


BMJ Open Home care/outpatient versus hospital admission in mild acute pancreatitis: protocol of a multicentre, randomised controlled trial (PADI_2 trial)

Elena Ramírez-Maldonado ^{1,2}, Marta Rodrigo-Rodrigo,¹ Sandra Lopez Gordo,³ Ariadna Sanchez,⁴ Daniel Coronado Llanos,⁵ Raquel Sanchez,⁶ Joao Vaz,⁷ Constantino Fondevila,⁸ Rosa Jorba-Martin,^{1,2} on behalf of the Catalan Pancreatitis Collaborative Group¹

To cite: Ramírez-Maldonado E, Rodrigo-Rodrigo M, Lopez Gordo S, *et al*. Home care/outpatient versus hospital admission in mild acute pancreatitis: protocol of a multicentre, randomised controlled trial (PADI_2 trial). *BMJ Open* 2023;**13**:e071265. doi:10.1136/bmjopen-2022-071265

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-071265>).

Received 02 January 2023
Accepted 16 May 2023



© Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Elena Ramírez-Maldonado; elena.ramirezmalonado@gmail.com

ABSTRACT

Introduction Acute pancreatitis (AP) is the third most common gastrointestinal disease resulting in hospital admission, with over 70% of AP admissions being mild cases. In the USA, it costs 2.5 billion dollars annually. The most common standard management of mild AP (MAP) still is hospital admission. Patients with MAP usually achieve complete recovery in less than a week and the severity predictor scales are reliable. The aim of this study will be to compare three different strategies for the management of MAP.

Methods/design This is a randomised, controlled, three-arm multicentre trial. Patients with MAP will be randomly assigned to group A (outpatient), B (home care) or C (hospital admission). The primary endpoint of the trial will be the treatment failure rate of the outpatient/home care management for patients with MAP compared with that of hospitalised patients. The secondary endpoints will be pain relapse, diet intolerance, hospital readmission, hospital length of stay, need for intensive care unit admission, organ failure, complications, costs and patient satisfaction. The general feasibility, safety and quality checks required for high-quality evidence will be adhered to.

Ethics and dissemination The study (version 3.0, 10/2022) has been approved by the Scientific and Research Ethics Committee of the 'Institut d'Investigació Sanitària Pere Virgili-IISPV' (093/2022). This study will provide evidence as to whether outpatient/home care is similar to usual management of AP. The conclusions of this study will be published in an open-access journal.

Trial registration number ClinicalTrials.gov Registry (NCT05360797).

BACKGROUND

Acute pancreatitis (AP) is one of the most common reasons for hospitalisation among gastrointestinal diseases worldwide. The costs caused by severe AP are higher than those for mild AP (MAP). Nevertheless, approximately 70% of hospital admissions for AP are MAP, so if savings in healthcare costs are to be achieved, it would be by lowering the

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A multidisciplinary team wrote this protocol.
- ⇒ The established treatment is the standard in patients with mild acute pancreatitis.
- ⇒ An Independent Data Monitoring Committee will be ensuring security and monitoring data.
- ⇒ The three-arm method of the study requires a multidisciplinary team on the project, which may limit the number of centres that can join.
- ⇒ Lack of blinding increases the risk of performance bias, since the participants will be aware of their group assignment.

cost of managing patients with MAP without complication or affecting patient safety and satisfaction.¹⁻⁷

Patients in the PADI_1 Study¹ from 2017 to 2019 were analysed, and these following observations were noted: (1) immediate oral low-fat solid diet to patients with mild and moderate AP is safe and feasible; (2) immediate oral refeeding was associated with a significant reduction in hospital length of stay (LOS) (3.4 vs 8.8 days, $p < 0.001$); (3) hospital costs were half as much, with savings of €1325.7/patient in the immediate oral compared with the conventional oral refeeding group; and (4) comparing the outcome of the groups showed no increased risk of complications.¹

This proposed study seeks to prospectively evaluate a new scope in the care of patients with MAP and is justified based on these three points: (1) patients with MAP usually achieve a complete recovery of their symptoms in less than a week with conservative management (intravenous hydration, analgesia and early diet); (2) clinical prognostic scoring systems, although criticised for their poor positive predictive value for severe AP, have

an excellent negative predictive value to determine which patients will have MAP early in their hospitalisation; and (3) factors that predict hospital readmission within 30 days in AP have been studied and can be applied.^{8–15}

The International Association of Pancreatology/American Pancreatic Association (IAP/APA) guidelines⁴ advise using the presence of systemic inflammatory response syndrome (SIRS) to predict severe AP at admission and persistent SIRS at 48 hours. The three dimensions recommended by the guidelines for risk approximation are: (1) host risk factors (age, comorbidity, body mass index), (2) clinical risk stratification (persistent SIRS), (3) monitoring response (persistent SIRS, blood urea nitrogen, creatinine). There are many predictive scoring systems and serum markers, but none have been shown to be better or worse predictors of severity than SIRS.⁴ Thus, the bedside index of severity in acute pancreatitis (BISAP) score, which includes the SIRS in its parameters, provides one more tool to approximate the patient's risk in the aforementioned three dimensions.

Ince *et al*¹⁰ showed that MAP can be safely treated at home with regular visits by a nurse under the supervision of a physician with large cost-savings. A recent cohort study, which included 419 patients, showed that after appropriate triage, patients with MAP can be safely discharged from the emergency room (ER) after a mean of 12 hours with improved outcomes and cost-savings.¹¹

Therefore, to carry out this study, which proposes comparing outpatient and home care treatment with hospitalisation for patients with MAP, strict criteria for predicting severity will need to be fulfilled. The main objective of this trial is to determine whether, in MAP cases, outpatient treatment or home care is similar to standard with hospital admission treatments in terms of diet tolerance, pain control, risk of severity, complications, patient's satisfaction and health cost.

METHODS

Diagnosis and classification of AP

According to the Revised Atlanta criteria 2012,¹² the diagnosis of AP requires two of the following three features: (1) onset of upper abdominal pain often radiating to the back; (2) serum lipase or amylase level at least three times higher than the normal upper limit; (3) characteristic findings of AP on imaging techniques such as contrast-enhanced CT, ultrasonography and/or MRI. Severity of AP was classified as mild (no organ failure, local or systemic complications), moderately severe (presence of transient organ failure, local complications or exacerbation of comorbid disease) or severe (persistent organ failure (>48 hours) affecting respiration, renal function or the cardiovascular system).¹²

Design

This is a randomised controlled, three-arm multi-centre trial. Patients with MAP will be randomly

divided into three groups (group A: outpatient treatment, group B: medical home care and group C: hospitalisation).

Study population

All patients diagnosed with MAP (after 24 hours in the ER) will be informed of the possibility of participating in the PADI_2 Study. After the informed consent form (ICF) is signed, the investigator will have access to the electronic patient report form (ePRF) and will generate random number that will be the treatment arm to follow (group A, B or C).

To confirm a MAP, severity scores (SIRS, BISAP) of patients who have been in the ER for 24 hours will be used (figure 1).

Inclusion criteria

The inclusion criteria are as follows: (1) patient older than 18 years of age; (2) diagnosed with AP using at least two of these three criteria: compatible abdominal pain, amylase or lipase level superior in threefold respective laboratory baseline levels, and suitable findings in imaging techniques (CT, ultrasound or MRI)⁴; (3) MAP; (4) signed written ICF; (5) compliance with outpatient or home care criteria; and (6) randomisation at 24 hours of stay in the ER.

Outpatient or home care criteria:

1. A companion who understands and accepts the process and who will cooperate with the patient's recovery at home.
2. A mobile or telephone to communicate with the patient or her family member.
3. The distance to the hospital should be a maximum of 45–60 min.

Exclusion criteria

The exclusion criteria are as follows: (1) pregnant or breastfeeding women; (2) abdominal pain >96 hours (4 days); (3) the possibility of poor oral intake or unable to eat for reasons other than AP; (4) pancreatic neoplasm, endoscopic retrograde cholangiopancreatography or trauma aetiology; (5) choledocholithiasis and/or cholangitis; (6) chronic or recurrent pancreatitis; (7) American Society of Anesthesiologists (ASA) ≥ 3 ; (8) expected moderate or severe acute pancreatitis; and (9) alcohol withdrawal syndrome for patients with alcoholism.

Sample size

Only two studies with a similar objective have ever been reported,^{10 11} and a treatment failure rate of 4%–12% was observed in the home monitoring (outpatient/home care) group. Using calculations for a non-inferiority study with an estimated 95% success rate, 80% power, 5% significance level and 10% inferiority limit, a sample size of 75 patients per study group was calculated (total=225 patients).

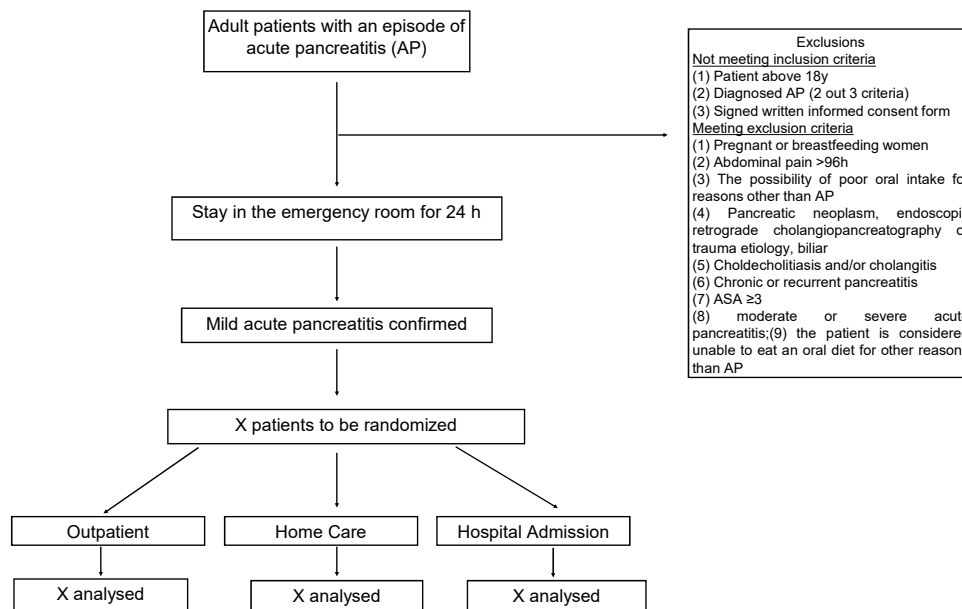


Figure 1 Flow chart of participants according to the SPIRIT 2013 statement.¹⁷ ASA, American Society of Anesthesiologists; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

Randomisation

Randomisation will use a computer-generated random number based on predefined randomisation lists created separately for each recruiting centre. The ePRF will implement a block randomisation method with a sequence of 1:1:1. After confirming a MAP and obtaining ICF, physicians on call at the different centres will have access to the ePRF and generate the randomisation sequence according to the REDCap (Research Electronic Data Capture) registry. Enrolment will be unblinded for patients and physicians due to the nature of the intervention.

Duration

The planned starting date of the study is 1 November 2022, and the planned finishing date of the study is 30 November 2024.

Intervention

After a 24-hour stay in the ER, the predictive factors of severity evaluation and the diagnosis of MAP will be confirmed, the patient will sign ICF and be randomised into group A, B or C (table 1). The experimental groups are A or B and the control group is C. For all the groups, the first follow-up will be at week 1, and the subsequent follow-up will be at 1–3 months after hospital discharge (table 1). The patients will be asked to complete the Security/Satisfaction Survey¹⁶ at the last follow-up.

Groups

Group A, outpatient: the patient is discharged and contacted by phone daily for 4 consecutive days by the investigators in the corresponding centre.

Group B, medical home care: the patient is discharged and contacted by phone/visits by a nurse/doctor daily for 4 consecutive days by the medical home care department in the corresponding centre.

Group C, hospital admission: the patient is hospitalised in the corresponding centre.

General treatment

General treatment, indicated by the IAP/APA guidelines⁴—fluid therapy, symptom control and dietary support—will be performed for the first 24 hours in the ER for all patients with AP. The early diet is PADI_1¹ (low-fat diet immediately). After 24 hours, the treatment will be oral intake (antiemetics, painkillers, diet) by all three groups. Blood samples will be obtained 48–72 hours after discharge from the following: group A in the hospital or nearly primary care provider, B home care team and C in the hospital. The patients will be asked to complete the Security/Satisfaction Survey¹⁶ at the last follow-up.

Predictors of severity

Predictors of severity will be considered when: (1) SIRS ≥2 criteria, (2) BISAP ≥2 score and (3) organ failure.

**Table 1** Schedule of enrolment, interventions and assessments according to the SPIRIT 2013 statement¹⁷

Study period	Enrolment			Allocation				Post-allocation		Close-out
	24 hours	0		Day1	Day2	Day3	Day 4 Discharge	Control Week 1	1–3 months after discharge	
Enrolment										
Eligibility screen	X									
Informed consent		X								
(List of other procedures)		X		X	BS			X	X	SSS
Allocation		X								
Interventions										
Group A: outpatient		X	X	X	X	X	X	X	X	X
Group B: home care		X	X	X	X	X	X	X	X	X
Group C: hospital admission		X	X	X	X	X	X	X	X	X
Assessments										
Questionnaire admission	X									
Questionnaire 24 hours		X								
Questionnaire 2–3 days							X			
Questionnaire 1 week								X		
Questionnaire and SSS ¹⁶ 1–3 months									X	SSS

Patients will be randomised to group A (outpatient), B (home care) or C (hospital admission). BS, blood sample; ER, emergency room; SSS, Security/Satisfaction Survey.

Discharge of patients

Patients will be counted as discharged from hospital/outpatient/home care, when: (1) oral feeding is tolerated ($\geq 50\%$ of plates), (2) there is absence of nausea and vomiting with treatment, (3) pain is controlled with oral analgesia (Visual Analogue Scale ≤ 2), and (4) there are clinical characteristics without predictors of severity.

Failure to meet the above-mentioned criteria within 1 week after ER discharge generates the need for hospital admission and must be considered as failed treatment in PADI_2.

Primary endpoint

The primary endpoint of the trial will be the treatment failure rate of the outpatient/home care PADI_2 management for patients with MAP compared with hospitalised patients.

The following will be considered failure of treatment: (1) diet intolerance ($< 50\%$ of plates), (2) uncontrolled nausea or vomiting despite treatment, (3) uncontrolled pain despite oral painkillers and (4) predictors of severity are present.

Secondary endpoints

Secondary endpoints that will be analysed are as follows: (1) abdominal pain relapse, (2) diet tolerance, (3) BISAP, (4) SIRS, (5) organ failure, (6) complications, (7) hospital readmission, (8) intensive care unit admission, (9) health costs, (10) patient satisfaction/security, (11) LOS and (12) analytical parameters (white cell count,

haematocrit, blood urea nitrogen, creatinine, amylase, lipase, glucose and bilirubin) at hospital admission and 24 hours and 72 hours after discharge from ER. Only direct costs will be calculated (all medications, services, salaries of healthcare professionals, equipment, hospital bed cost) in the coordinating hospital.

Monitored parameters

There will be a large assortment of parameters monitored during the study (medical history, ASA score, physical examination, laboratory tests, diagnostic imaging, therapy, interventions, cost, satisfaction survey¹⁶). Data collection on the ePRF will be done electronically in REDCap/PADI_2 (see the Data management section).

Clinical parameters: mean arterial pressure, heart rate, temperature, Glasgow scale and abdominal pain.

Analytical parameters: white cell count, haematocrit, blood urea nitrogen, creatinine, amylase, lipase, glucose and bilirubin.

Trial organisation

PADI_2 is coordinated by the Joan XXIII University Hospital of Tarragona, Spain, the group that published the PADI_1 Study that permitted advances in AP treatment.

Coordinating Committee

The Coordinating Committee (CC) will be led by ER-M, RJ-M, MR-R and RM (surgeons, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain); CF (surgeon, IdiPAZ, CIBEREHD, La

Paz University Hospital, Madrid, Spain); SLG (surgeon, Health Consortium Maresme, Matarò, Spain); AS (gastroenterologist, Barcelona Clinic Hospital, IDIBAPS, CIBEREHD, University of Barcelona, Barcelona, Spain); SLG and DCL (surgeons, Moise's Broggi Hospital, CSI, Barcelona, Spain).

Independent Data Monitoring Committee

The Independent Data Monitoring Committee (IDMC) will manage data, data security and monitoring.

Data review team

Members are a delegated investigator, biostatistician and data manager.

Data management and statistical analyses

Data management

Data will be managed by the IDMC, and ePRF will be used. The investigator will ensure that the data in the ePRF are complete and accurate. Detailed data flow will be described in a Data Management Plan reflected in a REDCap/PADI_2 user manual. Data from completed ePRFs will be accepted under the direction of the data manager at IDMC. Any incongruous or missing recordings in the ePRFs will be returned to the investigator using a Data Query Form and documented for each individual subject before a clean file status is declared. All changes to ePRFs will be recorded. Before database lock, the data review team will decide and document necessary steps related to any issue in the database and define the analysis sets. They will also be responsible for protecting confidentiality of patients before, during and after the trial.

Study populations

Three populations will be defined:

Safety analysis population: all patients with confirmed MAP enrolled in the study.

Per-protocol population (PPP): all enrolled patients who completed the study following all the rules.

Intention to treat (ITT): the set of all randomised participants who start a treatment, excluding consent withdrawals.

Withdrawal of a participant from PPP

Any investigator and the IDMC can submit recommendations for dropouts from the PPP group with reasons given to the CC. All recommendations will be archived. The CC will discuss all available information, and if the change in the protocol is expected to have any relation to the interventions and results of the study, the case will not be included in the final per-protocol analysis. Immediate dropout from the per-protocol group will be ordered if: (1) any of the exclusion criteria are diagnosed during AP, (2) any predictor of severity is present, (3) parameters required for answering the primary endpoints are missing or (4) there are serious medical reasons not related to AP (eg, heart attack, accidents, etc).

Applied software

Data collection on the ePRF form and randomisation will be done electronically in REDCap 9.8.0/PADI_2. Statistical analysis will be performed using Statistical Analysis System V.9.4 or SPSS V.21 (or later) statistical packages. Microsoft MS Word will be used for reporting.

Statistical methods

First, the descriptive analysis will be carried out for each variable. Central tendency (mean or median) and dispersion (SD or IQR) measures will be provided for quantitative variables, and absolute frequencies and percentages for qualitative variables.

Between-group comparisons for quantitative variables under the assumption of normality will use a one-way analysis of variance with Tukey's post hoc test to compare means of pairs of groups. In case of non-normality, the Kruskal-Wallis test will be used and multiple comparisons carried out with Mann-Whitney tests, adjusting p values by Bonferroni. For qualitative variables, the χ^2 test will be used, applying Fisher's exact test when deemed necessary. Actuarial survivals will be calculated using the Kaplan-Meier method and their comparison between groups will be carried out using the log-rank test. All the outcomes will be analysed in ITT population (defined as participants randomised). The confidence level will always be 95% and p values reported with sensible precision.

In the multivariate survival analysis, the Cox regression method will be used, while for the multivariate analysis of risk factors, the logistic regression method will be used. Variables that show statistical significance in the univariate analysis and/or those that are prognostic factors in the bibliography and theoretical framework will be introduced to the statistical model.

Early quality assessment

An early quality assessment check will be performed on the first 70 patients. The IDMC will independently review the trial-related documents and activities, to ensure the rights, safety and welfare of participants are respected and the clinical data are credible. The similarity of the groups will also be checked at the beginning of the study. The IDMC will report these findings to the CC. The CC will discuss all the information, and if the differences are expected to have any relation to the interventions and results of the study or the overall dropout rate from PPP is >20% of all participants randomised or allocated into each group or the differential dropout rate is >15% between groups, the study should be reassessed and the IDMC will make recommendations regarding reassessment of power calculation, extension of recruitment period, extension of number of study centres or trial completion.

Interim analyses and premature termination of the study

The IDMC may also recommend stopping the trial early for ethical reasons if one group clearly shows evidence of significant benefit. An interim analysis on the primary endpoint will be performed when 50% of patients have

been randomised and discharged. The interim analysis will be carried out by the IDMC, which will report to the CC.

The Haybittle-Peto boundary method will be used in this study. This method states that if the interim analysis shows a probability of ≤ 0.001 that a difference as extreme or more between the treatments is found, given that the null hypothesis is true, then the trial should be stopped early.

Centres

The trial will start in four centres, which also participated in the PADI_1: Joan XXIII University Hospital of Tarragona, Barcelona Clinic Hospital, Health Consortium Maresme and Moise's Broggi Hospital, after which the study is open for other centres. The IDMC will always audit the centre and report to the CC. The CC may decide whether the centre meets the requirements to join the study. Compulsory requirements for a centre are as follows: (1) treats at least 30 patients with AP annually, (2) has a home care department, (3) besides the regular medical team, the centre must appoint at least one doctor and one nurse specifically for the trial, and (4) all investigators need to attend a preliminary meeting where all the details of the study are discussed fully and have qualified as investigators by completing a course, either online or face-to-face.

Authorship aspects

Authorship is based on international guidelines: all authors must fulfil the International Committee of Medical Journal of Editors criteria (see www.icmje.org/journals.html). All collaborating centres providing over 25 patients can be afforded one author. Every additional 20 patients will provide the centre an additional author. Every centre can also include formal 'collaborators' on the project, which the journal will be asked to list in PubMed at final publication. The first three authorship positions are reserved for the study coordinators (ER-M, MR-R, SLG) and the last two authorship positions are reserved for the senior investigators (RJ-M, CF). All other authors will be listed in numerical order according to the number of patients contributed to the study. Collaborators will be listed in alphabetical order as part of the 'Catalan Pancreatitis Collaborative Group'.

Feasibility

As a general protocol to treat AP at the Joan XXIII University Hospital, patients with AP receive PADI_1 treatment adjusted to the IAP/APA guidelines.⁴ Patients in PADI_1 receive diet immediately on their arrival in the ward from the ER once their symptoms have been controlled. Comparing the outcome of this treatment protocol with the nil per os protocol used in most hospitals showed that patients enjoyed benefits with no increasing risk of complications. About 100 patients are admitted to the existing PADI_1 hospitals annually. Therefore, if no other

institution joins this study, it can be completed within 2–3 years.

Safety

Since no unknown drugs/therapy are used in the study, no adverse or serious adverse events are expected/interpretable that would be attributable to the intervention during the trial. As for the outpatient group, although it is a telephonic follow-up, it will be performed daily by the investigator team, asking for clear clinical parameters. Blood samples will also be obtained on the same day as in the other groups to identify predictors of severity that require immediate hospital admission. In this trial, the IDMC will examine safety variables after every 20 patients complete the programme. Investigators will also report adverse or serious adverse events on a separate form, which must be sent to the IDMC and CC. The CC will discuss, and if the adverse effect is confirmed, it will be reported to the relevant Institutional Ethical Committee (<http://www.iispv.cat>).

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The trial is registered at the ClinicalTrials.gov registry (NCT05360797) and received relevant ethical approval by each centre:

- ▶ University Hospital of Tarragona Joan XXIII (coordinating centre), with the reference number 093/2022 issued by the Scientific and Research Ethics Committee of the Institut d'Investigació Sanitària Pere Virgili-IISPV.
- ▶ Maresme Health Consortium, with the reference CEIm 34/22 issued by the Scientific and Research Ethics Committee of the Mataro Hospital.
- ▶ Barcelona Clinic Hospital, with the reference HCB/2022/0812 issued by the Scientific and Research Ethics Committee of the Barcelona Clinic Hospital.
- ▶ Moise's Broggi Hospital, with the reference PR273/22 (CSI22/66) issued by the Scientific and Research Ethics Committee of the Bellvitge Hospital University.
- ▶ Althaia University Hospital, with the reference CEI22-111 issued by the Scientific and Research Ethics Committee of the Fundació Catalana d'Hospitals.
- ▶ Garcia de Orca EPE Hospital, with the date 27 February 2023 issued by the Scientific and Research Ethics Committee of the Garcia de Orca EPE Hospital.
- ▶ La Paz University Hospital, with the reference HULP 6364 issued by the Scientific and Research Ethics Committee of the La Paz University Hospital.

At the end of the project, we will disseminate our results to the medical community and publish it as open access.

Author affiliations

¹General and Digestive Surgery Department, Joan XXIII University Hospital in Tarragona, Tarragona, Spain

²Biomedicine Department, Rovira i Virgili University, Tarragona, Spain

³General and Digestive Surgery Department, Maresme Health Consortium, Mataro, Spain

⁴Gastroenterology Department, Clinic Barcelona Hospital University, Barcelona, Spain

⁵General and Digestive Surgery Department, Hospital de Sant Joan Despi Moisès Broggi, Sant Joan Despi, Spain

⁶General and Digestive Surgery Department, Manresa Public Health Foundation, Manresa, Spain

⁷General and Digestive Surgery, Hospital Garcia de Orta EPE, Almada, Portugal

⁸General and Digestive Surgery Department, La Paz University Hospital, Madrid, Spain

Twitter Raquel Sanchez @Raquel_SJ7

Acknowledgements The principal investigator wish to thank Dr Péter Hegyi and the Hungary Pancreatic Study group for everything they have contributed to their process as a researcher. The authors wish to thank Editage (www.editage.com) for their assistance in editing and improving this manuscript.

Collaborators The Catalan Pancreatitis Collaborative Group (in alphabetical last name order, with permission): Sonia Babiloni, University Hospital of Tarragona Joan XXIII, Tarragona, Spain; Laia Blanco, Hepato-pancreato-biliary and Transplant Surgery Department, Vall d'Hebron University Hospital, Barcelona, Spain; Sandra M Bacca, Maresme Health Consortium, Matarò, Spain; Joaquim Balsells, Vall d'Hebron University Hospital, Barcelona, Spain; Carme Boqué, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Pablo Collera Ormazabal, Althaia University Hospital, Xarxa Assistencial Universitària de Manresa, Sant Joan de Déu Hospital, Manresa, Spain; Ignasi Elizalde, Barcelona Clinic Hospital, IDIBAPS, CIBEREHD, University of Barcelona, Barcelona, Spain; Laia Estalella, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Maria Teresa Fernández Planas, Maresme Health Consortium, Matarò, Spain; Lidia Florit Serra, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Inmaculada Fonoll, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Nil Gómez Vallvé, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Sergio González, Moisés Broggi Hospital, CSI, Barcelona, Spain; Jara Jimmy, Arnau de Vilanova University Hospital, Lleida, Spain; Jiazhen Li, Clinical Nutrition Department, The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu, China; Erik Llácer-Millán, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Rui Pedro Major Branco, Hospital Garcia de Orca EPE, Almada, Portugal; Robert Memba, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Carme Mias, Arnau de Vilanova University Hospital, Lleida, Spain; David Nicolas, Barcelona Clinic Hospital, IDIBAPS, CIBEREHD, University of Barcelona, Barcelona, Spain; Elizabeth Pando, Vall d'Hebron University Hospital, Barcelona, Spain; Mihai-Calin Pavel, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Eva Pueyo-Pérez, University Hospital of Tarragona Joan XXIII, Rovira i Virgili University, Tarragona, Spain; Jing Quiao, The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu, China; Teresa Soriano, Vall d'Hebron University Hospital, Barcelona, Spain; Guillem Soy, Barcelona Clinic Hospital, IDIBAPS, CIBEREHD, University of Barcelona, Barcelona, Spain; Eva Vaquero, Barcelona Clinic Hospital, IDIBAPS, CIBEREHD, University of Barcelona, Barcelona, Spain; Marina Vila Tura, Maresme, Health Consortium, Matarò, Spain; Pengyu Wu, Gastroenterology Department, The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu, China; Heng Xi, The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu, China; Wen Zhong, The Third People's Hospital of Chengdu, Affiliated Hospital of Southwest Jiaotong University, Chengdu, China.

Contributors ER-M, SLG, CF and RJ-M participated in all phases of the study with the help of other authors in the different parts. Conception and design—ER-M, RJ-M, SLG, AS and CF. Administrative, technical or logistical support—ER-M, RJ-M, SLG, AS, CF, DCL, RS, JV and MR-R. Drafting of the article—ER-M, RJ-M, SLG, AS, CF, DCL, RS, JV, MR-R and the Catalan Pancreatitis Collaborative Group. Critical revision of the article for important intellectual content—ER-M, RJ-M, SLG, AS, CF, DCL-L, RS, JV and MR-R. All authors read and approved the final manuscript.

Software

Validation

Funding This study was funded by Catalan Society of Surgeons and Spanish Association of Surgeons.

Competing interests None declared.

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

Patient consent for publication Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Elena Ramírez-Maldonado <http://orcid.org/0000-0001-9213-7212>

REFERENCES

- Ramírez-Maldonado E, López Gordo S, Pueyo EM, *et al*. Immediate oral refeeding in patients with mild and moderate acute pancreatitis: a multi centre. *Ann Surg* 2021;274:255–63.
- Lodewijkx PJ, Besselink MG, Witteman BJ, *et al*. Nutrition in acute pancreatitis: a critical review. *Expert Rev Gastroenterol Hepatol* 2016;10:571–80.
- Greenberg JA, Hsu J, Bawazeer M, *et al*. Clinical practice guideline: management of acute pancreatitis. *Can J Surg* 2016;59:128–40.
- Working Group IAP/APA Acute Pancreatitis Guidelines. IAP/APA evidence-based guidelines for the management of acute pancreatitis. *Pancreatology* 2013;13:e1–15.
- Tenner S, Baillie J, DeWitt J, *et al*. American college of gastroenterology guideline: management of acute pancreatitis. *Am J Gastroenterol* 2013;108:1400–15.
- Isaji S, Takada T, Mayumi T, *et al*. Revised Japanese guidelines for the management of acute pancreatitis 2015: revised concepts and updated points. *J Hepatobiliary Pancreat Sci* 2015;22:433–45.
- Jacobson BC, Vander Vliet MB, Hughes MD, *et al*. A prospective, randomized trial of clear liquids vs. low-fat solid diet as the initial meal in mild acute pancreatitis. *Clin Gastroenterol Hepatol* 2007;5:946–51.
- Serra Pla S, Garcia Monforte N, Garcia Borobia FJ, *et al*. Early discharge in mild acute pancreatitis. is TI possible? Observational prospective study in a tertiary-level hospital. *Pancreatology* 2017;17:669–74.
- Kumar VV, Treacy PJ, Li M, *et al*. Early discharge of patients with acute pancreatitis to enchanted outpatient care. *ANZ J Surg* 2018;88:1333–6.
- Ince AT, Senturk H, Singh VK, *et al*. A randomized controlled trial of home monitoring versus hospitalization for mild non-alcoholic acute interstitial pancreatitis: a pilot study. *Pancreatology* 2014;14:174–8.
- Anderson K, Shah I, Yakah W, *et al*. Prospective evaluation of an emergency department protocol to prevent hospitalization in mild acute pancreatitis: outcomes and predictors of discharge. *Pancreatology* 2023;23:299–305.
- Banks PA, Bollen TL, Dervenis C, *et al*. Classification of acute pancreatitis - 2012: revision of the Atlanta classification and definitions by international consensus. *Gut* 2013;62:102–11.
- Pando E, Alberti P, Mata R, *et al*. Early changes in blood urea nitrogen (BUN) can predict mortality in acute Pancreatitis: comparative study between BISAP score, APACHE-II, and other laboratory markers. *Can J Gastroenterol Hepatol* 2021;2021:6643595.
- Wu BU, Johannes RS, Sun X, *et al*. The early prediction of mortality in acute pancreatitis: a large population based study. *Gut* 2008;57:1698–703.
- Kui B, Pintér J, Molontay R, *et al*. EASY-APP: an artificial intelligence model and application for early prediction of severity in acute pancreatitis. *Clin Transl Med* 2022;12:e842.
- Ministerio de Sanidad Y Política Y IMS health: evaluación de la Percepción de Los Pacientes Sobre La Seguridad de Los Servicios Sanitarios. 2010. Available: https://www.sanidad.gob.es/en/organizacion/sns/planCalidadSNS/docs/informe_validacion_cuestionario.pdf
- Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.