BUDESONIDE ORODISPERSIBLE TABLETS REDUCE ESOPHAGEAL STRICTURE FORMATION AFTER ENDOSCOPIC SUBMUCOSAL DISSECTION: RESULTS OF A MULTINATIONAL, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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High-dose budesonide orodispersible tablets (2 mg twice daily for 8 weeks) significantly reduced esophageal stricture formation after endoscopic submucosal dissection compared to placebo, with 66.7% of patients remaining stricture-free versus 42.4% (p=0.0098).

KEY POINTS

- In a double-blind randomized trial of 102 patients undergoing esophageal ESD for squamous cell carcinoma (defects ≥50% circumference) or Barrett's high-grade dysplasia/adenocarcinoma (defects ≥75% circumference), high-dose budesonide achieved the primary endpoint of no stricture at 8 weeks in 66.7% versus 42.4% with placebo.
- Among patients requiring dilation, the mean number of dilations was lower with high-dose budesonide (2.8) compared to placebo (4.3).
- Candidiasis occurred in 29.1% of high-dose budesonide patients versus 2.5% with placebo, but all cases recovered and no serious adverse events related to study drug were observed.
- Stricture prevention was numerically higher with high-dose budesonide when mucosal defects involved ≥75% and <95% of circumference (92.0% vs 58.8% placebo), but lower when defects involved ≥95% (26.3% vs 0%).
- Stricture prevention rates with high-dose budesonide were similar for both squamous cell carcinoma (77.3% vs 53.8% placebo) and Barrett's high-grade dysplasia/adenocarcinoma (58.6% vs 35.0% placebo).

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