

ADVANCES IN GASTROENTEROLOGY AND GI SURGERY



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Mobile Health Technology: Tracking Postop Recovery to Improve Outcomes

“Readmission after gastrointestinal surgery is a common problem for patients,” says **Heather L. Yeo, MD, MHS**, a colorectal surgeon in the Section of Colon and Rectal Surgery at NewYork-Presbyterian/Weill Cornell Medical Center. “However, many readmissions are potentially preventable. They can occur due to ileus or surgical site infection, with dehydration among the most common problems after colectomy.”

Dr. Yeo, who trained in both surgical oncology and colon and rectal surgery with a particular focus on rectal cancer, focuses much of her clinical research on improving the surgical experience for patients. “As we’ve become better at treating disease, patients are living longer and so quality of life and how they spend their life is very important,” says Dr. Yeo. “GI cancers can result in a high rate of postsurgical complications and readmissions, with older patients having the highest rate. There is clear evidence that intense follow-up and monitoring can reduce these problems, however, few physician practices have the resources to do that.”



Dr. Heather L. Yeo

To address this issue, Dr. Yeo turned to mobile health technology with help from Cornell Tech, the technology campus of Cornell University – and with input from physicians and nurses – to develop a mobile app specific to patients undergoing GI surgery and conduct a pilot study of an encrypted mobile

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Proton Pump Inhibitors: The Risk-Benefit Equation

Over the last 10 to 20 years proton pump inhibitors (PPIs) have become one of the top oral medications in the United States. According to a study published in *JAMA* in 2015 on trends in prescription drug use, the use of proton pump inhibitors in non-institutionalized adults in the United States doubled from 3.9 percent in 1999 to 7.8 percent in 2012. During the same period, the number of studies reporting PPI-related adverse effects also doubled.

“With this proliferation of use, there is more and more power to study the possibility of adverse effects of these drugs,” says **Daniel E. Freedberg, MD, MS**, a gastroenterologist with NewYork-Presbyterian/Columbia University Medical Center. “After studying proton pump inhibitors for a long time, we now understand the risks well enough. What we should focus on instead is the benefit of

these drugs. PPIs perform well when given for appropriate indications, in situations where they confer a substantial benefit. But when there is a soft indication for the drug, potential adverse effects begin to look more significant.”

Many of the feared consequences of PPI use remain inconclusive. Having looked at large data sets to assess the adverse effects, Dr. Freedberg and his colleagues note that attaching a cause to the medications is open to interpretation given the potential of other contributing factors and individual characteristics of the patients taking PPIs.

“Many of the adverse effects associated with the use of PPIs are unlikely to be related to the drugs themselves,” says Dr. Freedberg. “Patients who use PPIs tend to have more underlying medical

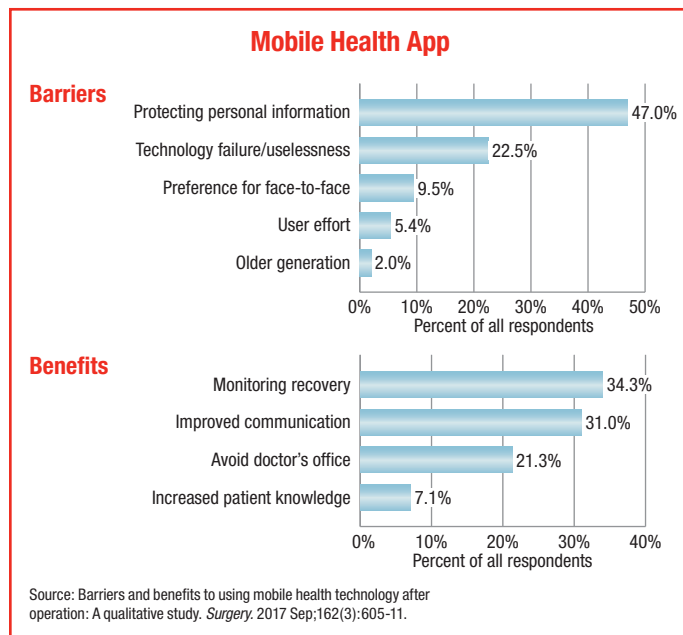
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Mobile Health Technology (continued from page 1)

app for patients with GI cancer following surgery. Dr. Yeo and her colleagues first utilized Cornell's Survey Research Institute's Empire State Poll to survey 800 New York State residents to determine their willingness to engage with a variety of mobile health technology functions, including wearing a tracker, completing a daily survey, and sharing updates with select family and friends. The survey revealed that protecting personal information was the most likely barrier to using the mobile health app; while the benefit of better monitoring of their recovery was most important to them.

"While older adults have a slightly lower rate of phone usage, the majority were more than willing to use the app if it would improve their postop recovery and if it were used for short periods of time, making it ideal for postoperative monitoring," says Dr. Yeo.



With grant funding from NewYork-Presbyterian/Weill Cornell's Center for Advanced Digestive Care and The Society for Surgery of the Alimentary Tract, the researchers developed the smartphone mHEALS app that works on both an Android and iOS device. The application has a wide range of functionalities, including collecting patient-reported outcomes, generating alerts for concerning symptoms, transmitting photos of surgical incisions, and recording a daily step count with a Fitbit.

"We decided to keep the app simple and easy to use with large fonts and big buttons that don't require complex dexterity," says Dr. Yeo. "It couldn't take a lot of time or energy to use."

The pilot study comprised 31 adult colorectal surgery patients who underwent either laparoscopic or open abdominal surgery for a variety of benign or malignant conditions at Weill Cornell between September 2015 and January 2017. During their hospital stay, patients were instructed to practice using the application, and they continued using it after discharge from the hospital until postoperative day 30.

To minimize excessive alerts, warnings were designed to be triggered only by serious conditions likely to require intervention, including vomiting, fever, and excessive ostomy output. Abnormal patient responses to survey questions, for example, fever, vomiting, or poor oral intake, triggered two alerts: one instructing the patient to contact the surgeon's office and one informing a clinician of the patient's abnormal

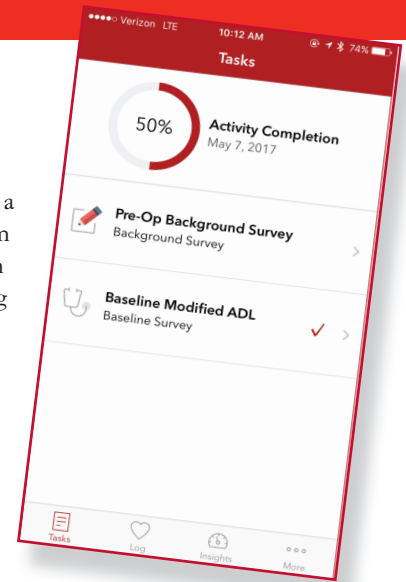
response. A surgeon reviewed the patient-submitted photographs on a daily basis, while the research team reviewed any alerts generated from the surveys and alerted the nursing staff to any concerns about individual patients.

"The results of our study demonstrate that it is feasible and easy to use a novel mobile health application to track postoperative recovery in patients after major abdominal colorectal surgery," says Dr. Yeo, who notes that the vast majority of patients (83.9 percent) contributed data at least 70 percent of the time during the first 30 postoperative days, and the number of patients participating did not decline with time. Only one patient, who had generated seven alerts prior to readmission, was readmitted.

"Overall, patients overwhelmingly found the application easy to use and would recommend it to a friend," says Dr. Yeo. "Patients also see this as an advantage in terms of cost and travel; for a lot of older adults, getting into New York City to see their physician is no small task."

Dr. Yeo and the Weill Cornell researchers have now begun a randomized controlled trial supported by the Damon Runyon Cancer Foundation in GI cancer patients using the next version of the application. "We're focusing on adults who are undergoing major GI cancer surgery – either laparoscopic or open – randomized to either a group using the app or one provided with the current standard of care, which consists of informational materials that we give to our patients," she says.

Dr. Yeo believes that the face-to-face interaction between a patient and physician and the use of mobile technology are not mutually exclusive. "Our app is a first proof of concept designed to empower patients to communicate with their physicians in order to improve postop care. We believe that mobile apps will define the future of healthcare," says Dr. Yeo. "The app also gives patients a sense of self-empowerment. Patients tend to be more active in recovery and in their own care if they know it is partly dependent on them. And we want to make sure that when our patients are having issues, we can identify them at the right time. Some patients will call in and tell you that they're having a problem, but some won't. They wait until things get too far along when they are already quite sick. This will allow us to gauge who needs to come in and be triaged."



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Proton Pump Inhibitors: The Risk-Benefit Equation (continued from page 1)



Dr. Daniel E. Freedberg

comorbidities than patients of the same age who don't use PPIs. They are also more likely to be obese and have a sedentary lifestyle. When you can't completely adjust for those baseline differences between PPI users and non-users, it becomes hard to tease apart whether a given bad outcome is from the drug or from those baseline differences. When evaluating whether a potential adverse effect from PPIs or any other medication is causal, you like to have

multiple kinds of evidence – we look for consistent associations, but also for plausible mechanisms linking the drug and the adverse event, dose-response effect, and evidence across studies with different designs.”

“With PPIs, it's helpful to look at where the drug is acting and what it's doing,” continues Dr. Freedberg. “PPIs have a very short plasma half-life. However, they have a long, effective duration because they act on the cells that line the stomach to powerfully block acid production. Therefore, any adverse effect is more likely to be related to the production of acid than to the brief time that PPIs or their metabolites spend in plasma.”

In an open-label crossover trial, Dr. Freedberg and his colleagues explored whether the acid suppressive effect of PPIs altered the colonic microbiome, facilitating *Clostridium difficile* infection. The researchers found that while PPIs did not change fecal microbial diversity beyond baseline variability, they significantly affected certain taxa, including Streptococcaceae and Enterococcaceae, and therefore may increase the risk for *C. difficile*.

“We know that gastric acidity confers some protection against enteric infections such as Salmonella,” adds Dr. Freedberg. “Long before PPIs were discovered, people who had no gastric acidity were recognized to be at risk for certain kinds of enteric infections. While our own work in *C. difficile* has shown that PPIs do change bacteria in the colon, conferring a small risk of infection, PPIs are not antibiotics. While they change specific bacteria, they don't wipe out colonic bacteria wholesale. The changes in the microbiome are relatively subtle and a good indication for the PPI will outweigh the absolute risk of an enteric infection, which is about one in a thousand.”

Dr. Freedberg advises that when the indication is appropriate, for example, prescribed for someone who has erosive esophagitis where there is damage to the end of the esophagus, continuing the medication is recommended because of the potential for recurrence. If the indication of the drug is inappropriate, for example, prescribed for nonspecific abdominal pain, and it's not helping the patient, there are no consequences to discontinuing the PPI and then it should be discontinued.

Reviewing the Evidence: Equivocal for Adverse Effects; Definitive for Benefits

Dr. Freedberg recently served as the lead author on an American Gastroenterological Association Clinical Practice Update presenting the best practice advice for PPIs based on the risks and benefits of long-term use of these medications. The paper includes assessments of the often equivocal evidence that has accrued since the use of PPIs expanded. Dr. Freedberg and his expert collaborators from South Denver Gastroenterology, PC, and Perelman School of Medicine, University of Pennsylvania, concur that “despite the long list of potential adverse effects associated with PPI therapy, the quality of evidence underlying these associations is consistently low to very low.”

On the benefits side, the majority of the evidence clearly demonstrates the effectiveness of PPIs in the treatment of gastroesophageal reflux disease and Barrett's esophagus, and as a preventive agent for bleeding in high-risk patients who take nonsteroidal anti-inflammatory medications. “Severe GERD with acid-related complications is among the most important indications for the use of a PPI,” says Dr. Freedberg. “The more complex GERD cases that benefit the most from PPIs are patients with the classic symptoms of heartburn or regurgitation, or those with comorbidities such as central obesity or large hiatal hernias. Patients who have mainly ‘atypical’ symptoms of GERD like cough are much less likely to benefit from PPIs.”

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Proton Pump Inhibitors: Best Practice Advice American Gastroenterological Association	
Best Practice Advice 1	Patients with GERD and acid-related complications should take a PPI for short-term healing, maintenance of healing, and long-term symptom control
Best Practice Advice 2	Patients with uncomplicated GERD who respond to short-term PPIs should subsequently attempt to stop or reduce them
Best Practice Advice 3	Patients with Barrett's esophagus and symptomatic GERD should take a long-term PPI
Best Practice Advice 4	Asymptomatic patients with Barrett's esophagus should consider a long-term PPI
Best Practice Advice 5	Patients at high risk for ulcer-related bleeding from NSAIDs should take a PPI if they continue to take NSAIDs
Best Practice Advice 6	The dose of long-term PPIs should be periodically reevaluated so that the lowest effective PPI dose can be prescribed to manage the condition
Best Practice Advice 7	Long-term PPI users should not routinely use probiotics to prevent infection
Best Practice Advice 8	Long-term PPI users should not routinely raise their intake of calcium, vitamin B12, or magnesium beyond the Recommended Dietary Allowance
Best Practice Advice 9	Long-term PPI users should not routinely screen or monitor bone mineral density, serum creatinine, magnesium, or vitamin B12
Best Practice Advice 10	Specific PPI formulations should not be selected based on potential risks

Source: *Gastroenterology*. 2017;152:706-15

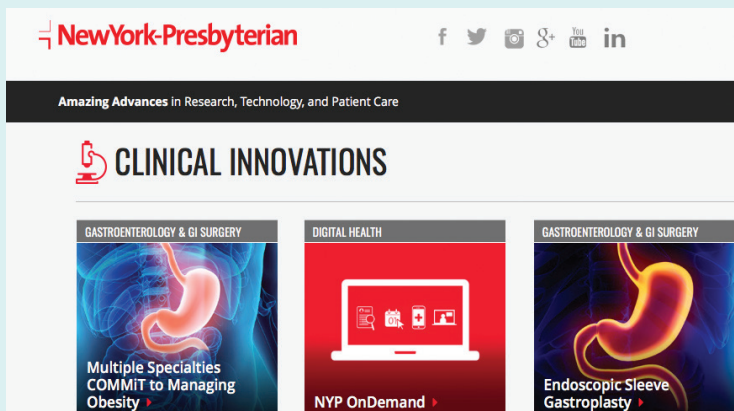
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Proton Pump Inhibitors: The Risk-Benefit Equation (continued from page 3)

For Barrett's esophagus, another significant indicator for the use of PPI, Dr. Freedberg and his colleagues recommend that dosing and duration should be based on monitoring each patient's developments. Those with Barrett's esophagus and symptomatic GERD should take a long-term PPI because they may benefit both with symptom relief and also in slowing the progress of Barrett's esophagus.

The third major indication is the use of PPIs in patients who take nonsteroidal anti-inflammatory drugs (NSAIDs), which put them at high risk for ulcer-related bleeding. "Patients who remain on NSAIDs, should remain on PPIs as they are highly effective in controlling ulcer-related bleeding in appropriately selected patients," says Dr. Freedberg. "The benefit in preventing ulcer-related bleeding outweighs the risk for select patients."

Dr. Freedberg wants to help physicians and patients understand the data surrounding the use of proton pump inhibitors. "PPIs are going to continue to be prescribed because they are incredibly useful

drugs in the treatment of acid-related disorders," says Dr. Freedberg. "The hope, however, is they'll be prescribed thoughtfully and that physicians will focus on indications rather than risks."

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