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International Survey on the Use and Indications for Staging Laparoscopy in Patients with Localized Pancreatic Ductal Adenocarcinoma

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OBJECTIVE

This international survey aims to investigate the clinical practice and views amongst pancreatic surgeons regarding the use, indications, and timing of staging laparoscopy in patients diagnosed with localized pancreatic ductal adenocarcinoma.

BACKGROUND

Pancreatic ductal adenocarcinoma (hereafter: pancreatic cancer) is known to be associated with a very poor five-year survival,² whereby for localized tumors, surgical resection combined with systemic chemotherapy provides the only chance for long-term survival.³

Multiple-phase contrast enhanced computed tomography (CT) is the standard modality for (suspected) pancreatic cancer, combined, when indicated, with magnetic resonance imaging (MRI) to exclude (liver) metastases.⁴ Nevertheless, approximately 10-20% of patients with localized pancreatic cancer who are explored with intention for a resection are intraoperatively found to have occult metastatic disease with either liver surface or peritoneal metastases.⁵

Surgical exploration without resection due to metastatic disease has been associated with worse 30-day mortality and worse overall survival.⁵ To avoid an unnecessary laparotomy and its associated negative side-effects, some guidelines state that a staging laparoscopy could be performed in all patients with localized pancreatic cancer, or only in patients at high risk of occult metastases.^{4,6} Some have also argued that staging laparoscopy could be considered prior to start neoadjuvant or induction therapy, since the presence of occult metastases may have consequences for the intention and type of therapy.^{4,6}

Although staging laparoscopy has proven to detect occult metastases in 10-45% of patients, particularly in the presence of predictors for occult metastases,⁷⁻¹¹ a decreasing trend in the use of the staging laparoscopy was reported in the United States when surgery is performed via laparotomy despite no change in the incidence of metastatic dissemination over time.¹²

There seems to be a lack of consensus on the use of the staging laparoscopy, regarding its indications, timing, and concomitant diagnostic procedures (e.g., cytological lavage, ultrasonography, and indocyanine green-fluorescence imaging) that may increase the sensitivity. To facilitate future research on the role of staging laparoscopy, facilitate the design of future prospective studies and support future guidelines, an international group of pancreatic surgeons decided to design this survey.

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METHODS

Study population

The survey will be spread among the following collaborative study groups and associations: International Hepato-Pancreato-Biliary Association, Asian Pacific Hepato-Pancreato-Biliary Association, European-African Hepato-Pancreato-Biliary Association, European Pancreas Club, Pancreas Club, European Consortium on Minimally Invasive Pancreatic Surgery, Japanese Society of Hepato-Biliary-Pancreatic Surgery, and International Collaborative Study Group on Locally Advanced Pancreatic Cancer. Only the survey results from surgeons who have performed pancreatic surgery in the last 12 months will be used for the analyses.

Definitions

This study addresses patients with localized pancreatic ductal adenocarcinoma (here: pancreatic cancer).

Localized pancreatic cancer is defined as a preoperative diagnosis based on cross-sectional radiological imaging without any signs of lymphatic distant metastases¹ or other distant metastases on imaging. Pathology proof is not mandatory for this survey as is in current clinical practice in patients not using.

Staging laparoscopy is defined as a laparoscopic procedure aimed at detecting occult metastases. This may include peritoneal washings with cytology as well as diagnostic intraoperative ultrasound. Some synonyms have been used in the literature as 'diagnostic laparoscopy', for simplicity we have used 'staging laparoscopy' consistently.

Staging laparoscopy prior to surgical exploration can be performed either in the same procedure (i.e., at the start) of exploratory laparotomy with the intend to resect but also earlier on as standalone procedure. To prevent confusion and issues with terminology, we exclude (intended) minimally invasive resections.

Study endpoints

See **Appendix 1** for the survey. Topics of interest that will be investigated are applicable on the current clinical practice for patients with **(suspected) localized pancreatic adenocarcinoma**, including:

- (1) Non-surgical diagnostics to assess the (risk of) metastatic disease at time of diagnosis;
 - Imaging (contrast-enhanced CT, MRI, PET);
 - Serum tumor markers (e.g., CA19.9, CEA, CA125, ctDNA, other tumor markers);
- (2) Current use of staging laparoscopy (e.g., all patients, never, selected patients);

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- (3) Indications for staging laparoscopy;
 - Upfront surgery, preoperative therapy, both populations;
 - Disease specific characteristics (e.g., tumor size, location, resectability; tumor markers).
- (4) Timing of staging laparoscopy;
 - In patients treated with preoperative therapy;
 - Prior to preoperative chemo(radio)therapy / after preoperative chemotherapy but prior to radiotherapy / prior to surgical exploration and during (/not during) the same surgical session;
 - In patients treated with upfront surgery;
 - During the same surgical session (yes/no).
- (5) Procedural details about staging laparoscopy;
 - Inspected intra-abdominal areas (e.g., liver, omentum, abdominal wall, extra-regional and regional lymph stations [2014 ISGPS definition],¹ vascular tumor involvement);
 - Concomitant procedures (e.g., cytological lavage [including analyzed parameters], intra-abdominal ultrasonography, indocyanine green fluorescence, including its indications).

Data collection

The survey is created with and submitted via Google Forms. In order to comply with the General Data Protection Regulation, the survey invitation will be sent to the coordinators of the participating international pancreatic associations, who then will forward to their members.

Plan for analyses

To calculate the response rate, each association's coordinator will be asked the number of surgeons that received and submitted the survey.

The survey outcomes will be descriptively presented. Differences in clinical practices among different continents and hospital volumes will be analyzed, using comparative statistical tests or sensitivity analyses.

POLICY SECURING

To correct for multiple surgeons from the same center answering the survey, surgeons will be asked to register their center. Importantly, no center-specific data will be published.

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AUTHORSHIPS

Authorships will be based on the recommendations from the international committee of medical journal editors (ICMJE). The first author will be the coordinator of this project (TFS), followed by KRDL and RTT as shared first and second author, respectively, followed by PL as third author. The other members of the project group are AO, TH, CLW, MHGK, CHJvE, BGK, PG, MAH, JYJ, MJT, MDC, and MGB.

One authorship will be available per collaborative study group/association who will accept the invitation and subsequently spread the survey among his/her members. This author should fulfill the ICMJE authorship regulations, meaning that this person should assess and comment on the study protocol with intellectual input and agree on the final manuscript. These authorships will be registered in the list of authors in alphabetic order.

ETHICAL PERMISSION

Ethical approval for this study will be requested at the Amsterdam UMC medical ethical committee.

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APPENDIX 1. SURVEY

INSTRUCTIONS

The questions in this survey apply to your current medical practice.

This survey focuses on patients diagnosed with localized pancreatic ductal adenocarcinoma (hereafter: pancreatic cancer), defined as the suspicion of a pancreatic cancer on cross-sectional radiological imaging (eventually pathology-proven) without any signs of extra-regional lymphadenopathy¹ or distant metastases on imaging.

Staging laparoscopy is defined as a laparoscopic procedure aimed at detecting occult metastases. This may include a diagnostic intraoperative ultrasound. Some synonyms have been used in the literature as 'diagnostic laparoscopy', for simplicity we have used 'staging laparoscopy' consistently.

Staging laparoscopy prior to surgical exploration can be performed either in the same procedure (i.e., at the start) of exploratory laparotomy with the intent to resect but also earlier as a standalone procedure in the diagnostic process.

To prevent confusion and issues with terminology, laparoscopy with intention for minimally invasive resection are NOT considered as *staging* laparoscopy.

Section 1. General information

1. Are you a surgeon?
 - Yes
 - No → end of survey
2. Have you performed oncological pancreatic surgery in the last 12 months?
 - Yes
 - No → end of survey
3. What describes the scope of your current expertise best?
 - Hepato-Pancreato-Biliary surgery
 - Pancreatic surgery
 - Liver surgery
 - Surgical oncology
 - Gastrointestinal surgery
 - General surgery
4. What (kind of) fellowship training have you followed during your training (multiple options possible)?
 - None
 - Surgical oncology
 - Hepato-Pancreato-Biliary surgery
 - Transplantation surgery

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5. How many years have you been in practice since the completion of your surgical training?

- ...

6. What is your current age?

- ...

7. In which country do you work?

- ...

8. In what type of medical center do you work?

- Academic center
- Teaching center
- Community center
- Private practice
- Other

9. Please register the center where you are currently working.*

- ...

**These data will not be published, but just collected to avoid overlap since multiple surgeons from an individual center might complete this survey.*

10. What is the annual number of pancreatic resections performed in your center, in average over the last 5 years?

- <20
- 20-40
- 41-80
- 81-120
- >120

11. What is the annual number of pancreatic resections performed by yourself personally, in average over the last 5 years?

- <10
- 11-20
- 21-40
- 41-80
- >80

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Section 2. Diagnostics to assess the (risk of) metastatic disease in patients with (suspected) localized pancreatic adenocarcinoma

12. Which of the following diagnostic modalities do you currently ROUTINELY use (i.e., in every patient) to assess the (risk of) metastatic disease? (multiple answers possible)

- Imaging
 - Multiple-phase contrast-enhanced CT
 - Liver-specific MRI
 - PET/CT
 - PET/MRI
 - Other MRI
 - If applicable, please specify the other MRI. If not, please answer 'not applicable'.
- Serum tumor markers
 - None
 - CA-19.9
 - CEA
 - CA-125
 - DUPAN-2
 - Circulating tumor DNA
 - Other tumor marker(s)
 - If applicable, please register the other tumor marker(s). If not, please answer 'not applicable'.

13. In what percentage of patients with localized pancreatic cancer do you perform an MRI liver to exclude liver metastases?

- 0%
- <10%
- 10-50%
- 51-95%
- >95%

Section 3. Current use of staging laparoscopy in patients diagnosed with (suspected) localized pancreatic cancer

14. In your personal view what is the minimum rate patients detected with occult metastases during routine staging laparoscopy that you would find acceptable to justify the staging laparoscopy as a routine procedure? (i.e., minimal clinically relevant yield)

- 0-9%
- 10-20%
- 21-30%
- 31-50%
- >50%

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15. In your personal experience, what is the rate of occult metastases during surgery for localized pancreatic cancer (all stages combined) in your center, regardless of the timing of the staging laparoscopy?

- ☐ <5%
- ☐ 6-10%
- ☐ 11-15%
- ☐ >15%
- ☐ Not applicable as we do not perform any staging laparoscopy at any stage.

16. Do you personally feel that future clinical practice guidelines should advise routine staging laparoscopy in all patients with localized pancreatic cancer (all stages combined)?

- ☐ Yes
- ☐ No
- ☐ Don't know

16.1. If yes, what do you consider the best timing for a staging laparoscopy in patients who receive neoadjuvant / induction therapy?

- ☐ Prior to neoadjuvant / induction therapy
- ☐ Only prior to surgery
- ☐ Both prior to neoadjuvant / induction therapy and prior to surgery

17. Is there a protocol for performing staging laparoscopy at any stage in specific patients diagnosed with localized pancreatic cancer in your center (note: this may include only one subgroup of patients with non-metastatic pancreatic cancer)?

- ☐ Yes
- ☐ No

17.1. If yes, is this protocol consistently used by all surgeons performing pancreatic surgery in your unit?

- ☐ Yes
- ☐ No
- ☐ Don't know

18. In patients diagnosed with localized pancreatic cancer who are planning to start with neoadjuvant/induction chemo(radio)therapy, will you perform a staging laparoscopy before starting with chemotherapy?

- ☐ No, never
- ☐ Yes, in all patients
- ☐ Yes, in selected patients based on specific criteria

19. In patients diagnosed with localized pancreatic cancer who already received neoadjuvant/induction chemotherapy, will you perform a staging laparoscopy before starting with subsequent radiotherapy?

- ☐ No, never
- ☐ Yes, in all patients
- ☐ Yes, in selected patients based on specific criteria

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- Not applicable since none of my patients are treated with radiotherapy as neoadjuvant/induction therapy

20. In patients diagnosed with localized pancreatic cancer who received neoadjuvant/induction chemo(radio)therapy and already underwent a staging laparoscopy before starting neoadjuvant/induction therapy where no metastatic disease was found, do you perform a staging laparoscopy again **after** neoadjuvant/induction therapy?

- No, never
- Yes, in all patients, regardless of subsequent surgery with intention for resection
- Yes, in all patients who are scheduled for subsequent surgery with intention for resection
- Yes, in selected patients regardless of subsequent surgery with intention for resection, where the indication for staging laparoscopy is based on specific criteria
- Yes, in selected patients only who are scheduled for subsequent surgery with intention for resection, where the indication for staging laparoscopy is based on specific criteria

21. Do you personally perform staging laparoscopy in patients diagnosed with localized pancreatic cancer who are scheduled to undergo a surgical exploration with intention for resection (either in a separate procedure before the laparotomy OR during the same surgical session as the laparotomy)?

- No, never
- Yes, in all patients who undergo upfront surgery
- Yes, in all patients who received neoadjuvant/induction therapy
- Yes, in all patients, both in case of upfront surgery or previous neoadjuvant/induction therapy
- Yes, in selected patients who undergo upfront surgery, based on specific criteria
- Yes, in selected patients who received neoadjuvant/induction therapy, based on specific criteria
- Yes, in selected patients, based on specific criteria, both in case of upfront surgery or previous neoadjuvant/induction therapy

22. In patients diagnosed with localized pancreatic cancer who are scheduled for surgical resection, when do you perform the staging laparoscopy? **This question only appears when answering 'yes' on question 21.**

- In a separate procedure than the laparotomy
- During the same surgical session as the laparotomy (i.e., at the beginning)

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Section 3.1 Specific criteria to perform staging laparoscopy

Question 23 until 28 will only appear when the answer on question 18, 19, 20 and/or 21 is 'Yes, in selected patients based on specific criteria'. In case the participant performs a staging laparoscopy on multiple moments, specific indication(s) has/have to specified for each moment separately if applicable.

23. Which of the following factor(s) do you use as indication for staging laparoscopy? (multiple answers possible)

- Tumor size
- Tumor location
- Resectability (i.e., primary resectable, borderline resectable, locally advanced)
- Indeterminate / suspicious findings on cross-sectional imaging
- Tumor markers
 - CA-19.9
 - CEA
 - CA-125
 - DUPAN-2
 - Circulating tumor DNA
 - Other tumor marker(s)
 - Please register the name of the tumor marker(s)
- Patient's physical/conditional status

24. At what **tumor size** do you consider this to be an indication for staging laparoscopy (this question only appears when the tumor size is selected as indication for staging laparoscopy)?

- ... - ... mm
- >... mm

25. In which **tumor location** do you consider this to be an indication for staging laparoscopy (this question only appears when the tumor location is selected as indication for staging laparoscopy)? (multiple answers possible)

- Pancreatic head/neck/uncinate process
- Pancreatic body/tail

26. Which **resectability status** (according to the 2022 NCCN resectability criteria) do you consider to be an indication for staging laparoscopy (this question only appears when the resectability is selected as indication for staging laparoscopy)? (multiple answers possible)

- Primarily resectable
- Borderline resectable
- Locally advanced
- Multivisceral tumor involvement (2014 ISGPS definition)

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27. What **serum CA-19.9** cut-off do you consider an indication for diagnostic laparoscopy (this question only appears when CA-19.9 is selected as indication for staging laparoscopy)? (please fill in the field that is applicable for you) (multiple answers are possible)

- CA-19.9 > ... U/mL at time of diagnosis / prior to upfront surgery
- CA-19.9 > ... U/mL after neoadjuvant/induction therapy
- Non-elevated CA-19.9
- Insufficient CA-19.9 reduction after/during neoadjuvant/induction therapy
- Stable elevated CA-19.9 after/during neoadjuvant/induction therapy
- Increase of CA-19.9 after/during neoadjuvant/induction therapy

28. What **serum CEA** cut-off do you consider an indication for staging laparoscopy (this question only appears when CEA is selected as indication for staging laparoscopy)? (please fill in the field that is applicable for you) (multiple answers are possible)

- CEA > ... ng/mL at time of diagnosis / prior to upfront surgery
- CEA > ... ng/mL after neoadjuvant/induction therapy
- Insufficient CEA reduction after/during neoadjuvant/induction therapy
- Stable elevated CEA after/during neoadjuvant/induction therapy
- Increase of CEA after/during neoadjuvant/induction therapy

Section 4. Procedural details about staging laparoscopy

Question 29 until 32 will appear separately for question 18, 19, 20, and/or 21 when staging laparoscopy is performed for all / selected patients.

29. In your hands, how long does a staging laparoscopy usually last (time between incision and end of staging laparoscopy)

- <10 minutes
- 10-19 minutes
- 20-30 minutes
- >30 minutes

30. To what extent do you personally inspect these intra-abdominal areas during staging laparoscopy? (multiple answers possible)

- Inspection of the liver
- Inspection of the omentum
- Inspection of the abdominal wall
- Inspection of the lesser sac
- Inspection of the caudal side of the transverse mesocolon
- Inspection of extra-regional lymph nodes (\pm frozen section)
- Vascular involvement of the tumor

31. Which of the following modalities do you personally use during staging laparoscopy? (multiple answers possible)

- None
- Cytological lavage

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- Intra-abdominal ultrasonography of the liver
- Indocyanine green fluorescence
- Intra-abdominal ultrasonography to assess the tumor resectability

32. When do you use cytological lavage during staging laparoscopy (this question only appears when cytological lavage is used)?

- Always
- In selected patients

33. What biochemical analysis from cytological lavage during staging laparoscopy are performed (this question only appears when cytological lavage is used) (multiple options are possible)?

- CA-19.9
- CEA
- ctDNA
- Other(s)
 - Please register the name(s) of the other tumor marker(s)

In case of the use of cytological lavage for 'selected patients', the same indications will be asked as question 23 to 28.

34. When do you make intra-abdominal ultrasonography of the liver during staging laparoscopy (this question only appears when intra-abdominal ultrasonography of the liver is used)? (multiple answers possible)

- Always
- In selected patients

In case of the use of intra-abdominal ultrasonography of the liver for 'selected patients', the same indications will be asked as question 23 to 28.

35. Which areas are inspected with indocyanine green fluorescence during staging laparoscopy (this question only appears when indocyanine green fluorescence is used)? (multiple answers possible)

- Liver
- Omentum
- Abdominal wall
- Extra-regional lymph nodes
- Vascular involvement of the tumor

36. When do you use indocyanine green fluorescence during staging laparoscopy (this question only appears when indocyanine green fluorescence is used)? (multiple answers possible)

- Always
- In selected patients

In case of the use of indocyanine green fluorescence in 'selected patients', the same indications will be asked as question 23 to 28.

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Section 5. Staging laparoscopy within randomized trials

37. When reading a randomized trial on neoadjuvant therapy in (borderline) resectable pancreatic cancer, would you like to see that the authors performed routinely staging laparoscopy before starting with neoadjuvant therapy?

1. Yes
2. No
3. Don't know

If yes, why (multiple answers possible)

- ... because it is also my normal practice
- ... because it reduces the number of 'wrongly selected' patients
- ... because in a trial I expect the researchers to be as strict as possible

If no, why (multiple answers possible)

- ... because I also do not perform staging laparoscopy in my normal practice
- ... because it is usually not done in clinical practice and a trial should reflect clinical practice as much as possible
- ... only for randomized trials on induction therapy in patients with locally advanced pancreatic cancer

Section 6. Comments

38. Thank you for completing this survey. Please feel free to add your comments, if any: