Benchmarking outcomes in pancreatoduodenectomy with portal vein resection

OBJECTIVE:

To conduct a retrospective multicenter cohort study to define benchmark values for best achievable outcomes following duodenopancreatectomy (DP) with portal vein resection (PVR).

INTRODUCTION

Pancreatoduodenectomy (PD) with portal vein resection (PVR) is performed for the achievement of complete resection (R0) in patients with locally advanced pancreatic head lesions. Despite most commonly performed in high-volume pancreatic surgery centers by experienced surgeons, best achievable outcomes, such as morbidity and mortality, following such complex procedure remain unknown.

Benchmarking is widely known as a valid quality assessment tool used to pursue improvement in the fields of banking or industrial manufacturing. Moreover, benchmarking has been applied in medicine as a tool for evaluating single-center outcomes by risk-adjusted comparisons to national data, however its use in the field has been considered more versatile and imprecise. The innovative idea of applying the benchmark concept to surgical specialties is to evaluate best achievable results in a well-defined low-risk patient cohort, with the aim to establish meaningful reference values for comparisons, for instance among centers or over time, or to further estimate the degree of implementation of novel surgical techniques.

Recent studies in the field of surgery have applied this methodology to set reference figures in liver resection as well as transplantation, esophagectomy and PD. However, PD with PVR is now an established procedure in several specialized centers worldwide yet benchmark outcomes remain ill determined and may be significantly different when compared to standard PD without PVR.

POLICY SECURING

Confidential center specific data: No center-specific data will be published. Instead, all complications or adverse outcomes will be anonymously reported, as fractions of the total study population. Each center, of course, will be free to publish their own data, as they wish.

Study data coordination: No data will be submitted or published without authorization from each participating center. Each center will be represented by three co-authors. In the ideal case there will be one junior author who will coordinate data collection with Dr. Dimitri Raptis, Nikolaos Machairas or Patricia Sánchez Velázquez (coordinators of the study).

Authorship: The study coordinators (Dimitri Raptis, Patricia Sánchez Velázquez and Nikolaos Machairas) will be the first, second and third authors. The last authorship position is reserved for the principal investigator (Giuseppe K. Fusai). All other authors will be listed in alphabetical order. Any publication, presentation or abstract on collected data will be delegated to all authors. Each center remains the possessor of their own data and additional reports on data collected will only be conducted in case of written author permission. All participating authors can suggest alterations to the study design or additional analyses to be performed.

Further use of cohort data: Future studies based on the collected data will hopefully emerge from this multicenter study.

METHODS

Benchmark Values

At hospital discharge and up to 12 months postoperatively

1. Mortality
2. Morbidity:
    a. Complication grading according to Clavien-Dindo
    b. Complication quantification with the CCI
    c. Fistula rates (reported according to both the International Study Group of Pancreatic Fistula (ISGPF) and Clavien-Dindo classification.
3. Readmission to hospital

Long-term (until end of follow up or death)

4. Portal vein thrombosis
5. Overall and disease-free survival (DFS) (for cancer only)

Subgroup Analyses

Comparison of outcomes between benchmark *versus* non-benchmark cases with or without portal vein resection (data obtained from the WhippleBenchmarks 1 study).

Study period:

• 10-year period from 1st Jan 2009 to Dec 31st 2018

Center eligibility

- Consider high volume centers in the respective countries.
- Minimum 50 cases of pancreatic surgery per year or 150 cases within 3 years
- Published in the area of pancreas surgery
- Prospective database available
- Include ≥ 3 continents

Patient eligibility (benchmark cases criteria):

Please note that, at this stage, the study will **include all cases (benchmark/non benchmark)** and exclusion criteria for benchmark analysis will be applied at a later phase.

Inclusion criteria:

1. Adults ≥ 18 years
2. Resectable **malignant or benign** diseases (i.e, all indications)
3. Open pancreaticoduodenectomy (all techniques allowed) with concurrent portal vein resection, but excluding arterial reconstruction

Exclusion criteria:

1. Patients < 18 years
2. Pancreatic resections other than pancreaticoduodenectomy and portal vein resection
3. Laparoscopic or robotic

Governance

Data will be collected via a secure, password protected, and encrypted online data management system. This platform uses a data entry management system (DEMS) to meet international standards for online databases including fully anonymous data. Data will not be published with hospital identifiers.

Data Collection

Local collaborators: All hospitals may have up to three local investigators; every center investigator will be in regular contact with the designated study coordinators (Dimitri Raptis, Patricia Sánchez Velázquez and Nikolaos Machairas) and will be responsible for:

- Gaining local research ethics approval if required
- Identifying and including all eligible patients
- Accurately collect baseline and follow-up data
- Submit data to the online DEMS database