September 20, 2004

Minister Ujjal Dosanjh

Minister's Office - Health Canada
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Ottawa, Ontario, Canada
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Re: Briefing Document on: Digestive Motility Diseases; A Medical and Social Crisis

Dear Honourable Ujjal Dosanjh,

Please find enclosed our briefing document developed to alert your office to the medical crisis faced by millions of Canadians. These Canadians have been left out of the Federal funding loop for research into their serious digestive disease. In part, this has occurred because the statistics and tragedy have not been brought to your attention.

Everyday, millions of Canadians suffer with upper digestive motility symptoms. The numbers will continue to grow in tandem with the escalating numbers of Canadians who develop Diabetes. Further, large numbers of women develop similar digestive motility problems and they have largely been ignored.

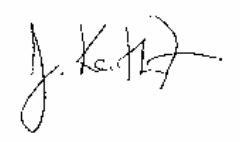
These motility diseases can progress to digestive failure. When clinical management of these patients becomes complicated, they often are referred to the United States for further diagnostic work and / or treatments. Why, because Canada lacks the expertise to deal with this very ill patient population.

Our non-profit association hears the stories from across Canada and we are powerless to help.

A serious funding commitment by the Federal government is needed immediately to develop a comprehensive strategy in order to deal with this crisis.

Please read the enclosed document. GPDA is prepared to meet with your office and can bring in experts in the field to help brief you further on this issue.

Sincerely,



Jeanne Keith-Ferris, RN, BScN
President/Founder, GPDA

Briefing Document
For:

Health Minister

The Honourable Ujjal Dosanjh

Digestive Motility Diseases; A Medical & Social Crisis

Prepared by the
Gastroparesis and Dysmotilities Association
(GPDA)

September 20, 2004

Preamble:

The Gastroparesis and Dysmotilities Association (GPDA) is a federally registered, Canadian, non-profit association representing individuals from across North America, suffering from gastrointestinal motility disorders.

The prepared document is meant to inform the federal government of the plight of millions of Canadians who are suffering from gastrointestinal motility (GI) disorders, also referred to as **digestive motility diseases.**

This area of digestive malfunction or failure represents a puzzling set of digestive neuro-muscular diseases characterized by asynchronous to paralyzed digestive propulsive action (motility) within segments, or in some cases, globally across the gastrointestinal tract. For families and sufferers, it represents a tragedy and a medical crisis. This community of suffering patients has, for too long, been without good medical guidance or any effective treatments to improve their quality of life.

This mechanical malfunction results from varied and complex derangements of biophysiological pathways within the enteric (aka gastrointestinal) nervous system. The end result, is universal symptoms, and ties these patients together with one voice, one face. Therefore, it is helpful to focus on the symptoms while remembering the confounding nature of the underlying processes at work. To serve our community of patients then, the federal government needs to recognize this group of digestive problems for what they are--a complex set of digestive diseases, or more specifically, digestive motility diseases.

Our patient group represents the far end of the disease and symptom spectrum, and accordingly, deserves a serious commitment by the federal government to apply resources for correcting this crisis.

On April 2, 2004 our non-profit association along with a panel of Digestive Disease Motility experts presented to the United States National Institutes of Health, National Institutes of Diabetes & Digestive & Kidney Diseases, Division of Digestive Diseases and Nutrition (NIDDK, DDDN) regarding the medical crisis for patients suffering from gastroparesis and the need for research funding into all aspects of digestive motility diseases.

This document outlines a description of these diseases, as well as examines how they plunder quality of life. It also focuses on their prevalence and cost to society; and finally, addresses the steps our government must take to help remedy this problem.

Briefing Document:

We are in a present-day epidemic of upper digestive symptoms, the vast majority of which are related to altered or ***abnormal digestive motility***. As much as 29 % of the Canadian population experience substantial upper gastrointestinal symptoms, which significantly affects their ability to work, eat, and sleep **1**. While heartburn traditionally grabs the spotlight, **digestive motility symptoms** (early satiety, nausea, vomiting, persistent feeling of fullness after eating, abdominal distention, diffuse upper abdominal discomfort to pain, excessive belching, and regurgitation) can present as a package, and **are the most prevalent and debilitating of the upper digestive symptom groups 1**. This upper digestive symptom complex can also be loosely called “dyspepsia”.

More Canadians suffer from **significant upper digestive** problems than from AIDS, inflammatory bowel disease, or hepatitis C. While these upper digestive symptoms may seem trivial compared to the disorders just mentioned, it is clear that individuals suffering from severe digestive motility diseases have substantial rates of morbidity and mortality, as well as some of the worst scores recorded on scientifically well-regarded quality-of-life surveys. Further, very little scientific headway has been made in the last 20 years in the area of digestive motility. This patient group has been left behind in funding for research, and consequently, does not have new treatments to embrace for improving quality of life.

Disabling upper digestive symptoms

The debilitating nature of upper digestive symptoms has been vastly underrated by our society. Of the upper digestive symptoms, nausea is the second most prevalent **1,2**. Using a standardized measure of quality of life in the evaluation of a list of fourteen individual digestive symptoms, vomiting was rated as the most debilitating, followed by abdominal pain and nausea **3**. These are the most common symptoms of digestive motility diseases, and in the case of some individuals with motility disease, occur in a severe, unrelenting, and life-threatening nature.

Gervais Tougas, MD at McMaster University in Hamilton, Ontario, was the lead investigator for the Canadian arm of the above cited study. Sampling from the general population, one thousand and thirty six Canadians from all regions of the country participated in this large epidemiological project. Called the DIGEST (Domestic/International GastoEnterology surveillance Study) study, it was the largest epidemiological study ever undertaken in the field of gastroenterology, looking at 14 common digestive symptoms and examining their prevalence, cost, and quality of life impact. Ten different countries participated and 5,500 adults were surveyed in this project.

What is digestive motility?

Gastrointestinal *motility*, or peristalsis, refers to the digestive tract's ability to contract, mechanically digest, and propel food along its hollow passageway. This muscular activity is orchestrated by a host of neurochemical /neuroelectrical events, working in exquisite balance of excitatory and inhibitory regulation. Science's understanding of the underlying biophysiology is still in its infancy.

What are digestive motility diseases?

- They represent abnormalities in the enteric nervous system with evidence of neuroendocrine / neuroelectrical abnormalities; and / or abnormalities of the enteric smooth muscle tissue--hence: enteric "neuro-muscular" disorders;
- They are a complex, multifactor, chronic, digestive disease state with possible genetic, physiological, social, immune, psychological, and environmental interplays;
- They can affect any region of the digestive tract, including ancillary digestive organs of the pancreas and gall bladder;
- They are impairments, of mechanical motor function of the esophagus, stomach, and intestines; which, when severe, can interfere with digestion, absorption, nutrition, and waste elimination; and
- At the severe end of the disease spectrum, they represent digestive organ failure.

These motility problems present as a spectrum from mild through severe. Although, each affected region has its own diagnostic term; but all share a weakened to flaccid, discordant function of motility. As many as a third of those suffering for years from troublesome, non-specific **digestive motility symptoms** may slowly progress to a more severe state. Generally speaking, young to middle-aged females make up the largest group to move on to a more severe state, for which no known cause can be identified. This unknown cause is labeled "idiopathic". These idiopathic forms show a variable course over the years, with symptom flair-ups followed by periods of quiescence. As well, many individuals affected with an enteric infection (whether bacterial, parasitic or viral) can then develop a post-infection dysmotility (or abnormal motility), which may slowly resolve (over a period of from two to five years) but, in the interim, can significantly impact quality of life to a disabling degree.

The four major motility diseases:

Gastroparesis (GP) refers to the motility disturbance occurring primarily in the stomach.
The term "gastro" refers to the stomach while "paresis" means weakness or paralysis. Also called "delayed gastric emptying" to describe the observed phenomenon found in gastric emptying studies, it is the most common of all the digestive motility diseases.

In its severe, classical form, gastroparesis is easily recognizable by most gastroenterologists. In its less severe form, it may take years to gain a proper diagnosis. Often, diagnosis rests upon the experience of the clinician since there is not a great deal of research nor is there a consensus to guide the definition or diagnosis of this disease.

The most troubling signs and symptoms of severe gastroparesis are unrelenting nausea and vomiting. These symptoms frequently occur along with abdominal pain due to the distended, poorly functioning stomach, and also with pain from chronic acid reflux into the esophagus and mouth as a consequence of gastric stasis. These symptoms currently have very few effective treatments, while some patients do not respond to any remedy.

Nutritional compromise is the hallmark of these unrelenting symptoms. Patients suffering from gastroparesis show a slow, insidious progression of malnourishment, and many will require jejunostomy tubes or total parenteral nutrition in order to stabilize their weight loss. The placement of tubes to re-hydrate and provide nutrition does **not** alleviate symptoms. Patients still "pool" secretions in their stomachs and vomit these up. Venting by gastrectomy tubes allows for the drainage of stomach secretions and gastric decompression, but this process further jeopardizes hydration and electrolyte balance, and again, does not alleviate the confounding and enormously difficult-to-manage symptom of nausea. Patients may require two or three prescription, anti-nauseant medications in their attempt to control this very debilitating symptom.

Chronic Intestinal Pseudo-obstruction (CIP)

Chronic intestinal pseudo-obstruction is the diagnostic name applied to the regional, paralytic motility disease affecting the small intestine. It often leads to a general failure of the entire digestive tract. Also called CIP, this motility disease has the greatest degree of morbidity and mortality. CIP usually has an insidious onset and may take from three to ten years for an accurate diagnosis to be obtained. The diagnosis of CIP is usually preceded by several years with nonspecific abdominal symptoms. During this time, many patients may undergo unnecessary, multiple, surgical interventions in the attempt to find a mechanical bowel obstruction. Delayed gastric emptying (gastroparesis), as well as puzzling autonomic nervous system (ANS) dysfunction, is also frequently found with CIP. The ANS dysfunction creates baffling symptoms resulting in urinary retention, sweating abnormalities, changes in heart rate, and blood pressure fluctuations.

The dyspeptic symptoms described above also occur with CIP, but this group of patients suffers to a far greater degree from intense abdominal pain. This intense pain often requires narcotic use. The narcotics then have the effect of further slowing down the weak digestive tract. Intractable constipation is also a predominating symptom with CIP, creating problems of severe fecal impaction. Secondary problems, such as "small bowel bacterial overgrowth", commonly occur and greatly impair the already compromised digestion. As well, co-morbidities of chronic pancreatitis, gall bladder failure, and/or liver impairment are not uncommon, and reflect a motility derangement of even the pancreatic and biliary ducts, causing pooling and stasis within these organs.

Intractable nausea, vomiting, and the vomiting of bile are seen with CIP. Nutritional support for this group of patients, having intestinal failure, is more dependent upon total parenteral nutrition (TPN). This method is required since insufficient nutrient absorption can occur with the poorly functioning intestines.

For clarification, enteral and total parenteral nutrition (TPN) are forms of nutritional support in which a liquid formula is infused through a catheter via an infusion pump. For enteral support, a catheter is run through the abdomen into the small intestine (jejunostomy). For TPN, a catheter is threaded through the chest wall into a large vein (central venous catheter) or a PICC line (peripherally inserted central catheter). Infusion rates with enteral feeding can be very slow due to intestinal spasms, and with TPN, due to vascular spasms. A meal can take many hours or as long as all day to infuse. This intervention usually does not halt nausea, vomiting, or abdominal pain. Finally, many who rely on parenteral nutrition, suffer, on average, approximately two life threatening blood infections each year as a complication of this form of feeding. TPN also carries a risk of liver failure and small bowel bacterial overgrowth.

If liver failure ensues from TPN, the only treatment option left for these patients is an intestinal transplant. Before the advent of total parenteral nutrition in the 1970s, many more patients died of CIP.

Even if good nutrition is restored with TPN, symptom bouts persist with flare-ups of pseudo-obstruction, creating a medical emergency. These unpredictable flare-ups lead to vomiting, excruciating abdominal pain, and abdominal distention from the air-filled small bowel. Life with CIP means repeated and prolonged hospital stays, a future inescapably intertwined with a local hospital. This patient group is often medially mismanaged since few patients are seen by any one medical centre. Patients become fearful as they are at the mercy of poor management. There are no centres of excellence to which these patients can turn for support, and no treatment consensus guidelines for physicians in order to help guide them in their medical management.

Colonic Inertia (CI):

Colonic inertia is the regional motility disease that primarily affects the colon. Also called slow transit constipation, it too is characterized by weak to flaccid tone with uncoordinated contractile activity within the colon. Its onset is insidious. Severe constipation with fecal impaction may result in problems of overflow diarrhea and fecal incontinence with bleeding anal fissures. This motility disease causes severe abdominal distention, unrelenting pain, and great risk of severe fecal impaction leading to complete blockage, dilation of the colon, and risk of intestinal rupture. A rupture results in spillage of fecal matter into the abdominal cavity causing a life-threatening infection known as "peritonitis". Surgical remedies are not always a quick fix since the motility disturbances can progress farther up the digestive tract, thus representing a more generalized disease of impaired motility.

Achalasia:

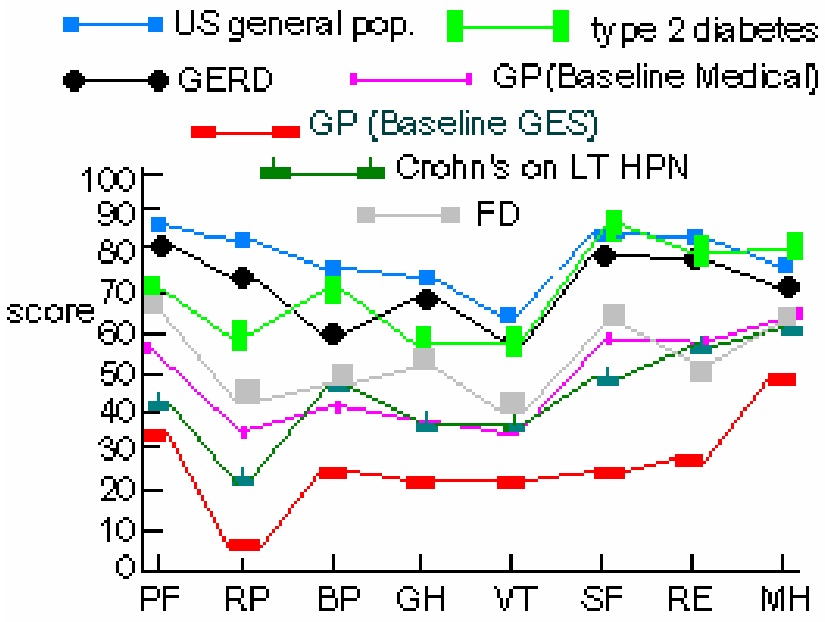
The motility disease affecting the esophagus is known as "achalasia," meaning "failure to relax". Characterized by dysphasia (difficulty in swallowing) of solids and liquids, substances entering the esophagus become trapped due to the persistent contraction of the lower esophageal sphincter (LES), a ring-like muscle surrounding the esophagus and acting as a valve at the gastroesophageal junction. Achalasia is further characterized by weak to absent peristaltic waves of motility within the esophagus. If unable to pass naturally into the stomach, these trapped contents must be expelled through voluntary regurgitation. Patients present with a number of symptoms, depending upon the stage at which the disease is diagnosed. In addition to the aforementioned difficulty in swallowing and regurgitation, symptoms can include severe chest pain due to esophageal muscle spasms (a sub-condition known as "vigorous achalasia"), heartburn/GERD, coughing, wheezing, and pneumonia. Progressive intolerance for food substances and consistencies, along with unanticipated obstructive instances, adversely affects a patient's general quality of life. Indeed, the unpredictable nature of the aperistalsis and LES malfunction makes achalasia an oppressive condition, with frequent choking, dramatic weight loss and malnutrition commonly experienced.

Many patients suffering from the more severe digestive motility diseases will often present with a blending of all the above-identified diseases.

The Quality of Life Tragedy

Nausea, vomiting and abdominal pain are the most debilitating digestive symptoms. This patient population suffers from these symptoms to the greatest extent; some with persistent symptoms spanning decades.

There is a paucity of scientific literature to paint the full picture. A well-regarded, validated quality-of-life measure commonly used by researchers, called the Medical Outcomes Study Short-Form General Health Survey (SF-36) allows for comparison among various diseases **4**. This quality-of-life tool has eight domains ranging from a low of 0 indicating severe difficulties to a high of 100 indicating no difficulties. The domains are as follows: limitations in physical functioning (PF), limitations in usual role activities due to physical health problems (RP), bodily pain (BP), perception of general health (GH), perception of general vitality (VT), limitations in social activities due to physical or emotional distress (SF), role limitations due to emotional health (RE), and perception of general mental health (MH).



Scale:

- "100" indicates no difficulties or impairment of function.
- "0" indicates severe impairments to functioning.
- PF = limitations in physical functioning
- RP = restriction of role functioning (example: activities of daily living)
- BP = bodily pain
- GH = general health
- VT = vitality
- SF = social functioning
- RE = restrictions in emotional health
- MH = general mental health perception

The above SF-36 scores show a comparison for the general American population, and:
Type 2 Diabetes--Patients with type II diabetes **5**,
GERD -- Patients suffering from heartburn disease, called gastroesophageal reflux disease **6**,
GP (baseline medical) -- GP is short for gastroparesis; these scores represent patients diagnosed with gastroparesis, who had SF-36 scores recorded prior to beginning a medical clinical trial **7**,
GP (baseline GES) -- These are the baseline scores for gastroparesis patients awaiting a clinical trial for gastric electrical stimulation (GES) **8**,
Crohn's on LT HPN -- These are the SF-36 scores on a group of patients with Crohn's disease, who have digestive failure from inflammatory bowel disease, and require long- term (LT) maintenance on home parenteral nutrition (HPN, aka TPN) **9**,
FD -- is the abbreviation for functional dyspepsia. Functional dyspepsia and mild gastroparesis represent a congruous patient population and many if not all, overlap into the same digestive motility disease spectrum **10**.

These scores from gastroparesis patients also show that patients with moderate to severe gastroparesis have SF-36 scores nearly as impaired as those suffering from digestive failure related to Crohn's disease.

Further, Abell et al's paper recorded baseline SF-36 scores before gastric electrical stimulation, and also measured symptom frequency and severity. These patients were representatives from the most severe end of the gastroparesis spectrum. Of this group of patients, some were vomiting fifty times per week. Many had been very symptomatic for more than half a decade. Their very low SF-36 scores provide a testament to the terrible effects of persistent nausea, vomiting, and abdominal pain.

The Diagnostic Tragedy

Many Canadian clinicians do not go beyond the routine tests to look for digestive motility dysfunction. Sufferers are then left feeling dismissed and their suffering minimized.

The diagnosis of motility diseases is a task fraught with difficulties. Extensive investigations using standard diagnostic tests such as blood work, abdominal ultrasound, computerized tomography, endoscopy, barium swallow, barium enemas, and colonoscopy may all culminate in normal results. Ordering the proper tests is incumbent upon the skill and expertise of the treating gastroenterologist. Manometry, or motility testing, considered by gastroenterologists who specialize in motility diseases as a very valuable

tool in confirming the diagnosis of motility problems, is provided by very few treatment centres. Esophageal and anal-rectal manometry is well established and fairly routine; however, use of manometry in other areas of the digestive tract is not. No doubt some restriction to obtaining these tests is due to inadequate reimbursement for the time-consuming job of reading these complex motility tracings, as well as to the lack of Canadian specialists with the expertise.

Electrogastrography (EGG) is also a helpful, adjunct, diagnostic tool that provides valuable, indirect evidence of digestive neuroelectrical rhythms. EGG as a diagnostic tool has a significant body of published, scientific literature behind it, and has been in clinical use by American motility specialists for over twenty years. It is an inexpensive, noninvasive tool and can provide valuable insight into the neruo-enteric integrity. In Canada, the majority of gastroenterologists do not recognize EGG as a valuable diagnostic tool. Again, no doubt, the lack of adequate reimbursement for the use of this tool is part of the impediment to more widespread application.

The prevailing attitude of many Canadian gastroenterologists is-- why bother with these specialized tests; they will not change the treatment approach. If significant money for research were available in this area, this attitude would change. Specialists would want to understand better what is going on with their patient group. They would want better means to define patients and to understand their biophysiological parameters in order to help focus research and to devise better treatment and diagnostic approaches.

What becomes readily apparent is the fact that specialized tools and clinical expertise, as well as research funding to help propel the motivation to understand, has been lacking. This adds up to a scientifically nebulous, poorly defined group of digestive diseases lost to all except the suffering patients.

As well, a historical, scientific, and social bias exists attributing these digestive diseases to a psychiatric, psychological, or stress-related origin. This common medical attitude is not supported by any medical research. This bias has greatly hindered scientific investigations.

Misdiagnosis frequently occurs with this patient group and the fallout can be disastrous. At the worst, parents of children suffering from digestive motility disease may be misdiagnosed with Muschausen by proxy, while adolescent girls may be misdiagnosed as having an eating disorder. At the very least, patients are dismissed by their doctors.

The Epidemiology Tragedy: prevalence and incidence.
Few epidemiology studies have been done on this group of remarkably costly digestive diseases which, collectively, are not rare.

In general, chronic, upper digestive symptoms **significantly** affect as much as 18% of the general North American population **2**, interfering weekly with school or work attendance, and resulting in significant health-care utilization as well as a poorer quality of life **1**. Abnormal motility is a lead player in these disastrous statistics.

From Dr. Tougas' research, this represents as many as 3.5 million Canadians suffer with digestive motility disturbance. Many Experts agree that some subsets of motility disturbances represent a continuum of pathology within which some progress onto more severe disease.

For the specific digestive motility diseases it helps to understand the various causes from which to extrapolate prevalence.

Digestive Motility Diseases may occur as primary diseases, which are idiopathic, or occur as secondary problems to other diseases or surgical interventions. When digestive motility problems result as a consequence of other diseases or surgeries, their debilitating nature can dominate the symptom picture deepening the suffering.

Common states which may lead to secondary digestive motility diseases are as follows: Diabetes, chronic hepatic failure, kidney failure, AIDS, scleroderma, Parkinson's disease, celiac disease, enteric eosinophilia, mitochondrial disease, Duchene's Muscular Dystrophy, Cerebral Palsy, spinal cord injuries, brain injuries, familial dysautonomia, heart/lung transplants, gastric surgery, and parasitic infections like Chagas disease or giardiasis. This is not an exhaustive list.

GP statistics

Gastroparesis may result from idiopathic or secondary causes. Kendall et al **11** provide a breakdown of causes: **33 % of all those with gastroparesis are idiopathic.** The next largest group to acquire gastroparesis is the diabetic group at 24%, followed by post- gastric surgeries and Parkinson's disease. These categories make up the preponderance of all gastroparesis causes. These statistics are also supported by a more recent publication by McCallum et al **12**.

Diabetic Gastroparesis:

- One in thirteen Canadians lives with diabetes and the numbers are growing (source: Canadian Diabetic Association).
- Five to ten percent of diabetics (especially Type I) suffer from clinically significant, symptomatic gastroparesis.
- Delayed gastric emptying (gastroparesis) of solid food, without pronounced digestive symptoms, (asymptomatic gastroparesis) occurs in up to half of Type I diabetics and as many as one third of Type II diabetics. This delayed emptying plays havoc with good blood sugar control **13**.

The gastroparetic stomach in diabetics is the focal point of a vicious cycle for poor glycemic control, and acceleration of diabetic complications **13**. This poor or erratic emptying of the stomach has the further effect of interfering with absorption of oral glycemic agents for treating Type II diabetics.

In severe diabetic gastroparesis, unrelenting nausea and vomiting sabotages options for kidney or pancreatic transplants. These primarily Type I diabetics are faced with a dismal future since currently there are precious few effective tools to wield against gastroparesis--they are left without transplant options.

CIP: Little information is available on the prevalence of CIP, but about 5% of all gastroparetic patients are found to have an associated CIP. Also, CIP affects men, women and children equally. Patients with systemic scleroderma can develop profound motility problems leading to digestive failure.

Colonic Inertia / slow transit constipation: Again, getting at the prevalence rates is difficult; however, constipation in the general population has been estimated from 2% to 28%. It must be recognized that abnormal motility plays a significant role in this overall picture. As well, people suffering form Parkinson's disease face significant, life threatening colonic inertia.

- The largest group to have colonic inertia is the idiopathic group.
- Mega colon (a complication of colonic inertia) carries about a 3% mortality rate.
- Idiopathic colonic inertia shows a female predilection.

Achalasia, is a rare disease, and is generally believed to affect approximately 1 in 200,000 people with all age groups represented and with no gender preference. Patients with scleroderma face significant problems of achalasia. For some scleroderma patients, abnormal digestive motility may involve their entire digestive tract.

The Treatment Tragedy

Astonishingly few medical treatment options exist for this group of patients. One can count on a single hand the numbers of medications (called prokinetic drugs) for treating these digestive diseases, all have been borrowed from other medical uses.

To illustrate the extent of the problem, while there has been an explosion of medical treatment options for gastro esophageal reflux disease (GERD), primarily aimed at acid suppression; many sufferers of GERD suffer as well with motility symptoms. For these patients, symptoms remain burdensome and debilitating despite acid suppressing treatment. Their motility symptoms continue to disrupt sleep, work/school attendance. The equation for treating the underlying digestive motor disturbance of GERD is missing therefore the burden of GERD + motility symptoms remains very high, significantly affecting the lives of millions of Canadians **1**.

For the more severe motor abnormalities of the stomach, that is gastroparesis, McCallum et al published a paper in 1985 titled "Review of the Current Status of Prokinetic Agents in Gastroenterology" **14**. In 2004, the drugs outlined in this paper are still the same, except for the loss of Cisapride. Cisapride was a valuable treatment option which decreased morbidity and mortality. Cisapride (Propulsid) has been pulled from the world wide market. Still available from Health Canada under the "Special Access Programme", many doctors remain unaware of this access.

One newer agent, Zelnorm (Tegaserod), developed for constipation-predominate irritable bowel syndrome, is now in clinical trials in the United States and Canada for medically treating diabetic gastroparesis. This single agent is the only new drug to come along in a very small armamentarium of treatment options.

Other treatment approaches such as surgery through resection of the stomach or small bowel have been used for palliation of symptoms, but the surgeries themselves carry risk of sequalae and/or mortality.

Gastric electrical stimulation, the implantation of a device for treating the symptoms of nausea and vomiting of gastroparesis, has shown very promising results. Though this device has been used in the United States for ten years and is approved for use by the Therapeutic Products Directorate of Health Canada, Canadians are still without a centre or expertise to provide this treatment option.

Mortality Tragedy

Mortality statistics exist for all of the digestive motility diseases and are the highest for CIP. Men, women, and children are affected.

For gastroparesis, published statistics could be found and reflect mortality rates of 5% **15**. Mortality rates for the diabetic gastroparetic patients are much higher. Symptomatic gastroparesis diabeticorum is associated with a grave prognosis. Approximately 30% die within 3 years; 56% may die within 5 years **16**. These statistics also reflect co-morbidities of autonomic neuropathy and often renal failure. However, uncontrolled diabetic gastroparesis may preclude these patients from transplantation options due to unrelenting vomiting. And as previously mentioned, early gastroparesis may be the culprit to accelerating the onset of diabetic co-morbidities. A more recent, but small study by Abell et al shows similar mortality comparisons. In a small group of 33 gastroparetic patients using prokinetics and antiemetic therapy, (5 males and 28 females with a mean age of 42 years) followed for 10 years, mortality was 43% for the diabetics and 13% for the idiopathic gastroparesis patients **17**. These patients were used as controls to compare the intervention of gastric electrical stimulation (GES). **Patients receiving GES showed marked decrease in mortality rates compared to controls 17.**

The Cost Tragedy: The cost to society is substantial. A handful of patients can run millions of dollars in hospitalization and nutritional support costs alone.

Costs related to moderate or severe digestive motility diseases are substantial. A handful of patients can cost the health care system multiple millions of dollars each year. So few treatment options mean reliance

upon enteral and parenteral nutrition due to the inability to keep solid food down or overwhelming bouts of nausea, bloating and abdominal pain causing food avoidance to try and minimize intolerable symptoms. Many patients also face symptom flare-ups leading to repeated hospitalizations due to uncontrolled pain or uncontrolled vomiting or severe fecal impaction.

- McCallum et al **12** cited statistics that followed Gastroparesis patients for a 5 year period. Over this time, 15% of all patients were still dependent on enteral or parenteral nutrition.

- Enteral formula costs vary and are not as expensive as home TPN costs, roughly though, enteral formulas may range from $30 to $50 per day.

- Cost for parenteral formula: canvassing one family in Calgary, Alberta whose daughter suffers from CIP, every other day supplemental home TPN costs were: $3,879.97 per month for formula, pump rental and supplies (tubing, needles, gauze and cleaning solutions).

- Hospitalization costs: a published study from the United States show substantial costs in hospitalization. Abell et al (GE 112(4): A2, 1997) found a cost of $6,972/month for hospitalization costs in gastroparesis patients.

- Again, borrowing from U.S. statistics, Bell et al **18** investigated the number of hospitalizations and discharges in one year (1998) for patients with Diabetic Gastroparesis in the State of North Carolina. The results based on the North Carolina Hospital Discharge database showed there were 1,476 discharges with total charges of $11,378,466 over 7850 total hospital days.

- Medication costs: Many of the gastroparesis patients depend upon anti-emetics, usually two different prescription anti-emetics taken over years to decades. Zofran or Ondansetron is one of the more effective prescription anti-emetics. In one year, the cost of this drug alone can equal the costs of nutritional support.

Summary

- Clearly a medical crisis exists for this group of patients. Significant, chronic digestive motility symptoms are ubiquitous in the Canadian population. A subset of these patients will go on to more profound symptoms which represent an ill defined digestive disease.

- Digestive Motility Diseases consume an enormous amount of medial care dollars. The burden of suffering for the patient and family takes a tremendous toll; especially coupled with the added impact of poor medical guidance, support, and lack of treatment options.

- Gastroparesis is the most common of the digestive motility diseases and is not rare. In Diabetics, it plays havoc with good blood glucose control helping to accelerate diabetic complications.

- Digestive motility diseases represent the severe end of the impaired digestive motility spectrum. Research efforts at this end of the spectrum would provide invaluable information and help provide insight and treatment options for all the digestive motility problems.

- There are precious few medical treatment options and once disease severity sets in, palliative surgical remedies (excluding gastric electrical stimulation) carry mortality statistics and may bring little relief from suffering.

Recommendations:

- A compelling need exists to fast track funding to address this crisis.
- Canadians' suffering from digestive motility diseases deserve better. This long forgotten patient group needs recognition, treatment options to improve quality of life, and centers of excellence in order to develop Canadian expertise.

The Canadian government should immediately:

Conduct surveys of individuals using nutritional support to determine how many have motility diseases and of these, how many have had to go out of country for diagnosis and treatment.

Conduct Epidemiology studies to determine the full extent of the Canadian problem.

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Establish a task force and consult with international experts to develop: Consensus guidelines on:

- Definitions,
- Diagnosis, and
- Treatment algorithms

Establish:

- A registry and data base, and
- Tissue bank and serum bank for genetic, immune and biophysiological research.

Finally

- **Develop Centers of Excellence to provide a safe haven, competent care and support network for patients.**

The Gastroparesis and Dysmotilities Association, representing Canadians suffering from digestive motility diseases seeks a dialogue with the Federal government to initiate the beginning steps to ameliorate this crisis.

Signed on behalf of Canadians living with Digestive Motility Diseases,

Jeanne Keith-Ferris, RN, BScN

References:

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