Safety of powered non-thermal endoscopic ablation device for Barrett's esophagus: a systematic review and meta-analysis

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ABSTRACT

Introduction
Endoscopic mucosal resection (EMR) is utilized for removing preneoplastic or neoplastic lesions from the gastrointestinal tract. EMR is recommended for patients with high risk for mucosal cancer, but the use of various thermal ablation techniques is associated with post-therapeutic stenosis. EndoRotor is a non-thermal device that suctions target epithelium into a small catheter where a spinning knife resects the mucosa, which may reduce the risk of scarring and stenosis. Therefore, we performed a systematic review and meta-analysis to evaluate the safety of EndoRotor for non-thermal ablation of Barrett's esophagus.

Methods
A systematic review of the literature was performed using Medline, Embase, Web of Science, and the Cochrane library database until June 2022 to identify all studies that evaluated the safety of non-thermal endoscopic resection devices for the ablation of Barrett's esophagus. Other outcomes of interest included rates of intraoperative bleeding, post-procedural bleeding, perforation, post-procedural stenosis, and post-procedural pain or discomfort. All analyses were conducted using comprehensive meta-analysis software.

Results
Five studies, including 70 patients, were included in the final analysis. There were four observational studies and one randomized controlled trial. The pooled rate of intraoperative bleeding was 39% (95% CI: 25.4-54.5%, I2=0) and post-procedural bleeding was 7.5% (95% CI: 2.6%-19.6%, I2=0). The pooled rate of perforation was 4.1% (1.3%-11.9%, I2=0), post-procedural follow-up stenosis was 11.2% (4.7%-24.2%, I2=0), and post-procedural pain or discomfort was 54.2% (95% CI: 41.5%-66.4%, I2=9.2%). The efficacy of EndoRotor was not evaluated given the lack of data reported in the included studies.

Discussion
The new EndoRotor resection device could be a viable alternative to existing ablative therapies for Barrett's esophagus. However, our study revealed significant adverse events. Therefore, larger randomized control trials are warranted to evaluate the risks and benefits of this novel device.

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INTRODUCTION

- Barrett's esophagus (BE) is a premalignant condition characterized by intestinal metaplastic transformation of the stratified squamous epithelium in the distal esophagus[1]
- BE is commonly treated with endoscopic ablation, but drawbacks to traditional thermal methods include inability to recover tissue samples and adverse events including scarring, stenosis, and perforation[2,3]
- EndoRotor® is a unique non-thermal resection device that suctions epithelium into a small catheter containing a spinning knife, and may have lower adverse events rates while allowing tissue collection for post-procedural evaluation
- Current data on EndoRotor® ablation therapy and outcomes in BE is limited

OBJECTIVE

To conduct a systematic review and meta-analysis of available literature to assess the safety of EndoRotor® for non-thermal ablation of Barrett's esophagus.

METHODS

- A comprehensive search strategy was used to identify randomized controlled trials and cohort studies that evaluated clinical safety outcomes in patients undergoing EndoRotor ablation for BE
- Given the presumed heterogeneity in studies, the random-effects model and DerSimonian-Laird approach were used as a priori to pool and compare outcomes
- All analyses were conducted using comprehensive meta-analysis software

RESULTS

The initial search revealed a total of 119 studies. Five studies (four observational studies and one randomized controlled trial), including 70 patients, met our inclusion criteria and were included in the final meta-analysis.

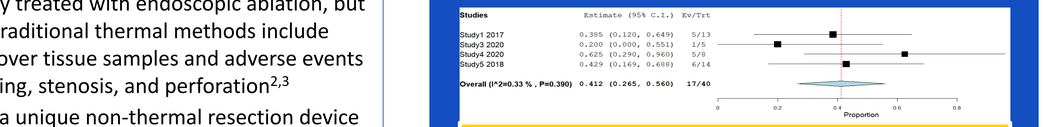

Figure 1. Intraoperative bleeding. The pooled rate of intraoperative bleeding was 41% (95% CI: 0.25-0.56, I2=33%).

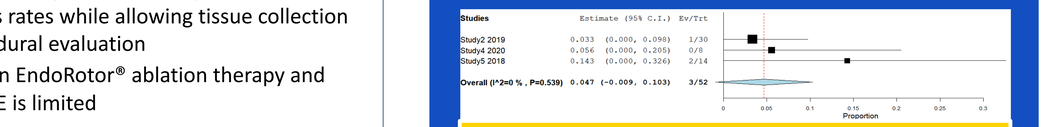

Figure 2. Postoperative bleeding. The pooled rate of postoperative bleeding was 4.7% (95% CI: -0.009-0.103, I2=0%).

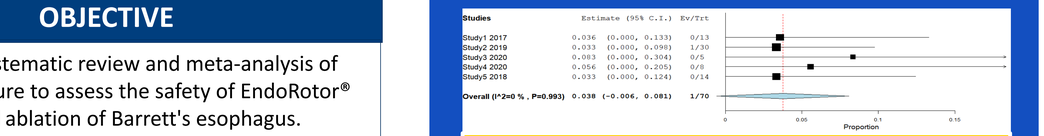

Figure 3. Perforation. The pooled rate of perforation was 3.8% (95% CI: -0.006-0.081, I2=0%).

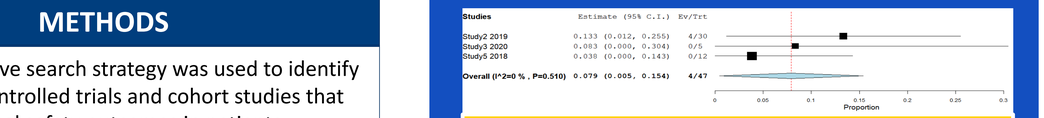

Figure 4. Post-procedural follow-up stenosis. The pooled rate of post-procedural follow-up stenosis was 7.9% (95% CI: 0.005-0.154, I2=0%).

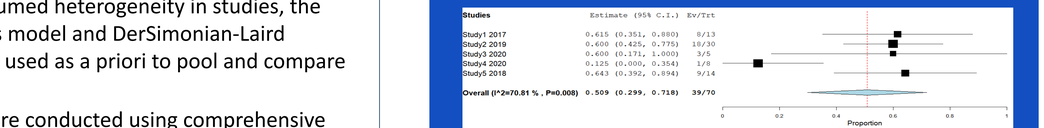

Figure 5. Post-procedural pain/discomfort. The pooled rate of post-procedural pain or discomfort was 51% (95% CI: 0.299-0.718, I2=71%).

DISCUSSION

- The small total number of patients (n=70) and differing inclusion/exclusion criteria of the studies present limitations to our meta-analysis
- The inclusion criteria mainly differed between studies in their inclusion of patients with refractory BE who already failed ablation therapy or previously underwent mucosal resection, which may impact our reported outcomes, as mucosal areas that already underwent and/or failed ablation/resection may be more prone to damage or scarring from previous procedures, and thus lead to higher rates of bleeding, perforation, or stenosis
- Important efficacy outcomes of EndoRotor® such as reduced recurrence of dysplasia were not evaluated given the lack of data reported

CONCLUSIONS

- EndoRotor® is a non-thermal resection device that may be a viable alternative to existing ablative therapies for Barrett's esophagus
- However, the risk of adverse events appears to be higher with EndoRotor® than RFA, although no head-to-head comparisons have been published
- The safety and efficacy of EndoRotor®, as well as it's role in prevention of recurrent dysplasia, require further investigation to better evaluate the risks and benefits of this novel device

References

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