Introduction

Endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) works by placing an RFA probe, inserted through an EUS needle, under EUS color Doppler guidance, into a target pancreatic lesion, delivering various energy outputs directly related to the size of the lesion for a variable amount of time or until an
electrical impedance of >500 Ohms is detected, suggesting that coagulative necrosis has occurred within the lesion [1]. This is confirmed by postoperative imaging with a computed tomography (CT) scan.

Unfortunately, given current National Comprehensive Cancer Network (CCN) guidelines, approximately 80% of patients with pancreatic ductal adenocarcinoma (PDAC) will have disease deemed unresectable at the time of diagnosis. [2] This creates a potential opportunity for EUS-RFA to provide a palliative option in their treatment plan. In cases of unresectable or locally advanced PDAC, EUS-RFA is a developing option with the potential to reduce or downstage the tumor burden. EUS-RFA is potentially a valuable tool for reducing tumor size by inducting coagulative necrosis from direct thermal destruction and/or triggering immunostimulation and antitumor antigens [3, 4].

Use of EUS-RFA in the pancreas also extends to treatment and ablation of small pancreatic neuroendocrine tumors (PNETs), pancreatic cystic neoplasms (PCN) which include mucinous pancreatic cystic neoplasms (MCN), and intraductal papillary mucinous neoplasms (IPMN) and other pancreatic tumors measuring <3 cm [1].

To date, several studies have evaluated use of EUS-RFA in the pancreas. The primary end point of this systematic review and meta-analysis is to evaluate technical and clinical success of EUS-RFA in locally advanced PDAC and other pancreatic tumors. Secondary endpoints were to recognize and study both early and late adverse events (AEs), given the thermosensitivity of pancreatic tissue.

Methods

Search strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, MEDLINE, Google-Scholar, Cochrane, LILACS, SCOPUS, and Web of Science databases (earliest inception to May 2019). We followed the preferred reporting systems for systematic reviews and meta-Analyses (PRISMA) guidelines to identify studies reporting on EUS RFA in pancreatic tumors [5]. An experienced medical librarian, using inputs from the study authors, helped with the literature search.

Key words used in the literature search included a combination of ‘EUS,’ ‘Endoscopic, and ‘Ultrasound’, ‘radiofrequency, ablation’, ‘tumor and pancreatic. The search was restricted to studies in human subjects and published in English language in peer-reviewed journals. Two authors (BD, JC) independently reviewed the titles and abstracts of studies identified in the primary search and excluded studies that did not address the research question, based on prespecified exclusion and inclusion criteria. The full text of remaining articles was reviewed to determine whether they contained relevant information. Any discrepancies in article selection were resolved by consensus, and in discussion between the co-authors.

The bibliographic section of the selected articles, as well as the systematic and narrative articles on the topic were manually searched for additional relevant articles.

Study selection

We included studies that evaluated the efficacy of and AEs associated with EUS-RFA in pancreatic tumors. Studies were included as long as they provided data needed for the analysis. Exclusion criteria were as follows: (1) studies using EUS-RFA in tumors other than pancreas, (2) studies performed in the pediatric population (Age <18 years), and (3) studies not published in the English language.

In cases of multiple publications from the same cohort and/or overlapping cohorts, data from the most recent and/or most appropriate comprehensive report were included.

Data abstraction and quality assessment

Data on study-related outcomes in the individual studies were abstracted onto a standardized form by at least three authors (BD, AD, JC), and two authors (BD, AD) performed the quality scoring independently.

The data collection was performed as number of reported events (n) out of the total number of patients (N) from each study. The collected data was treated akin to single group cohort studies and therefore we used the Newcastle-Ottawa scale for cohort and case-control studies to assess the quality of studies [6]. This quality score consisted of 8 questions, the details of which are provided in Table 1.

EUS-RFA technique

EUS-RFA is a procedure that requires a unipolar probe deployed under ultrasound guidance to the center of the tumor. A generator is activated to release a certain wattage for a set amount of time that varies and specific to each RFA model. The probe is
then rotated, and the process is repeated from one to four times. An internal cooling system is sequentially employed to prevent thermogenic damage to surrounding tissue. Post-operative computed tomography (CT) scans were performed to compare the change in size of the enhanced tissue of the tumor to a pre-operative CT, as well as to assess for any complications [3].

**EUS-RFA needles and catheters**

Two types of RFA probes were used in our meta-analysis. A STARmed needle of different sizes (18G/19G/22G) was most commonly used to deliver RFA energy [3, 4, 7–12]. This operative needle is associated with a pump cooling the needle with help of chilled saline which prevents charring of the tip and improves accuracy of ablation.

The rest of the studies used the Habib catheter for delivery of RFA energy [13–16]. This is a monopolar electrode without a cooling system which is inserted inside a standard EUS FNA needle and attached to an electrosurgical generator [17]. The different RFA needles/catheters and ablative energy settings used in our study population are listed in Table 2.

**Outcomes assessed**

**Primary outcome**

Technical success and clinical success of EUS-RFA in pancreatic tumors

**Table 2.** EUS-RFA Needle/catheter with RFA energy used in different studies.

| Author          | Catheter/Needle used | RFA Energy |
|-----------------|----------------------|------------|
| Oleinikov [11]  | STARmed 19 G         | 50 W       |
| Barthet [1]     | STARmed 18 G         | 50 W       |
| Scopelliti [3]  | STARmed 18 G         | Lesions > 3 cm – 30 W and Lesions < 3 cm-20 W |
| Crino [9]       | STARmed 18 G         | 30 W       |
| De la Serna [8] | STARmed 18 G and 19 G| 50 W       |
| Choi [7]        | STARmed 18G and 19 G | 50 W       |
| Thosani [12]    | STARmed 19 G and 22 G| –          |
| Goyal [13]      | Habib catheter (1Fr)/22 G | 10 W       |
| Malikowski [14] | Habib catheter       | 10 W       |
| Wang [16]       | Habib catheter/22 G | 10W-15 W   |
| Song [4]        | STARmed 18 G         | 20W-50 W   |
| Lakhtakia [10]  | STARmed 19 G         | 50 W       |
| Pai [15]        | Habib catheter (1Fr)/19 and 22 G | 5 – 25 W |

**Secondary outcomes**

1. Total AEs
2. Analysis of individual AEs

**Definitions**

Technical success was defined as the successful placement of the needle within the pancreatic lesions with safe margins from the surrounding vital structures to avoid potential thermal injuries and application of radiofrequency ablation based on impedance.

Clinical success was defined as decrease in lesion size and presence of hypodense area (necrosis) on CT scan after the procedure in case of unresectable locally advanced pancreatic adenocarcinoma, metastatic pancreatic lesions, and other benign pancreatic tumors. In case of PNETs, it was defined as improvement in symptoms along with decrease in lesion size and presence of hypodense area on CT scan.

Overall, locally advanced unresectable pancreatic carcinoma was defined in two studies as per 2016 NCCN guidelines: in cases of tumor contact greater than 180° with major arteries such as the celiac trunk (CT), the superior mesenteric artery (SMA) and the first jejunal branch, involvement of the aorta, unreconstructable involvement of vessels such as the hepatic artery (HA), the superior mesenteric vein (SMV), and the portal vein (PV), and contact with the most proximal draining jejunal branch into SMV and SMV or PV occlusion (due to the tumor or bland thrombus).

AEs were divided into early (<7 days) and late (>7 days to 3 months). In the early group, subgroup analysis was then done to calculate the pooled rates of individual AEs.

**Statistical analysis**

We used meta-analysis techniques to calculate the pooled estimates for each outcome following the methods suggested by DerSimonian and Laird using the random-effects model [18]. When incidence of an outcome was zero in a study, a continuity correction of 0.5 was added to the number of incident cases before the study was entered into the statistical model [19]. We assessed heterogeneity between study-specific estimates by using Cochran Q statistical test for heterogeneity, and the I² statistics. [20, 21] In this, values < 30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively [22].

All analyses were performed using Comprehensive Meta-Analysis (CMA) software, version 3 (BioStat, Englewood, New Jersey, United States).

**Results**

**Search results and population characteristics**

From an initial pool of 84 studies, 13 studies reported use of EUS-RFA in pancreatic lesions [1,3,4,7–16]. The schematic diagram of study selection as per PRISMA guidelines is illustrated in Fig. 1.

Mean age was 61.42 (range 45–69) years with a predominantly male population. The “mean” median lesion was 27.21 mm (range 9–49.2). Mean follow-up post-procedure
was 6.5 months (range 1 – 12). Four studies used Habib catheters and nine studies used STARmed needles. Patient demographics are described in Table 3.

Characteristics and quality of included studies

Twelve studies were prospective and one study was retrospective. Three studies were multicenter and the rest were single center. No studies were population based. All studies reported adequately on the technical success, adverse events, assessment, and factors were comparable between the study groups. Ten of 13 studies reported on location of pancreatic tumor and clinical success. Overall, five studies were considered of high quality, six were of medium quality and two were low-quality studies. A detailed assessment of study quality is given in Table 1.

Meta-analysis outcomes

A total of 134 patients were included in the analysis and 165 EUS-RFA procedures were performed on these patients. Of 134 patients, 27.94% (38) had unresectable locally advanced PDAC, 40% (53) had metastasis to the pancreas and 30% (41) had other lesions which included IPMNs, mucinous cysts, solid pseudopapillary neoplasm, and microcystic adenomas. The most common location was the head (51.6%) followed by the body of the pancreas (39.5%).

The primary outcomes of the study were technical and clinical success of EUS-RFA. The pooled technical success rate calculated out of the total number of procedures was 100% (95% CI [99.18 – 100], I² = 0%). The pooled clinical success rate calculated out of the total number of patients was 91.58% (95% CI [82.5 – 98.08], I² = 21.5%) (Fig. 2, Fig. 3).

The secondary outcome was to assess AEs associated with EUS-RFA. The pooled overall AEs were 14.67% (95% CI [4.77 – 27.46], I² = 56.19%) (Fig. 4). In individual AE analysis, abdominal pain was the most common side effect 9.82% (95% CI [3.34 – 18.24], I² = 23.76%). No bleeding was noted, and post-procedure pancreatitis was noted in two patients. Perforation and procedure-related infections were noted in one patient each (Table 4).

Delayed AEs (> 7 days) were reported in two studies including three patients [1, 11]. In the Oleinokov study, two patients developed mild pancreatitis between 7 and 10 days post-procedure, which resolved on the second or third day of the hospitalization. In the Barthet study, one patient developed stenosis of the main pancreatic duct 1 week after the procedure and underwent pancreatic duct stenting.

Validation of meta-analysis results

Sensitivity analysis

To assess whether any one study had a dominant effect on the meta-analysis, we excluded one study at a time and analyzed its effect on the main summary estimate. On this analysis, no single study significantly affected the outcome or the heterogeneity.

Heterogeneity

We assessed dispersion of the calculated rates using I² percentage values. The I² tells us what proportion of the dispersion is true versus chance [19]. The pooled rates of technical success and clinical success showed low heterogeneity and pooled overall early AE rates showed moderate heterogeneity.

Publication bias

Publication bias was difficult to estimate properly as we were evaluating one-arm studies with dichotomous outcomes and most of the studies were fairly small.

Discussion

The primary measured outcomes of the studies included in this meta-analysis were the technical and clinical success of EUS-RFA in treating pancreatic lesions, both malignant and potentially malignant. The pooled technical success rate was 100% (95% CI [99.18 – 100], I² = 0%) for all types of pancreatic lesions. In the 13 studies we examined, 12 studies reached 100% technical success, including Barthet et al who examined the highest number of lesions at 31. The remaining one study had technical success of 94%. Scopelliti et al, who had a 100% technical success rate, pointed out logistical and anatomical limitations such as scarring from previous radiation or inability to maneuver the stiff probe to the target site [3].

The pooled clinical success rate was 91.58% (95% CI [82.5 – 98.08], I² = 21.5%). Given the wide range of pancreatic lesions being treated, the success rate was defined as decrease in tu-
Table 3: Description of 13 studies used in the final analysis.

| Author          | Study year | Study type | No. of patients | Mean age | Males | Females | No. of procedures | Indication                  | Technical success | Clinical success |
|-----------------|------------|------------|-----------------|----------|-------|---------|-------------------|---------------------|------------------|-----------------|
| Oleinikov [11]  | 2019       | prospective | 18              | 60.4     | 10    | 8       | 18                | Advanced pancreatic cancer | 0           | 18             |
| Barthet [1]     | 2018       | prospective | 29              | 62.4     | 14    | 15      | 31                | Neuroendocrine          | 0           | 14             |
| Scopelliti [3]  | 2018       | prospective | 10              | 62       | 7     | 3       | 10                | Metastatic to pancreas    | 10          | 0              |
| Crino [9]       | 2018       | prospective | 8               | 67       | 8     | 0       | 8                 | Other                | 7            | 0              |
| De la Serna [8] | 2018       | prospective | 9               | 69       | 9     | 0       | 14                | Advanced pancreatic cancer | 0           | 3              |
| Choi [7]        | 2018       | prospective | 10              | 51.4     | 4     | 6       | 16                | Neuroendocrine           | 0           | 8              |
| Thosani [12]    | 2018       | retrospective | 21              | 62       | 13    | 8       | 34                | Metastatic to pancreas    | 1           | 3              |
| Goyal [13]      | 2017       | prospective | 5               | 63.6     | 4     | 1       | 5                 | Other                | 2            | 1              |
| Malikowski [14] | 2017       | prospective | 4               | 66       | –     | –       | 4                 | Other                | 0            | 1              |
| Wang [16]       | 2016       | prospective | 3               | 62.7     | –     | –       | 5                 | Other                | 3            | 0              |
| Song [4]        | 2016       | prospective | 6               | 62       | 1     | 5       | 8                 | Other                | 6            | 0              |
| Lakhtakia [10]  | 2016       | prospective | 3               | 45       | 3     | 0       | 3                 | Other                | 3            | 0              |
| Pai [15]        | 2015       | prospective | 8               | 65       | 1     | 7       | 9                 | Other                | 2            | 0              |

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| Study                  | ES (95% CI)            | % Weight | Technical success (out of no. of procedures) | Number of procedures |
|------------------------|------------------------|----------|----------------------------------------------|----------------------|
| Wang (2016)            | 100.00 (56.55, 100.00) | 3.21     | 5                                             | 5                    |
| Song (2016)            | 100.00 (67.56, 100.00) | 4.96     | 8                                             | 8                    |
| Scopelleti (2018)      | 100.00 (72.25, 100.00) | 6.12     | 10                                            | 10                   |
| Crino (2018)           | 100.00 (67.56, 100.00) | 4.96     | 8                                             | 8                    |
| Lakhtakia (2016)       | 100.00 (43.85, 100.00) | 2.04     | 3                                             | 3                    |
| Oleinokov (2019)       | 94.44 (74.24, 99.01)   | 10.79    | 17                                            | 18                   |
| Pai (2015)             | 100.00 (70.09, 100.00) | 5.54     | 9                                             | 9                    |
| De la Serna (2018)     | 100.00 (78.47, 100.00) | 8.45     | 14                                            | 14                   |
| Goyal (2017)           | 100.00 (56.55, 100.00) | 3.21     | 5                                             | 5                    |
| Choi (2018)            | 100.00 (80.64, 100.00) | 9.62     | 16                                            | 16                   |
| Thosani (2018)         | 100.00 (89.85, 100.00) | 20.12    | 34                                            | 34                   |
| Malikowski (2017)      | 100.00 (51.01, 100.00) | 2.62     | 4                                             | 4                    |
| Barthet (2018)         | 100.00 (88.97, 100.00) | 18.37    | 31                                            | 31                   |

Overall (I²= 0.00%, P=1.00) 100.00 (99.18, 100.00) 100.00

**Fig. 2** Overall pooled technical success rate of EUS-RFA in pancreatic tumors.

| Study                  | ES (95% CI)            | % Weight | Clinical success (out of no. of lesions) | Number of lesions   |
|------------------------|------------------------|----------|------------------------------------------|---------------------|
| Wang (2016)            | 100.00 (43.85, 100.00) | 4.02     | 3                                         | 3                   |
| Song (2016)            | 100.00 (60.97, 100.00) | 6.97     | 6                                         | 6                   |
| Scopelleti (2018)      | 100.00 (72.25, 100.00) | 10.34    | 10                                        | 10                  |
| Crino (2018)           | 100.00 (67.56, 100.00) | 8.72     | 8                                         | 8                   |
| Lakhtakia (2016)       | 100.00 (43.85, 100.00) | 4.02     | 3                                         | 3                   |
| Oleinokov (2019)       | 83.33 (60.78, 94.16)   | 15.64    | 15                                        | 18                  |
| Pai (2015)             | 100.00 (67.56, 100.00) | 8.72     | 8                                         | 8                   |
| De la Serna (2018)     | 77.78 (45.26, 93.68)   | 9.55     | 7                                         | 9                   |
| Choi (2018)            | 70.00 (39.68, 89.22)   | 10.34    | 7                                         | 10                  |
| Barthet (2018)         | 77.42 (60.19, 88.60)   | 21.67    | 24                                        | 31                  |
| Overall (I²= 21.50%, P=0.25) | 91.58 (82.50, 98.08) | 100.00   |                                           |                     |

**Fig. 3** Overall pooled clinical success rate of EUS-RFA in pancreatic tumors.
### Table 4  Early and delayed adverse events in EUS-RFA.

| Author       | Total early adverse events | Pancreatitis | Bleeding | Perforation | Infection | Abdominal pain | Others | Late adverse events |
|--------------|-----------------------------|--------------|----------|-------------|-----------|----------------|--------|---------------------|
| Oleinikov [11] | 0                           | 0            | 0        | 0           | 0         | 0              | 0      | 2                   |
| Barthet [1]   | 9                           | 1            | 0        | 1           | 1         | 6              | 0      | 1                   |
| Scopelliti [3] | 6                           | 0            | 0        | 0           | 0         | 2              | 4      | 0                   |
| Crino [9]     | 3                           | 0            | 0        | 0           | 0         | 3              | 0      | 0                   |
| De la Serna [8] | 2                          | 0            | 0        | 0           | 0         | 2              | 0      | 0                   |
| Choi [7]      | 2                           | 1            | 0        | 0           | 0         | 1              | 0      | 0                   |
| Thosani [12]  | 1                           | 0            | 0        | 0           | 0         | 1              | 0      | 0                   |
| Goyal [13]    | 0                           | 0            | 0        | 0           | 0         | 0              | 0      | 0                   |
| Malikowski [14]| 0                           | 0            | 0        | 0           | 0         | 0              | 0      | 0                   |
| Wang [16]     | 0                           | 0            | 0        | 0           | 0         | 0              | 0      | 0                   |
| Song [4]      | 2                           | 0            | 0        | 0           | 0         | 2              | 0      | 0                   |
| Lakhtakia [10]| 0                           | 0            | 0        | 0           | 0         | 0              | 0      | 0                   |
| Pai [15]      | 2                           | 0            | 0        | 0           | 0         | 2              | 0      | 0                   |

**Fig. 4** Overall pooled total early adverse events.
nom size, necrosis of tumor as evidenced by hypo-enhanced areas noted on post-intervention CTs, and/or decrease in symp-
toms caused by functioning pancreatic tumors. Ten of 13 stud-
ies noted the clinical success rate [1, 3–11, 15, 16]. Of these, six
studies showed 100% pooled clinical success rates with the re-
maining four reporting clinical success rates ranging from 70 %
to 83%. Many noted a sustained linear regression of the tumor
with time when comparing CTs from 7 days post-procedure to
CTs at 30 days post-procedure [1, 3, 10, 11].
No significant correlation was found between ablation time,
radiofrequency strength, and sustained reduction in tumor
burden. For example, Crino et al. used 30 W to produce a 30 %
reduction in locally advanced PDAC, while Choi et al employed
20 to 50 W to see a 58.9 % reduction in tumor size [7, 9]. Multi-
ple sessions of EUS-RFA were employed in all studies.
EUS-RFA can be used successfully to treat PNETs regulated to
surveillance, or to ablate lesions in patients who refuse surveil-
lobe or decline surgery due to its invasiveness; individuals who
are not surgical candidates because of comorbidities; and
young patients with PNETs associated with MEN-1 in whom
pancreas-sparing options are preferable [23]. In non-functional
PNETs, Berthet et al noted 86% had diminished by at least 50%
in size or completely by 12 months following ablation [1]. Func-
tional PNETs exhibited a sustained attenuation of clinical symp-
toms such as hypoglycemia or diarrhea, rapid normalization of
secreted hormone levels, and sustained significant decrease in
size of the neoplasm. PNETs had a pooled clinical success rate
ranging from 83 % to 100 % [10–13].
The secondary endpoint of this meta-analysis was to analyze
AEs associated with EUS-RFA. The overall pooled incidence of
AEs was 14.67 % (95 % CI [4.77–27.46], I² = 56.19 %). AEs were
divided into early (< 7 days) and late (> 7 days). The most com-
mon early AE was self-resolving abdominal pain (9.82 % (95 % CI
[3.34–18.24]), I² = 23.76 %). There was one report of self-resolv-
ing pancreatitis. In that instance, Choi et al. recommended a
5-mm margin from the pancreatic duct to avoid pancreatitis.
Delayed AEs were reported in two studies [1, 3]. In all patients,
no correlation was found between AEs and ablation time or en-
ergy settings.
Limitations of our meta-analysis include the fact that 10 of
13 studies were single-center studies with 10 or fewer patients
[3, 4, 7, 9, 10, 13–16]. Our meta-analysis also showed moderate
to substantial heterogeneity. The studies pertaining to pancre-
atric neuroendocrine tumors all had short follow-up periods un-
der 1 year [7, 8, 10, 11, 14].

Conclusion
Overall, EUS-RFA has exhibited both high technical and clinical
success with minimal AEs in addressing locally advanced unre-
sectable PDAC and other pre-malignant pancreatic lesions
where curative surgery is not an option. In the future, EUS-RFA
may become a more widely used approach to treatment of a
myriad of pancreatic lesions. Further long-term multicenter
prospective studies are needed to correlate our findings.

Competing interests
The authors declare that they have no conflict of interest.

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