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Body surface gastric mapping to determine gastric motility patterns associated with delayed gastric emptying after pancreaticoduodenectomy. Gastric Electric Mapping after Pancreatoduodenectomy study protocol

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ABSTRACT

Introduction Delayed gastric emptying (DGE) is frequent after pancreaticoduodenectomy (PD). Although often associated with postoperative pancreatic fistula, the precise pathogenesis in patients with no underlying complications remains unclear. There is evidence to suggest that, after surgery, aberrant electrical pathways are formed in the stomach which could contribute to the development of DGE.

Gastric Alimetry is a novel technology which measures the electrical activity of the stomach non-invasively using an array of electrodes applied to the skin of the abdomen. This technique, termed body surface gastric mapping (BSGM), has been validated in normal controls and in patients with functional dyspepsia syndromes. This study will investigate the efficacy and feasibility of using BSGM to assess gastric motility in patients who undergo PD.

Methods and analysis This prospective cohort study will be conducted at a single large volume hepatobiliary unit in the UK. 50 patients who are planned to undergo PD will be included. BSGM measurement will be performed at four timepoints viz: preoperatively, day 4 postoperatively, at discharge and 6 months postoperatively. Key parameters of BSGM measurement, including wave amplitude, frequency and directional vector, will be measured at each timepoint and compared between different patient subgroups. Symptoms will be self-reported by patients during the recording using an iPad application designed for this purpose. Quality of life and patient experience will be assessed using standardised questionnaires at the end of the follow-up period.

Ethics and dissemination The protocol has been approved by the research ethics committees of Newcastle University and the Health Research Authority (HRA) of the UK (ethical approval IRAS ID 305302). Findings will be published in peer-reviewed journals and presented at national and international conferences.

Trial registration number This study will automatically be registered with the ISRCTN registry by the HRA as part of the ethics approval process.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Measurement of gastric electrophysiology will be conducted at multiple timepoints in the patient journey to assess both the acute effect of surgery and degree of resolution.
⇒ Patient symptoms and gastric electrophysiology will be measured synchronously, yielding accurate data to analyse the association between clinical and physiological outcomes.
⇒ The effect of potential confounding factors, such as postoperative pancreatic fistula and surgical technique, will be examined.
⇒ The sample size may not be large enough for subgroup analysis.
⇒ The follow-up period is only 6 months, and long-term effects on gastric function may not be detected.

INTRODUCTION

Pancreaticoduodenectomy (PD) is a complex surgical procedure which is performed for a variety of indications including benign and malignant diseases of the distal bile duct, duodenum and pancreas. Pylorus-preserving PD (PPPD) and pylorus-resecting PD (PRPD) are the most common variations. PRPD involves resection of the distal portion of the stomach and re-establishing gastroenteric continuity with anastomosis between the stomach and jejunum, while PPPD involves resection distal to the pylorus and duodenojejunal anastomosis. Previous RCT's (Randomised Controlled Trials) have demonstrated that both techniques are associated with comparable oncological outcomes.[1]

Delayed gastric emptying (DGE) is a major complication of PD which occurs in up to 70% of patients who undergo PD.[2] Management of DGE can involve a prolonged course

Table 1 International Study Group of Pancreatic Surgery delayed gastric emptying consensus definition[6]

Grade	NGT required	Unable to tolerate solid oral intake by POD	Vomiting/gastric distension	Use of prokinetic medication
A	4–7 days or reinsertion after POD 3	7	±	±
B	8–14 days or reinsertion after POD 7	14	+	+
C	>14 days or reinsertion after POD 14	21	+	+

NGT, Nasogastric Tube; POD, Postoperative day.

of total parenteral nutrition and nasogastric drainage to prevent vomiting, causing significant distress for patients,[3] delayed hospital discharge[4] and increased healthcare costs. A recent cost analysis estimated that the extra costs associated with DGE are approximately £8500 per patient.[5]

DGE is diagnosed clinically based on the International Study Group of Pancreatic Surgery (ISGPS) definition, which includes symptoms of vomiting and the need for nasogastric drainage (table 1).[6] Various objective tests of gastric function have been investigated, but they are not routinely used to diagnose DGE as they are not readily available, are difficult to administer in postoperative patients or do not correlate well with symptoms. For example, gastric fluoroscopy, which involves ingestion of radiopaque contrast solutions, can demonstrate gastric stasis, but this has not been shown to correlate with symptoms of DGE.[7] In contrast, the results of gastric scintigraphy analysis correlate with symptoms of DGE[8] but are not readily available and are difficult to administer in postoperative patients. Finally, although gastric manometry can accurately assess gastric contractions,[9 10] the test requires invasive placement of probes and causes significant patient discomfort.

Although often associated with postoperative pancreatic fistula (POPF),[11] the pathogenesis of DGE remains unclear. Various surgical modifications to the gastroenteric reconstruction technique have been employed in an attempt to prevent this complication,[1] but none have been proven to consistently prevent DGE. There is evidence to suggest that, following resection and anastomosis of part of the stomach, aberrant electrical pathways are formed which could contribute to the development of DGE.[12]

Under physiological conditions, gastric contractions are finely coordinated by a complex network of the bioelectrically active interstitial cells of Cajal (ICC). These cells transmit the propagation of waves towards the pylorus, facilitating ejection of food into the duodenum. The duodenum, in turn, has a similar but functionally separate network of ICCs which coordinates peristalsis in the first part of the small intestine. The pylorus acts as an electrical barrier, preventing impulses being transmitted retrograde towards the stomach.[13] After gastrojejunostomy, abnormal gastrointestinal pathways are formed that transmit retrograde electrical activity to the stomach. These aberrant pathways, which have been identified in animal[14] and human studies, have been shown to cause symptoms of nausea and vomiting in patients who have undergone Billroth 1 gastrectomy.[15]

Earlier studies of gastric electrical activity required an invasive technique with electrodes placed on the serosal surface of the stomach at the time of surgery. Less invasive body surface electrical recordings were available, but employed only 2–4 electrodes, were unreliable and have thus not been widely adopted in clinical practice.[16] To address these limitations, a novel technique called body surface gastric mapping (BSGM) has been developed and refined over the last 5 years. BSGM uses a 64-electrode array (the Gastric Alimetry device) which is applied to the surface of the skin to detect and analyse the electoral impulses from the stomach non-invasively. This technology has been validated in healthy controls[17] and in patients with functional dyspepsia, where aberrant electrical patterns were found to correlate closely with symptoms of gastroparesis.[16]

The proposed study aims to investigate the utility and feasibility of using BSGM in patients who have undergone PD. Furthermore, the findings of the study could contribute to the understanding of the fundamental pathophysiology which underlies DGE in this group of patients and guide the development of more effective interventions to manage this significant postoperative complication.

METHODS AND ANALYSIS

This protocol was designed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials Statement[18] and the Standards for Reporting Diagnostic accuracy studies checklist.[19] The study will be conducted in accordance with the principles of Good Clinical Practice.

Patient and public involvement

None.

Study design and setting

This is a single centre prospective cohort study conducted at Freeman Hospital in Newcastle upon Tyne, UK. The department of Hepato-Pancreato-biliary (HPB) surgery at Freeman hospital is the tertiary referral centre for malignant and complex benign pathologies of the pancreas and duodenum and treats patients from the entire Northeast region of England. The first author (KM) and clinical nurse specialists (JL and SC) are responsible for the day-to-day support for the study.

Recruitment will begin on 7 November 2022. The authors estimate a period of 1 year of recruitment will be required to achieve the target participant number (n=50).

Inclusion and exclusion criteria

Inclusion criteria:

- Patients undergoing PD for malignant or benign disease of the pancreas, distal bile duct or duodenum.

Exclusion criteria:

- Under 18 years of age.
- Previous gastric surgery.
- Postoperative complication requiring surgical intervention.
- Major wound sepsis or rash.
- History of skin allergies or extreme sensitivity to cosmetics or lotions.
- Pregnant women.
- Vulnerable groups, for example, cognitive impairment or inability to give consent.

Operative procedure

The operative technique will be chosen by the surgeon in the course of normal clinical management. PPPD involves transection of the duodenum distal to the pylorus and duodenojejunostomy, while in PRPD, the stomach is transected proximal to the pylorus with gastrojejunostomy. With both reconstructive techniques, the anastomosis will be fashioned in the antecolic position at 50–60 cm from the hepaticojejunostomy.

At the end of the procedure, the Prineo dressing system will be applied to patients' wounds. This secure dressing has a relatively small footprint and will not be disturbed by the application of the electrode array.

Study tests

BSGM recording protocol

The BSGM recording procedure will be conducted at multiple timepoints:

- Preoperatively.
- Day 4 postoperatively.
- At discharge.
- 6 months after discharge.

Excess hair will be removed, and the patient's skin will be prepared using NuPrep gel, which reduces skin impedance for enhanced detection of electrical impulses. The 64-channel electrode array will be applied to the anterior abdominal wall and connected to a portable data logger (figure 1). Passive recordings will then be completed over a 4-hour period, and slow wave characteristics including wave direction, amplitude, frequency and direction vector will be analysed, together with the gastric meal response.

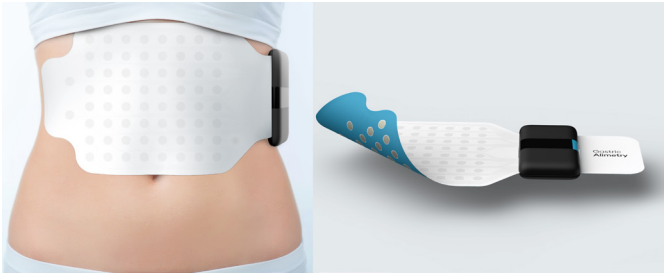

Figure 1 Alimetry electrode array.

Symptom and patient feedback logging

While undergoing BSGM, patients will be asked to record their abdominal symptoms using an application designed for this study run on a tablet computer (online supplemental appendix 1). If the patient is unable to use the provided tablet, a member of the research team will interview the patient and record symptoms using the same application.

After the recording session, participants will be asked to complete a feedback form to assess their satisfaction with the BSGM process, identify adverse events and assess whether the symptom-logging process was clear and easy to use.

Quality of life and patient experience assessment

Patients will complete validated quality of life questionnaires preoperatively and at 6 months postoperatively. These will include the Patient Assessment of Upper GastroIntestinal Disorders-Quality of Life (PAGI-QOL) (online supplemental appendix 2) and EQ-5D-5L questionnaires. They will also complete a short questionnaire on their experience of undergoing the BSGM test (online supplemental appendix 3).

Study outcomes

The primary outcome is the pattern of gastric electrical activity as characterised by wave spectral (frequency and amplitude), spatial (wave directional vector) and stability (rhythm index) parameters. These parameters will be compared at different timepoints, by presence versus absence of DGE, by PRPD versus PPPD and by presence versus absence of POPF.

Secondary outcomes include symptom, QoL and patient satisfaction scores. Symptoms assessed include nausea, vomiting, fullness, heartburn and abdominal pain. QoL scores will be measured using the PAGI-QOL and EQ-5D-5L questionnaires, and a qualitative assessment of patient satisfaction with the BSGM test procedure will be assessed with a questionnaire designed for this purpose.

Participant timeline

Participant schedule of events is summarised in table 2. After giving informed consent and passing eligibility screening, participants will undergo a preoperative BSGM recording session in the outpatient clinic. The day 4 and discharge recording will be conducted in the surgical wards and will not interrupt standard clinical care. The final 6-month recording will be conducted in the outpatient clinic. To prevent excessive travel, every effort will be made to have the preoperative and 6-month follow-up recordings be done on the same day as the participant's normal scheduled outpatient visits. If this is not possible, the participant will be reimbursed for travel costs.

Sample size

The sample size calculation was based on the primary outcome (gastric wave parameters). As this is a novel study, there is no data in the literature which examines the

Table 2 Schedule of enrolments, tests and assessments

Timepoint	< D-1	D0 (surgery)	D4	Discharge	6 months (end)
Enrolment					
► Eligibility screen	X				
► Consent	X				
Test					
► Body surface gastric mapping recording	X		X	X	X
► QoL questionnaires	X				X
► Patient experience questionnaire					X
Assessments					
► Baseline: age, sex, body mass index, ECOG status, diagnosis and history of smoking medical comorbidities	X				
► Amplitude, frequency, vector and rhythm index	X		X	X	X
► QoL score	X				X
► Qualitative patient experience					X
► Intraoperative: resection type		X			
► Postoperative: delayed gastric emptying (Y/N), postoperative pancreatic fistula (Y/N), bile leak (Y/N), chyle leak (Y/N), sepsis (Y/N), organ dysfunction (Y/N) and need for NGT (Y/N)		◆———	———	———◆	

ECOG, Eastern Cooperative Oncology Group.

use of BSGM in patients who have DGE after PD. Based on a similar study in patients who had undergone sleeve gastrectomy[20] and assuming equal proportions between groups with an alpha=0.05 and power=80%, a minimum sample size of 50 is required to determine an effect size.

Recruitment and consent

Potential participants will be identified at the Freeman Hospital weekly multidisciplinary team meeting, where patients for pancreatoduodenectomy will be confirmed. After patients have been consented for their operation in the surgical outpatient department, they will be invited to participate in the study. The details of the study including the duration, procedures and potential adverse effects will be conveyed in the presence of the lead clinician and any questions addressed. Information leaflets as well as contact details for the study patient liaison will be provided.

It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights and with no obligation to give the reason for withdrawal.

Data collection methods

At recruitment, participant baseline demographic, medical history and indication for PD will be recorded. Intraoperative, postoperative and follow-up data will be extracted from clinical records. DGE will be diagnosed based on the ISGPS definition.

Primary outcome

BSGM parameters will be determined and recorded by the Alimetry device. The decision of PRPD versus PPPD will be made by the operating surgeon. DGE and POPF will be independently diagnosed by the clinical team based on the ISGPS definitions[6 21] in the course of standard postoperative care.

Secondary outcomes

Self-reported symptom logging will be recorded on a tablet application designed for this purpose. The QoL and patient experience questionnaires will be administered by the researchers.

Data management

Patient preoperative and perioperative clinical records will be accessed from the Freeman Hospital electronic medical record system. Relevant patient data will be stored on a secure password-protected electronic database.

BSGM and patient-reported symptom data will be automatically uploaded to the Alimetry cloud-based server. No identifiable patient or clinical data will be included in this upload. The database will only be accessible by

the Principal Investigator (PI) and team of researchers. Access may be granted to the ethics committee for monitoring purposes.

Data integrity will be maintained with data validation tools built into the database and with regular checks by the data manager for accuracy and prevention of missing data. The database will be backed up weekly.

Statistics and analysis plan

Differences in patterns of gastric electrical activity between groups (DGE vs no DGE, POPF vs no POPF and PRPD vs PPPD) will be compared using Fisher's exact test for categorical variables (wave direction) and T-test for continuous variables (frequency, amplitude and rhythm index).

Self-reported symptom scores will be tested for association with BSGM data using Pearson's correlation coefficient. QoL and patient experience scores, as measured by questionnaires, will be reported as averages.

All statistical analysis will be performed using the R-Studio statistical software package.[22]

Patient

The risk to the patient is low with reactions to the skin preparation or adhesive material being the only potential adverse effect. The BSGM procedure has to date been performed with over 200 participants with no serious adverse events reported. The BSGM system also has CE certification and is approved for use in the UK.

In the unlikely event of an adverse event, the details will be recorded by the principal investigator. The lead clinician will determine whether the adverse event requires the patient to withdraw from the study.

Ethics and dissemination

Local Hospital Trust sponsorship and UK Health Research Authority Research Ethics Committee (REC) approval have been obtained (ethical approval IRAS ID 305302. North West—Greater Manchester Central Research Ethics Committee, REC reference 22/NW/0148, 8 June 2022).

Non-identifiable and anonymised data and findings will be published in peer-reviewed journals and presented at national and international conferences. Patient consent includes granting permission for the dissemination of non-identifiable data.

There are no conflicts of interest to declare.

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Contributors KM and SP designed the study and authored the study protocol. JL, SC and MJ reviewed and contributed to the study protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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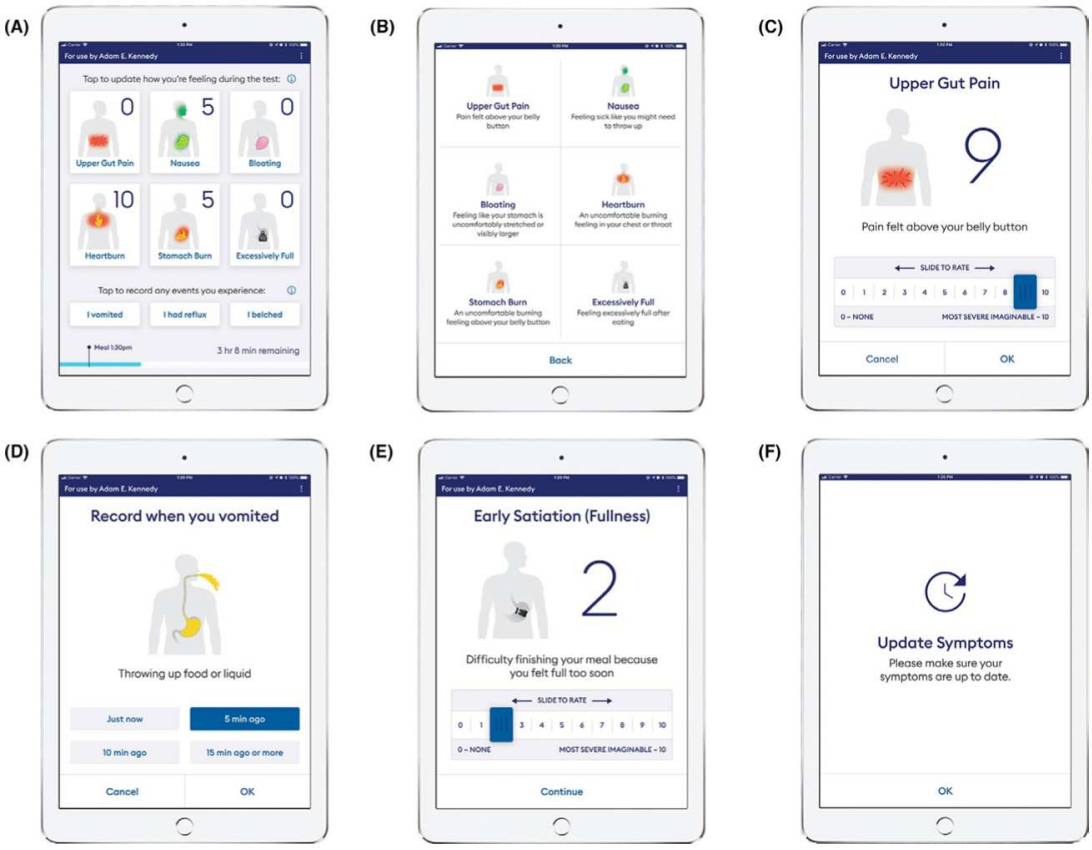
APPENDIX 1 - IPAD SYMPTOM LOGGING APP



Appendix figure 1: Screenshots of the iOS Symptom-Logging App. (A) Post meal symptom dashboard display; (B) Symptom explanations display; (C) Upper gut pain symptom display; (D) Vomiting event logging display; (E) Early satiation symptom display; and (F) Symptom reminder display.

APPENDIX 2 - PAGI-QOL QUESTIONNAIRE

The following questions ask about how some of the gastrointestinal problems you may be experiencing (such as pain, discomfort or other problems) may have affected your overall quality of life and well-being in the past 2 weeks.

Please answer every question by circling the number that best represents your opinion. There are no right or wrong answers.

During the past 2 weeks, because of your gastrointestinal problems, how often…	**None of the time**	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
1. Have you had to depend on others to do your daily activities?	0	1	2	3	4	5
2. Have you avoided performing your daily activities?	0	1	2	3	4	5
3. Have you had difficulty concentrating?	0	1	2	3	4	5
4. Has it taken you longer than usual to perform your daily activities?	0	1	2	3	4	5
5. Have you felt tired?	0	1	2	3	4	5
6. Have you lost the desire to participate in social activities such as visiting friends or relatives?	0	1	2	3	4	5
7. Have you been worried about having stomach symptoms in public?	0	1	2	3	4	5
8. Have you avoided performing physical activities or sports?	0	1	2	3	4	5
9. Have you avoided traveling?	0	1	2	3	4	5
10. Have you felt frustrated about not being able to do what you wanted to do?	0	1	2	3	4	5
11. Have you felt constricted in the clothes you wear?	0	1	2	3	4	5
12. Have you felt frustrated about not being able to dress as you wanted to?	0	1	2	3	4	5
13. Have you felt concerned about what you can and cannot eat?	0	1	2	3	4	5

14. Have you avoided certain types of foods?	0	1	2	3	4	5
15. Have you restricted eating at restaurant or at someone's home?	0	1	2	3	4	5
16. Have you felt less enjoyment in food than usual?	0	1	2	3	4	5
17. Have you felt concerned that a change in your food habits could trigger your symptoms?	0	1	2	3	4	5
18. Have you felt frustrated about not being able to choose the food you wanted to?	0	1	2	3	4	5
19. Have you felt frustrated about not being able to choose the type of beverage you wanted to?	0	1	2	3	4	5
20. Has your relationship with your spouse or partner been disturbed?	0	1	2	3	4	5
21. Has your relationship with your children or relatives been disturbed?	0	1	2	3	4	5
22. Has your relationship with your friends been disturbed?	0	1	2	3	4	5
23. Have you been in a bad mood?	0	1	2	3	4	5
24. Have you felt depressed?	0	1	2	3	4	5
25. Have you felt anxious?	0	1	2	3	4	5
26. Have you felt angry?	0	1	2	3	4	5
27. Have you felt irritable?	0	1	2	3	4	5
28. Have you felt discouraged?	0	1	2	3	4	5
29. Have you been stressed?	0	1	2	3	4	5
30. Have you felt helpless?	0	1	2	3	4	5

APPENDIX 3 - PATIENT SATISFACTION QUESTIONNAIRE

The following questions assess your overall experience with the Alimetry gastric mapping device. Please select the option which best represents your experience:

	STRONGLY DISAGREE	**DISAGREE**	**UNSURE**	**AGREE**	**STRONGLY DISAGREE**
I UNDERSTAND THE REASON THE DEVICE WAS USED IN MY CASE					
I UNDERSTAND HOW THE DEVICE WORKS AND WHAT IT IS MEASURING					
I FELT COMFORTABLE WHEN THE DEVICE WAS APPLIED TO MY ABDOMEN (STOMACH)					
I FELT COMFORTABLE WHEN THE DEVICE WAS REMOVED FROM MY ABDOMEN (STOMACH)					
I FELT COMFORTABLE DURING THE MEASUREMENT PROCESS					
THE MEASUREMENT PROCESS DID NOT TAKE TOO LONG					
USING THE DEVICE DID NOT INTERFERE WITH OR DELAY MY RECOVERY FROM SURGERY					
USING THE DEVICE HAS BENEFITTED MY RECOVERY					
I WOULD RECOMMEND USING THE DEVICE TO A FRIEND OR RELATIVE					