Evidence Map of Pancreatic Surgery—A living systematic review with meta-analyses by the International Study Group of Pancreatic Surgery (ISGPS)

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Background: Pancreatic surgery is associated with considerable morbidity and, consequently, offers a large and complex field for research. To prioritize relevant future scientific projects, it is of utmost importance to identify existing evidence and uncover research gaps. Thus, the aim of this project was to create a systematic and living Evidence Map of Pancreatic Surgery.

Methods: PubMed, the Cochrane Central Register of Controlled Trials, and Web of Science were systematically searched for all randomized controlled trials and systematic reviews on pancreatic surgery. Outcomes from every existing randomized controlled trial were extracted, and trial quality was assessed. Systematic reviews were used to identify an absence of randomized controlled trials. Randomized controlled trials and systematic reviews on identical subjects were grouped according to research topics. A web-based evidence map modeled after a mind map was created to visualize existing evidence. Meta-analyses of specific outcomes of pancreatic surgery were performed for all research topics with more than 3 randomized controlled trials. For partial pancreatectoduodenectomy and distal pancreatectomy, pooled benchmarks for outcomes were calculated with a 99% confidence interval. The evidence map undergoes regular updates.

Results: Out of 30,860 articles reviewed, 328 randomized controlled trials on 35,600 patients and 332 systematic reviews were included and grouped into 76 research topics. Most randomized controlled trials were from Europe (46%) and most systematic reviews were from Asia (51%). A living meta-analysis of 21 out of 76 research topics (28%) was performed and included in the web-based evidence map. Evidence gaps were identified in 11 out of 76 research topics (14%). The benchmark for mortality was 2% (99% confidence interval: 1.8–2.4) for partial pancreatectoduodenectomy and <1% (99% confidence interval: 0.0–1.0) for distal pancreatectomy. The benchmark for overall complications was 53% (99% confidence interval: 46.6–61) for partial pancreatectoduodenectomy and 50% (99% confidence interval: 44.3–80) for distal pancreatectomy.

Conclusion: The International Study Group of Pancreatic Surgery Evidence Map of Pancreatic Surgery, which is freely accessible via www.evidencemap.surgery and as a mobile phone app, provides a regularly updated overview of the available literature displayed in an intuitive fashion. Clinical decision making and evidence-based patient information are supported by the primary data provided, as well as by living meta-analyses. Researchers can use the systematic literature search and processed data for their own projects, and funding bodies can base their research priorities on evidence gaps that the map uncovers.
Web of Science, and the Cochrane Central Register of Controlled Trials. No restrictions were applied regarding language or publication date. The search strategy for all databases aimed to cover the whole field of pancreatic surgery and was published in detail in the protocol. The last search for version 1 was performed on April 11, 2021.

**Study selection**

Patients with any kind of disease requiring pancreatic surgery were considered eligible. Interventions that aimed to affect surgical outcome, including medical devices (e.g., stapler versus scalpel resection in distal pancreatectomy), perioperative management (e.g., prehabilitation of patients or intraoperative fluid management), surgical strategy (e.g., open versus laparoscopic access to the abdominal cavity), drug use (e.g., somatostatin analogs to avoid complications), and nutrition (e.g., immunonutrition to avoid complications) were included. Interventions like endoscopic retrograde cholangiopancreatography, radiologically guided punctures, or similar were only included when they were compared to a surgical intervention. Moreover, studies on neo/adjuvant treatment or pancreatic transplantation were excluded since they would constitute a separate thematic evidence map.

RCTs and systematic review (SRs) with or without meta-analysis were deemed eligible for inclusion. SRs were only eligible if they met minimum quality requirements, i.e., the SR must include at least 2 established literature databases and provide a critical appraisal with validated tools, such as the Cochrane Collaboration tool for assessing risk of bias for RCTs or the ROBINS-I for nonrandomized studies.

Following the recommendations of the Cochrane Collaboration, 2 reviewers independently screened the titles, abstracts, and full texts of the identified articles. A third reviewer resolved any disagreement between the 2 reviewers.

**Data extraction**

Two reviewers using predefined items carried out all stages of data extraction and quality assessment independently. Any disagreement was resolved by discussion and consensus or by consulting a third reviewer. The outcomes of interest were mortality, postoperative pancreatic fistula (graded as biochemical leak, B, or C, if the ISGPS definition was used), delayed gastric emptying (graded as A, B, or C, if the ISGPS definition was used), post-pancreatectomy hemorrhage (graded as A, B, or C, if the ISGPS definition was used), bile leak (graded as A, B, or C, if the International Study Group of Liver Surgery definition was used), chyle leak (graded as A, B, or C, if the ISGPS definition was used), intra-abdominal fluid collection/abscess, overall morbidity (if available, according to the Clavien-Dindo classification), comprehensive complication index, survival (described as 1-, 2-, 3-, 4-, and 5-year survival rates, as well as overall survival), length of hospital stay, and operation time. The full list of extracted items for RCTs and SRs is included in the protocol.

Furthermore, the methodological quality of included RCTs was assessed with the Cochrane Collaboration tool for assessing risk of bias 2.0. Five standard domains of bias were assessed: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. These domains were rated as “high risk of bias,” “low risk of bias,” or “some concerns.” Finally, an overall risk of bias judgment was made. The overall risk of bias was considered high risk of bias if at least 1 domain had a high risk of bias or if there were some concerns in 3 or more domains. The overall risk of bias was considered low if there were some concerns in at least 1 domain. The overall risk of bias was low risk of bias if all domains were rated as low risk of bias. The binding of patients, surgeons, data collectors, outcome assessors, and data analysts was assessed as “blinded,” “not blinded,” or “not reported.” Furthermore, information on funding was recorded as “industry,” “independent,” or “not reported.”

**Data synthesis**

The ISGPS Evidence Map of Pancreatic Surgery is freely accessible via the internet. All included RCTs and SRs are clustered according to the type of operation, disease, and intervention. Consequently, studies on the same research topics are grouped together, e.g., pylorus preservation versus pylorus resection (intervention: surgical strategy) in partial pancreateoduodenectomy (operation) for tumors or chronic pancreatitis (disease). Existing SRs are displayed within the evidence map and are used to identify missing RCTs within a research topic (evidence gap). No quantitative data from SRs are extracted, and no critical appraisal of SRs—despite the quality criteria for inclusion mentioned above—is performed. Ongoing RCTs and unpublished terminated RCTs according to the World Health Organization trial registry are also displayed within the evidence map; these will be replaced as results become available.

**Creation of the evidence map**

Instructions and a summary, as well as a section containing definitions and international guidelines, appear in the center of the evidence map. The map itself is configured as a mind map in a manner that is intuitive and hierarchically leads its reader from the center (pancreatic surgery as a whole) via main topics (e.g., partial pancreateoduodenectomy) and subtopics (e.g., entero-enteric anastomosis) to individual research topics (e.g., pylorus preservation versus pylorus resection). Red boxes indicate evidence gaps, and in green boxes, existing studies are shown. Within a research topic, existing RCTs and SRs are plotted with the name of the first author and year of publication. For every study, the conclusion of the article, the citation, and a direct link to the article on the journal homepage are provided. Processed data from RCTs are available for future meta-analyses.

**Quantitative analyses and the Grading of Recommendations Assessment, Development, and Evaluation**

R (version 3.6.4) is used for statistical analysis. All RCTs that investigate exclusively 1 type of operation are pooled to create a summary of the ISGPS Evidence Map of Pancreatic Surgery. A pooled complication rate with a 99% confidence interval computed by a meta-analysis of proportions is provided for benchmarking purposes. Further, bubble plots mapping all RCTs by type of operation to type of intervention, type of disease to type of intervention, and type of disease to type of operation are created. Within the bubble plots, the sample size of the trials is expressed by bubble size. If an RCT contains more than 1 operation or disease, the largest group within it is taken to represent the whole sample. The geographical region where a trial took place is indicated by a color code. Processed data from every RCT are provided to allow for meta-analysis. Continuous values are converted to mean and standard deviation if reported otherwise. The standard deviation is reported as (o) if only the mean was available and as (–2) if only the median was available. Within the processed data, the Clavien-Dindo classification is not displayed if morbidity was only reported as “major complications” or incomplete. If no “a” or “b” subclass was reported for grade 3 or 4 complications, these complications are summarized in the processed data as 3a or 4a, respectively.
Living meta-analyses are performed for research topics if more than 3 RCTs are included and at least 3 data sets for an outcome are available. Dichotomous data are pooled in a Mantel-Haenszel model to estimate odds ratios and associated 95% confidence intervals. For continuous data, mean differences and associated 95% confidence intervals are calculated using an inverse-variance model. A random effects model is used due to general clinical heterogeneity. For dichotomous and continuous data, a prediction interval and an exact P value are calculated. Statistical heterogeneity is evaluated via the I² statistic. An I² <25% is considered low statistical heterogeneity, and an I² >75% is considered high statistical heterogeneity.

If more than 2 interventions are compared within a research topic, a state-of-the-art Bayesian network meta-analysis is performed. Either linear or logistic random effects models are applied. Pooled effect estimates obtained in the network meta-analysis (adjusted mean differences or log odds ratios) are provided with 95% credibility intervals. Furthermore, a treatment ranking based on the probability of being the most efficient arm is carried out.

If more than 10 trials are available, funnel plots are created and tested for asymmetry to evaluate the risk of publication bias using the Harbord test. Funnel plots are only displayed in case of statistically significant asymmetry.

Furthermore, for each outcome in the meta-analyses, the certainty of the evidence is rated using the Grading of Recommendations Assessment, Development and Evaluation system. This system includes limitations in the design from the risk of bias...
assessment as mentioned above, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results, and publication bias. Thus, the certainty of evidence is rated as “very low,” “low,” “moderate,” or “high” for each outcome.

Living systematic review and meta-analyses

The map will be updated at least every 3 months, according to the above-mentioned steps. Moreover, relevant new articles found by hand search or discovered via social media will be scrutinized and added immediately. All new RCTs and SRs will be added to the map under their respective research topics. The date of last update will be reported in the center of the map. Meta-analyses will be renewed when new RCTs become available, thus resulting in living meta-analyses. For every meta-analysis, the date of calculation will be provided. These updated meta-analyses will be peer-reviewed by members of the ISGPS unaffiliated with the University of Heidelberg.

Results

The ISGPS Evidence Map of Pancreatic Surgery is freely accessible via www.evidencemap.surgery. This paper-based publication represents version 1. Altogether, 30,860 articles were found via systematic literature search, and 29,021 articles were excluded after title and abstract screening. Of these 1,837 articles, 328 RCTs (including 35,600 patients) and 332 SRs were eventually included. These articles were grouped into 76 research topics. Figure 1 shows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart of this process.

Origin and topics of included studies

The highest number of RCTs has, so far, been conducted in Europe (46%), followed by Asia (37%) and North America (14%). Other geographical regions—Africa, Australia and New Zealand, and South America—contributed around 1% each (Fig 2, RCT). Regarding SRs, the most studies were conducted in Asia (51%), followed by Europe (38%), North America (8%), and Australia/New Zealand (3%). South America and Africa contributed less than 1% (Fig 2, SR).

Bubble plots are shown in the summary of the evidence map online. The 3 bubble plots show that RCTs for operations other than pancreatectoduodenectomy are scarce and that even fewer RCTs exist for relatively rare diseases such as neuroendocrine neoplasms or intraductal papillary mucinous neoplasms.

Critical appraisal (bias)

The summary of the quality assessment is shown in Table I. The overall risk of bias judgment was deemed high in 54% of RCTs. In 36% of RCTs, there were some concerns, and the remaining 10% of RCTs had a low risk of bias. About 23% of patients were blinded; however, most of the RCTs did not report blinding of study contributors. Funding remained unclear in half of the RCTs. Apparently, 9% of RCTs were sponsored by industry, and 43% were nonindustry funded.

Map content

The current map consists of 7 main topics: “partial pancreatectoduodenectomy,” “distal pancreatectomy,” “pancreatitis,” “trauma,” “palliative measures,” “various perioperative interventions,” and “other surgical aspects.” The main topic, partial pancreatectomy, contains 6 subtopics (“pancreatic anastomosis,” “entero-enteric anastomosis,” “bile duct anastomosis,” “drainage,” “surgical aspects,” and “minimally invasive surgery”) with 27 individual research topics. The main topic, distal pancreatectomy, contains 4 subtopics: “drainage,” “minimally invasive surgery,” “pancreatic remnant,” and “surgical aspects.” A total of 15 research topics are plotted. The main topic, pancreatic islet, is divided into the subtopics “chronic pancreatitis” and “acute pancreatitis,” containing a total of 6 research topics. “Trauma” and “palliative measures” comprise 1 research topic each. Various perioperative interventions is another main topic, with 3 subtopics (“pharmaceutical cotreatments,” “nutrition,” and “minimally invasive surgery”) and 17 research topics in total. Finally, the main topic, other surgical aspects, entails research topics that do not fit into any of the other main topics. Living meta-analyses are performed for 21 out of 76 research topics (28%). Table II summarizes the map contents and shows if a living meta-analysis is conducted.

Evidence gaps, ie, missing RCTs, were identified within 11 out of 76 research topics (14%): “total versus partial pancreatectoduodenectomy,” “autologous coverage after partial pancreatectoduodenectomy,” “robotic versus laparoscopic partial pancreatectoduodenectomy,” “radical antegrade modular pancreatic anastomosis versus standard distal pancreatectomy,” “celiac axis resection in distal pancreatectomy,” “robotic versus laparoscopic distal pancreatectomy,” “time point of surgery for chronic pancreatitis,” “multivisceral resection in pancreatic surgery,” “resection versus nonsurgical management of pancreatic neuroendocrine tumors,” “frozen section analysis during pancreatic surgery,” and “volume-outcome relationship in pancreatic surgery.”
was 23% (3,016 patients; 99% CI: 17–0%).

Social media concept and mobile app.

90%).

pancreatectomy, the benchmark for mortality was 89%). In 3,011 patients from 24 RCTs undergoing distal mortality was 2% (99% con...evidence map online. In 17,039 patients from 160 RCTs...professionals and patients alike with such a resource. After a systematic review of literature, all existing evidence from RCTs and SRs on pancreatic surgery are included, assessed, and plotted in the intuitive form of a mind map. The body of evidence that the map provides will be updated at least every 3 months and made freely accessible at www.evidencemap.surgery; thus, health care professionals, patients, and funding bodies can access a living overview of highly relevant data.

This project combines 2 innovative methods of evidence-based medicine: a living systematic review and evidence mapping. The fact that published data derived from SRs are at risk of being outdated or redundant with the ever-increasing body of evidence in literature, a living SR, which results in a higher level of validity, helps to overcome this problem. Evidence mapping is an emerging approach, but the term has not yet been universally defined. The ISGPS Evidence Map of Pancreatic Surgery envisions a novel interpretation of evidence mapping, plotting the available evidence in the form of a mind map allows processed evidence to be presented by topic and at a glance. Besides fulfilling the needs of evidence-based medicine, this project also addresses the issue of how best to use modern technology to communicate scientific data. Consequently, the map is freely available via the internet, and its scope, contents, and updates are (and will continue to be) distributed via a variety of social media platforms.

The ISGPS Evidence Map of Pancreatic Surgery addresses the needs of all stakeholders in the health care system. First, in times of economic constraints, there is a need to avoid wasteful expenditure in medical research. However, science should remain as unrestricted as possible and should be allowed to follow international trends, like the use of octreotide or robotic surgery. Without a global strategy, important knowledge gaps remain and result in multiple publications on less urgent questions. A harmonization by national and international funding bodies to support important research projects might be the solution. However, it is difficult for interdisciplinary funding bodies to maintain a regular overview of the existing research in a specific field, such as pancreatic surgery.

Further benchmarks are available in the summary of the online map.

Social media concept and mobile app

In addition to the map’s website (www.evidencemap.surgery), a mobile app is available for Android and iPhone (EVIglance app).

Further, a social media presence for the ISGPS Evidence Map of Pancreatic Surgery was established. Twitter presentations on research topics (with and without surveys) are published regularly (@evidencemap). Updates are shared via Facebook (fb.com/evidencemap), where the inaugural presentation of the evidence map was streamed from the World Pancreas Forum in Bern, Switzerland on February 6, 2020. Finally, every video created concerning the ISGPS Evidence Map of Pancreatic Surgery is available on YouTube. Professionals and patients are thus provided with an interactive forum via social media and are also able to contact the study team directly via email (info@evidencemap.surgery).

Discussion

Ideally, overviews of scientific literature must be up-to-date, comprehensive, critically appraised, and presented in a lucid way. The ISGPS Evidence Map of Pancreatic Surgery aims to provide pancreatic surgeons, other medical professionals, students, and patients alike with such a resource. After a systematic review of literature, all existing evidence from RCTs and SRs on pancreatic surgery are included, assessed, and plotted in the intuitive form of a mind map. The body of evidence that the map provides will be updated at least every 3 months and made freely accessible at www.evidencemap.surgery; thus, health care professionals, patients, and funding bodies can access a living overview of highly relevant data.

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Ongoing and unpublished terminated RCTs are displayed within their respective research topic.

Benchmarks

Forest plots of benchmarks are displayed in the summary of the evidence map online. In 17,039 patients from 160 RCTs undergoing partial pancreateoduodenectomy, the benchmark for mortality was 2% (99% confidence interval [CI]: 1%–2%; range: 0%–22%; I² = 77%). The benchmark for overall complications was 53% (61 RCTs; 7,474 patients; 99% CI: 46%–61%; range: 15%–133%; I² = 91), and the benchmark for postoperative pancreatic fistula according to the ISGPS definition was 14% (99 RCTs; 12,013 patients; 99% CI: 12%–17%; range: 0%–66%; I² = 89%). In 3,011 patients from 24 RCTs undergoing distal pancreatectomy, the benchmark for mortality was <1% (99% CI: 0%–1%; range: 0%–3%; I² = 29%). The benchmark for overall complications was 59% (1,058 patients; 99% CI: 44%–80%; range: 32%–100%; I² = 86%), and the benchmark for postoperative pancreatic fistula according to the ISGPS definition was 23% (3,016 patients; 99% CI: 17%–30%; range: 5%–60%; I² = 90%).

Further benchmarks are available in the summary of the online map.

Table I

<table>
<thead>
<tr>
<th>Bias arising from the randomization process</th>
<th>Bias due to deviations from intended interventions</th>
<th>Bias due to missing outcome data</th>
<th>Bias in measurement of the outcome</th>
<th>Bias in selection of the reported result</th>
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<tbody>
<tr>
<td>Low risk of bias</td>
<td>190 (58%)</td>
<td>100 (30%)</td>
<td>284 (87%)</td>
<td>73 (22%)</td>
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<tr>
<td>Some concerns</td>
<td>129 (39%)</td>
<td>224 (68%)</td>
<td>39 (12%)</td>
<td>249 (76%)</td>
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<tr>
<td>High risk of bias</td>
<td>9 (3%)</td>
<td>4 (1%)</td>
<td>5 (2%)</td>
<td>6 (2%)</td>
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</table>

Overall risk of bias judgment

<table>
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<tr>
<th></th>
<th>Low risk of bias</th>
<th>Some concerns</th>
<th>High risk of bias</th>
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<tbody>
<tr>
<td>Patients</td>
<td>74 (23%)</td>
<td>40 (12%)</td>
<td>37 (11%)</td>
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<tr>
<td>Physicians</td>
<td>61 (19%)</td>
<td>94 (29%)</td>
<td>63 (19%)</td>
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<tr>
<td>Data collectors</td>
<td>193 (59%)</td>
<td>194 (59%)</td>
<td>228 (70%)</td>
</tr>
<tr>
<td>Outcome assessors</td>
<td>30 (9%)</td>
<td>30 (9%)</td>
<td>286 (87%)</td>
</tr>
<tr>
<td>Statisticians</td>
<td>142 (43%)</td>
<td>142 (43%)</td>
<td>311 (95%)</td>
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<th>Funding</th>
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<tr>
<td>Blinded</td>
<td>74 (23%)</td>
<td>40 (12%)</td>
<td>37 (11%)</td>
</tr>
<tr>
<td>Not blinded</td>
<td>61 (19%)</td>
<td>94 (29%)</td>
<td>63 (19%)</td>
</tr>
<tr>
<td>Not reported</td>
<td>193 (59%)</td>
<td>194 (59%)</td>
<td>228 (70%)</td>
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The ISGPS Evidence Map of Pancreatic Surgery offers the perfect springboard for such an approach. By its application, funding bodies may objectively assess which research projects would fill existing gaps of knowledge, thus enabling them to prioritize funding.

Second, the evidence map is a valuable resource for planning new clinical trials. Its structure enables researchers to easily view the current state of research and permits them the opportunity to identify specific areas that warrant meaningful research. Key data for estimated effect sizes can be taken directly from the living meta-analyses and can serve as the basis for sample size calculations. Moreover, references derived from high-quality research on the effectiveness and safety of different surgical procedures are needed during the writing stage. Thanks to the pooled outcomes estimates, hard comparators can be provided with a 95% CI as a benchmark. These, along with the living meta-analyses, enable the ISGPS Evidence Map of Pancreatic Surgery to serve as a comprehensive source of robust data when writing trial proposals or publications.

Additionally, this endeavor supports writing synoptic evidence, ie, reviews and evidence-based patient information. Scientists are provided with a quick overview of existing SRs, which can help them to focus on novel research questions and to prevent redundant publications. The map will also be an important comparative tool for future literature searches, data extraction, and critical appraisal. Again, the aspect of benchmarking is addressed and fulfilled here.

Furthermore, clinicians and patients alike can obtain a rapid overview of existing treatments and their comparative effectiveness. Unlike fixed guidelines, clinicians can interpret the literature.
themselves, for individual patients and clinical situations, which again follows the evidence-based medicine approach. Finally, this project can inspire other researchers to create similar maps for their particular fields of research.

In conclusion, the ISGPS Evidence Map of Pancreatic Surgery, which is freely accessible via www.evidencemap.surgery and as a mobile phone app, provides a regularly updated overview of the available literature displayed in an intuitive fashion. Clinical decision-making and evidence-based patient information are supported by the primary data provided, as well as by living meta-analyses. Researchers can use the systematic literature search and processed data for their own projects, and funding bodies can base their research priorities on evidence gaps that the map uncovers.

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Conflict of interest/Disclosure

None of the authors has a secondary interest (as defined by the International Committee of Medical Journal Editors guidelines) that might inappropriately influence their contribution to this work.

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