Hot snare polypectomy versus endoscopic mucosal resection for small colorectal polyps: a randomized controlled trial (HSP vs HSPSI)

NCT No. : NCT 02239536

Document date : August 30, 2019

Methods

The study is a prospective randomized-controlled trial and was performed at two academic hospitals (Seoul St. Mary's Hospital and Incheon St. Mary's Hospital) from June 2014 to December 2017. The study protocol was approved by the Institutional Review Board of the Catholic Medical Center (Assignment No. XC14TIMI0039K) and registered with clinicaltrials.gov (NCT 02761213). Informed consent was obtained from all patients before they were enrolled.

Study population

Patients who underwent a screening, surveillance, or diagnostic colonoscopy were prospectively enrolled in the study. The inclusion criteria were patients with over the age of 30 years who provided informed consent and who had at least one small colorectal polyp (5-10 mm) with neoplastic features on narrow band imaging (NICE classification II).

Patients were excluded if they have a bleeding tendency or ever taken antiplatelet or anticoagulation therapy within 1 week before undergoing the procedure, an inflammatory bowel disease such as Crohn's disease and ulcerative colitis, a polyposis syndrome, or an inability to provide informed consent. When detecting the ineligible polyps with NICE classification I/III or more than a size of 10 mm, they were treated as per usual clinical protocol.

Procedures

All patients were prepared with a 2-L polyethylene glycol plus ascorbic acid solution (Coolprep®, Taejoon Pharm., Seoul, Korea). All colonoscopy was performed by two highly experienced endoscopists (L.B.I. and K.J.S.) using a high-definition endoscope (CF-HQ290I, CF-H260AI, or PCF-Q260AZI; Olympus Co, Japan). The morphology of the polyp was described by Paris classification. The size of a detected polyp was measured using the opening width of the biopsy forceps. When an eligible polyp (a 5-10 mm polyp with NICE classification II) were detected, it was randomly allocated to either HSP or EMR group. An oval snare (SnareMaster®, Olympus Co, Japan or Optimos®, Taewoong Co, Korea) with Endocut or Forced Coagulation current of an electrosurgical unit (VIO300D; Erbe Elektromedizin GmbH, Tubingen, Germany) was used for polypectomy. When the polyp was assigned to EMR group, submucosal injection with normal saline was performed in advance of polypectomy. The resected specimen was retrieved using endoscope suction channel. Two biopsies were obtained

from the most probable residual tissue at the polypectomy site after irrigation, air inflation, and close observation with white-light and narrow-band imaging. Each patient was allowed for enrollment of a maximum of 2 sequential polyps from the cecum.

Immediate bleeding indicates continuous bleeding over 30 seconds requiring any form of endoscopic hemostasis (epinephrine injection, clipping or coagulation) immediately or within 24 hours after polypectomy whereas delayed bleeding was defined as bleeding from the post-polypectomy site between 24 hours and 2 weeks after polypectomy.

The resected specimens and biopsy specimens were reviewed by 3 highly-experienced gastrointestinal pathologists who were blinded to the clinical information and resection techniques for evaluation the involvement of adenomatous tissue at the resection margin. Complete resection was defined as absence of neoplastic tissue from the two additional biopsies of the polypectomy site whereas involvement of resection margin was defined as absence of neoplastic tissue at the margin of the resected specimen. When the involvement of resection margin could not be determined because of electrocautery effect or tangential tissue section, it was classified as "inconclusive."

Study outcomes

The primary study outcome was a comparison of complete resection rates between two polypectomy techniques.

The secondary outcomes included involvement of resection margin and post-polypectomy adverse events including immediate/delayed bleeding and perforation between the two groups.

Sample size calculation and statistical analysis

There was no exact report of the incomplete resection rate of HSP and EMR for 5-10 mm neoplastic polyps at the time of the study design. We assumed the incomplete resection rate of HSP to be 15% and that of EMR was 5%. Estimated sample size was 310 polyps (155 per group) with a α-value of 0.05, power of 80%, and a 10% of dropout rate.

Chi-square test or the Fisher's exact test was used to compare categorical variables. The unpaired 2-sample t test was used for continuous variables. Binary logistic regression was used for multivariate analysis. All data analyses were performed by using Statistical Package for the Social Science for Windows (version 24, IBM corp. SPSS Inc, Chicago, Ill, US).