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EDITORIAL

Organ and function preservation in gastrointestinal cancer: Current and future perspectives on endoscopic ablation

Youssef Yousry Soliman, Megan Soliman, Shravani Reddy, James Lin, Toufic Kachaamy

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Abstract

The escalating prevalence of gastrointestinal cancers underscores the urgency for transformative approaches. Current treatment costs amount to billions of dollars annually, combined with the risks and comorbidities associated with invasive surgery. This highlights the importance of less invasive alternatives with organ preservation being a central aspect of the treatment paradigm. The current standard of care typically involves neoadjuvant systemic therapy followed by surgical resection. There is a growing interest in organ preservation approaches by way of minimizing extensive surgical resections. Endoscopic ablation has proven to be useful in precursor lesions, as well as in palliative cases of unresectable disease. More recently, there has been an increase in reports on the utility of adjunct endoscopic ablative techniques for downstaging disease as well as contributing to non-surgical complete clinical response. This expansive field within endoscopic oncology holds great potential for advancing patient care. By addressing challenges, fostering collaboration, and embracing technological advancements, the gastrointestinal cancer treatment paradigm can shift towards a more sustainable and patient-centric future emphasizing organ and function preservation. This editorial examines the evolving landscape of endoscopic ablation strategies, emphasizing their potential to improve patient outcomes. We briefly review current applications of endoscopic ablation in the esophagus, stomach, duodenum, pancreas, bile ducts, and colon.

Key Words: Gastrointestinal cancer; Endoscopic ablation; Organ preservation; Complete clinical response; Neoadjuvant therapy; Endoscopic oncology; Palliative treatment

Core Tip: Endoscopic ablation of precancerous lesions is widely accepted in the luminal gastrointestinal tract. In unresectable gastrointestinal malignancy, the palliative role of endoscopic ablation is growing. Recently, the prospect of endoscopic ablation is expanding to include downstaging previously unresectable disease, as well as contributing to non-surgical complete clinical response as an adjunct therapy. The prospect for synergy in improving overall survival while balancing the quest for organ and function preservation warrants methodical investigations.

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INTRODUCTION

Gastrointestinal cancers are a diverse group of malignancies making up over one-quarter of all cancer cases, and arise from the esophagus, stomach, liver, biliary tract, pancreas, small intestine, colon, and rectum[1]. Collectively, these cancers are a major global health burden due to their significant morbidity, mortality, and cost burden.

The National Comprehensive Cancer Center (NCCN) is a not-for-profit alliance of leading cancer centers in the United States with the vision of defining and advancing high-quality, high-value, patient-centered cancer care. NCCN clinical practice guidelines and recommendations are commonly referenced in cancer care. Surgical resection is generally recommended for most locoregional gastrointestinal cancers without targetable mutations as first-line of treatment. In cases of borderline resectable and/or locally advanced disease, neoadjuvant treatment is considered[2-12]. This approach has been more promising in esophagogastric and colorectal cancers[13-16] than in pancreaticobiliary cancers[17-20]. This difference is at least in part due to the lack of unanimous commensurate improvement in overall survival with the improvement in complete histopathologic resection rates in pancreaticobiliary cancers. Furthermore, post-operative complications are significant considerations even when curative resections are achieved[21,22].

There has been growing interest in organ preservation approaches. Total neoadjuvant therapy (TNT) followed by a "watch and wait" strategy has been increasingly studied. The esophagus and the rectum tend to be major areas of interest. For example, the CROSS trial reported no viable tumor cells in 23% of patients with adenocarcinoma and 49% of squamous cell carcinoma of the esophagus who received neoadjuvant chemoradiotherapy followed by esophagectomy [23]. The surgery as needed for oesophageal cancer (SANO) trial reported non-inferiority in overall survival (OS) and improved short-term health-related quality of life of neoadjuvant chemoradiation with active surveillance and surgery as needed *vs* standard surgery[24]. In rectal cancer, the OPRA trial found that organ preservation was possible in half of the patients who underwent TNT[25]. In the other half with disease recurrence who ultimately needed to undergo surgery, there was no statistically significant difference in disease-free survival post-operatively. International consensus groups establish a framework for studying and standardizing the topic[26]. Other systemic treatment strategies for complete clinical response continue to be proposed and studied[27]. Therefore, organ and function preservation approaches encompass minimally invasive systemic therapy, radiation therapy, minimally invasive surgeries, and endoscopic resection of accessible tumors < T1b[2,5,6,12].

In cases where complete endoscopic or minimally invasive resection is not feasible, endoscopic ablation can have a role in disease mitigation. This is particularly in palliation of advanced disease by debulking an obstructive mass that is refractory to systemic and locoregional therapy. Endoscopic ablation adds to the growing repertoire of palliative endoscopic modalities[28]. Therefore, in addition to treating pre-malignant and early-stage lesions, endoscopic ablation has the potential for palliation as well as integration in organ preservation and down-staging disease strategies. We review endoscopic ablation modalities that have been considered in the continuum of gastrointestinal cancers.

ESOPHAGEAL DISEASE

Endoscopic ablation of dysplastic Barrett esophagus with radiofrequency ablation (RFA) (Figure 1) has been shown to have high rate of complete eradication of dysplasia and intestinal metaplasia, as well as a reduced risk of disease progression to adenocarcinoma[29]. Liquid nitrogen spray cryotherapy (LNSC) (Figure 2) and balloon cryotherapy (BC) (Figure 3) have been shown to eradicate dysplasia at rates of approximately 80%[30]. In patients with intramucosal adenocarcinoma related to Barrett, both RFA and LNSC were found to be effective[31]. In early esophageal squamous cell neoplasia, RFA and BC have been found to be safe and effective with repeat treatments as necessary until eradication of

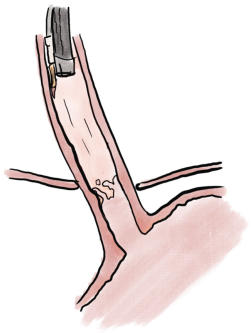

Figure 1 Diagram of endoscopic radiofrequency ablation in the esophagus.

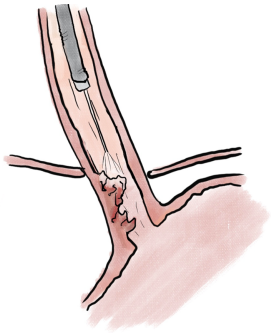

Figure 2 Demonstration of liquid nitrogen spray cryotherapy in the esophagus.

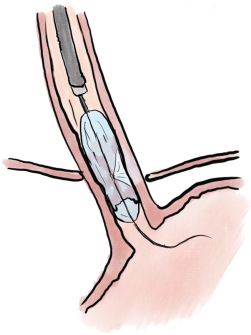

Figure 3 Cryoballoon ablation in the esophagus.

the neoplasia[32-34]. On the palliative front, in a prospective multi-center study of 55 patients with inoperable esophageal cancer, LNSC has been found to improve dysphagia and quality of life after a mean of 3.2 treatments[35].

Moreover, a pilot study of a single session of neoadjuvant LNSC in 21 patients reported improvement in dysphagia in 71% of patients. Among 9 patients with locally advanced cancer who completed chemoradiation, 6 had negative mucosal biopsies, with 5 having clinical complete response[36]. These studies on cryotherapy had low serious adverse events and are promising. The potential of synergy of endoscopic ablation with systemic treatment warrants further studies.

GASTRIC DISEASE

Gastric dysplasia has been shown to be readily eradicated with endoscopic RFA in no more than 3 sessions 8 wk apart [37]. Argon Plasma Coagulation (APC) has also been shown to be comparable to RFA for eradicating low-grade intraepithelial neoplasia, though RFA was touted to be more appropriate in larger lesions that are flat, whereas APC was favored in smaller and more protrusive lesions[38]. Endoscopic laser therapy has also been successfully used in eradicating intramucosal gastric cancer, with up to 75% of patients found to have no residual tumor on laparotomy[39]. In residual gastric tumors following endoscopic resection, APC achieved curative ablation in 73.2% after a single session, and up to 86.6% following an extra session of APC[40].

In subepithelial gastrointestinal tumors (GIST), case reports of endosonographic fine needle injections (FNI) for ablation with ethanol[41] and RFA[42] have been successful in cases where patients either rejected or had prohibitive comorbidities to surgical resection. In this class of tumors, appropriately selected neoadjuvant and/or adjuvant tyrosine kinase inhibitors tend to have a favorable effect in disease control as well[15].

DUODENAL DISEASE

Whereas endoscopic resection is the mainstay in mucosal disease, the complexity of duodenal anatomy and endoscopic positioning may necessitate adjunct modalities. In non-ampullary adenomas, endoscopic cryoballoon ablation (Figure 4) was successful in 12 of 17 (71%) of cases, with 13 of 17 (76.5%) having had previous attempts at endoscopic resection[43].

In ampullary tumors that were removed *via* snare papillectomy, 18 of 86 (20.9%) were found to have < 20 mm intraductal extension without evidence of metastatic disease. These were treated with intraductal electrocautery ablation using a 6 Fr cystotome, with a 100% success rate and no recurrence over a median follow-up of 20 months. Among these patients, 8 of 18 (44%) had evidence of high-grade dysplasia or adenocarcinoma, which were eradicated[44]. Intraductal RFA was prospectively studied among multiple centers in France for treatment of residual adenoma following papillectomy. Twenty patients were identified, with each undergoing a single session of RFA. Successful eradication was 85% at 6 months and 70% at 12 months[45]. The long-term effects of RFA were examined in 29 patients who underwent intraductal RFA as an adjunct modality following papillectomy. Eradication of dysplasia was demonstrated in 93% of patients within 1-2 months, and 76% of patients in long-term follow-up up to a median of 776 d[46]. These data samples are promising given that the traditional alternate approach is a pancreaticoduodenectomy[11].

PANCREATIC DISEASE

Pancreatic neuroendocrine tumors (PNETs) have been prime candidates for endoscopic therapies given the prospect of avoiding surgical resections. Endoscopic ultrasound-guided ethanol ablation (EUS-EA) (Figure 5) was found to result in PNET ablation in 24 of 40 (60%) patients with tumors < 2 cm in diameter[47].

With RFA, a multicenter prospective study noted complete necrosis of PNETs to be 7 of 15 (46.7%) in 6 months and 6 of 11 (54.5%) in 12 months. Importantly, all 13 patients with functional PNETs had complete clinical response[48]. In another prospective multicenter study, 12 of 14 (86%) PNETs had complete resolution at 12-month follow-up[49]. This study also included 17 pancreatic cystic neoplasms - 16 of which were intraductal pancreatic mucinous neoplasia. At 12 months, 11 had complete response and disappeared on subsequent imaging[49].

For locally advanced pancreatic adenocarcinoma (PDAC), RFA was correlated with tumor regression (> 50% reduction in size) in 6 of 10 patients who had a range of 1-4 sessions of treatment. One patient who had portal confluence encasement, as well as abutment of the celiac axis, common hepatic and mesenteric arteries had a significant tumor reduction and underwent a standard pancreaticoduodenectomy[50]. In a phase II randomized controlled trial, EUS-guided thermal ablation (Figure 6) has also been shown to be numerically promising in 6-month progress-free survival in locally advanced PDAC, though statistically not significant[51]. More recently, a small study incorporating EUS FNI of large surface area microparticle paclitaxel with standard of care for locally advanced pancreatic cancer found that 8 of 10 patients became resectable[52].

Ablative therapies of pancreatic tumors have profound implications. On the PNET and cystic neoplasm fronts, the prospect of organ and function preservation is tremendous in lieu of surgical resections. On the PDAC front, the potential of downstaging disease from unresectable to resectable carries remarkable implications for the overall treatment of pancreatic cancer.

BILIARY DISEASE

Endobiliary ablation has been primarily utilized for palliative therapy in cholangiocarcinoma (CCA). A randomized trial of 65 patients with unresectable extrahepatic CCA (eCCA) who underwent biliary stenting and RFA had a significantly longer overall mean survival of 13.2 months *vs* 8.3 months, with a longer mean stent patency of 6.8 months *vs* 3.4 months, and with no significant difference in adverse events[53]. This has been corroborated in a multicenter randomized controlled trial with 174 patients randomized in a 1:1 ratio - each undergoing 2 index endoscopic interventions. The median overall survival was higher in the RFA group at 14.3 *vs* 9.2 months. Post-procedural Karnofsky performance scores were higher in the RFA group until 9 months. Acute cholecystitis was more frequent in the RFA group, but other adverse events were comparable[54]. In another study in patients with hilar biliary obstruction, 30 patients underwent endobiliary RFA for ingrowth occlusion after self-expandable metal stent placement. Technical success was possible in 28 of 30 (93.3%) of patients. Clinical success was achieved in 20 of the 28 patients who underwent RFA (71.4%), while recurrent biliary obstruction occurred in 9 of 20 (45%) of patients in a median of 163 d[55]. Another endobiliary ablative modality includes photodynamic therapy (PDT). A randomized trial of 43 patients who underwent endobiliary PDT alone *vs* in combination with S-1 (an oral anticancer drug combining a fluorouracil prodrug with an inhibitor of fluorouracil phosphorylation). A higher 1-year survival rate of 76.2% *vs* 32%, higher overall survival at 17 months *vs* 8 months, as well as higher progression-free survival at 10 months *vs* 2 months was noted in the combination group

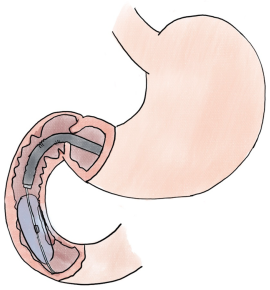

Figure 4 Cryoballoon ablation in the duodenum.

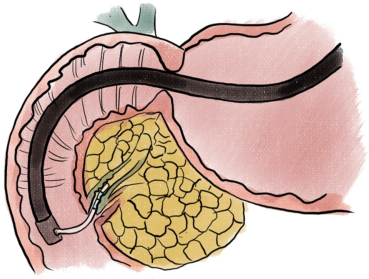

Figure 5 Endobiliary ablation for palliation.

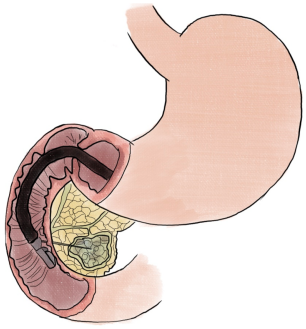

Figure 6 Endoscopic ultrasound with fine needle ablation/injection.

compared to PDT. There were no significant differences in adverse events or quality of life in either group[56].

Endobiliary ablation of CCA is typically limited to extrahepatic and hilar disease. The available data are supportive of a synergy of systemic treatment and endobiliary ablation in further improving survival[57].

COLORECTAL DISEASE

Endoscopic ablation in colorectal disease has been largely used in the context of precursor polyps as an adjunct modality to endoscopic resection. Endoscopic thermal ablation of the margins of large colon polyps has a lower recurrence rate 1.4% *vs* 27.1% in incomplete thermal ablation[58]. Endoscopic argon plasma coagulation (APC) of recurrent adenomatous tissue successfully eradicated polyps in 9 of 11 (82%) of patients[59]. Moreover, a multicenter study found that APC of polyp margin and base after EMR was associated with significantly lower recurrent adenomatous tissue than margin-only ablation (0.9% *vs* 8.8%)[60].

In the early 2000s, endoscopic laser photoablation was used to treat large sessile polyps with low- or high-grade dysplasia. Follow-up after 28 months with 4.3 treatment sessions per polyp resulted in complete eradication of 61% of polyps[61]. The application for palliation of bleeding and obstruction in rectal cancer has not been as promising[62].

RFA for palliation of rectosigmoid tumors was studied in 12 patients who were planned for surgical resection. In the 10 patients who had a specimen resected, 82% of the tumor mass was noted to be destroyed attributable to ablation[63]. In patients with inoperable cancer, a phase I study of 10 procedures of endoscopic calcium electroporation in 6 patients who

needed palliation had no adverse events. Five of the six patients reported symptom relief. One patient, who received concurrent systemic therapy was noted to have complete clinical response on follow-up 12 wk thereafter[64]. In such cases, the potential transition from a purely palliative role to a possible adjunct modality for organ preservation warrants further analysis and evaluation.

CONCLUSION

Endoscopic ablation encompasses a broad spectrum of modalities and techniques. The roles and applications are further stratified by disease process and anatomy of the target organ. Ablation of precancerous lesions in the luminal gastrointestinal tract has been a proven premise in cancer prevention and organ preservation. In the pancreas, the utility of endosonographic ablation in cystic neoplasms and PNETs has the potential of avoiding surgical resection - thereby highlighting the prospect of organ preservation. In cases of locally advanced or unresectable pancreatic adenocarcinoma, the tangible outcome is downstaging disease to a resectable stage thereby targeting improvement in overall survival. Studies on the latter category continue to emerge. Localized tumor injection and ablation as adjuncts to systemic therapy continue to have merit given the poor survival rates in pancreatic cancer. Furthermore, the costs and comorbidities of total esophagectomy, pancreaticoduodenectomy and abdominoperineal resections reinforce the need for organ preservation strategies.

It is important to reframe gastrointestinal malignancy into a systemic process that can elicit an immune response, which can be leveraged in treating the underlying disease. In addition to the debulking effect from local ablation, the targeted destruction of the local tumor can induce the exposure of cellular debris - a source of tumor antigens. Coupled with necrosis and a proinflammatory environment, antigen-presenting cells including dendritic cells infiltrate that environment and amplify the systemic immune response[65]. Furthermore, beyond triggering an immune response, a phase I clinical trial reported changes in cancer-associated gene expression after endoscopic ablation with calcium electroporation[66]. Therefore, the systemic implications of endoscopic ablation may go beyond the local effects of debulking and potentiating an immune response. For example, preclinical predictive numerical models utilizing confocal endomicroscopy have been shown to correlate with the degree of thermal injury as reflected by a ratio between damage depth over mucosa and submucosa thickness[67]. The optimal modality and dosimetry of ablation continue to be areas of active inquiry, especially with a paradigm shift to organ preservation such as in the SANO and OPRA trials[24,25].

Finally, multi-cancer early detection tests have the prospect of identifying early-stage cancers that otherwise have no screening protocols. Early detection may expand organ preservation treatment options including neoadjuvant ablation. This may have a significant impact in diseases where resection may be difficult, such as pancreaticobiliary malignancy. Ultimately, balancing such paradigm shifts with standard-of-care practices entails multidisciplinary discussions centered around the patient's unique circumstances and preferences.

FOOTNOTES

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