View results

Respondent

24 Anonymous

87:33
Time to complete

1. Project Number - (Can be found on email)

IP1031/2

Your information

2. Name: *

John Leeds

3. Job title: *

Consultant Pancreaticobiliary Physician and Endoscopist

4. Organisation: *

Newcastle Upon Tyne Hospitals NHS Foundation Trust

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Society of Gastroenterology

7. Nominated/ratified by (if applicable):

Dr Joe Geraght

8. Registration number (e.g. GMC, NMC, HCPC) *

4545136

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

I am very familiar with this procedure and use of the technology. I have been using this since 2012 and have the most extensive clinical experience in the UK. I have also published several papers on its usage.

11. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

This procedure is not widely deployed mainly as the NICE guidance states that it is not currently for routine use in clinical practice and should only be used as part of a registry or research. This technology could be incorporated into routine clinical practice as it requires little training to bolt on for current practitioners. This technology is used by any specialist that can perform ERCP which includes gastroenterologists, surgeons and radiologists. It is also used percutaneously but interventional radiologists but this is outside the remit of this guidance.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [x] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) It needs to define the difference between primary and secondary endobiliary RFA

14. Is the proposed indication appropriate? If not, please explain

Yes but again needs defining as to as which point it is applied.

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel approach although other countries are routinely using it despite the evidence for this not being completely there.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This technology is generally a bolt on to current standard of care.

Current management

18. Please describe the current standard of care that is used in the NHS.

For primary RFA candidates, the standard of care is endoscopic stent insertion to allow primary palliation of jaundice in patients with newly diagnosed malignant biliary obstruction. For secondary RFA candidates, the standard of care is endoscopic clearance of the obstructed stent and often stent insertion to allow biliary drainage in patients with an existing stent in place.

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

There are currently 2 probes that are marketed for this purpose. Other possible technologies include brachytherapy (internal radiation) and photodynamic therapy. Both of these are difficult to perform routinely and photodynamic therapy had negative trials meaning this is now not an option.

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

Our review has shown that in primary RFA there is a significant improvement in survival compared to patients that have stent alone however there was no information concerning quality of life. There was no difference in some of the adverse event rates other than cholecystitis but this needs more data.

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Currently patients with malignant biliary obstruction undergoing ERCP. More information would be needed to determine whether it truly benefits those with occluded stents.

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    There is potential for this procedure to improve survival in selected groups and may reduce the need for readmission and reintervention however this has not yet been shown.

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    A facility that can deliver ERCP (most hospitals in the UK) can deliver endobiliary RFA. The additional technology requires a specific catheter to deliver and one of the companies that makes a catheter also has a specific generator whereas the other plugs into existing equipment in most endoscopy rooms.

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Yes but this is minimal. Most competent ERCP practitioners could be shown how to perform this additional procedure over a small number of cases.

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    This is currently not well reported in most studies that have been performed. For primary RFA, our review showed that the rates of bleeding, perforation, pancreatitis and cholangitis are not different to standard care but there was a significant increase in the rate of cholecystitis which needs more investigation. There was not sufficient data on secondary RFA to make any assessment at all.

26. Please list the key efficacy outcomes for this procedure/technology?

    Survival, quality of life, adverse event rates, technical success rate, cost effectiveness, readmission rate, reintervention rate, combined effect with other treatments eg chemotherapy.

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    For primary RFA, the only current efficacy is survival although a recent study has not confirmed this. There is minimal data on adverse event rates, technical success rates and cost effectiveness. The other outcomes have not been well enough reported.
    For secondary RFA, technical success rate appears good but none of the other efficacy outcomes have been sufficiently studied.

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Huge uncertainty about the effect of the technology in standard practice. Most are using this for secondary RFA despite this being the area with the least evidence.

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

1. Tarar ZI, Farooq U, Gandhi M, Ghous G, Saleem S, Kamal F, Imam Z, Jamil L. Effect of radiofrequency ablation in addition to biliary stent on overall survival and stent patency in malignant biliary obstruction: an updated systematic review and meta-analysis. Eur J Gastroenterol Hepatol. 2023 Jun 1;35(6):646-653. doi: 10.1097/MEG.0000000000002568. Epub 2023 Apr 25. PMID: 37129575.
2. Beyer F, Rice S, Orozco-Leal G, Still M, O'Keefe H, O'Connor N, Stoniute A, Craig D, Pereira S, Carr L, Leeds J. Clinical and cost effectiveness of endoscopic bipolar radiofrequency ablation for the treatment of malignant biliary obstruction: a systematic review. Health Technol Assess. 2023 May;27(7):1-118. doi: 10.3310/YYMN9802. PMID: 37212444.
3. Awadelkarim B, Long M, Wong T, Geraghty J, Oppong K, Nayar M, Leeds JS. P175 Bipolar endoscopic radiofrequency ablation for the management of occluded metal stents due to tumour ingrowth. Gut 2022;71:A125-A126.
4. Nayar MK, Oppong KW, Bekkali NLH, Leeds JS. Novel temperature-controlled RFA probe for treatment of blocked metal biliary stents in patients with pancreaticobiliary cancers: initial experience. Endosc Int Open. 2018 May;6(5):E513-E517. doi: 10.1055/s-0044-102097. Epub 2018 Apr 18. PMID: 29713676; PMCID: PMC5906122.
5. Dutta AK, Basavaraju U, Sales L, Leeds JS. Radiofrequency ablation for management of malignant biliary obstruction: a single-center experience and review of the literature. Expert Rev Gastroenterol Hepatol. 2017 Aug;11(8):779-784. doi: 10.1080/17474124.2017.1314784. Epub 2017 Apr 7. PMID: 28362129.
6. OP117 Endobiliary Radiofrequency Ablation and Biliary SEMS versus Biliary SEMS alone for unresectable malignant hilar biliary stricture – A comparative study. N. Jagtap 1 , S. Lakhtakia 1 , C. Saikumar 1 , S. Asif 1 , M. Ramchandani 1 , R. Kalapala 1 , J. Basha 1 , M. Tandan 1 , Z. Nabi 1 , R. Gupta 1 , G. V. Rao 1 , D. N. Reddy 1 DOI 10.1055/s-0043-1765121.
7. P244 Lack of effect of endoluminal radiofrequency ablation on survival and stent patency in patients with cholangiocarcinoma and pancreatic cancer: randomised controlled trial. J. Jarosova 1 , L. Zarivjanova 2 , I. Cibulkova 3 , J. Mares 1 , P. Macinga 1 , A. Hujova 1 , O. Urban 2 , J. Hajer 3 , J. Spicak 1 , T. Hucl 1 DOI 10.1055/s-0043-1765248.
8. eP174 Endobiliary radiofrequency ablation for malignant biliary obstruction due to perhilar cholangiocarcinoma (RACCOON-p): a prospective pilot study. J. A. Fritzsche 1 , 2 , 3 , M. C. Wielenga 1 , 2 , 3 , O. Van Delden 4 , 2 , 3 , J. I. Erdmann 5 , 3 , H. J. Klümpen 6 , 3 , , L J van Wanrooij 7 , 3 , P. Fockens 1 , 7 , 2 , 3 , C. Y. Ponsioen 1 , 2 , R. P. Voermans 1 , 2 , 3. DOI 10.1055/s-0043-1765459.

31. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Clinicaltrials.gov

32. Please list any other data (published and/or unpublished) that you would like to share.

The biggest problem with the current literature is the combination of endoscopic RFA with percutaneous and this has major metholodogical issues. Outcomes from percutaneous approaches are worse than endoscopic and the cancer types behave differently so cannot be simply extrapolated from each other.

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

UK performs about 40 - 50,000 ERCP's per year and of these about 20% are for malignant obstruction so upto 10,000 patients per year if only one treatment is needed.

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Indication, technical success rate, clinical success rate, adverse event rate, effect upon quality of life, patient related outcome and experience measures.

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

bleeding, perforation, pancreatitis, cholangitis, cholecystitis, readmission rate, reintervention rate, mortality rate. 7 days, 30 days, 6 months and 1 year.

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Please see the recommendations from our HTA review which shows the current gaps in the knowledge and potential for further research

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [x] Indirect
- [ ] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

I have used both of the current probes and in the past (>12 months) have received honoraria for talks given about endobiliary RFA.

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

40. Name: *

John Leeds

41. Date: *

05/06/2023

View results

Respondent

57 Anonymous

16:03
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1031/3 Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer

Your information

2. Name: *

Simon Everett

3. Job title: *

Consultant Gastroenterologist

4. Organisation: *

Leeds Teaching Hospitals NHS Trust

5. Email address: *

6. Professional organisation or society membership/affiliation: *

FRCP, member BSG and ESGE

7. Nominated/ratified by (if applicable):

BSG Endoscopy committee

8. Registration number (e.g. GMC, NMC, HCPC) *

3591497

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am very familiar with ERCP having practiced for > 20 years.
I am familiar with RFA but have not used it in ERCP due to it not yet being approved

11. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

RFA is used widely in other areas of gastroenterology practice, particularly Barrett's oesophagus. It is used less frequently to ablate lesions under EUS guidance and I have seen this application a few times. It is also used in a few centres in ERCP for tumour ablation but not in my centre.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is an extended practice indication. Current standard of care is biliary stenting. From a technical/procedural standpoint RFA would be a straightforward extension of ERCP practice. As the technology is in use elsewhere the innovation is in whether it would have efficacy in improving biliary stenting.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

It would be in addition to biliary stenting. It is unlikely to replace it.

Current management

18. Please describe the current standard of care that is used in the NHS.

Biliary stenting at ERCP

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    No

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

    If efficacious this would extend the duration of successful biliary stenting, which will improve quality and duration of life in patients with malignant biliary obstruction.

    There is also a subset of patients with benign disease treated with biliary stenting in whom the stent becomes embedded. RFA may have a role in releasing such embedded stents.

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    Primarily patients with malignant biliary obstruction requiring stenting. This will most likely be patients whose obstruction is in the proximal biliary tree (liver hilum or intrahepatic biliary tree)

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes, if efficacious it would reduce hospital attendances with blocked biliary stents requiring repeat intervention.

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Standard ERCP set up. Will need RFA power unit.

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Training required in setting the power but otherwise this would be standard ERCP skill set.

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Risks are likely to be very limited aside from an unnecessary and costly procedure.

26. Please list the key efficacy outcomes for this procedure/technology?

duration of stent patency

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

The main issue is lack of proof of efficacy

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Not that I am aware of

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

None relevant

31. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Not that I am aware of

32. Please list any other data (published and/or unpublished) that you would like to share.

NA

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Unknown

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Stent patency and reintervention rates
Hospital attendances
Patient QOL
Overall survival

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Bleeding
Perforation
Restenosis

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

NA

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

40. Name: *

Simon Everett

41. Date: *

16/01/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1031/3 Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer**

Your information

Name:	Nagy Habib
Job title:	Professor of Hepatobiliary Surgery
Organisation:	Imperial College London
Email address:	
Professional organisation or society membership/affiliation:	Royal College of Surgeons of Edinburgh
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	2814849

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been an Hepatopancreatobiliary surgeon for 40 years and undertake complex liver, pancreas and biliary surgery. I was the inventor of the device via an Imperial College London Start Up Company, EMcision Limited. This company was created to develop medical/surgical devices using radiofrequency energy to ablate tumours in patients with liver, biliary and pancreas cancer.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own?	This device is used principally by endoscopists, so I have not personally used the device. It was used successfully by the Endoscopy team at Imperial College Healthcare NHS Trust who also carried out the first clinical trial (*Steele AW et al GIE 2011; Kallis Y et al Dig Dis Sci 2015*)

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. Other (please comment)
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes The technique and the original device were invented in 2012. At that time, it was a novel procedure to relieve and palliate biliary obstruction caused by pancreatic or other cancer. Since then it has been used around the world and in particular the USA. It won an Edison Gold award for Medical Innovation in March 2020 and is the first radiofrequency device indicated in the USA for malignant or benign tissue ablation in the pancreatic and biliary tract. Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or	Addition to existing SoC

	would it be used as an addition to existing standard care?	
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The endobiliary RF device was acquired by Boston Scientific in 2018 and is manufactured and marketed by them. No modifications were made. The original procedure remains unchanged as far as I know. No.

Current management

6	Please describe the current standard of care that is used in the NHS.	Endoscopic placement of a self-expanding biliary stent to relieve and obstruction for pancreatic and other cancer
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	I do not know of any other device.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Increases the time interval between stent interventions for malignant obstructions in the biliary and pancreatic ducts and also destroys the tumour. Application of radiofrequency ablation in solid tumours suggests that the RFA may have beneficial effects beyond the simple local ablation of tumour tissue. Some evidence suggests that RFA may play a role by inducing indirect anti-tumoral effects [*Hansler J et al 2006*]. Several potential mechanisms are postulated, including the induction of anti-tumoral T cell responses via the release of tumour antigen secondary to RFA-induced tissue necrosis or via the stimulation of local inflammatory responses [*den Brok MH 2004*]. Endobiliary RFA induces the coagulative necrosis of tissue within the biliary stricture where it is deployed [*Itoi T et al 2012*]. It is possible that similar mediators and pathways may account for the differences in survival noted in our analysis, though this is pure speculation as our retrospective study was not intended or designed to address this. Treatment options for patients with advanced pancreatic cancer are limited, with palliative chemotherapy providing only modest survival advantage and radiotherapy having limited effect. There are limited data on other endoscopic therapeutic biliary interventions. Prospective studies on the use of photodynamic therapy (PDT) in unresectable hilar cholangiocarcinoma suggest improvements both in biliary drainage and in patient survival [*Ortner ME, et al 2003*]. 5 year survival in a patient with advanced pancreatic cancer following radiofrequency ablation of pancreatic tumour has been recently reported from the USA: hiips://www.click2houston.com/news/local/2023/02/24/houston -doctor-discovers-way-to-treat-pancreatic-cancer-during-clinical-trial/ Treatment with the EndoHPB can lead to longer duration of stent patency, shorter hospital admission and better quality of life [*Kong Y-L et al Surg Endosc 2022*] Bokemeyer A et al published in Sci Rep 2019 a case control study of endoscopic radiofrequency ablation which showed prolonged survival of patients with unresectable hilar cholangiocellular carcinoma. In patients with advanced cholangiocarcinoma a meta-analysis report of endobiliary treatment options showed increased survival in patients receiving endoscopic RFA (*Rebhun J et al. World Journal of Gastrointestinal Endoscopy 2023*).

9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with pancreatic cancer and cholangiocarcinoma complicated by biliary obstruction
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Endobiliary RF has the potential to improve the pathway for patients with pancreatic cancer and biliary obstruction by improving outcomes in this group of patients. It will reduce the need for repeated visits and hospital stays with infected and blocked stents.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Endoscopy Suite RF probe and a RFA generator No changes required at the facility.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training to use the device and the RFA generator. This is a simple procedure requiring very little training.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature)	If the device is not used as specified in the manufacturer IFU then thermal damage could be caused to adjacent organs. Potential bleeding and bile duct perforation could occur, but I am not aware that it ever happens when the device applied as recommended.

	Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Patent biliary duct which allows free drainage of bile and prevents stasis and consequent infection – better quality of life with potential prolongation of survival if combined with treatment with checkpoint inhibitor an chemotherapy.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not as far as I know
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. NB: Endoscopy Suite required

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	

	us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I do not know
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	In the UK around 8,800 people are diagnosed with and 8,700 people die from pancreatic cancer each year. Most of these cases could be eligible for RF at the time of stent placement (29 patients each day are diagnosed in the UK)
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Endoscopic biliary RF ablation may provide prolonged stent patency. One study has shown prolonged metallic biliary stent patency by an average of 13% (from 8.4 months to 9.5 months) in patients with unresectable extrahepatic cholangiocarcinoma. Treatment with the EndoHPB can lead to longer duration of stent patency, shorter hospital admission and better quality of life [*Kong Y-L et al Surg Endosc 2022*] Bokemeyer A et al published in *Sci Rep 2019* a case control study of endoscopic radiofrequency ablation which showed prolonged survival of patients with unresectable hilar cholangiocellular carcinoma. In patients with advanced cholangiocarcinoma a meta-analysis report of endobiliary treatment options showed increased survival in patients receiving endoscopic RFA (*Rebhun J et al. World Journal of Gastrointestinal Endoscopy 2023*).

		Adverse outcome measures: Thermal injury to adjacent organs if the IFU is not followed Bleeding Perforation.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**NAGY HABIB**
Dated:	**07June2023**