WIRELESS ELECTRODE PATCHES SHOW INTRAPATIENT REPRODUCIBILITY IN A LONGBUDINAL STUDY OF PATIENTS WITH CROHN'S DISEASE IN REMISSION

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Background: Crohn’s disease (CD) patients would benefit from a non-invasive indicator of gut function to better predict changes in disease state, such as the onset of flare. A study of CD patients using non-invasive wireless electrode patches (G-Tech Medical, Mountain View, CA) that read myoelectric signals from the gut over 3 days is underway at Stanford University’s IBD center. The study will include 40 patients presenting in flare and 30 in remission to be tested at t=0, 1, 3, and 6 months. In addition, one-time tests will be performed on 20 healthy controls.

Aims: Herein, we report on the first 6 CD patients tested at t=0 and 1 month while in remission.

Methods: Each patient wore 3 abdominal patches (each 2.7” diameter) for 3 consecutive days while pursuing regular daily activities and meals (Figure 1). Each patch recorded 4 channels of myoelectric activity from the stomach, small intestine and colon, and transmitted the raw data to an iPod Touch, which relayed the data to a secure cloud server. Data were later downloaded and processed to remove artifacts, create frequency spectra, and search them for peaks representing rhythmic motor activity. We find that, nominally, stomach activity appears at 3 cycles/minute (cpm), small intestine at 6–12 cpm, and colon at 12–25 cpm.

Results: Figure 2 shows peak spectra for the 6 patients at t=0 and t=1 month. Individual peaks represent motor activity at a specific frequency associated with the stomach, small intestine, or colon. Each patient has a unique overall pattern, or GutPrint, reflecting the frequencies and levels of activity of their GI motility. The GutPrint for each individual reproduces well at the second test and is easily recognizable for each subject. Although the peak amplitudes may vary, virtually all of the peaks that appear at specific frequencies at t=0 are also present at 1 month representing a quantifiable signature that reflects each patient’s unique motility.

Conclusion: The G-Tech patch system provides a practical and noninvasive, physiologic means of measuring motor activity of the gut over multiple days. Its intra-patient reproducibility allows for the possibility of measuring changes to gut performance over time, whether naturally- or drug-induced, showing promise in CD monitoring.

Figure 1. System diagram of the wireless electrode patch system. Non-invasive patches on the patient’s abdomen collect raw myoelectric data for 3 full days. Data is streamed to an iPod Touch carried by the patient, and from there uploaded to a secure cloud server for processing. Patients go about normal daily activities while wearing the patches.

Figure 2. Peak spectra for 6 Crohn’s Disease remission patients at t=0 and 1 month. Peak spectra are histograms in 0.2 cpm bins of the frequencies and amplitudes of peaks detected in FFT spectra, in 10 minute time windows over the course of the 3 day tests. Upper row – tests at t=0; lower row – tests at t=1 month.
Background: For years, the gold standard for Ulcerative Colitis (UC) remission was mucosal appearance during endoscopy. However, recent literature suggests histological or “deep” remission is important for preventing flares and maintaining clinical remission. There are now validated histological scoring systems to identify subclinical inflammation, the simplest being the Nancy Histology Index (NHI). Colonoscopy with histological evaluation is the gold standard for UC monitoring, but frequent endoscopy is not always possible. Literature reporting the utility of fecal calprotectin (FC) in detecting subclinical inflammation is limited. We sought to evaluate the correlation of FC and C-reactive protein (CRP) with NHI scores better assess their role in detecting subclinical UC.

Methods: We retrospectively evaluated clinical data and pathology slides of 69 UC patients that were collected over 6-months period at University of Kentucky. Pathology slides were scored according to NHI by a trained researcher and verified by an IBD pathologist. Presence of acute activity was defined as NHI >2. Mayo endoscopic scores (MES) were based on endoscopic reports from one expert endoscopist. Endoscopic remission was defined as MES ≤2. FC and CRP were recorded if collected within a month of endoscopy. FC was defined as elevated ≥120 mcg/g or borderline (50.1–120 mcg/g). Elevated CRP was defined as > 0.9 mg/dl.

Results: 33 of the 69 (47.8%) patients analyzed were in endoscopic remission. 17 of those 33 (51.5%) patients in endoscopic remission had acute histological activity (NHI >2), 7 (21.2%) patients with acute histological activity completed FC testing. Of the 7 who submitted FC, 4 were elevated, and 1 was borderline. 15 of the 17 NHI positive patients submitted CRP; 4 (26%) were elevated. Finally, among the 17 patients with NHI >2, four patients flared within a year (Table 1). In these 4 flared patients, FC was abnormal in 3 patients. CRP was negative in these three patients. One patient did not complete a FC or CRP. Conversely, of the 16 patients with quiescent UC and NHI <2 only 1 patient flared within a year. FC and CRP were not completed at the time of endoscopy.

Conclusion: We successfully identified an important subset of UC patients in clinical and endoscopic remission with active histological activity. Most patients in this subset had elevated fecal calprotectin levels. This suggests fecal calprotectin can be used for disease monitoring to proactively identify subclinical activity before a flare. Our findings suggest that biopsies should be performed in all UC patients even in the absence of endoscopic abnormality, and fecal calprotectin should be ordered at regular intervals to pre-emptively detect and prevent UC flares.

Table 1. Demographic and disease characteristics of study population.

<table>
<thead>
<tr>
<th>Endoscopic Recurrence</th>
<th>Patients - number (%)</th>
<th>Age - years</th>
<th>Female Sex - number (%)</th>
<th>Disease Limited to Ileum - number (%)</th>
<th>Strictureing and/or Perforating Disease - number (%)</th>
<th>Current or Former Smoker - number (%)</th>
<th>History of Prior Surgery - number (%)</th>
<th>Biologic Therapy Post-Operatively - number (%)</th>
<th>Rejection Beyond Ileum - number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (RS ≥ i1)</td>
<td>17 (48.6%)</td>
<td>59.6 ± 18</td>
<td>3 (60%)</td>
<td>1 (100%)</td>
<td>5 (100%)</td>
<td>3 (60%)</td>
<td>4 (80%)</td>
<td>4 (80%)</td>
<td>3 (60%)</td>
</tr>
<tr>
<td>No (RS i0-i1)</td>
<td>16 (51.4%)</td>
<td>40.7 ± 15</td>
<td>2 (33%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (33%)</td>
<td>1 (20%)</td>
<td>1 (20%)</td>
<td>2 (33%)</td>
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P112 CORRELATION OF FECAL CALPROTECTIN TO COLONOSCOPIC FINDINGS FOR DETECTION OF RECURRENT OF CROHN’S DISEASE IN THE POST-OPERATIVE SETTING AT A SINGLE ACADEmIC CENTER

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Introduction: Patients with Crohn's disease (CD) who undergo a first surgery are at higher risk of having a subsequent surgery in light of recurrence of disease. Significant evidence suggests that a postoperative colonoscopy evaluating recurrence at the anastomosis using the Rugeerts score (RS) can predict risk of repeat surgery. Given the invasive nature of colonoscopy, there has been increasing interest in using noninvasive biomarkers to predict disease recurrence. Studies have shown variability in the operating characteristics of the fecal calprotectin (FC) assay with sensitivities and specificities for detecting recurrence ranging widely from 48–95 and 58–79%, respectively. A recent meta-analysis demonstrated a pooled sensitivity of 70% when using an optimal FC cut-off of 150 mcg/g. We sought to delineate how FC correlates with RS at our institution and to identify a cutoff for significant recurrence.

Methods: We performed a retrospective review of adult patients with CD who underwent surgery followed by a colonoscopy within 18 months of surgery with the additional inclusion of FC testing within 2 weeks of the colonoscopy. Patients were identified at our institution via ICD 9 and 10 codes and the electronic medical record. The primary outcome of interest was a comparison of mean FC for those without endoscopic recurrence (defined as RS ≤10) to those with significant endoscopic recurrence (defined as RS ≥12-14). Other variables assessed included gender, disease location and phenotype, and extent of surgery (Table 1).

Results: A total of 12 patients met the inclusion criteria. 7 patients (58.3%) were female. Age at time of surgery ranged from 21 to 73 years (mean 37.9). Only 1 patient (8.3%) had a nonstricturing, nonpenetrating phenotype. After surgery, 11 patients were on biologic or combination therapy and 1 patient was not on any medical therapy. 5 patients (42%) demonstrated endoscopic recurrence by RS with mean FC of 883.7 mcg/g, as compared to mean FC of 83.6 mcg/g for those without recur- rence. There was a positive correlation between FC and RS with a Spearman’s rank correlation coefficient of 0.86 (p = 0.0004).

Conclusions: Our results demonstrate a strong correlation between FC and RS. Using a cutoff for FC of 150 mcg/g, we demonstrate sensitivity and specificity of 100%. This further supports the possibility of using FC as a surrogate to possibly defer colonoscopy in those post-operative CD patients with low FC. Study limitations include the retrospective nature and small sample size, recognizing that in years past FC was not as readily available or used in this setting. Future considerations include larger, prospective studies looking at FC and other noninvasive biomarkers in this post-operative setting.

Table 1. Demographic and disease characteristics of study population.