

preventing contamination (with an estimated relative risk of >3-fold higher). This is not surprising, given that the new duodenoscopes have cap attachment points that create additional crevasses beyond the elevator that must be manually cleaned.

Whereas the MAUDE data have various limitations,² including challenges with identifying potential duplicate/follow-on reports (although this applies equally to all categories of duodenoscopes here), the data presented here may underestimate these issues, because it did not include the 41 reported adverse events filed for international models or the 137 events filed under the related removable cap model numbers, some of which (but not all) may have been duplicates.

Two recent independent analyses of new innovations reported in the MAUDE database from 2018 through a portion of 2021 (April and June 2021 cutoffs, respectively) provide corroboration for these findings (although neither did a comparative analysis with conventional duodenoscopes).^{3,4} Along with the new data presented here, it is difficult to avoid the conclusion that these innovations not only may be ineffective in reducing contamination (this applies only to the removable caps) but also may increase the risk of both technical failure and direct injury to patients (this applies to both kinds of innovations). A more comprehensive examination of the true incidence of adverse events and effectiveness against contamination of the new duodenoscopes is therefore urgent and essential for the sake of patients undergoing this procedure.

DISCLOSURE

Dr Pasricha is a consultant for, and has ownership interest in, GE Scientific.

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<https://doi.org/10.1016/j.gie.2022.03.010>

Giant cell reaction subsequent to ORISE gel lifting agent captured on endoscopic ultrasound



To the Editor:

We read with interest the article by Olivás et al,¹ which discusses ORISE gel-related foreign body giant cell reaction (FBGCR) leading to submucosal findings that may be misinterpreted during surveillance endoscopy. FBGCR is increasingly documented in the literature as lifting agents become more commonly used in endoscopic practice.² We demonstrate a case of lifting agent-related FBGCR leading to an EUS finding of an 8-mm submucosal thickness.

A 56-year-old woman was undergoing colonoscopy after a positive fecal immunochemical test result. She was found to have a 1-mm polyp in the ascending colon and 2 polyps in the rectum (4 mm proximal and 14 mm distal) (Fig. 1). The rectal polyps were removed by the use of EMR with ORISE gel (Boston Scientific, Marlborough, Mass, USA) (Fig. 2). Histologic analysis revealed tubular adenomas with high-grade dysplasia.

Colonoscopy in December 2020 revealed a submucosal nodule in the rectum 50 mm from the anal verge (Fig. 3). EUS demonstrated 8 mm of rectal wall submucosal thickening (Fig. 4). After the patient was lost to follow-up, she underwent repeated colonoscopy in October 2021, which showed postmucosectomy scars in the rectum. Histologic analysis did not demonstrate any residual adenomatous tissue at the scar site; however, the submucosal nodule in the distal part of the rectum was still present.

Subsequent MRI demonstrated an area in the distal part of the rectum suggestive of lymphadenopathy. After referral to a colorectal surgeon, the patient underwent full-thickness biopsy. A final histologic examination demonstrated FBGCR, negative for dysplasia or malignancy.

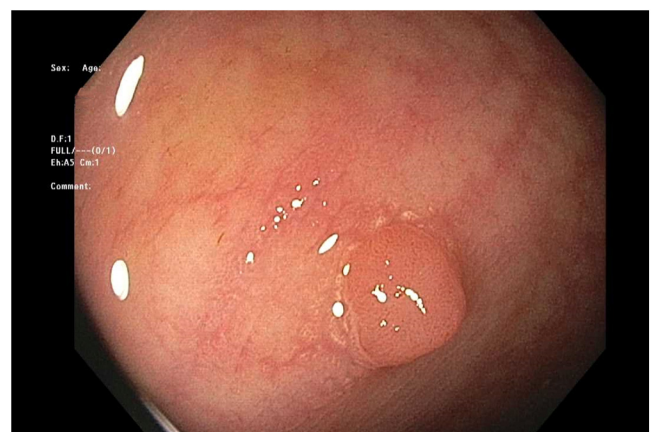


Figure 1. Two polyps in the rectum.

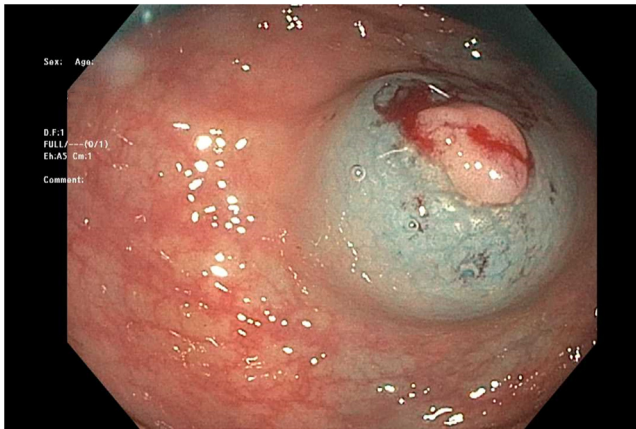


Figure 2. Rectal polyp after submucosal injection with ORISE gel.

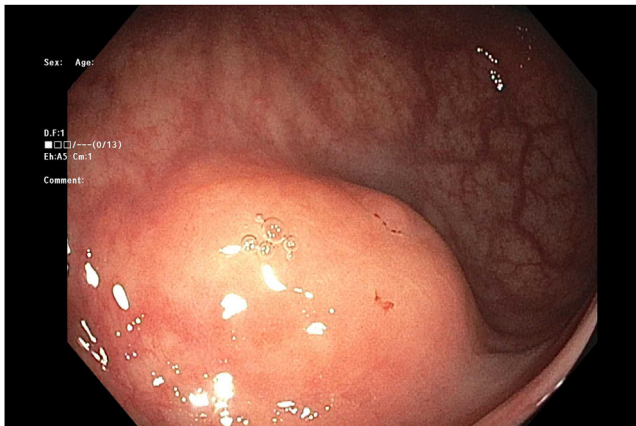


Figure 3. Submucosal lesion at the post-EMR site as seen on surveillance colonoscopy.

This case demonstrates FBGCR due to ORISE visualized endoscopically, histologically, and endosonographically.^{3,4} Identification of the abnormal US findings detailed here is of important clinical benefit. In patients undergoing endoscopic procedures where ORISE gel is used, endoscopists should recognize the potential of FBGCR leading to submucosal abnormalities on EUS. Awareness of this artifact can help reduce misidentification of pathologic tissue and decrease the need for unnecessary diagnostic interventions.

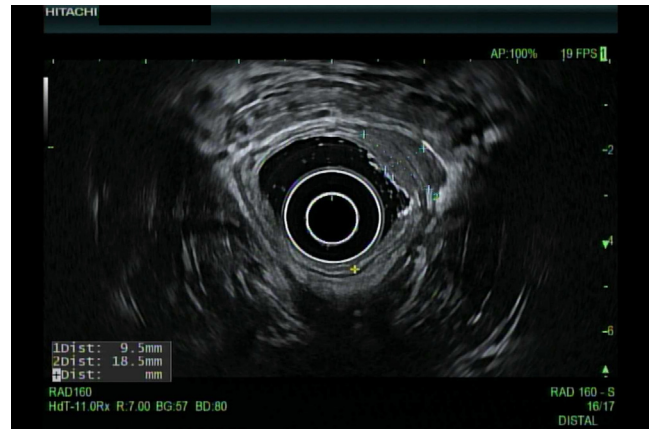


Figure 4. Submucosal lesion at the post-EMR site as seen on endosonographic imaging.

DISCLOSURE

Both authors disclosed no financial relationships.

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