

B10 臨床組-醫師

冷切與熱切法對於切除大腸小型息肉的比較:全國多中心隨機臨床試驗

Cold Versus Hot Snare Polypectomy for Small Colorectal Polyps: A Pragmatic Randomized Controlled Trial

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Background:

Cold snare polypectomy (CSP) was considered as effective in reducing the risk of delayed post-polypectomy bleeding. However, previous randomized controlled trials (RCTs) are mainly conducted in high-risk subjects using anticoagulants rather than in average-risk population.

Aim:

Investigate the risk of delayed bleeding after CSP and hot snare polypectomy (HSP)

Method:

This is a multicenter RCT performed in to six Taiwanese centers (ClinicalTrials. gov: NCT03373136). A minimal of 4258 subjects were considered as necessary using delayed bleeding as the primary outcome based on previous meta-analyses. Subjects having colorectal neoplasm sized 4 to 10 mm were randomly assigned to either CSP or HSP arm. Lesions exceeding this size range were managed as per the preference of individual endoscopist. The primary measurement was the risk of delayed bleeding. Secondary measurement included event of emergency service (ES) visit, procedure time, tissue retrieval rate, and en-bloc resection rate. All enrolled subjects were interviewed by telephone on day 2 and day 14 after colonoscopy to access delayed bleeding.

	CSP	HSP
	(N=2,137)	(N=2,133)
Age - years, mean (SD)	61.7 (9.7)	61.9 (10.2)
Gender, no. (%)		
Male	1,273 (59.6)	1,306 (61.2)
Female	864 (40.4)	827 (38.8)
History of colonic polyps, no. (%)	1,014 (47.4)	1,037 (48.6)
Body mass index, kg/m ² (SD)	24.9 (3.8)	25.1 (3.8)
Colorectal cancer history, no. (%)	46 (2.2)	44 (2.1)
Smoking, no. (%)		
Current	409 (19.1)	395 (18.5)
Past	284 (13.3)	274 (12.9)
Never	1,444 (67.6)	1,464 (68.6)
Current use of alcohol, no. (%)		
Yes	285 (13.3)	253 (11.9)
No	1,852 (86.7)	1,880 (88.1)
Anticoagulants use, no. (%)	51 (2.4)	49 (2.3)
With discontinuation	40/51 (78.4)	43/49 (87.8)
Antiplatelet agents use, no. (%)	246 (11.5)	240 (11.3)
With discontinuation	225/246 (91.4)	210/240 (87.5)
Colonoscopy results		
Complete colonoscopy, no. (%)	2,122 (99.3)	2,119 (99.3)
Number of polyps, mean (SD)	2.3 (2.0)	2.4 (2.0)

Table 1: Baseline characteristics of participants between two groups

Result:

During the period of August 2018 to August 2020, a total of 7,596 subjects were assessed for eligibility, and 4,270 were successfully randomized and finished two telephone interviews. Totally 2,133 and 2,137 subjects were randomized into HSP and CSP arms, respectively (**Figure 1**). The characteristics of participants and polyps were shown in **Table 1** and **Table 2**. The risk of delayed bleeding was significantly higher in HSP than in CSP [31(1.5%) *vs.* 8(0.4%), p<0.001]. There were 8 severe delayed bleeding, which was defined as drop of hemoglobin more than 2mg/dL, requiring hemostasis, or transfusion, in HSP group and 1 in CSP group [8(0.4%) *vs.* 1(0.05%); p=0.02]. Events of ES visit were higher in HSP [13(0.61%) *vs.* 4(0.19%); p=0.03]; mean polypectomy time (sec) was significantly longer in HSP [142.3(±188.9) *vs.* 106.7(±152.2); p<0.001]; tissue retrieval rate (HSP: 98.4% *vs.* CSP: 98.7%, p=0.21) and en-bloc resection rate (HSP: 97.2% *vs.* CSP: 96.8%, p=0.37) were equivalent between two groups (**Table 3**).

Figure 1: Study flow diagram



Table 2: Characteristics of polyps between two groups

	CSP	HSP
	(1=4,995)	(IN=5,045)
Mean size, mm (SD)	6.0 (3.2)	6.1 (3.3)
Diminutive (<5 mm), no. (%)	1,271 (25.4)	1,284 (25.5)
Small (5-10 mm), no. (%)	3,471 (69.5)	3,486 (69.1)
Large (>10 mm), no. (%)	253 (5.1)	275 (5.5)
Location, no. (%)		
Proximal	2,654 (53.1)	2,770 (54.9)
Morphology, no. (%)		
Non-polypoid	2,242 (44.9)	2,142 (42.5)
Pathology, no (%)		
Invasive cancer	26 (0.6)	14 (0.3)
Adenoma	3,496 (70.0)	3,538 (70.1)
High-grade dysplasia	30 (0.9)	36 (1.0)
Sessile serrated lesion	230 (4.6)	240 (4.8)
Non-neoplastic lesion*	1,176 (23.5)	1,170 (23.2)
Failed tissue retrieval, no. (%)	67 (1.3)	83 (1.6)
hle 3. Outcomes measurement het	ween two grouns	
CSP	HSP	Rick Difform

CSP = cold snare polypectomy; HSP = hot snare polypectomy.

Primary outcomes

Delayed post- polypectomy bleeding	8 (0.4%)	31 (1.5%)	-1.1 (-1.7 to -0.5)
Rectal bleeding with spontaneous stop	7 (0.3%)	23 (1.1%)	-0.8 (-1.3 to -0.3)
Severe bleeding	1 (0.05%)	8 (0.4%)	-0.3 (-0.6 to -0.05)
Endoscopic hemostasis	1 (0.05%)	4 (0.2%)	-0.1 (-0.4 to 0.06)
Secondary outcomes			
Mean polypectomy time,	119.0	162.9	-44.0
seconds (SD)	(147.0)	(156.3)	(-53.1 to -34.9)
Successful tissue retrieval	98.7%	98.4%	0.3 (-0.2 to 0.8)
Emergency service visit	4 (0.2%)	13 (0.6%)	-0.4 (-0.8 to -0.04)
Hospital admission	2 (0.09%)	1 (0.05%)	0.05 (-0.1 to 0.2)

(N=2,133)

Difference in Mean

(95% CI)

(N=2,137)

Conclusion

CSP significantly reduced the risk of delayed post-polypectomy bleeding, including both severe and mild events. We concluded that CSP is safer than HSP in resecting colorectal polyps sized 4 to 10 mm.