Cap-Assisted Colonoscopy Increases Detection of Advanced Adenomas and Polyps

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ABSTRACT

Background: Cap-assisted colonoscopy (CAC) has been reported to increase the adenoma detection rate (ADR) in Asian population. However, CAC trials in non-Asian population have had conflicting results. Studies in North America have shown an improvement in ADRs with the use of CAC, but it mainly included white and African American patients. Given the lack of prospective studies of CAC in Hispanics, we conducted this randomized controlled trial.

Materials and Methods: This is a randomized controlled trial comparing CAC with standard colonoscopy (SC) in patients undergoing screening or surveillance colonoscopy. Our primary outcome was the ADR. Secondary outcomes were polyp detection rate, mean polyp and ADR, advanced ADR (AADR) and detection rates based on polyp morphology and location.

Results: A total of 440 patients were included in the study (88.5% Hispanic). Cecal and terminal ileum intubation rates were similar in both groups (CAC: 97% and 86% versus SC: 99% and 81%, respectively). CAC did not improve ADR in comparison with SC (0.65 versus 0.52; $P = 0.079$); however, CAC had a higher AADR in comparison with SC (9.9% versus 4.6%; $P = 0.049$). CAC detected significantly more pedunculated polyps as compared with flat and sessile polyps ($P = 0.011$). Complication rates were similar in the CAC and SC groups (0.9% versus 0%).

Conclusions: In a predominantly Hispanic population, no difference was seen in the mean ADR with the use of CAC. However, CAC, when compared with SC, resulted in an increased AADR and mean polyp detection rate.

Key Indexing Terms: Polyp detection rate; Adenoma detection rate; Screening colonoscopy; Cap-assisted colonoscopy.
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INTRODUCTION

Screening colonoscopy is an essential diagnostic tool in the early detection of precancerous colonic lesions, preventing the progression of these lesions to cancer. Population-based and case-control studies found a 50% reduction in colorectal cancer incidence and up to a one-third reduction in mortality from colorectal cancer after screening colonoscopy.[1-3] Recently, cap-assisted colonoscopy (CAC) was proposed as a technique to improve the ADT. The CAC is a transparent hood that is attached to the distal end of the colonoscope and allows depressing the colon folds to visualize hidden polyps behind the folds. However, most data supporting CAC came from trials in Asian and European countries with the potential of a different population bias. Only 2 studies were published in North America supporting the role of CAC in increasing adenoma detection rate (ADR).[4,5] One study consisted of only white and African American patients, whereas the other study did not report baseline ethnic characteristics. Although U.S. and Asian studies have suggested an improvement in ADR by using CAC, several European[6,7] and Australian studies[8] have showed no significant difference in polyp or ADRs. Although ADR has traditionally been the benchmark for evaluating the effectiveness of colonoscopy in preventing colon cancer, more recent studies suggest that mean ADR may be a more accurate and an objective measure, as it is a true measurement of inspection of the entire colon.[9,10]

It was noted that colon cancer incidence is increasing among Hispanics compared with the non-Hispanic white population in New Mexico.[11] Mortality from colon cancer was also higher in Hispanics compared with non-Hispanic whites in the United States.[12] Although this can be explained by the lack of access to healthcare, the possibility of a higher prevalence of adenoma in Hispanic population is not completely ruled out. ADR in Hispanics is not well studied. Most data on this subject is driven from retrospective case-control studies and showed conflicting results.[13,14] Our university practice is located on the US-Mexico border, which is an ideal setting to study the ADR in Hispanics and the efficacy of CAC in increasing the ADR in this population. We hypothesized that CAC will significantly increase ADR compared with standard colonoscopy (SC) in a predominately Hispanic population at a large tertiary-care referral center.

METHODS

Study Design

This is a prospective, randomized study that compared mean ADR, mean polyp detection rate (PDR), overall PDR, ADR and advanced ADR (AADR) in patients undergoing a screening colonoscopy with and without CAC in 1-to-1 allocation ratio.

The study was approved by the Institutional Review Board of Texas Tech University Health Science Center. The study was registered at Clinicaltrial.gov under this identifier number: NCT01601431. The study was entirely funded by a seed grant from the Department of Internal Medicine at Paul L. Foster School of Medicine. Authors of this study had access to the study data and had reviewed and approved the final manuscript. Inclusion criteria were adult patients (age: 50-80 years) who underwent screening or surveillance colonoscopy. Patients who were pregnant, had a prior history of colonic surgeries, Crohn's colitis, ulcerative colitis, colon cancer and with poor bowel preparation were excluded.

Study participants were recruited from patients undergoing screening or surveillance colonoscopy at the University Medical Center at El Paso. Only cases performed by the attending physician without any fellows' involvement were recruited. Our university-based practice is an open-access referral system. Randomization was done using opaque sealed envelopes. Because of the nature of the procedure, neither the physician nor the assistant was blinded. Our primary outcome was comparing ADR between CAC and SC. Secondary outcomes were comparing PDR, mean PDR and ADR, AADR and detection rates based on polyp morphology and location in both groups.

Data Collection

After signing the informed consent, patient's baseline characteristics including comorbidities, cecal intubation time and rate, terminal ileum (TI) intubation time and withdrawal time were collected. The total number of adenomas and polyps detected along with the characteristics were recorded. The quality of the bowel prep and any complications up to a week after the procedure were also noted.

Equipment and Techniques

All procedures were performed using Olympus colonoscopes (CFQ-180, PCF Q 180 Colonoscope, Olympus America Inc., Center Valley, PA) and 19-in high-definition monitor (OEV 191H; Olympus America Inc.). For the CAC group, a transparent plastic cap (Disposable Distal Attachment, Model D-201-15004; Olympus America Inc.) was fitted to the distal end of the colonoscope. Procedures were performed under moderate sedation. Three gastroenterologists and 1 surgeon performed the study's procedures (M.O., R.G., M.Z. and B.D.). All procedures were performed entirely by attending physicians, without any fellow involvement. All attending physicians had performed a minimum of 20 cases of CAC before the study as a prerequisite to joining the study. Timing of the procedure was started at the time of the digital rectal examination. A research assistant (M.E.) was in charge of keeping track of the procedure timing and adherence to the study protocol. Cecal intubation time was calculated from the time of the start of the procedure to the time when the scope reached the cecum. To simulate normal practice experience, each physician was given up to 5 minutes after reaching the cecum to intubate the TI. Failed TI intubation was defined as the inability to intubate the TI after 5 minutes from cecal intubations. There were no limits on the number of trials for TI intubation within the 5-minute frame. Withdrawal time was calculated from the moment the endoscopist started withdrawing the colonoscope from the cecum to examine the colon. Withdrawal time did not include time for cleaning, washing of the colonic mucosa or time for polypectomy. The endoscopist defined the colonic mucosa preparation quality as excellent, good, fair or poor. The total number of polyps removed and polyp characteristics were recorded. Patients were followed up for 1 week after the procedure for possible postprocedure complications. Histologic results of the polyp removed were followed up within 1 week.

Measurements

Our primary outcome measure was ADR, which was calculated by dividing the total number of patients with at least 1 histologically confirmed adenoma by the total number of patients undergoing screening or surveillance procedures. The PDR was calculated by dividing the number of patients in which at least 1 polyp was detected (and endoscopically removed), by the total number of patients who underwent colonoscopy. Sessile serrated polyps were considered as adenomatous polyps in our study analysis. The rationale for this decision was that sessile serrated polyps have the same follow-up protocol as adenomatous polyps after screening colonoscopy given the malignant potential. Any detected adenomas were defined as an advanced adenoma if they had 1 or more of the following characteristics: polyp size $\geq$10 mm, villous histology or showed high-grade dysplasia, as defined by the US Multi-Society Task Force on Colorectal Cancer.[15,16] AADR was calculated by dividing the number of patients in which 1 or more advanced adenomas were detected by the total number of patients who underwent screening or surveillance colonoscopies.

Data Analysis

Based on prior studies, which showed an increased ADR from 13-15% using CAC, and based on our current ADR of 30%, the estimated number of subjects in each arm of the study was 200 (assuming 80% power). Given the possibility of 10% poor preparation during