

Endoscopic vs. Surgical Ampullectomy vs. Pancreaticoduodenectomy (ESAP)

for ampullary neoplasm



Pancreas2000/European Pancreatic Club study group



Dear friends,

As you might know, our group, on the behalf of the Pancreas2000/EPC program, is conducting a multinational retrospective study on the management of ampullary neoplasm and their outcomes after endoscopic or surgical resection.

Due to the rarity of these tumors and procedures, it is vital to include as many centers as possible: every contribution, even small ones, is fundamental in order to succeed!

You are therefore all invited to contribute with your patients! And in case you know any other center that might be interested in this study, we kindly ask you to let us know.

Don't miss the chance to contribute in a largely unexplored field!

Note that that the deadline for data collection is **31st July, 2019.**

Each participating Center will be cited either as co-author or contributor based on the number of patients and the journal publication policy. This study is approved by our local ethical review boards (ERB). You will receive our ERB confirmation, an ERB application form for your Center, the project synopsis and our data collection template attached to this letter. Please find our study protocol attached.

If you have any question or you want to discuss the study details please contact:
esap.study@gmail.com

On behalf of the ESAP-Group,

With kind regards

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STUDY PROTOCOL

Endoscopic versus Surgical Ampullectomy vs Pancreaticoduodenectomy (ESAP) for ampullary neoplasm

*Project conducted under the auspice of
Pancreas 2000 and the European Pancreatic Club*

Background :

Management of ampullary lesions includes endoscopic ampullectomy (EA), surgical ampullectomy (SA) and pancreaticoduodenectomy (PDD).

Only few studies comparing these three techniques have been reported and with small patient population. Consequently, there no clear guidelines available concerning the choice of the method of resection (EA, SA, or PDD).

Objectives :

Main objective:

To detail outcomes in term of complete resection, recurrences, need for complementary resection, morbidity and mortality after EA/SA/PDD

Secondary objectives :

- To detail outcome of patients who underwent radiofrequency ablation following R1 EA
- To detail outcome of patient who underwent endoscopic ampullectomy (EA), surgical ampullectomy (SA) or pancreaticoduodenectomy (PDD) for ampullary neuroendocrine tumors
- To detail outcome of patient who underwent surgery following incomplete resection after EA
- To detail outcome of patient who underwent ampullectomy of the minor papilla
- To detail outcome of patient with an hereditary syndrome associated with ampullary neoplasm (Familial Adenomatous Polyposis (FAP), Lynch syndrome, Neurofibromatosis type 1 (NF1) and others)
- To determine outcome in rare non-mesenchymal tumours for ampullary lesions (e.g. paraganglioma, leiomyoma, leiomyosarcoma and others)

Type of study:

A multicenter retrospective study

Study period:

- Endoscopic ampullectomy : From 01/01/2007 to 31/7/2018
- Surgical ampullectomy and PDD : From 01/01/2004 to 31/7/2018

Main inclusion criteria (see IRB for details):

All the patients who underwent endoscopic or surgical resection for histologically proven ampullary lesions strictly located to the ampulla (T1 and T2 for adenocarcinoma). This includes adenocarcinoma, adenoma, neuroendocrine tumors and others.

Main exclusion criteria (see IRB for details):

- Peri-ampullary lesions
- Whipple or other interventions for stages higher than T2

Minimum follow-up required:

1 year post procedure

Data collection deadline:

31st July, 2019

Authorship criteria:

Each center will be cited either as Author or Contributor based on the number of patients and the journal publication policy.