which relieves visceral hypersensitivity. This is a twelve week study with six visits. Patients will receive study drug and study-related medical care at no cost. Participants will be compensated up to $400 for their participation.

**ARDELYX:**
Contact Renuka Kelapure
(919) 843-7892

Patients who are eligible for this study should have an IBS-C diagnosis per Rome III criteria. These patients should also have had a colonoscopy within 5 years and since the onset of IBS-C symptoms.

This is a double-blind, placebo controlled study with RDX5791, which is a NHE3 inhibitor, which reduces Na+ reuptake, increases net fluid volume of GI tract, and facilitates intestinal transit. This is an eight week study with four visits. Patients will receive study drug and study-related medical care at no cost, and will be compensated up to $300 for their participation.

**F³ STUDY - FINDING FOODS FEARFUL: A study of children and adolescents with a fear of trying new foods**
Contact: Miranda Van Tilburg, PhD
(919) 843-0688

If you think your child has a fear of trying new foods and/or has such a limited food variety that it gets in the way, join our online registry of parents who have a child who struggles with food neophobia. Your responses will help us learn more about this behavioral pattern so we can develop new treatments, help parents feel less blamed, and learn more about the development of taste preferences in general.

**Healthy Controls Needed for Research Study**
Contact: Lenore Keck, RN
(919) 966-8329
http://ibsstudy.com

We are conducting a research study investigating a broad range of factors that may cause or influence IBS. We are looking for subjects without IBS or any other gastrointestinal (stomach or bowel) symptoms to participate.

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**NARCOTIC BOWEL SYNDROME:**
Contact Megan Bouma
(919) 843-4422

Patients with Narcotic Bowel Syndrome have been treated with high doses of narcotics for any number of pain disorders. Initial use of narcotics relieves the pain, but after long term use tachyphylaxis occurs in spite of increasing doses. These patients experience increasing abdominal pain as well as other GI symptoms. Treatment involves gradual detoxification from the narcotics.

The study we are performing is purely observational, in an effect to better describe the NBS patient population and their response to detoxification. Contact with the research coordinator will occur at four time periods: 1) Pre-detox 2) Post-detox 3) Three months after detox 4) Six months after detox. Contact will include a series of questionnaires. Patients will be compensated up to $100 for completing the study.

Contact Christina Davis pre detox – (919)966-0792

This is an open label study where the patient will take the drug for eight weeks. Drug, physicals, and lab work will be provided at no cost to the patient. Patients will be compensated up to $350 for completing the study.

**SEROQUEL:**
Contact Megan Bouma
(919) 843-4422

Patients who would benefit most from the Seroquel Study are those with moderate to severe painful functional bowel disorder (which could include IBS, Constipation with pain, chronic functional abdominal pain) who have not responded to antidepressant therapy. These patients will have already been on one of the antidepressants listed below for at least four weeks and have not experienced adequate relief. Seroquel is believed to have a synergistic effect when added to a current regimen of these antidepressants due to its interaction with serotonin, dopamine, histamine, and adrenergic receptors in the brain. Patients not responding to the following therapies would qualify.

**SNRIs**

- Cymbalta - Duloxetine
- Savella - milnacipran
- Effexor - venlafaxine
- Pristiq - desvenlafaxine

**TCAs & Other**

- Imipramine
- Desipramine
- Amitriptyline
- Remeron - mirtazapine

**SSRIs DO NOT QUALIFY**

This is an open label study where the patient will take the drug for eight weeks. Drug, physicals, and lab work will be provided at no cost to the patient. Patients will be compensated up to $350 for completing the study.
A Functional Magnetic Resonance Imaging (fMRI) Scanning Environment Enhances Visceral Pain in Patients with Irritable Bowel Syndrome (IBS)

**Abstract**

**Introduction:** Several aspects of the CNS processing of pain are dysfunctional in IBS, which is characterized by hypersensitivity and abnormal endogenous pain modulation (EPM). Pain perception and EPM are strongly influenced by psychological factors, such as anxiety, expectations, hypervigilance and stress (1). Brain fMRI is used to study pain processing and has shown aberrant sensory processing in IBS in areas governing these psychological responses, as well as EPM. The scanning environment itself, however, potently stimulates precisely such psychological factors, which may result in altered sensory processing. The effect of the fMRI environment on pain processing in IBS has to the best of our knowledge never been reported.

**Aims & Methods:** We studied the effect of the fMRI scanning environment on pain perception and EPM in 12 IBS patients (7 female, 5 male). Foot heat and rectal distension sensation and pain thresholds were determined using an ascending method of limits. Subsequently, moderate foot and rectal pain at an intensity between 30-60 (computerized VAS 0-100) were applied separately and together (heterotopic stimulation for induction of EPM).

**Results:** Pain intensities out- and inside the scanner with the correlations between out- and inside data were assessed by linear regression.

**Results:** Pain intensities out- and inside the scanner with the correlations between out- and inside data were assessed by linear regression.

**Discussion:** These data support our previous finding of compromised DNIC in IBS. However, a larger sample size will be needed to adequately control for alternative explanations of pain reduction such as psychological factors, rarely addressed in other IBS protocols. Only by controlling for non-specific effects can evidence of deficient DNIC be attributed to endogenous analgesic mechanisms. [Supported by grants R24DK067664, R01DK331369, and UL1RR025747].

**Conclusions:** The IBS-SAT is a reliable and valid measure of patient satisfaction with IBS care. As a new condition specific instrument, it is likely to be a useful tool for quality measurement, health services research, and trials of clinical interventions.

**Development and Validation of the Irritable Bowel Syndrome Symptom Inventory (IBS-SI)**

**Abstract**

**Background:** Satisfaction with care is an important measure of quality from the patient’s perspective and may also affect outcomes. Currently, no standard measure of patient satisfaction with IBS care exists. Accordingly, a multi-item, condition specific instrument is needed.

**Methods:** Using standard qualitative methods, we conducted focus groups to obtain items that patients identified as associated with satisfaction in their IBS care. These and additional items identified by experts were placed into a preliminary questionnaire, which was refined through pilot testing and cognitive debriefing by additional patients, as well as standard statistical methods. The resulting instrument along with several external validation measures were then administered to 300 adult U.S. patients. Factor analysis was performed to identify clinically relevant subscales and then psychometric properties were assessed.

**Results:** The final IBS-SAT has 37 items across five clinically relevant subscales (connection with provider, education, benefits of visit, office attributes, and access to care). The IBS-SAT has extremely high internal consistency reliability (Cronbach’s alpha = 0.96). Convergent validity was established by correlations between the IBS-SAT and a single, global satisfaction with care question (r = 0.68; p<0.001), as well as a generic, multi-item satisfaction scale (Psychometric Satisfaction Questionnaire-18) (r=0.75, p<0.001). Discriminant (known groups) validity was established across groups stratified based on provider communication (Communication Assessment Tool) (p<0.001). IBS-Quality of Life (p<0.001), and number of unmet expectations (p<0.001).

**Conclusions:** The IBS-SAT is a reliable and valid measure of patient satisfaction with IBS care. As a new condition specific instrument, it is likely to be a useful tool for quality measurement, health services research, and trials of clinical interventions.

**Diffuse Nociceptor Inhibitory Controls (DNIC) Are Compromised in Patients with Irritable Bowel Syndrome (IBS) Compared to Healthy Controls (HC)**

**Abstract**

**Introduction:** Studies have consistently shown a dysregulation of the endogenous pain modulatory mechanism known as DNIC in IBS patients which may contribute to visceral hyperalgesia. In DNIC, descending serotonergic and opioidergic pain inhibitory signals are initiated by one pain stimulus that then suppresses pain from a second heterotopic pain stimulus. The DNIC effect is defined as the difference between pain ratings from a phasic noxious test stimulus (TS), administered with a concurrent tonic noxious heterotopic conditioning stimulus (CS) compared to the TS pain ratings without a noxious CS. Aim: To compare DNIC in IBS and HC by using somatic TS and CS, and to assess the association between DNIC and visceral sensitivity.

**Method:** Subjects were 40 pre-menopausal females (20 with IBS and 20 age-matched HC, mean age 28 years). The TS were 8 heat pulses (peak=52°C, Inter-stimulus interval of 2 seconds) applied to the left palm. The TS was submersion of the right hand in painful 100°C water. Differences in Average Pain Ratings (APR) of the TS (scale 0-100) during painful CS and the APR during the non-painful CS (hand submersion in 30°C water) were compared between groups in a counter-balanced sequence. Water pain ratings (100°C) were acquired (0-100) and group differences in psychological measures were assessed. Pain ratings from rectal distensions delivered by barostat were acquired from IBS patients using ascending method of limits.

**Results:** IBS subjects demonstrated deficient DNIC compared to HC (F=8.9(1,38), p<0.005, effect size:η2=.19). Rather than decreasing during noxious counter-irritation (100°C), APR increased in IBS, while appropriately decreasing in HC. Although there were group differences in pain ratings for the 100°C CS (IBS=66±5°C (F=5.3(1,38), p<0.028), when entered as covariates in a Repeated Measures ANCOVA, they did not explain the group differences in DNIC (F=5.1,1,37), p=0.03, effect size:η2=.12). DNIC measures were not significantly correlated with visceral pain ratings (r=−.369, p<.15). IBS subjects also reported greater anxiety, depression, catastrophizing, somatization, and life stress (p<0.05). After controlling for these psychological measures, group differences in DNIC no longer significance. A larger study is planned to determine whether these group differences in DNIC are explained by group differences in psychological factors.

**Discussion:** These data support our previous finding of deficient DNIC in IBS. However, a larger sample size will be needed to adequately control for alternative explanations of pain reduction such as psychological factors, rarely addressed in other IBS protocols. Only by controlling for non-specific effects can evidence of deficient DNIC be attributed to endogenous analgesic mechanisms. [Supported by grants R24DK067664, R01DK331369, and UL1RR025747].
Exploring the Mechanism of a Probiotic Combination VSL#3 in Irritable Bowel Syndrome (IBS): A Randomized Double-Blind Placebo Controlled Study

Authors: Reuben K. Wong, Cao Yang, Claudio De Simone, Guanghui Song, Jennie Y. Wong, Shyam Prakash, Kheh YU Ho

Background & Aims: Probiotics have treatment efficacy in IBS, but the exact mechanism remains obscure. One hypothesis is the mediation of melatonin levels, leading to changes in gastrointestinal motility. This study aims to investigate the effects of a probiotic, VSL#3, on symptoms, sleep parameters and pain sensitivity in IBS, and relate these parameters to circadian melatonin levels.

Methods: 42 IBS patients were randomly assigned to receive 4 capsules of either VSL#3 (n=21) or placebo (n=21) daily, for 6 weeks. Pre and post-treatment, subjects completed bowel and psychological questionnaires, and underwent rectal sensitivity testing.

Results: VSL#3 and placebo decreased the mean IBS Symptom Score from 224.5 to 158.0 (p<0.05), and 226.4 to 183.5 (p<0.05), respectively. The VSL#3 subjects had a larger improvement (66.5%) than the placebo group (42.9%), and the difference was statistically significant amongst males (p=0.002). Abdominal distension decreased (-18.5 vs. -7.3, p<0.05) compared to placebo. Changes in pain tolerance threshold and improvement in abdominal pain scores (r=0.51, p=0.02) was seen with VSL#3 but not placebo.

Conclusions: VSL#3 reduced abdominal pain duration and distress intensity in IBS subjects. Rectal pain thresholds were improved in VSL#3 subjects, with a significant change in abdominal pain scores. The improvement in symptoms correlated with a rise in morning systemic melatonin, which was significant in males and subjects with normal circadian rhythm. We postulate that the probiotic acts by influencing melatonin production, hence modulating IBS symptoms, in individuals with a “normal” circadian rhythm, but not in those with a baseline disordered circadian rhythm.

How Good Are Individuals At Predicting Diarrhea Based On Perceived Triggers and Warning Sensations? A Diary Study

Author: Ofok Su, Palsson, Marsha J. Turner, Jeffrey S. Baggett, William E. Whitehead

Aim: To assess how accurate individuals are at predicting diarrhea onset based on triggering events (e.g., eating something known to cause diarrhea) and warning sensations (e.g., gurgling sounds).

Methods: Individuals 18+ age with unexplained diarrhea at least once per week were invited to complete a 60-day diary and a questionnaire about diarrheal warning events and the people with inflammatory bowel disease, colitis disease, lactose intolerance, short bowel syndrome, dumping syndrome, GI surgery history, others in IBS cluster or non-cluster, use the washroom in the last month of antibiotics or other drugs with diarrhea side-effect, or diarrhea occurring every day. For a 60-day period, subjects used a printed pocket diary to record their bowel and psychological indices nor sleep parameters. There was no significant changes following treatment were observed in psychological indices nor sleep parameters. There was an increase in salivary morning melatonin levels in males (5.43±mg/ml vs 9.74±mg/ml, p<0.007), which was correlated (r=0.61, p=0.058) with improved satisfaction in bowel habits. When subjects were grouped into normal and abnormal circadian patterns, a slight trend was shown an increase in morning melatonin levels with VSL#3 treatment (3.19±mg/ml vs 6.58±mg/ml, p=0.07), which significantly correlated with improved satisfaction in bowel habits (r=0.68, p=0.04). Similarly, subjects with a normal circadian melatonin had higher increases in morning melatonin levels (-123.8 vs. -45) and abdominal pain duration (-27.8 vs. -12.9) when treated with VSL#3 vs. placebo. They also had significantly improved satisfaction with bowel movements and quality of life.

Conclusions: VSL#3 reduced abdominal pain duration and distress intensity in IBS subjects. Rectal pain thresholds were improved in VSL#3 subjects, with a significant change in abdominal pain scores. The improvement in symptoms correlated with a rise in morning systemic melatonin, which was significant in males and subjects with normal circadian rhythm. We postulate that the probiotic acts by influencing melatonin production, hence modulating IBS symptoms, in individuals with a “normal” circadian rhythm, but not in those with a baseline disordered circadian rhythm.

DDW ABSTRACTS
Background and Aims: Narcotics are increasingly prescribed for chronic pain in non-malignant disease. Despite growing evidence for their adverse effects in inflammatory bowel disease (IBD), 5-13% of IBD outpatients and an unknown number of IBD inpatients receive narcotics. We sought to study the degree of narcotic use between IBD patient and non-IBD controls, objective measures of disease activity and other associated factors, including prior diagnosis of IBD IRRITABLE BOWEL SYNDROME (IBS), in hospitalized patients with IBD.

Methods: We performed a retrospective cohort study of all adult IBD patients admitted from May 2008 to May 2009 to University of North Carolina. We collected demographic and disease specific information, inpatient narcotic use (excluding that used for procedural sedation) obtained from billing records and converted to intravenous narcotic-use (as measured by the RSS) and sexual relationship. When compared, there was no difference in the RSS scores (4.25 ± 0.20 vs. 4.19 ± 0.20, p=0.78) and sexual relationship (6.47 ± 0.20 vs. 6.21 ± 0.20, p=0.64), between the IBS and control patients. IBS patients reported higher disease severity and narcotic use: 71.4% of non-narcotic users had moderate/severe FTQ findings as compared to 58.3% of patients with IBS (p=0.47).

Conclusions: A majority of patients with IBS are prescribed narcotics for pain control during hospitalization in spite of data on increased complications with narcotic use. Risk factors for narcotic use include duration of disease, CD and factors related to CD (surgery, smoking), psychiatric diagnoses, and IBD-IBS.

Inflammatory Bowel Disease Activity and Narcotic Use During Hospitalization
Author: Millie D. Long, Edward L. Barnes, Hans H. Henrhyf, Douglas A. Drossman

Background and Aims: Background and Aims: Studies have described the burden experienced by caregivers and next-of-kin of organic or psychiatric disorder. The mothers were asked to complete the following questionnaires: the Japanese Irritable Bowel Syndrome Evaluation (IBES), and Parental Bonding Instruments (PBI). Fifty-one in-patients and their mothers were included in this study. The IBES is a self-report inventory and consists of 98 items covering 6 domains: symptoms, relationship with mother, relationship with father, daily activities, relationship with significant others, and maternal personality. The PBI is a self-report inventory consisting of 50 items that assesses the quality of the relation between the parents and children in the domains of affective care and controlling care.

Results: The Japanese IBES demonstrated good internal consistency (Cronbach’s α; 0.83) and high reproducibility (intra-class correlation coefficient; 0.88, p<0.001). 101 non-pregnant mothers who had a 7-year-old child were recruited by advertisement from the community in Sendai, Japan. None of the mothers or children had any gastrointestinal (GI) symptoms in the US [Levy RL, et al. Am J Gastroenterol 2004]. The aim of the study was to determine whether these findings replicate in Japanese children and whether parenting bonding behaviors exert an independent effect on child’s GI symptoms and impaired daily activities.

Methods: 311 non-pregnant mothers who had a 7-year-old child completed the IBES and the Parental Bonding Inventory during a high-fat meal. Heart rate variability was calculated by barostat, baseline at individual operating pressure (IOP) sustained colonic distension at IOP=20 mmHg, and following a high-fat meal. Heart rate variability was calculated by frequency domain analysis of 5-minute electrocardiogram segments obtained during each condition. Low frequency (LF) and high frequency (HF) bands were analyzed to assess sympathetic and parasympathetic activity, respectively, and the LF/HF ratio was calculated. Colonic pain threshold was determined by the ascending method of limits (AML) protocol. Motility index was calculated as the sum of the areas of all contractions divided by recording time. Subjective 6-point pain scores and whole blood serotonin levels were measured before and after the meal. Psychological symptoms were assessed by the Brief Symptom Inventory-18 (BSI-18).

Conclusions: A noxious visceral stimulus enhances sympathetic activity in both IBS and healthy subjects. In patients with IBS, greater postprandial sympathetic activity is associated with greater colonic motility, which may contribute to postprandial symptoms. Contrary to expectation, whole blood serotonin was decreased after meal ingestion in IBS patients. [Supported by R01DK63669 and UL1RR025747]

Increased Stomach Aches in Children Are Associated with Parent IBS Status and Maladaptive Parenting in Japan
Author: Reuben K. Wong, Douglas A. Drossman, Carolyn B. Morris, Stephan R. Weinland, Jane Leserman, Yuming J. Hu, Shinkai I. Bangdiwala

Background and Aims: Irritable bowel syndrome (IBS) runs in families. It has been reported that parent IBS status and solicitude response to child’s illness impact child gastrointestinal (GI) symptoms in the US [Levy RL, et al. Am J Gastroenterol 2004]. The aim of the study was to determine whether these findings replicate in Japanese children and whether parenting bonding behaviors exert an independent effect on child’s GI symptoms and impaired daily activities.

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Increased Postprandial Colonic Motility is Associated with Symptomatic Nerve Activity in Patients with Irritable Bowel Syndrome

Background and Aims: Background and Aims: Studies have described the burden experienced by caregivers and next-of-kin of organic or psychiatric disorder. The mothers were asked to complete the following questionnaires: the Japanese Irritable Bowel Syndrome Evaluation (IBES), and Parental Bonding Instruments (PBI). Fifty-one in-patients and their mothers were included in this study. The IBES is a self-report inventory and consists of 98 items covering 6 domains: symptoms, relationship with mother, relationship with father, daily activities, relationship with significant others, and maternal personality. The PBI is a self-report inventory consisting of 50 items that assesses the quality of the relation between the parents and children in the domains of affective care and controlling care.

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Narcotic Bowel Syndrome: Characterization of 30 Patients and Preliminary Results After Detoxification
Author: Andrea Crane, Mary Jannelli, Ellen Wells, Eilish Clark, R. Kulkarni-Kelapure, Yuming J. Hu, Megan E. Houpe, Joseph Zimmerman, Ceciel T. Rooker, Shrikant I. Bangdiwala

Introduction. Narcotic Bowel Syndrome (NBS) is a recently recognized condition characterized by a paradoxical increase in abdominal pain associated with continued or escalating doses of narcotics. This pilot study evaluated the clinical and psychosocial features of patients with NBS and the response to in-hospital detoxification (detox) treatment.

Methods. Between Nov. 2008 and Sept. 2010, 30 patients seen by the GI consult service at UNC with presumed NBS were placed on a recommended detox program (Grunkemeier D. et al Clin Gastro & Hepato 2007). Clinical, psychosocial, health status and detox related data were obtained pre and post detox. In addition, accessing the NC Controlled Substances Reporting System provided data on whether and when patients from NC may have restarted prescription narcotics. Results. Of the 30 patients detoxed, 63.3% met predefined criteria, and 82.8% were diagnosed with NBS. Patients had a variety of diagnoses (27% IBS and other functional, 27% IBD and other structural, 13% fibromyalgia and other functional somatic, 3% other: post-op, back pain, etc.). They reported high health care use (14.79±6.60 visits/months/6; 8.616±4.9 hospitalizations/2 yrs, 6.641±4 surgeries/lifetime), and 83.3% were jobless. Despite high dosages of narcotics (total IV morphine equivalent 81.8±35.3mg/day, pain scores were rated severe (52.92±2.52 VAS; 264.1±13.5 FBDOS; Mcgill Pain 59.14±7.7; greater than labor or post op pain). Multiple symptoms were reported (n=37/87±23) and rated as moderate to severe. Psychosocial scores showed high Catastrophizing (20.5±8.2); poor daily function (5.35±4.63); 28.47±12.7, mental 33.3% worse than tetraplegia); 30% were clinically depressed and 33.3% anxious (HADS). Detox (mean 12.2±14.0 days) was safely and successfully completed by 27 patients. 4 patients were prescribed tramadol by the discharge physician, but only 1 patient requested to leave the hospital on narcotics. At post detox, pain had decreased significantly (0.1% vs. 30.6% reduction of 0.1% at 0.03), and non-abdominal pain: 31.1% (p=0.01) on VAS and 34.0% on Mcgill Pain Scale. Pain was reduced 19.8% (p=0.01), and general well being was good/excellent in 48.8%. A rigid definition for a clinical responder was met in 52.2% and was predicted by lower predetox depression scores. A 30% reduction in pain occurred in 51.9%, and 66.7% achieved adequate relief. Of the 23 patients from NC, the NC Controlled Substances Reporting System, 54.6% went back on narcotics for 43.8±67.9 days.

Conclusion. Despite severe pain and poor health status and coping, almost all patients with NBS undergoing detox go off narcotics and have significant improvement in pain and coping. However, over 1/3 are back on narcotics at 6 weeks. Clinicians, patients and the general public need to be educated about the adverse consequences of using narcotics for treating non-malignant pain.
Background: Symptoms of refractory gastroesophageal reflux disease (GERD) are highly prevalent among patients presenting to gastroenterology practices. pH-impedance (pH-MII) testing is commonly employed in this patient population, however the optimal diagnostic strategy is unclear.

Objective: To evaluate the cost-effectiveness of pH-MII testing on vs. off PPIs in patients with refractory GERD symptoms.

Methods: A cost-utility analysis using a hybrid decision tree–Markov model with a 10-year time horizon was performed. The model included patients with refractory GERD symptoms who were randomized to pH-MII testing on vs. off PPIs. The primary outcome was cost-effective analysis of pH-MII on PPIs compared to pH-MII off PPIs. Probabilistic sensitivity analysis was performed to carry out the model uncertainty.

Results: In the base-case analysis, a strategy of pH-MII testing on PPIs cost $44,069 and yielded 6.28 QALYs per patient, vs. $50,104 and 5.93 QALYs per patient on PPIs dominated testing off PPIs, being both less costly and yielding a larger number of QALYs. In one-way sensitivity analysis, the base-case interpretation was highly sensitive to symptom response to LNF. If this response declined below 50% in patients who had persistent nonacid reflux when tested on PPIs, a strategy of testing off PPIs became dominant. Probabilistic sensitivity analysis revealed that the strategy of pH-MII on PPIs was the dominant or cost-effective strategy 99% of the time at a willingness-to-pay threshold of $50,000/QALY.

Conclusions: In patients with refractory GERD symptoms, testing on therapy is a cost-effective strategy. As more data regarding the implications of the management decisions based on test results become available, the optimal testing strategy can be further clarified.

The Effect of Operator Experience on Treatment of Dysplastic Barrett’s Esophagus with Radiofrequency Ablation

Author: William J. Bulisiewicz, Sarina Pasincha, Evan S. Dellon, Ryan D. Madanick, Nicholas J. Shaheen

Background: Radiofrequency ablation (RFA) is an endoscopic ablation modality that typically requires multiple treatment sessions to fully eliminate dysplastic tissue. It is unclear if increasing experience reduces complications and improves treatment results. Aim: To assess whether experience impacts symptom response bias to over-report pain. These data demonstrate exaggerated Temporal Summation in a subset of IBS patients who did not have a psychological bias to over-report pain. This is the first study to assess Temporal Summation in IBS. [Supported by R24DK067664, R01DK31369, and UL1RR025747]

Background: Symptoms of refractory gastroesophageal reflux disease (GERD) are highly prevalent among patients presenting to gastroenterology practices. pH-impedance (pH-MII) testing is commonly employed in this patient population, however the optimal diagnostic strategy is unclear.

Objective: To evaluate the cost-effectiveness of pH-MII testing on vs. off PPIs in patients with refractory GERD symptoms.

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Conclusions: In patients with refractory GERD symptoms, testing on therapy is a cost-effective strategy. As more data regarding the implications of the management decisions based on test results become available, the optimal testing strategy can be further clarified.
Utility of the Balloon-Evacuation Test for Identifying Patients with Dyssynergic Defecation

Authors: Giuseppe Chiorriano, Oreste Pieramico, Italo Vantini, Steve Heymen, William E. Whitehead

Abstract

Some have suggested the balloon evacuation test (BET) could substitute for anorectal manometry (ARM) in identifying patients with dyssynergic defecation (DD) and save cost.

Aims: (1) Assess test-retest reliability of the BET. (2) Determine its optimal duration. (3) Determine sensitivity and specificity of BET for detecting DD prior to ARM. As defined paradoxical contraction or failure to relax pelvic floor during attempted defecation during ARM. (4) Explore reasons for lack of agreement between BET and ARM.

Methods: 110 consecutive patients presenting to gastroenterology or surgery clinics for refractory constipation were invited into a one-month study; 4 declined. At enrollment all patients completed symptom questionnaires, underwent BET and were then instructed to inflate a balloon to 30 g per day and to keep a daily symptom diary for 30 days. The BET was repeated after 30 days in all patients. For patients who did not have a satisfactory response to fiber therapy (n=83), a Simatran transit study, anorectal manometry (ARM), and pelvic floor EMG during straining were also performed. Defecography was performed in patients who were unable to evacuate the balloon but were not dysynergic on ARM. The BET test involved insertion of a Foley catheter into the rectum above the level of the anal canal, injecting 50 ml of water at approximately body temperature into the balloon, and instructing the patient to go into a toilet alone and evacuate the balloon. They were asked at 1, 2, 4, and 5 minutes if they had been successful.

Results: Average age was 43.5 years (range 21-72 years), and 13/106 were males. Agreement was 100% between the 2 BETs completed by 106 patients; patients evacuated the balloon in less than 1 minute, an additional 6.6% required up to 2 minutes, and the remaining 49.1% were not able to evacuate the balloon within 5 minutes. Sensitivity defined by ARM is the gold standard, the specificity of the BET is 100% (no patient who was able to evacuate the balloon was dysynergic on manometry), sensitivity was 60.2% and positive predictive value (PPV) was 63.5%. The 19 patients who had abnormal BET but were not dysynergic on ARM included 7 who had rectal prolapse on physical examination and another 7 who failed to contract their abdominal wall muscles when straining (determined by physical exam). The appropriate duration for the BET is 2 minutes, and the test is 100% reproducible. Specificity of BET is 100%; a normal BET rules out dyssynergic defecation. The PPV is only modest because 36.5% of subjects with an abnormal BET are not dysynergic. However, these discordant cases (14/19) could be explained by physical exam findings. (Supported by R01DK13639)

Visceral Hypersensitivity in Functional Dyspepsia (FD) Demonstrated By Individual Capsaicin Titrator

Authors: Yong Xao, Xinhua Li, Reuben K. Wong, Khek Yu Ho, Clive H Wilder-Smith

Abstract

Background: The dyspeptic symptoms in patients with FD are often food-related, suggesting that abnormal chemosensitivity (sensitization) may contribute to the etiology of FD. TRPV1 receptors on chemoaffenter affeerent neurons are known to play a prominent role in the regulation of visceral pain and chemoaffenter function, including visceral sensitivity. A TRPV1 gene polymorphism (G1135C) has in Japanese FD patients been shown to influence upper gastrointestinal sensation. (1) TRPV1 pathways can be selectively activated using the ligand capsaicin and are implicated in sensory sensitization. Gastric sensation in healthy controls and FD patients has been studied using a fixed dose of capsaicin; albeit with wide variability in largely non-painful sensations. (2) However, the study of sensitization mechanisms involving high threshold C-fibers (including C-fibers in TRPV1 receptors) requires adequately intense stimulation levels of pain.

Aims & Methods: (1) Assess test-retest reliability of the BET. (2) Determine its optimal duration. (3) Determine sensitivity and specificity of BET for detecting DD prior to ARM. As defined as paradoxical contraction or failure to relax pelvic floor during attempted defecation during ARM. (4) Explore reasons for lack of agreement between BET and ARM.

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June 16th, 2011 will forever mark a major milestone in the effort to advance our scientific understanding of functional gastrointestinal disorders and motility disorders (FGIMDs). On this date, the Functional Gastrointestinal and Motility Disorders Research Enhancement Act (H.R. 2239) was introduced in the U.S. House of Representatives. This legislation, which was crafted by the International Foundation for Functional Gastrointestinal Disorders (IFFGD) to expand research in this field and improve the development of treatment options, was introduced on a bipartisan basis by Congressman F. James Sensenbrenner, Jr., a Republican from Wisconsin, and Congressman James Moran, a Democrat from Virginia.

Beyond raising critical awareness of FGIMDs on Capitol Hill, H.R. 2239 seeks to establish a Centers of Excellence program in FGIMDs at five academic medical centers in the U.S. The legislation would also grant NIH new authority to expand its research portfolio in this area and coordinate research activities with the Department of Defense and the Veterans Administration. H.R. 2239 also calls on the Food and Drug Administration to improve review, approval, and oversight of treatments developed for FGIMDs.

While the introduction of this legislation represents meaningful progress after years of congressional outreach by FGIMD advocates such as Dr. Douglas Drossman, Co-Director of the UNC Center for Functional GI & Motility Disorders, more needs to be done to ensure H.R. 2239 is passed into law. In order for this legislation to move forward in the legislative process, additional House Representatives need to support it by becoming “co-sponsors.” Every American has a House Representative, and the only way they will become a co-sponsor of H.R. 2239 is if one of their constituents (you) reaches out to their office and asks them to do so. Below please find talking points to assist you with reaching out to your House Representative to ask them to co-sponsor H.R. 2239.

Additional, official information on H.R. 2239 can be found at http://iffgd.org/HHR2239.

To CALL Your Representative

• Identify your House Representative by visiting www.congress.gov and entering your zip code in the prompt underneath the “Get involved” heading on the right hand column of the page. Your Representative will be the name/link under “Representatives” within the left column. Click on their name, and then click on their tab labeled “Contact” to view their contact information.

• Call your Representative’s Office. [DC phone (the 202 number) and ask to speak to the staff member who handles health issues; you will likely receive their voicemail. Be prepared to leave the following message or make the following request over the phone.]

[My name is ______ and I am constituent from [your town or neighborhood]. I would like to call your office and talk about the legislative proposal introduced by Congressman F. James Sensenbrenner, Jr. at H.R. 2239. It is called the Functional Gastrointestinal and Motility Disorders Research Enhancement Act. This legislation would expand research in the field of Functional Gastrointestinal and Motility Disorders and improve the development of therapies for these disorders. It is also important to ensure that patients with these disorders can access the care they need. I urge you to support this legislation and become a co-sponsor. Thank you for your time and consideration of this request.]

To WRITE Your Representative

• To write your representative, visit www.house.gov and enter your zip code in the search field at the top of the page underneath the heading “Find Your Representative.” Then, click on the name that appears in the left hand column to visit your representative’s personal webpage.

• On your representative’s personal webpage there will likely be a “contact” button. This button may send you to a page with a general email address, but it will likely send you to a webpage that needs to be submitted to e-mail the Representative. Please send the following message via e-mail or submitted through the web form.

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• To write your representative, simply click on the “write email” button on their webpage.

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Steve is retiring from the University and our Center on October 31 after an amazing 13 years. During that time he completed and published two large randomized controlled trials on pelvic floor biofeedback – one on dysyneurogenic defecation type constipation and another on fecal incontinence. These were seminal publications which have changed clinical practice for these disorders by demonstrating that biofeedback is a highly successful treatment. As a follow-up to this work, Steve played a key role in persuading UNC Hospitals to establish a dedicated pelvic floor biofeedback laboratory, and he recruited Mary Schultz to staff this clinic. This Biofeedback Clinic is absolutely unique in gastroenterology and has been a tremendous success; it has had a waiting list of 2-3 months almost since its inception and brings new referrals from many departments within UNC and from outside of the university.

Although Steve’s research shows that biofeedback is a highly effective treatment for fecal incontinence, he was concerned that biofeedback services are limited to a few academic medical centers and are not available to most patients. Therefore he led an effort to develop a standardized conservative treatment for fecal incontinence that can be learned and used by nurses in primary care to treat this disorder. He showed this approach to be very effective, but randomized clinical trials have not yet been conducted.

While actively working on these research accomplishments, Steve also enrolled in and completed doctoral studies in Biological Psychology here at UNC, receiving his Ph.D. in 2007. In the process, Steve inaugurated a new line of research on visceral pain. For his Ph.D. dissertation he tested central nervous system (CNS) contributions to visceral pain perception in patients with Irritable Bowel Syndrome (IBS). Normally the brain sends out signals to the spinal cord to down-regulate pain perception, but Steve’s dissertation showed that IBS patients are deficient in the ability to do this. This may help to explain the chronic nature of IBS pain and may provide a new target for treatment of IBS.

Steve is very young to retire from academic research. However, in response to the cut-back in research funding by the NIH, he decided to start a clinical practice for biofeedback in the community. He will see patients in Pittsboro and Cary, and will also teach a new course at UNC on pelvic floor disorders as well as those in need of anxiety and stress management. He is a good friend to many of us, and we will miss him. He will continue to be affiliated with our division as an adjunct faculty member. We wish Steve much success in his private practice. We are grateful for his many contributions to the successes of our department over the years and look forward to continued connections with him in the future.

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Opportunity to Support

Contributions from individual donors and grants from foundations and corporations are essential to enhancing and expanding the Center’s comprehensive and multi-disciplinary approach to clinical care, research, training and education in functional GI and motility disorders.

Memorial Research Fund

The Alan Wayne Ducoff Memorial Fund provides an opportunity for families and friends to remember and honor their loved ones by making a designated contribution to the Center’s research program. To make a donation to the Alan Wayne Ducoff Memorial Fund, please check off the appropriate box on the donation form.

Make your check payable to: UNC Center for Functional GI & Motility Disorders

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I would like to make a donation to the Center. Enclosed is my donation in the amount of:

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☐ Psychological Services
☐ Research Studies
☐ Constipation
☐ Fecal Incontinence
☐ Other

Make your check payable to:

UNC Center for Functional GI & Motility Disorders

OR: Include the following credit card information

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Credit card #: __________________________
Expiration date: __________
Signature: __________________________

Center Tax ID#: 56-6057-494

For more information about supporting the Center, please contact Sarah Barrett at slbarret@med.unc.edu.
Upcoming Chat Schedule

Our popular An Evening with the Experts chat series kicks off the new year with Christine Dalton, PA-C, discussing, “How Well Do You Know IBS?” All chats are scheduled the first Tuesday of every month, from 8-10 pm EST. Please access the chat by logging onto our website at www.med.unc.edu/ibs, and access the chat portal found on our homepage.