OBJECTIVE:

To conduct a retrospective multicenter cohort study to define benchmark values for best achievable outcomes following duodenopancreatectomy (DP). A secondary aim will be to identify the minimal follow-up necessary to properly assess morbidity associates with DP.

INTRODUCTION

With the growing complexity and costs of modern surgical practice, convincing and unbiased quality assessment becomes mandatory. The notion of quality assessment is widely recognized and used in the world of business and manufacturing. A possible tool of quality assessment is benchmarking. Benchmarking is a process of measuring performance in order to enable for outcome comparison and improvement within a specific domain. In the surgical community, however, such standard outcome measures and multicenter comparison of results have been poorly developed and benchmarking for the best possible results for specific procedures is lacking.

A first landmark study defining benchmark outcomes for liver resection were presented at the 2016 ASA meeting in Chicago and published last Fall Ann Surg (Rössler et al, 2016) (1). More recently benchmark values were established for liver transplantation (submitted) and esophagectomy (presented at ESA 2017, Ann surg in press).

Duodeno-pancreatectomy is a high-risk procedure still associate with significant mortality (2-10%) and very high morbidity (>60%). To identify the best possible outcome (i.e. benchmarking), data from high-volume centers in **low risk patients** will be analyzed. These benchmark outcomes will serve as "controls" for comparison with any future analyses of PD.

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.

Authorship: No data will be submitted or published without authorization from each participating center. Each center will be represented by two to three co-authors.
In the ideal case there will be one junior author who will coordinate data collection with Dr. Patricia Sánchez Velázquez (coordinator of the study from Zurich).

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

METHODS

Benchmark Values (each will be measured at hospital discharge, 3m, 6m and 12 months):

1. Mortality
2. Morbidity:

   a. Complication grading according to Clavien-Dindo (2)
   b. Complication quantification with the CCI (3)
   c. Fistula rates (reported both according to according to the International Study Group of Pancreatic Fistula (ISGPF)(4) and Clavien-Dindo classification.
3. Readmission to hospital
4. Disease free survival (DFS) and Overall survival (OS) (reported only at one year)

Study period:

• 1st Jan 2013-Dec 31st 2015 (3 year)

Center eligibility

- Consider largest program in the respective countries.
- Min. **50 cases per year** or **150 cases** within 3 years (i.e. the study period)
- 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 only the benchmark cases**.

Inclusion criteria:

1. Adults ≥ 18 years
2. Resectable **malignant or benign** diseases (i.e, all indications)
   a. Duodenopancreatectomy (all techniques allowed)
   b. Including portal vein resection, but excluding arterial reconstruction
3. No significant co-morbidities (see exclusion criteria bellow)
4. No laparoscopic/robotic procedures

Exclusion criteria:

1. Central and distal pancreatectomies.
2. Extended duodenopancreatectomy (including pancreas body) and total pancreaticododenectomy
3. R2 resection (macroscopic positive margin)
4. Extrapancreatic (non nodal) metastases
5. Previous major abdominal surgery (E.g. bariatric surgery, gastrectomy, splenectomy or liver surgery **should be excluded)**
   i. Ad note not excluded cholecystectomy, appendectomy, lower GI track surgery
6. Co-morbidities:
   a. BMI ≥ 35 (11)
   b. Cardiac disease (according to ref 5)
      i. Congestive heart failure (CHF) onset or exacerbation in 30 days prior to surgery
      ii. History of angina pectoris within 1 month of surgery
      iii. Myocardial infarct within 6 months prior to surgery
      iv. History of percutaneous coronary intervention or cardiac surgery (5).
      v. Atrial fibrillation (6)

Ad Note: arterial hypertension **is not considered** as cardiac disease

c. Chronic renal failure (7): ≥ stage 3 (GRF<60ml/min per 1.73 m^2 or Creatinine > 1.8 mg/dl or 160 µmol/l)
d. Use of anti-coagulation: Non-vitamin K antagonist oral anticoagulants (NOACs) and Vitamin K antagonist and clopidogrel
   Note: patients under Aspirin 100mg **should not been excluded** (8,9)
e. Lung disease: chronic obstructive pulmonary disease with FEV1<80%(10)
f. Diabetes: when use more than 2 oral antidiabetes drugs or insulin

Governance

Data will be collected via a secure; password protected, and encrypted online data management system, provided by the University Hospital of Zurich. 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: Most hospitals will have two local investigators; a senior and a junior investigator. The junior collaborator will be in regular contact with the study coordinator in Zurich (Dr. Patricia Sanchez Velazquez, *Patricia.SanchezVelazquez@usz.ch*). The junior investigator will be responsible for:

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

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