



Standards for reporting on surgery for chronic pancreatitis: a report from the International Study Group for Pancreatic Surgery (ISGPS)



Ajith K. Siriwardena, MD^{a,*}, John Windsor, MD^b, Nicholas Zyromski, MD^c, Giovanni Marchegiani, MD^d, Dejan Radenkovic, MD, PhD^e, Catherine Morgan, MD^f, Ioannis Passas, MD^g, Attila Olah, MD^h, Kevin C. Conlon, MDⁱ, Martin Smith, FCS^j, Olivier Busch, MD^k, Minas Baltatzis, PhD^a, Marc G. Besselink, PhD^k, Charles Vollmer, MD^l, Carlos Fernandez-del Castillo, MD^m, Helmut Friess, MDⁿ, Giuseppe Garcea, MD, FRCS^o, Sean Burmeister, MD^p, Thilo Hackert, MD^q, Keith D. Lillemoe, MD^m, Richard Schulick, MD^r, Shailesh V. Shrikhande, MD^s, Andrew Smith, MD^t, Luca Gianotti, MD^u, Massimo Falconi, MD^v, David Adams, MD^f, Mustapha Adham, MD^w, Roland Andersson, MD^x, Marco Del Chiaro, MD^r, John Devar, FCS^j, Santhalingam Jegatheeswaran, FRCS^a, Hjalmar van Santvoort, PhD^y, Igor Khatkov, MD, PhD^z, Jakob Izbicki, FACS^{aa}, Markus Büchler, MD^q, John P. Neoptolemos, MChir, FRCS^q, Claudio Bassi, MD^d, Christos Dervenis, MD^{g,1}

^a Department of Surgery, Regional Hepato-Pancreato-Biliary Unit, Manchester Royal Infirmary, United Kingdom

^b Department of Surgery, University of Auckland, New Zealand

^c Department of Surgery, Indiana University School of Medicine, Indianapolis, IN

^d Clinic for Digestive Surgery, Pancreas Institute, Verona University Hospital, Italy

^e Department of Surgery, Clinical Center of Serbia and School of Medicine, University of Belgrade, Serbia

^f Department of Surgical Oncology, Medical University of South Carolina, Charleston, SC

^g Department of Surgery, Metropolitan Hospital, Athens, Greece

^h Department of Surgery, Petz Aladar Hospital, Gyor, Hungary

ⁱ Hepato-Pancreatico-Biliary Unit, Department of General Surgery, Trinity College Dublin, Tallaght Hospital, Ireland

^j Department of Surgery, Chris Hani Baragwanath Academic Hospital, Johannesburg, South Africa

^k Department of Surgery, Amsterdam UMC, University of Amsterdam, The Netherlands

^l Department of Surgery, Penn Medicine, University of Pennsylvania, Philadelphia, PA

^m Department of Surgery, Massachusetts General Hospital and the Harvard Medical School, Boston, MA

ⁿ Department of Hepato-Pancreato-Biliary Surgery, Klinikum rechts der Isar, Technische Universität München, Germany

^o Department of Surgery, University Hospitals of Leicester, United Kingdom

^p Department of General, Visceral, and Transplantation Surgery, University of Cape Town Health Sciences Faculty and Surgical Gastroenterology Unit Grootte Schuur Hospital, South Africa

^q Department of Surgery, University of Heidelberg, Germany

^r Department of GI and HPB Surgical Oncology, University of Colorado School of Medicine, Aurora, CO

^s Pancreato-Biliary Unit, Tata Memorial Hospital, Mumbai, India

^t Department of Surgery, St James University Hospital, Leeds, United Kingdom

^u Pancreatic Surgery Unit, School of Medicine and Surgery, San Gerardo Hospital, University of Milano-Bicocca, Monza, Italy

^v Digestive Surgery Department, San Raffaele Scientific Institute, 'Vita-Salute' University, Milan, Italy

^w Department of Surgery Lyon Civil Hospital, France

^x Dept of Hepato-Pancreato-Biliary Surgery, Clinical Sciences Lund, Lund University, Sweden

^y Regional Academic Cancer Center Utrecht, The Netherlands

^z Moscow Clinical Scientific Center, Moscow University of Medicine and Dentistry, Russian Federation

^{aa} University Medical Center Hamburg-Eppendorf, Germany

* Reprint requests: Professor Ajith Siriwardena, MD, FRCS, Regional Hepato-Pancreato-Biliary Surgery Unit, Manchester Royal Infirmary, Manchester M13 9WL, UK.

E-mail address: ajith.siriwardena@mft.nhs.uk (A.K. Siriwardena).

¹ Additional collaborators listed separately.

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ABSTRACT

Background: The International Study Group for Pancreatic Surgery provides globally accepted definitions for reporting of complications after pancreatic surgery. This International Study Group for Pancreatic Surgery project aims to provide a standardized framework for reporting of the results of operative treatment for chronic pancreatitis.

Methods: An International Study Group for Pancreatic Surgery project circulation list was created with pre-existing and new members and including gastroenterologists in addition to surgeons. A computerized search of the literature was undertaken for articles reporting the operative treatment of chronic pancreatitis. The results of the literature search were presented at the first face-to-face meeting of this International Study Group for Pancreatic Surgery project group. A document outlining proposed reporting standards was produced by discussion during an initial meeting of the International Study Group for Pancreatic Surgery. An electronic questionnaire was then sent to all current members of the International Study Group for Pancreatic Surgery. Responses were collated and further discussed at international meetings in North America, Europe, and at the International Association of Pancreatology World Congress in 2019. A final consensus document was produced by integration of multiple iterations.

Results: The International Study Group for Pancreatic Surgery consensus standards for reporting of surgery in chronic pancreatitis recommends 4 core domains and the necessary variables needed for reporting of results: clinical baseline before operation; the morphology of the diseased gland; a new, standardized, operative terminology; and a minimum outcome dataset. The 4 domains combine to give a comprehensive framework for reports.

Conclusion: Adoption of the 4 domains of the International Study Group for Pancreatic Surgery reporting standards for surgery for chronic pancreatitis will facilitate comparison of results between centers and help to improve the care for patients with this debilitating disease.

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Introduction

The International Study Group for Pancreatic Surgery (ISGPS) has provided globally accepted definitions for reporting of post-pancreatectomy complications.^{1–4} Starting in 2005, the definition of postoperative pancreatic fistula rapidly became widely adopted and replaced the range of definitions that had existed beforehand; thereafter, the ISGPS went on to update the definition of postoperative pancreatic fistulas and to provide definitions of post-pancreatectomy hemorrhage, delayed gastric emptying, and postoperative chyle leak, which have also become important components of our contemporary reporting standards of pancreatic surgery.^{1–5}

The ISGPS broadened its scope from standardizing terminology for describing the complications of pancreatic surgery to providing guidance on aspects of pancreatic surgery for malignant disease with the publication in 2014 of a consensus statement on borderline resectable pancreatic cancer.⁶ Further publications reported on indications for pancreatectomy without a prior tissue diagnosis of cancer and the extent of lymphadenectomy during oncologic resections.^{7,8} These reports reflected a need for greater standardization of the conduct and reporting of surgery for pancreatic cancer.

In parallel, the last 2 decades have also witnessed an expansion in knowledge in relation to chronic pancreatitis.^{9–11} The genetic basis and the clinical course of this disease are now better understood.¹¹ In addition to these advances in knowledge of the pathobiology of chronic pancreatitis, there has been an accompanying increase in the types of procedures reported for the operative treatment of this disease. These procedures include various types of drainage of the main pancreatic duct, partial pancreatic resections, and combinations of both. Eponymous terms such as Puestow, Frey, or Beger are typically used to describe some of these procedures, but there is variation among centers and surgeons in the conduct and reporting of these operations.^{12–15} For example, the Frey procedure has been reported to be a partial coring of the head of the pancreas but also a form of duodenum-preserving pancreatic head

resection.¹⁵ Also, current usage of the term “Puestow” typically describes the Partington-Rochelle procedure and not the original eponymous Puestow-Gillesby operation, which included a limited distal pancreatectomy, splenectomy, and the application of a Roux loop to the opened pancreatic duct in the remnant gland.¹⁶

Furthermore, there is also variation in reporting of the clinical baseline at the time of operation, which renders comparison of the cohorts in different centers difficult. In addition, there is increasing recognition of variations in morphology of the diseased pancreas, in particular in relation to aspects such as the presence or absence of a pancreatic head mass, ductal dilatation, and ductal strictures which influence both the choice of operative procedure and the eventual outcome.¹⁷

Thus the aim of this ISGPS project is to provide for the first time a standardized framework for reporting of operative treatment of chronic pancreatitis. To permit meaningful comparison, such a reporting framework must balance on the one hand the requirement to be sufficiently practical so that it can be adopted for general use while providing sufficient information on baseline disease, morphology of the diseased gland, operative intervention, and outcome.

Methods*Participants*

Members of the ISGPS were invited to participate. Members who wished to participate were added to a project circulation list. In order to include new members, further individuals were also included with preference being given to individuals who had published scientific work in this area.

Strategy of the literature search

A computerized search of the literature using the Scopus database (Scopus; Elsevier B.V Amsterdam, The Netherlands) was

Table I

Consensus statement of the ISGPS – Reporting standards on surgery operations for chronic pancreatitis

Domain 1: Clinical baseline prior to surgery
1. Etiology ^{*,18}
2. Duration of symptoms
3. Opiate use [†]
4. Duration of opiate use
5. Presence/absence of diabetes mellitus ^{‡,19}
6. Presence/absence of exocrine insufficiency ^{§,17}
7. Prior intervention (radiologic, endoscopic, or surgical)
8. Quality of life prior to operation (EQ-5D-5L or similar) ²⁰
9. Employment status prior to operation

EQ-5D-5L, European quality of life measure.

* Etiology should follow the TIGAR-O reporting system. Alcohol consumption should be quantified in units and duration in years, cigarette smoking should be quantified in pack/year. Gene mutations involved in hereditary pancreatitis should be reported.

† Opiate use should be reported in morphine equivalents (current daily or weekly use).

‡ Diet-controlled, non-insulin, and insulin-dependent diabetes using the terminology and reference ranges of the World Health Organization.

§ PEI should be formally assessed, either by measurement of fecal elastase, secretin-enhanced magnetic resonance cholangiopancreatography, or by measurement of coefficient of fat absorption.

undertaken covering the period between January 1970 and January 2019. For reference, articles reporting series of patients having undergone operative treatment for chronic pancreatitis were identified by using the keyword and MeSH heading “chronic pancreatitis” in combination with a range of operative procedures undertaken for chronic pancreatitis. Studies were evaluated to assess the quality of reporting of the parameters of the patients’ clinical baseline, pancreatic gland morphology, and postoperative clinical outcome. The results of the literature search were presented at the first face-to-face meeting of this ISGPS project group.

Construction of standards document

An outline reporting standards document was produced by discussion during an initial meeting of the ISGPS held during the 13th World Congress of the International Hepato-Pancreato-Biliary Association in Geneva, Switzerland in September 2018. An electronic questionnaire was then sent to all current members of the ISGPS. Responses were collated and further discussed at international meetings in North America, Europe, and at the International Association of Pancreatology World Congress in Cape Town, South Africa in 2019. A final consensus standards document was produced by integration of multiple iterations.

Results

In order to produce a comprehensive yet practical reporting framework for patients undergoing operative treatment for chronic pancreatitis, it is necessary to provide information in 4 core domains. These are the clinical baseline of the patients before operation, the morphology of the diseased gland, an objective description of the operation, and a minimum outcome dataset.

Clinical baseline before operation (Table I)

In order to produce a comprehensive assessment of any elective operation undertaken for painful chronic pancreatitis and operations for other related complications such as portovenous obstruction, pseudocysts, biliary obstruction, duodenal obstruction, etc, it is necessary to have information on the clinical baseline before operation. A modern reporting system should integrate with

Table II

Consensus statement of the ISGPS – Reporting standards on operations for chronic pancreatitis

Domain 2: Morphology of diseased pancreas
1. Maximum duct size
2. A-P diameter of pancreatic head
3. Pancreatic gland calcification
4. Ductal stones
5. Ductal strictures.
6. Patency status of portal vein
7. Concomitant biliary stricture
8. Concomitant duodenal stenosis

A-P diameter, antero-posterior diameter of the head of the pancreas.

other classification and reporting systems; therefore, we chose to adopt reporting of etiology using the TIGAR-O categorization.¹⁸ Duration of symptoms, opiate use, and duration of opiate use should be reported. The presence or absence of diabetes mellitus before operation together with the type (diet-controlled, non-insulin, and insulin-dependent) should be recorded using current reference ranges outlined by the World Health Organization.¹⁹ Also, there should be an assessment of the presence or absence of pancreatic exocrine insufficiency (PEI) before operation.¹⁷ We acknowledge that there is no internationally accepted standard diagnostic test for PEI, and that there is wide variation in available tests across health care systems. Thus, currently acceptable tests (each of which have their limitations) include measurement of fecal elastase and secretin-enhanced magnetic resonance cholangiopancreatography. In North America, the coefficient of fat absorption is generally accepted as the gold standard for the diagnosis of steatorrhea, which is characteristic of severe PEI. The coefficient of fat absorption is currently the only test accepted by the American Food and Drug Administration and the European Medicines Agency for the detection and monitoring of PEI in clinical trials.¹⁷ Baseline assessment before operation should also report on whether patients have undergone prior intervention (radiologic, endoscopic, or surgical). There should be an assessment of quality of life using a validated questionnaire²⁰ along with information on employment status.

Morphology of the diseased gland (Table II)

The presence or absence of a pancreatic head mass is defined according to the criteria provided recently by the report of the United European Gastroenterology Group.¹⁷ Key information includes the maximal diameter of the main pancreatic duct, presence of gland calcification, ductal stones, and ductal strictures. The presence of extrapancreatic complications influences the selection of operative procedure and thus should also be reported.

Standard operative descriptors (Table III)

Planned (elective) operations for chronic pancreatitis should be reported in a structured, objective, descriptive format—for example longitudinal pancreateojejunostomy with or without partial pancreatic head resection.

Minimum outcome data (Table IV)

A report on inpatient morbidity using the widely accepted Dindo-Desmartines-Clavien system should be used.²³ Information should be provided on postoperative opiate use, postoperative diabetes mellitus, and postoperative exocrine insufficiency, and whether these are new in the postoperative period. Standard information should be provided using other ISGPS terminology on

Table III

Consensus statement of the ISGPS – Reporting standards on operations for chronic pancreatitis

Domain 3: Standard operative descriptors
1. Longitudinal pancreaticojejunostomy ¹²
2. Longitudinal pancreaticojejunostomy with partial pancreatic head resection ¹³
3. Duodenum-preserving subtotal pancreatic head resection with transection at neck of pancreas ¹⁴
4. Duodenum-preserving subtotal pancreatic head resection without transection at neck of pancreas ²¹
5. Pancreatoduodenectomy
6. Total Pancreatectomy ± islet autotransplantation ²²
7. Distal pancreatectomy ± splenectomy

postoperative pancreatic fistula, postoperative pancreatic hemorrhage, delayed gastric emptying, and postoperative chylous fistula.^{1,2,4,23} Information should be provided on re-operation, postoperative mortality, and quality of life after operation.

Discussion

This document is the first attempt at standardizing the reporting of the operative treatment for chronic pancreatitis. Previous reports from the ISGPS have provided definitions for complications of pancreatic surgery and also guidance on standards of pancreatic surgery for cancer. Therefore an extension of the role of the ISGPS into reporting standards after elective operations for chronic pancreatitis represents a logical development. The format employed by the group for this project is similar to that previously used. Members of the ISGPS are recognized global leaders in the field of pancreatic surgery and provided their time and expertise as before. Although the document deals predominantly with issues of relevance to the pancreatic surgical community, for the first time in the history of the ISGPS, input was also sought from gastroenterologists with expertise in pancreatology.

The process of production of the report is also similar to that used previously by the ISGPS with a comprehensive literature search being undertaken to assess prevailing standards of reporting of operative treatment for chronic pancreatitis. The literature search demonstrated substantial heterogeneity in reporting, which compromises the ability to compare reports from different centers and also limits the ability to evaluate the different procedures which have been reported.

The initial face to face meeting during the International Hepato-Pancreato-Biliary Association World Congress in Geneva defined 4 domains critical to any future report. The ISGPS believes that all 4 domains were indispensable and combine to build to a reporting standards document. They are intended to provide minimum criteria for reporting. During the selection of these domains, the need to maintain a balance in order to produce a practical document was constantly discussed.

An electronic questionnaire was then sent to all current members of the ISGPS. Responses were collated and further discussed at international meetings in North America, Europe, and at the International Association of Pancreatology World Congress in Cape Town, South Africa in 2019. A final consensus standards document was produced by integration of multiple iterations. The final consensus standards consists of 4 core domains for reporting. The first domain assesses the clinical baseline of the patients before operation. The second domain addresses the morphology of the diseased gland, because it is increasingly recognized that variations in disease process influences the selection of procedure and outcome.

Arguably the most important and novel component of the ISGPS document on reporting standards for the operative treatment for

Table IV

Consensus statement of the ISGPS – Reporting standards on operations for chronic pancreatitis

Domain 4: Minimum outcome dataset
1. In-patient morbidity using the Dindo–Demartines–Clavien system. ²³
2. Postoperative opiate use.
3. Postoperative diabetes mellitus ^{19,*}
4. Postoperative exocrine insufficiency. ¹⁷
5. In-patient stay (d) and re-admission.
6. Re-operation within 90 d.
7. Operative mortality (in-patient, 90 d and 12 mon)
8. Quality of life after operation (EQ-5D-5L or similar) ²⁰
9. Employment status after operation

EQ-5D-5L, European quality of life measure.

* Diet-controlled, non-insulin-dependent, or insulin-dependent diabetes according to the criteria of the World Health Organization.

chronic pancreatitis is the description of operative procedures by the component of procedure undertaken rather than by an exclusively eponymous title. It is emphasized that although the list covers the majority of elective procedures undertaken for painful chronic pancreatitis, it is not of necessity a comprehensive rendering of all procedures. This document does, however, illustrate that description of the operation by the component of the procedure undertaken is feasible and allows for a more objective report. It may be that the use of eponymous terms will continue, but standardization of the components of procedures by objective description of what was done will aid more consistent reporting.

The final domain is a minimum outcome dataset. This essentially addresses immediate and intermediate outcomes after operation.

In conclusion, this document represents the first ISGPS document on reporting standards for the operative treatment for chronic pancreatitis and provides 4 domains which cover the clinical baseline of the patients, the disease morphology, the operative procedure, and the postoperative outcomes. All future reports on elective operative intervention for painful chronic pancreatitis should provide information on all 4 domains of this reporting standards document. This standardization will facilitate comparison of results between centers and help to improve the care for patients with this debilitating disease.

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Conflict of interest/Disclosure

No authors have any conflicts of interest.

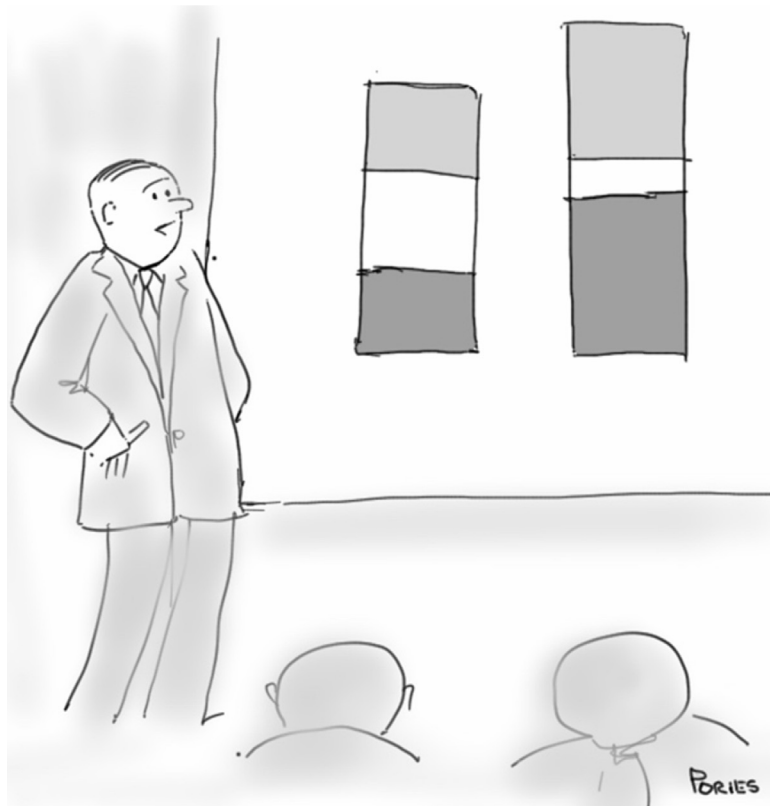
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“As I see it, given the rising costs in the hospital and the increased charges for drugs, the only option is to reduce the salaries of our employed physicians.”