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Radiation exposure during modern therapeutic endoscopic ultrasound procedures and standard alternatives

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ABSTRACT

Background and study aims Therapeutic EUS (t-EUS) is increasingly being adopted in clinical practice in tertiary referral centers; however, little is known about radiation exposure (RE) metrics and diagnostic reference limits for it.

Methods Kerma-area product (KAP [Gy·cm^2]), Air Kerma and fluoroscopy time were retrospectively evaluated for all consecutive t-EUS procedures performed in San Raffaele Institute between 2019 and 2021. For EUS-guided choledochoduodenostomies (EUS-CDS) and gastroenterostomies (EUS-GE), an equal number of endoscopic retrograde cholangiopancreatographies (ERCPs) plus metal stenting and duodenal stents were included respectively for comparison.

Results Data from 141 t-EUS procedures were retrieved (49% pancreatic cancer, 38% peripancreatic fluid collections). EUS-CDS (N = 44) were mainly performed fluoroless, while ERCPs required a significantly higher RE (KAP = 25 [17–55], P < 0.0001). Fluid collection drainage (EUS-FCD) with lumen apposing metal stents (LAMS, N = 26) were performed fluoroless, while EUS-FCD with double-pigtail plastic stents (DPPS, N = 28) required higher RE (KAP = 23 [13–45]). EUS-guided gallbladder drainage (EUS-GBD, N = 6) required scarce RE (KAP = 9 [3–21]) for coaxial DPPS placement. EUS-GE (N = 27) required higher RE than duodenal stenting (KAP = 44 [28–88] versus 29 [19–46], P = 0.03). EUS-guided hepaticogastrostomies (EUS-HGS, N = 10) had the highest RE among t-EUS procedures (KAP = 81 [49–123]). Procedure complexity or intervening complications were evaluated and resulted in higher RE within each procedure.

Conclusions t-EUS procedures have different RE (P < 0.000001). EUS-CDS, EUS-GBD, and EUS-FCD with LAMS can be performed with no-to-mild radioscopy, unlike standard alternatives. However, radioscopy remains essential in case of technical difficulties or complications. EUS-GE and EUS-HGS involve a high RE. Endoscopists involved in t-EUS might experience RE higher than category standards, which indicates a need for increased awareness and personalized preventive measures.

Introduction

Therapeutic endoscopic ultrasound (t-EUS) procedures are increasingly being adopted in the daily clinical practice at tertiary referral centers [1]. However, little is known about radiation exposure (RE) for patients and physicians involved with these procedures, mostly regarding an era in which lumen apposing metal stents (LAMS) were not yet available. While the International Commission on Radiological Protection recommends use of diagnostic reference levels to monitor the real-world clinical practice of procedures involving fluoroscopy, no standard diagnostic reference levels are available for t-EUS [2].

The aim of this study was to analyze the RE of modern t-EUS procedures involved in biliary drainage, gastric outlet obstruction, and acute cholecystitis management.

Methods

This was a retrospective evaluation of a prospectively maintained database of all consecutive t-EUS procedures performed in San Raffaele Institute between 2019 and 2021, performed in a dedicated room with a mobile, under-couch, C-arm fluoroscopic system (Ziehm Vision RFD, Reggio Emilia, Italy).

T-EUS procedures

Information on procedures was retrieved through electronic search of an endoscopic reporting program (Endox, TESI, Milan, Italy) in which t-EUS procedures are grouped together under the same label (EUS-guided drainage). EUS-guided choledochoduodenostomy (EUS-CDS), fluid collection drainage (EUS-FCD), gallbladder drainage (EUS-GBD), hepaticogastrostomy (EUS-HGS) and gastroenterostomy (EUS-GE) were included.

All procedures were performed by three experienced therapeutic endosonographers (PGA, MCP, GV) who completed their training in each performed procedure before the study interval. No significant change has been introduced during the study interval in the technical phases or devices used for each individual procedure.

Briefly, in our Institution EUS-CDS and EUS-GBD are usually performed through free-hand placement of electrocautery-enhanced LAMS. EUS-FCD are performed either by free-hand LAMS placement (necrotic collections) or with double-pigtail plastic stents (DPPS) through a sequence involving needle-guidewire-cystotome-stent (homogeneously fluid collections) [3]. For EUS-GBD and EUS-FCD with LAMS, we usually place coaxial DPPS, for which fluoroscopy is used according to endoscopist preference. EUS-GE is usually performed through the wireless simplified technique (WEST) i. e. through free-hand LAMS placement after jejunal distention through an oro-jejunal tube [4]. EUS-HGS is performed through a needle-guidewire-cystotome-stent sequence, using a purpose-specific partially-covered metal stent [5].

Technical steps deviating from the above-mentioned standard techniques (e. g. LAMS placement over a guidewire; misdeployments; additional stents placement) were registered as "intraprocedural troubles" and reported in detail.

Comparators

For t-EUS procedures having a standard endoscopic alternative, we identified an equivalent number of cases performed for the same indication, during the same interval, using the same fluoroscopic machinery: for EUS-CDS, an equal number of ERCPs with metal stenting for distal malignant biliary ostruction; for EUS-GE, an equivalent number of duodenal stenting for malignant antro-duodenal obstruction. Baseline characteristics between the groups are compared in **Supplementary Table 1** and **Supplementary Table 2**.

Radiologic exposure metrics

RE was evaluated based on three cumulative RE metrics. Fluoroscopy time (FT) measured in seconds. Cumulative Air Kerma ($K_{a,ref}$, where Kerma stands for kinetic energy released in a mass) measured in mGy as an indicator of cumulative dose at a fixed interventional reference point. Kerma-Area product (KAP) measured in Gy·cm^2 represents the product of $K_{a,ref}$ integral and the beam area in a plane perpendicular to the beam axis, and is a more reliable estimator of the radiation dose received by the patient [2].

Variables

Together with RE dose metrics, the following variables were extracted: demographic characteristics of patients (age, sex), underlying disease, technical success (yes/no), and intraprocedural troubles (yes/no).

Intraprocedural troubles (e. g. stent misdeployment; LAMS placement over a guidewire; placement of additional stents) were registered as reported in the Exam Report. Procedures without any reported inconveniences were defined as "Trouble-free."

Statistics

Mann-Whitney-U and Kruskal-Wallis tests were used as appropriate for comparing RE metrics of different t-EUS procedures, and of t-EUS procedure versus a standard endoscopic alternative. KAP values distribution are shown as box-and-whiskers plots.

Ethics

All patients provided written informed consent. This research was conducted under the PROTECT Protocol (Local IRB approval ID: 178/INT/2020, Clinical Trial Identifier: NCT04813055).

Results

A total of 141 t-EUS procedures were performed during the study interval (EUS-CDS = 44; EUS-FCD-DPPS = 28; EUS-FCD-LAMS = 26; EUS-GE = 27; EUS-HGS = 10; EUS-GBD = 6). During the same timeframe, 44 ERCPs and 27 duodenal stent placements were selected as controls as previously described, for a total of 212 included procedures.

Patients' characteristics are reported in ▶ **Table 1**. Median age was 66 (range 58–73), 57 % were male, 65 % had pancreatic cancer and 26 % had a peripancreatic fluid collection.

▶ **Table 1** Characteristics of included patients.

Variable	Total N = 212	Only t-EUS procedures N = 141
Age, median [IQR]	66 [58–73]	66 [58–73]
Male, n (%)	120 (56.6 %)	77 (54.6 %)
Primary disease		
Pancreatic cancer	138 (65.1 %)	69 (48.9 %)
Peripancreatic fluid collections	54 (25.5 %)	54 (38.3 %)
Pseudocyst/postsurgical/WOPN	30/17/7	30/17/7
Cholangiocarcinoma	6 (2.8 %)	6 (4.3 %)
Acute cholecystitis	4 (1.9 %)	4 (2.8 %)
Others (among others duodenal/gastric/ovarian cancer)	10 (4.3 %)	8 (5.7 %)
Procedure		**Technical Success**
EUS-choledochoduodenostomy, n (%)	44 (20.8 %)	43 (97.7 %)
ERCP with SEMS, n (%)	44 (20.8 %)	
EUS-FCD-DPPS, n (%)	28 (13.2 %)	28 (100 %)
EUS-FCD-LAMS, n (%) – coaxial DPPS = 96.2 %	26 (12.3 %)	26 (100 %)
EUS-gastroenterostomy, n (%)	27 (12.7 %)	26 (96.3 %)
Duodenal stent, n (%)	27 (12.7 %)	
EUS-hepaticogastrostomy, n (%)	10 (4.7 %)	9 (90 %)
EUS-gallbladder drainage, n (%)	6 (2.8 %)	6 (100 %)

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; DPPS, double-pigtail plastic stent; FCD, fluid collection drainage; IQR, interquartile range; LAMS, lumen apposing metal stent; SEMS, self-expandable metal stent; t-EUS, therapeutic EUS; WOPN, walled-off pancreatic necrosis.

Technical success rates were 100 % for EUS-FCD-DPPS, EUS-FCS-LAMS and EUS-GBD, 97.7 % for EUS-CDS, 96.3 % for EUS-GE and 90 % for EUS-HGS.

KAP, $K_{a,ref}$ and FT were respectively available for 84.4 %, 96.2%, and 100 % of the procedures.

Radiation exposure

RE metrics are shown in ▶ **Table 2** and ▶ **Fig. 1**.

There was a significant difference in the median value of $K_{a,ref}$, KAP and FT between different t-EUS procedures, with EUS-CDS, EUS-FCD-LAMS and EUS-GBD being in the lower quartile, EUS-GE and EUS-HGS in the higher quartile, while EUS-FCD-DPPS showed intermediate exposure ($P < 0.000001$)

Radiation exposure of t-EUS versus comparators

EUS-CDS had significantly lower KAP than ERCP-SEMS performed for the same indication (0 [0–0] vs. 25.44 [17.21–54.84] Gy·cm^2, $P < 0.0001$), because most EUS-CDSs were performed without fluoroscopy. EUS-GE had a higher KAP than duodenal stenting (43.54 [27.95–88.22] versus 29.42 [19.42–45.55] cGy·cm^2, $P = 0.03$), despite the comparable $K_{a,ref}$ ($P = 0.1$).

Radiation exposure according to procedure complexity

RE was compared for procedures with intraprocedure troubles (see **Supplementary Table 3** for detailed description) versus those without such complications (▶ **Fig. 2** and **Supplementary Table 3**).

A difference was evident for EUS-CDS, where misdeployments or over-the-wire LAMS placement for a poorly-dilated duct required a median KAP of 26.62 [0–58.05] Gy·cm^2 versus no radioscopy in the complication-free procedures ($P = 0.02$)

The KAP of complex EUS-GE and EUS-HGS was higher than complication-free procedures, without reaching statistical significance due to a high basal KAP.

ERCPs with difficult cannulation according to European Society of Gastrointestinal Endoscopy guidelines [6] required higher RE than smooth cannulations ($P = 0.045$).

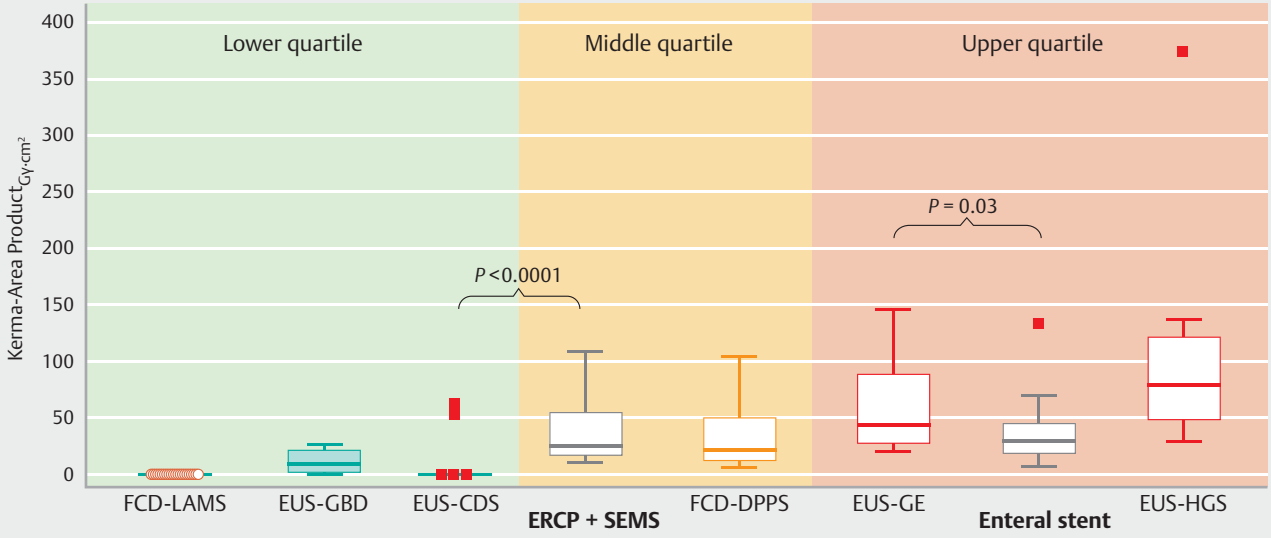
Discussion

The International Commission on Radiological Protection recommends the use of procedure-specific diagnostic reference levels as a tool to analyze and optimize RE for both patients and physicians, usually obtained collecting RE measures from different health facilities and using the 75th percentile of median values as reference [2]. These values serve to monitor local

▶ **Table 2** Radiologic exposure metrics. Median values and interquartile range of each RE metrics according to specific endoscopic procedure are reported.

Variable	Air Kerma (mGy)	*P* value	Kerma Area Product (Gy·cm²)	P value	Fluoroscopy Time (s)	*P* value
		Overall <0.000001; For trend 0.03		Overall <0.000001; For trend 0.0003		Overall <0.000001; For trend 0.003
EUS-Choledochoduodenostomy	0 [0–2]	<0.0001	0 [0–0]	<0.0001	0 [0–2]	<0.0001
ERCP with SEMS, median [IQR]	237 [161–452]		25.44 [17.21–54.84]		97 [71–192]	
EUS-FCD-LAMS, median [IQR]	0 [0–0]		0 [0–0]		0 [0–0]	
EUS-GBD, median [IQR]	43 [3–155]		8.58 [2.45–20.58]		16 [2–60]	
EUS-FCD-DPPS, median [IQR]	270 [187–455]		22.99 [13.02–45.05]		99 [69–159]	
EUS-GE, median [IQR]	349 [268–673]	0.1	43.54 [27.95–88.22]	0.03	201 [146–315]	0.03
Duodenal stent, median [IQR]	342 [217–435]		29.42 [19.42–45.55]		142 [113–203]	
EUS-HGS, median [IQR]	1304 [503–1676]		81.24 [49.39–122.74]		286 [218–430]	

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; DPPS, double-pigtail plastic stent; FCD, fluid collection drainage; LAMS, lumen apposing metal stent; SEMS, self-expandable metal stent.
EUS-choledochoduodenostomy, EUS-fluid collection drainage with LAMS and EUS-gallbladder drainage lie in the lower quartile of RE, whereas EUS-GE, EUS-hepaticogastrostomy and duodenal stenting lie in the upper one.

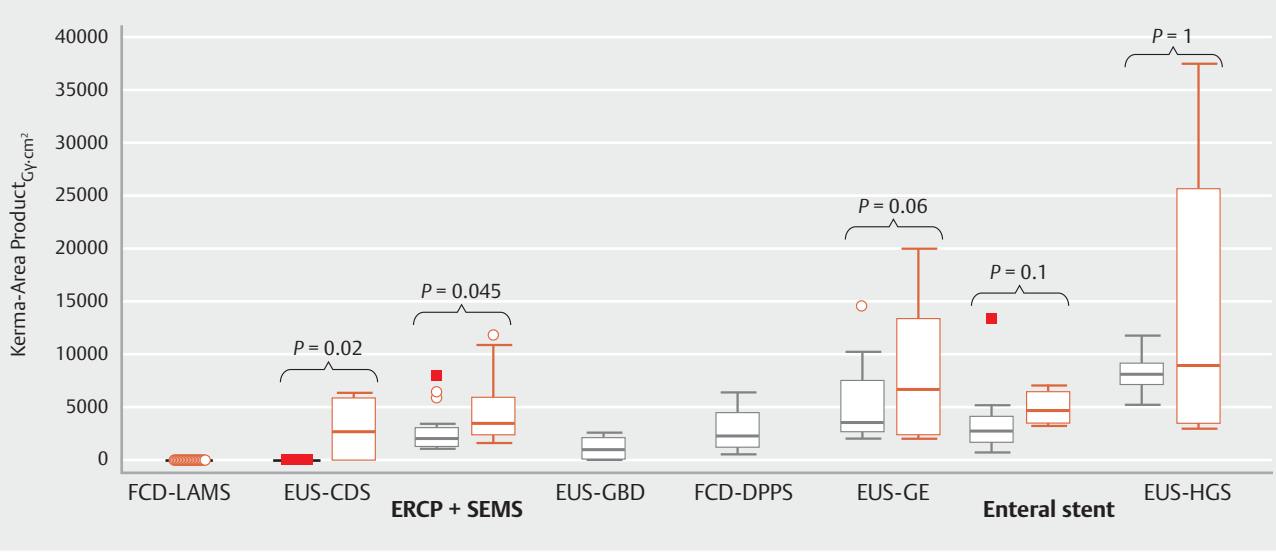


▶ **Fig. 1** Box-and-whiskers plots of Kerma-Area Products (KAP) values distribution according to each t-EUS procedure. Different colors represent the lower (green), intermediate (yellow) and higher (red) quartiles in which median values of KAP for each t-EUS procedure are distributed. EUS-guided choledocoduodenostomies (EUS-CDS) are further compared with ERCP with metal SEMS placement as well as EUS-guided Gastroenterostomies (EUS-GE) are compared with duodenal stent placements (*P* values shown above the bracket).

clinical practice, as for example if RE consistently exceeds identified references.

Pancreatobiliary endoscopy is the area of gastrointestinal endoscopy in which ionizing radiation is used the most. The 2012 ESGE Guideline on Radiation Protection underscored that limited information was available regarding mean KAP values for therapeutic ERCP, between 8 and 33 Gy·cm² [7]. The guideline also suggested that KAP be recorded in each ERCP report [7], even if this practice has not been implemented.

The advent of therapeutic EUS has enormously changed clinical practice in pancreatobiliary endoscopy units, introducing new possibilities for biliary obstruction, gastric outlet obstruc-



▶ **Fig. 2** Kerma-Area Products (KAP) for each t-EUS procedure, further stratified by procedure complexity. For each endoscopic procedure, box-and-whiskers plots of values distribution are separately represented for "trouble-free" procedures in black and procedures with inconveniences (when any) in orange. *P* values of comparisons are reported above brackets.

tion, and acute cholecystitis management [1]. However, little is known regarding RE for patients and physicians. Whereas EUS adds endosonographic guidance for accessing a target organ, many procedures involve technical steps for which radiologic guidance remains fundamental.

One recent prospective multicenter study evaluated RE of 13,000 gastrointestinal procedures in 23 Japanese hospitals. However, only 374 (2.8 %) were t-EUS procedures, with no insight on different subtypes [8]. The only available publication in this field is a retrospective study comparing 105 t-EUS procedures and 372 ERCPs showing an higher KAP of the former [9]. However, all t-EUS procedures were performed with a needle-guidewire-dilation-stent technique. Conversely, the introduction of LAMS allows one-step and free-hand access and stent deployment, significantly reducing procedure risks and theoretically allowing for fluoroless release. Moreover, it has also paved the way for newer procedures, such as EUS-guided anastomoses.

To the best of our knowledge, no paper describes RE of t-EUS procedures performed with LAMS, and none describes EUS-GE. Moreover, no paper has compared t-EUS with standard endoscopic alternatives having the same indication and anatomy.

Our paper found that some t-EUS procedures were mainly performed fluoroless.

Among these, EUS-CDS has an established role in palliation of distal malignant biliary obstruction when ERCP fails [1], so as to be even investigated as an upfront alternative to ERCP, because it has the potential to reduce the rate of acute pancreatitis [10]. In this scenario, a reduced RE might be an additional advantage.

EUS-GBD may be performed fluoroless as well; in our study additional radioscopy was used for prophylactic coaxial DPPS, and resulted in a very low RE, much lower than expected for percutaneous cholecystostomy (P-GBD), which is entirely performed under radioscopic guidance. This adds to the advantages in terms of reduced acute cholecystitis recurrence [11], and the possibility of direct endoscopic cholecystoscopy for stone clearance [12].

As for peripancreatic fluid collections, endoscopic drainage is the established initial treatment modality [13], either by DPPS or LAMS. In our study, the latter was mainly performed fluoroless, while the former required a higher RE to guide the needle-guidewire-cystotome-stent sequence. While this might appear to be an argument in favor of LAMS, a recent randomized controlled trial found an increased rate of stent-related complications (mostly bleeding) in the LAMS group [14], and therefore, advantages (i. e. the possibility of endoscopic necrosectomy) must be weighed against these safety issues. It is our opinion that the two procedures are to be used for different indications: LAMS for walled-off necrotic collections whereas DPPS for pseudocysts or "clear" collections [3].

In this study, two of the t-EUS procedures had the highest RE. EUS-GE is emerging as a valuable treatment option for management of gastric outlet obstruction, being as effective as surgical bypass while having increased clinical success and reduced long-term dysfunction when compared to duodenal stenting [1, 15]. Our study shows that RE of EUS-GE and duodenal stenting seem of the same order of magnitude, being slightly significantly higher for the former. In our center, fluoroscopy is mainly needed for oro-jejunal tube placement; we strongly believe that full control of jejunal distention, the possibility of depicting anatomy with contrast, and the ability to endosonographically visualize of the tube are key for increasing technical success [4, 16].

Finally, in our study, EUS-HGS had the highest RE among t-EUS procedures. EUS-HGS involves a multistep sequence for biliary access, cholangiography, duct cannulation, and tract creation. Millimetric precision is also required for stent place-

ment, the uncovered part of which must be placed inside the biliary tree, while the covered part is deployed transhepatically and transgastrically; all these steps must be performed under real-time radioscopic guidance. However, the alternative to this procedure would be percutaneous transhepatic biliary drainage, for which comparable RE has been reported [17].

We also compared "trouble-free" procedures with procedures with any inconveniences, confirming that procedure complexity is a determinant of RE. For example, whereas most EUS-CDS were performed fluoroless, radioscopy was fundamental in case of stent misdeployment. This is also in keeping with ESGE indications suggesting that t-EUS procedures should be performed in a radiology-equipped endoscopic suite, as this might impact the readiness to solve intraprocedural troubles [18].

What clinical consequences could be inferred from these data for everyday practice? T-EUS procedures are mostly used in the setting of symptom palliation in cancer patients. Most procedures do not systematically require revision. Finally, most alternatives require radioscopic guidance as well. For all these reasons, RE of t-EUS is not expected to represent a major issue from the patient perspective.

Conversely, implications for health care professionals can be inferred. T-EUS expertise is usually centralized in few referral centers and endoscopists, most of which are also involved in ERCP. For all these reasons, it might be expected that interventional endosonographers would have higher exposure to RE. Each health care professionals involved in radiology-guided procedures usually attends an educational radioprotection course, is equipped with personal protective equipment such as lead aprons and glasses, and wears at least two dosimeters, one outside and the other inside the apron [7]. Additional measures might be implemented to generally reduce RE. Educational interventions could be aimed at increasing awareness about how technical settings and beam collimation influence RE and image quality, especially if technical support for fluoroscopy is not available. Newer fluoroscopy systems incorporating artificial intelligence-guided adjustment might further reduce RE to patients and physicians [19].

This study has some limitations. First, the retrospective nature might lead to missed data. However, t-EUS procedures were grouped together under the same label in our endoscopic reporting system, substantially nullifying this risk. There were some missed RE measures, but at least FT was available for all cases.

Moreover, the use of fluoroscopy during each procedure might be driven by the experience of the endoscopist, and therefore, we cannot exclude a role of the learning curve in influencing RE. However: 1) We included in this study only procedures performed during the last 3 years; 2) All procedures were performed by three experienced therapeutic endosonographers, who had completed their training in each procedure before the study interval; 3) There was no or marginal involvement of trainees in these advanced procedures; and 4) No significant change in the technical phases and the devices used during each procedure was made during the study interval. Although some residual effect of increasing experience might exist, the clearly different values identified for different t-EUS procedures despite the use of medians and interquartile ranges (marginalizing the role of outlier values) strongly suggest that the results were driven by the procedures themselves rather than by other confounders.

Despite all these limitations, this is the first study analyzing RE of t-EUS procedures performed with modern technologies such as LAMS (the only reporting EUS-GE) and comparing some of these procedures to standard endoscopic alternatives.

Conclusions

These data should prompt increased awareness of the RE risk among health care professionals involved in t-EUS, and further educational initiatives to ideally reduce this exposure, eventually facilitating a personalized surveillance schedule for pancreatobiliary endoscopists performing both t-EUS and ERCPs. Finally, these RE metrics might provide an initial indication of diagnostic reference levels, while regulators identify validated ones for monitoring real-world clinical practice.

Competing interests

The authors declare that they have no conflict of interest.

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