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Increased capture of post-endoscopic retrograde cholangiopancreatography adverse events by delayed (day 7) follow-up calls: a prospective comparison of physician- and nurse-initiated calls

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Abstract

Background Endoscopic retrograde cholangiopancreatography (ERCP) is a high-risk endoscopic procedure. We recently found that physician-initiated post-ERCP follow-up calls on day 7 post-ERCP increased adverse event capture. Subsequently, we prospectively evaluated the utility of nurse-initiated follow-up calls, comparing these with physician-initiated calls to assess the impact of transitioning this responsibility to a nurse.

Methods This prospective study was conducted on consecutive patients undergoing ERCP at our academic tertiary care medical center. Patients received phone calls on days 1 and 7 post-ERCP, from either an endoscopist or a nurse coordinator, using a standardized script to assess delayed complications (pancreatitis, non-pancreatitis abdominal pain, bleeding, infection, perforation), and unplanned health encounters.

Results A total of 448 ERCP patients (239 physician calls, 209 nursing calls) were included. Physician calls were more successful than nursing calls in reaching patients on both day 1 (96% vs. 74%, P<0.001) and day 7 (91% vs. 63%, P<0.001). Nursing calls were significantly longer than physician calls on both days. A higher adverse event capture rate by physician calls compared to nursing calls was evident on day 1 (3.5% vs. 2.4%, P=0.04) and day 7 (10.6% vs. 6.3%, P=0.004). Physician follow-up calls on day 7 resulted in substantially more patients triaged to the Emergency Department, primary care and oncology clinics (P<0.001).

Conclusions Physician calls were significantly more effective than nurse calls in reaching patients, capturing adverse events, and triaging patients to appropriate care. These data support the value of physician-initiated calls, at least following the most complex procedures.

Keywords Endoscopic retrograde cholangiopancreatography, adverse event, complication, follow up

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has a high potential to cause perforation and bleeding, compared to general endoscopic procedures, and is associated with the unique adverse events of cholangitis and pancreatitis [1-6]. ERCP-associated adverse event rates vary between 4% and 15%, a range that most likely reflects differences in procedure volume, procedure setting and endoscopist expertise [1,4,5]. In a prior study, we demonstrated that this variability in adverse event rates also reflects their limited detection and reporting, as a result of heterogeneity in, or even an absence of, postprocedural follow-up practices [7].

ERCP has become a higher risk procedure over time, with the escalating complexity of cannulation [8], and because now most ERCPs are performed for therapeutic indications [9,10].

A growing subset of ERCPs are now performed on patients who are elderly, have malignancy, and have complex altered anatomy—factors that are associated with more ERCP-associated adverse events [8,11-18). Furthermore, low-volume centers predominate in the United States ERCP practice setting [19]. This is notable because of the volume-outcomes relationship for ERCP, with higher volume centers having higher success rates and lower rates of adverse events, while the inverse is true for low-volume centers [16-19]. These trends imply that increasing challenges will be encountered when performing ERCP.

Given the elevated ERCP-associated procedural risk in the present era, detection of post-ERCP adverse events is crucial. Based on our prior study demonstrating that physician-initiated follow-up calls help facilitate the capture of procedure associated adverse events [7], we adopted the institutional practice of reaching out to each patient on Day 1 and Day 7 post-ERCP to assess for adverse events. These calls were initially conducted by the endoscopist; however, as clinical and endoscopic volumes escalated for advanced endoscopists at our institution, this approach became increasingly impractical. Ideally this follow-up call would be conducted by a nurse coordinator who participates in the care of endoscopy patients. The question remained, however, whether the efficacy of these follow-up calls would be preserved when the task was shifted from endoscopist to endoscopy nurse. In this study we evaluated the yield of physician versus nurse follow-up calls at the previously determined highest yield time points of 1 and 7 days following ERCP.

Patients and methods

We evaluated consecutive ERCP patients from March 2019 to October 2019. The Stanford Institutional Review Board evaluated and classified this as a study focused on quality improvement. The advanced endoscopy fellow participated in most of the procedures included in this study. We prospectively recorded characteristics for each patient, as well as hospitalization status, anesthesia type (general anesthesia or monitored anesthesia care), patient comorbidities, and indication, interventions performed during the procedure, and fellow involvement.

During the encounter for pre-procedure consent and examination, adverse events associated with ERCP (pancreatitis, perforation, infection, and bleeding) were described and their potential associated symptoms were reviewed. We encouraged all patients to contact us through the electronic medical record messaging system (online platform for patients to send email-like health messages to their care team), or by telephone call, with any post-ERCP concerns or symptoms. We advised patients that they would undergo physician assessment prior to discharge after ERCP, and would receive telephone calls 1 day and 7 days after ERCP from a member of our care team. We asked patients to make themselves available for these calls. The timeline of post-procedure follow up is shown in Fig. 1.

Calls for assessment post-ERCP were assigned to either the physician or the endoscopy nurse follow-up call group on an alternating day basis (e.g., Monday: RN, Tuesday: MD, Wednesday: RN, Thursday: MD, Friday: RN, Monday: MD) to minimize the impact of variations in volume and patient mix from day to day, and to maximize the feasibility of this study. Both the physician and the endoscopy nurse had access to the patient's electronic medical record, including all medical history, laboratory tests, etc. The group assignment was unknown to the endoscopist and care team prior to the timing of the Day 1 follow-up call. A telephone in the hospital in a secure location was used to contact patients and a standardized previously validated post-procedure script was used for capture of ERCP-associated adverse events [7]. This script was used for both telephone calls, 1 and 7 days post-procedure (Appendix 1). When ERCP was performed on an inpatient basis and patients remained admitted following the procedure, day 1/7 assessments were carried out in person using the script. Script findings were entered into a secure database after each of the post-procedure assessment encounters. Patients with symptoms that raised concern about post-ERCP pancreatitis were directed to the emergency department or urgent care for further evaluation, and laboratory studies were ordered to facilitate the diagnostic workup. The physician and nurse conducting the follow-up calls did not have access to each other's secure database. Patient-initiated telephone and electronic healthcare encounter details were also recorded in this database.

Classification and grading of adverse event severity were adapted from the consensus guidelines of Cotton *et al* [20]. Unplanned healthcare encounters (UHE) were defined as unscheduled outpatient or emergency room visits or hospitalizations following ERCP. Indications and findings for these visits were documented. For each of these encounters, we documented the diagnosis, adverse event type and severity, as well as the duration of hospitalization and any need for surgical and/or endoscopic (re)intervention.

Statistical analysis

Student's *t*-test, Pearson's chi-square and Fisher's exact tests (for data with sparse distribution) were applied for descriptive statistical analysis. Generalized linear models and multivariate logistic regression models were used to analyze risk factors for UHE and adverse events. All test results were 2-tailed. Statistical significance definition was $P<0.05$.

Results

Follow-up calls made to patients undergoing a total of 448 consecutive ERCP procedures were analyzed. Of these calls, 239 were physician-initiated and 209 were nurse-initiated. The telephone number from the electronic medical record was disclosed to and checked with the

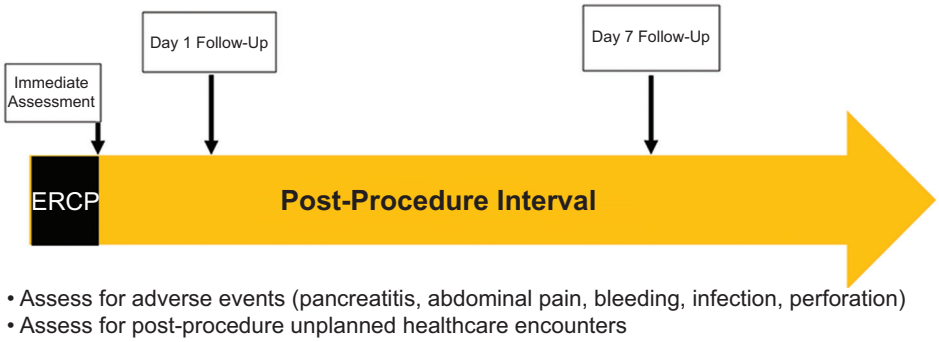

Figure 1 Flow diagram for post-procedure follow-up calls

patient at the time they entered the study. However, for 14% of patients, the primary telephone number in our electronic medical record turned out to be incorrect, either because it had changed, or because it had been incorrectly recorded in the system. Reasons for the change included elderly patients now residing with their family members or in assisted living facilities, change in apartment/home and/or transition from a land line to a mobile telephone number, with elimination of the land line.

Patient characteristics

Patients undergoing ERCP had a mean age of 66.7±12.2 years, and this did not differ significantly between the physician- and nurse-initiated call groups (P=0.63). Females comprised 59% of all patients; 83% of ERCPs were performed on an outpatient basis and 17% on an inpatient basis. Patients' American Society of Anesthesiologists classes were as follows: (I: 4%, II: 68%, III:27%, IV: 1%) (Table 1).

Procedure indications

Table 2 shows the indications for ERCP and interventions performed during ERCP. The most common indication was malignant bile duct stricture (28%). Most ERCPs were performed for a biliary indication (97%), and cholangiopancreatoscopy was performed in 14% of procedures. There were no significant differences in any parameters between the nursing and physician follow-up call groups, consistent with the block randomization nature of the follow-up call group assignment.

Day 1: Characteristics of telephone calls

Physician calls were more successful than nursing calls in reaching patients on Day 1 (96% vs. 74%, P<0.001, Fig. 2). In the physician call group, 18 (7.5%) patients were reached on a second call, 10 (4.2%) on a third call, while 4% of patients could not be contacted after 3 unsuccessful phone calls. In the

Table 1 Patient demographics

Characteristics	Value
Total ERCPs	448
Physician call	239
Nurse coordinator call	209
Sex	
Male	41%
Female	59%
Hospitalization status	
Outpatient	83%
Inpatient	17%
ASA class	
I	4%
II	68%
III	27%
IV	1%

ERCP, endoscopic retrograde cholangiopancreatography; ASA, American Society of Anesthesiologists

Table 2 ERCP Indications and interventions

Total ERCPs	448
Indication	
Benign biliary stricture	111 (25%)
Malignant biliary stricture	127 (28%)
Pancreatic duct stricture	6 (1%)
Pancreatic duct stone	8 (2%)
Choledocholithiasis	90 (20%)
Abnormal LFT/imaging	65 (15%)
Primary sclerosing cholangitis	15 (3%)
Bile leak	7 (2%)
Other	19 (4%)
Ampulla status	
Index	152 (34%)
Subsequent	296 (66%)
Interventions performed	
Biliary sphincterotomy	131 (29%)
Pancreatic sphincterotomy	6 (1%)
Stent placement	370 (83%)
Stone/debris extraction	215 (48%)
Papillary balloon dilation	18 (4%)
Combined EUS/ERCP procedure	40 (9%)
Cholangiopancreatoscopy	64 (14%)

ERCP, endoscopic retrograde cholangiopancreatography; LFT, liver function test; EUS, endoscopic ultrasound

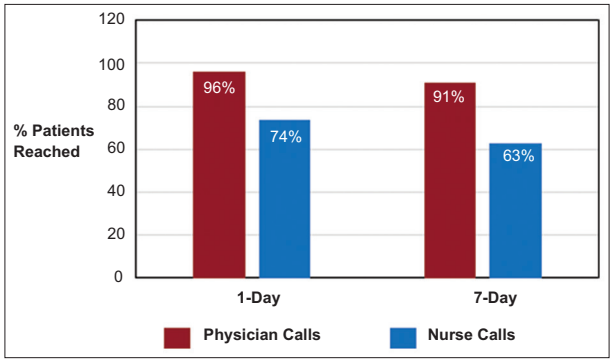

Figure 2 Comparison of percentages of patients reached with nursing and physician follow-up calls

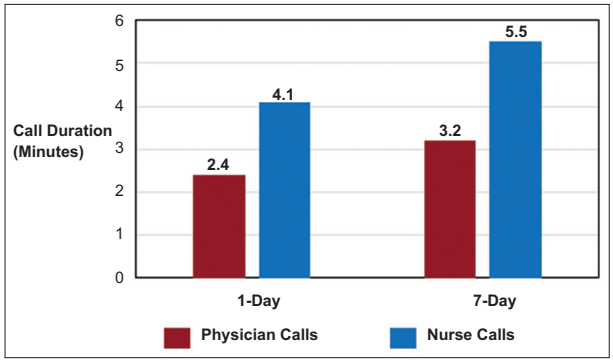

Figure 3 Comparison of durations of nursing and physician follow-up calls

nursing call group, 8 (3.8%) patients were reached on a second call, no additional patients were reached on a third call, while 26% of patients could not be contacted after 3 unsuccessful phone calls.

Day 7: Characteristics of telephone calls

Physician calls were more successful than nursing calls in reaching patients on Day 7 (91% vs. 63%, P<0.001, Fig. 2). In the physician call group, 20 (9.2%) patients were reached on a second call, 12 (5.5%) patients were reached on a third call, while 9% of patients could not be contacted after 3 unsuccessful phone calls. In the nursing call group, 7 (5.3%) patients were reached on a second call, no patients were reached on a third call, while 37% of patients could not be contacted after 3 unsuccessful phone calls.

Follow-up call duration

The mean call duration on Day 1 was 2.4±0.8 min for physician calls and 4.1±1.1 min for nursing calls (P=0.005, Fig. 3). On day 7, the mean call duration was 4.1±0.6 min for physician calls and 5.5±0.8 min for nursing calls (P=0.03, Fig. 3).

Post-ERCP adverse events/UHE detected on Day 1 and Day 7 physician follow up

The overall rate of adverse events was 1.8% immediately post-procedure (1.3% pancreatitis, 0.5% infection, 0% perforation, Fig. 4). On Day 1 follow up, the cumulative adverse event rate, including UHE, rose to 3.8% in the physician call group (additional 2% pancreatitis, 0% infection, 0% bleeding) and to 10.5% on day 7 (additional 1.2% pancreatitis, 0.8% infection, 0.4% bleeding, 4.2% UHE) (Fig. 4). The cumulative detection of adverse events was higher for Day 7 than for Day 1 or the immediate post-ERCP assessment (P<0.001, Fig. 4).

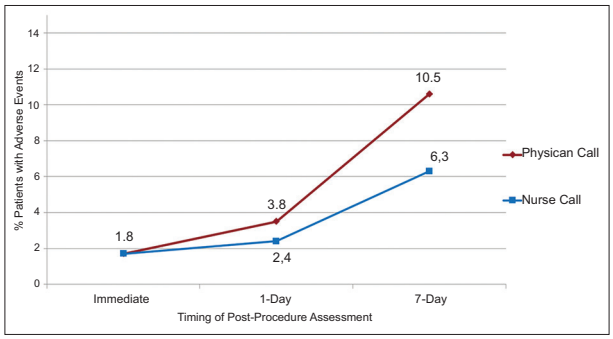

Figure 4 Adverse events and unplanned healthcare encounters captured by physician (red) and nursing (blue) follow-up calls

Post-ERCP adverse events/UHE detected on Day 1 and Day 7 nurse follow up

The overall rate of adverse events was 1.8% immediately post-procedure (1.3% pancreatitis, 0.5% infection, 0% perforation, Fig. 4). The cumulative adverse event rate, including UHE, rose to 2.4% on Day 1 in the nursing call group (additional 0.8% pancreatitis, 0% infection, 0% bleeding) and to 6.3% on Day 7 (additional 2% pancreatitis, 0% infection, 0.5% bleeding, 1.4% UHE) (Fig. 4). The cumulative detection of adverse events was higher for Day 7 than for Day 1 or the immediate assessment post-ERCP (P<0.05, Fig. 4).

Patients directed to appropriate care by Day 1 and Day 7 follow-up calls

After the physician follow-up call on Day 1, 4 patients (1.7%) were sent to primary care (1 patient), or to the Emergency Department (ED; 3 patients). No patients were admitted following ED or clinic evaluation. No patients from the nursing call group were sent for additional care following the Day 1 follow-up call.

After the Day 7 physician follow up calls, 15 patients (6.2%) were directed to additional medical care that included primary care (5 patients), oncology clinic (4 patients) or the ED (6 patients). After these physician calls, hospital admission

was ordered for a subset of patients (5 patients, 2.1%). An unscheduled repeat ERCP was performed within 48 h of this call for a subset of patients in the physician call group (6 patients, 2.5%).

Following Day 7 nurse follow-up calls, 5 patients (2.4%) were directed to additional medical care in the ED. Two patients were admitted to the hospital after nursing follow-up calls (1%). No unscheduled urgent ERCP was performed in the 48 h after the Day 7 follow-up call in the nursing call group.

Discussion

Gastroenterological societies have confirmed the need for accurate data surrounding post-ERCP adverse event assessment and follow up [21,22]. Adverse event data are most accurate when collected prospectively, through direct patient interaction. Physician-initiated calls after ERCP have been shown to capture more adverse events than traditional post-procedure follow-up the day after ERCP [7]. We acknowledge that endoscopists often have many clinical and other demands on their time, and these demands may preclude endoscopist-initiated follow-up calls to all patients 1 and 7 days post-ERCP. Ideally, this follow-up protocol could be assigned to nurses, with escalation to physicians for select triage and management decisions that may arise. Accordingly, we undertook this study to evaluate the utility of nurse-initiated early (day following ERCP) and delayed (7 days following ERCP) calls in detecting ERCP-associated adverse events. In the original study evaluating early and delayed post-ERCP follow-up calls, there was a strikingly higher proportion of patients reached by physician follow-up calls after ERCP (92-95%), compared with staff and nursing calls during the pre-study period (19%) [7]. It was not possible to discern whether the dramatically lower percentage of patients reached by nursing follow-up calls in the pre-study period was due to patients not being advised to expect follow-up phone calls, failure to use the best telephone number to reach patients after ERCP, or the fact that these calls were made by nursing staff as opposed to physicians.

We found that, after patients had been primed to expect a follow-up call specifically on Day 1 and Day 7 post procedure, and the best phone number for reaching patients had been determined, a substantially higher percentage of patients were reached by nurse follow-up calls in the present study compared to our original study (74% vs. 19%, respectively). This higher percentage of patients who were contacted by nursing calls on Day 1 relative to historic data is noteworthy, and underscores the importance of clear communication with patients regarding follow-up calls, as part of a robust infrastructure to support the detection of endoscopic adverse events.

Nevertheless, nursing follow-up calls, conducted by a single endoscopy nurse coordinator for consistency, were overall less successful in reaching patients compared to physician calls on both Day 1 and Day 7. The initial nursing calls reached a lower proportion of ERCP patients, and subsequent calls (2nd and 3rd attempts) were less successful in reaching patients who did not answer the initial call. There are some potential explanations for this finding, including the possibility that patients were more responsive to physician-initiated, rather than nurse-initiated contact; or that physicians were more highly motivated to reach the patient, because of their involvement in the study, and were thus more persistent. However, most endoscopists take pride in a profound sense of ownership of the outcomes of their endoscopy patients. We believe it is likely that advanced endoscopists are motivated to assess their patient's outcomes post-ERCP, independently of the study environment.

The timeline and rates of post-ERCP adverse events were informative and, importantly, these align with and validate data from the original physician-initiated ERCP follow-up call study [7]. The additional point of nursing contact 7 days following ERCP had some impact in directing some patients towards more extensive follow-up care. However, physician-initiated follow-up calls directed proportionally more patients to further assessment and care than did nursing calls, and led to additional ERCPs being performed. These additional ERCPs were performed based on information gathered during the physician-initiated follow-up call. The explanation for this is likely to be multi-faceted. Endoscopists develop a rapport and care relationship with patients, which could prompt patients to share symptoms that might not otherwise have been shared with a nurse who is not longitudinally involved in the patient's care. Alternatively, patients may have reported mild and seemingly unrelated concerns from the interval prior to the day 7 call, and a nurse may not have recognized the need to send the patient for subsequent follow up, based on these subtle symptoms. Additionally, the UHE and repeat ERCP rate may be relatively high at our center, given its tertiary care nature, which also accounts for the fact that many patients are elderly and have multiple comorbidities. In the original physician-initiated ERCP follow-up study, some symptoms reported during the phone call 7 days after ERCP were not directly related to the procedure (e.g., changes in goals of care, anxiety, pulmonary and urinary symptoms) [7]. While they were not directly related to the ERCP, the physician interaction through that call improved overall care delivery [7].

Attending endoscopists are busy and their schedules may not be consistent with calling post-procedure patients for follow up. If endoscopists or facilities are unable to call all patients 7 days after ERCP, options might include shifting this responsibility to advanced endoscopy fellows (where available), so that they develop a sense of ownership and understanding of adverse events associated with the procedures they perform, or involving another gastroenterologist or nurse practitioner in the care and follow up of advanced endoscopy patients. Alternatively, specific higher-risk ERCP patient populations could be targeted for physician follow up. Including patients who are have more complex, prolonged procedures in this population, and having nurses initiate follow-up calls for the remainder, may be a feasible approach to enhance post-ERCP care.

Limitations of this study include its single-center nature. The study was conducted in a tertiary care center in which patients tend to have significant comorbidities, and high complexity ERCPs are performed. Consequently, the findings we report may not fully generalize to community practice. The nursing follow-up calls were carried out by an endoscopy nurse, but the medical

education of a nurse differs from that of a physician and there is potential for this difference to impact the triaging differences observed in the study. The Hawthorne Effect is a concern, and can have an impact on prospective observational studies. Both physician and nurse were aware of the study and ongoing prospective data collection, and neither shared outcomes data with the other. Thus, although the Hawthorne Effect cannot be ruled out, it should apply equally to physician and nurse follow-up calls, minimizing its impact on the study findings.

In conclusion, endoscopist follow up after ERCP with both early (Day 1) and delayed (Day 7) calls accurately captures post-ERCP adverse events. However, this approach is time-consuming and draws upon the resources and infrastructure of the healthcare system. When endoscopists are not available to initiate these follow-up calls, endoscopy nurse-initiated calls still carry value. The present study demonstrates that 7-day follow-up calls result in higher cumulative adverse event capture than 1-day follow-up calls, for both nurse and physician-initiated calls. Based on these adverse event capture rates, the approach for follow up after ERCP to optimize the capture of adverse events may involve targeting the highest risk ERCP patient populations for physician follow-up calls, and having nurses initiate follow-up calls for the lower risk patients.

Summary Box

What is already known:

- Endoscopic retrograde cholangiopancreatography (ERCP) is one of the highest-risk endoscopic procedures
- Physician-initiated post-ERCP follow-up calls on Day 7 post-ERCP lead to higher rates of adverse event capture relative to immediate post-ERCP assessment
- Endoscopists are busy and it may not be feasible for an endoscopist to call each patient twice following ERCP for adverse event assessment

What the new findings are:

- Nurse-initiated follow-up calls were superior to immediate post-ERCP assessment in the detection of ERCP-associated adverse events
- Nurse-initiated follow-up calls were less likely to reach patients than physician-initiated calls
- Physician calls were significantly more effective than nurse calls in reaching patients, capturing adverse events and triaging patients to appropriate care

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Supplementary material

Appendix 1 Telephone script for post-ERCP follow-up calls

Hello, my name is_____and I am calling from Stanford Hospital. May I speak with (Patient Name)?
(If patient is not available)
Thank you very much. I will attempt to reach (Patient Name) at another time.
Goodbye.

(If patient is available/answers the telephone)
I am calling to followup with you after your ERCP (yesterday/last week).
Have you been hospitalized or evaluated in the emergency room, or in an urgent care/primary care setting at any point since your procedure?
(if yes) Was this visit planned/scheduled prior to ERCP?
(if healthcare encounter was not planned pre-ERCP) Could you please provide details regarding the hospitalization/visit and share records from that admission?
Have you undergone any additional endoscopic or surgical procedures related to your bile duct or pancreatic duct at any point since your procedure?
(if yes) Could you please provide details regarding that procedure and share records from that admission?
Have you experienced worsening or new fevers/chills, jaundice, nausea/vomiting or abdominal pain since the ERCP?
(if yes) discuss and record which symptoms are present, whether they were present pre-ERCP and, if present pre-ERCP, whether ttey improved/worsened in the interval following the procedure.
Have you experienced any black or bright red bowel movements? Have you vomited blood or coffee ground-like material since theprocedure.
(if yes) discuss and record which symptoms are present, whether they were present pre-ERCP and, if present pre-ERCP, whether they improved/worsened in the interval following the procedure.
Have you experienced any other symptoms or illnesses you associate with the procedure you underwent as part of this study?
(if yes) Could you please explain your symptoms and how you feel they relate to the procedure?
(If any responses concerning for acute illness based on the above questions, will instruct patient to proceed directly to the nearest emergency room)

Thank you very much for your time. Please do not hesitate to contact us via telephone (MyHealth with any questions or concerns that arise prior to our next telephone call. I will check with you again in 6 days (if post-ERCP Day 1 Call).
Thank you very much for your time. Please do not hesitate to contact us via telephone (MyHealth with any questions or concerns that arise prior to our next telephone call. I will check with you again in one week (if post-ERCP Day 7 Call).
Thank you very much for your time. Please do not hesitate to contact us via telephone (MyHealth with any questions or concerns that arise prior to our next telephone call. I will check with you again in 2 weeks (if post-ERCP Day 14 Call).
Thank you very much for your time. Please do not hesitate to contact us via telephone (MyHealth with any questions or concerns that arise, (if post-ERCP Day 30 Call).

ERCP, endoscopic retrograde cholangiopancreatography