The safety of radiofrequency ablation using a novel temperature-controlled probe for the treatment of residual intraductal lesions after endoscopic papillectomy

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#### Disclosure statement

• All authors have nothing to disclose

# Aim of study

• To determine the **safety** of RFA using a **novel temperaturecontrolled RF probe** for the treatment of <u>residual intraductal</u>

lesions after endoscopic papillectomy.

#### Methods

- Retrospective study, single tertiary center (Seoul St. Mary's H)
- November 2017 to June 2019
- A cohort of patients that received RFA for residual intraductal lesions after endoscopic papillectomy
- A novel temperature-controlled probe (ELRA<sup>™</sup>, STARmed, Goyang, Korea) was used for intraductal RFA

#### Methods

• RFA catheter: 7Fr large, 175cm long,



bipolar electrodes of 4mm width and 11mm length

- RF generator set: maximum temperature of 80°C, power 7W
- RFA time: within 90 seconds
- After RFA, prophylactic biliary and pancreatic stents were inserted
- Follow-up endoscopy: 1-2 months  $\rightarrow$  3-6 months within 1year from RFA  $\rightarrow$  6 months x2  $\rightarrow$  every 1year

## Methods

- Primary endpoint
  - The incidence of adverse events after intraductal RFA
- Secondary endpoint
  - The rate of successful endoscopic treatment
    - defined as the absence of adenomatous tissue in the follow-up biopsy

## Results

#### Table 1 Clinical Characteristics of 10 Patients

| Patient<br>No. | Age<br>(years) | Sex | Adenoma<br>Size (mm) | Adenoma<br>Pathology | Initial<br>Deep/Lateral<br>margin<br>involvement | Duct (s)<br>involved | Intraductal<br>extension<br>length (mm) | Worst<br>ductal<br>pathology | Time from<br>Papillectomy<br>to RFA (days) | No. of<br>RFA<br>sessions | ERBD/<br>ERPD<br>after<br>RFA | Final<br>follow-up<br>pathology | Follow-up<br>duration<br>(days) |
|----------------|----------------|-----|----------------------|----------------------|--|----------------------|---|------------------------------|--|---------------------------|-------------------------------|---------------------------------|---------------------------------|
| 1              | 70             | Μ   | 25                   | TA-HGD               | +/-  | CBD, PD              | 6, 11                                   | TA-HGD                       | 2  | 1                         | +/+                           | Normal                          | 333                             |
| $2^{\dagger}$  | 75             | F   | 15                   | TV-HGD               | +/-  | CBD                  | 10                                      | TV-HGD                       | 6  | 1                         | +/+                           | ADC m/d                         | 622                             |
| 3              | 23             | Μ   | 7                    | TA-LGD               | _/_  | CBD                  | 7                                       | TA-LGD                       | 1150                                       | 1                         | +/-                           | Normal                          | 570                             |
| 4              | 54             | Μ   | 15                   | TA-LGD               | _/_  | CBD, PD              | 10, 10                                  | TA-LGD                       | 86   | 1                         | +/+                           | Normal                          | 275                             |
| 5              | 36             | F   | 10                   | TA-LGD               | _/_  | CBD, PD              | 5, 5                                    | TA-LGD                       | 728  | 1                         | +/+                           | Normal                          | 357                             |
| 6              | 71             | Μ   | 10                   | TA-LGD               | _/_  | CBD, PD              | 8, 5                                    | TA-LGD                       | 738  | 1                         | +/+                           | Normal                          | 74                              |
| 7              | 26             | F   | 4                    | TA-LGD               | UA   | CBD, PD              | 10, 4                                   | TA-LGD                       | 410  | 1                         | +/+                           | Normal                          | 231                             |
| 8              | 74             | Μ   | 10                   | TA-LGD               | -/-  | CBD                  | 7                                       | TA-LGD                       | 122  | 1                         | +/+                           | Normal                          | 123                             |
| 9              | 74             | F   | 10                   | TA-LGD               | -/-  | CBD, PD              | 10, 5                                   | TV-LGD                       | 132  | 1                         | +/+                           | Normal                          | 186                             |
| 10             | 64             | F   | 30                   | TA-LGD               | UA   | CBD, PD              | 10, 4                                   | TA-LGD                       | 4  | 1                         | +/+                           | Normal                          | 91                              |

ADC, adenocarcinoma; CBD, common bile duct; ERBD, endoscopic retrograde biliary drainage; ERPD, endoscopic retrograde pancrea tic drainage; F, female; HGD, high grade dysplasia; LGD, low grade dysplasia; M, male; m/d, moderately differenti ated; No., number; PD, pancreatic duct; TA, tubular adenoma; TV, tubulovillous adenoma; UA, unable to assess.

<sup>†</sup>Patient No. 2 showed high grade dysplasia on follow -up biopsy 2 months after endoscopic papillectomy, and adenocarcinoma on the pathologic results of subsequent surgical treatment.

#### Flowchart summarizing overall results



PPPD, pylorus preserving pancreaticoduodenectomy; ADC, adenocarcinoma.

## Results

**Table 2**Adverse Events

| Characteristics                                   | <i>n</i> (Patient No.) |
|---|------------------------|
| Pancreatitis                                      | 2 (Patient No. 5, 7)   |
| Cholangitis                                       | 0                      |
| Bleeding  | 0                      |
| Perforation                                       | 0                      |
| Nonsymptomatic biliary stricture detected at ERCP | 1 (Patient No. 1)      |

ERCP, endoscopic retrograde cholangiopancreatography

# Conclusion

- RFA using a temperature-controlled RF probe showed acceptable safety without serious side effects in 10 patients with residual intraductal lesions after endoscopic papillectomy.
- Avoiding excessive heat using temperature-controlled RFA is expected to reduce adverse events, and future prospective studies are needed to confirm whether this method is significantly safer than other RFA methods.