Device :
- Soft assembling peptide Purassat® (3D matrix, Japan)
- Gel syringes of 3 and 5 ml
- Soft catheter introduced in the operating channel

Inclusions:
- EMR or ESD for superficial digestive lesion or neoplasia
- No perforation during resection

High Risk patients:
- Pursued aspirin therapy
- Anticoagulant bridge
- Liver cirrhosis
- Large duodenal resections > 2 cm

Table 1: Overall results in the different locations

<table>
<thead>
<tr>
<th>Location</th>
<th>Number</th>
<th>Hemoglobin</th>
<th>Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td>17</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Stomach</td>
<td>37</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Colon</td>
<td>10</td>
<td>0.8</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Table 2: Results depending on the technique.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Number</th>
<th>ESD</th>
<th>Forceps ESD</th>
<th>ESD per minute</th>
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</thead>
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<tr>
<td>EMR</td>
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<td></td>
<td></td>
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Conclusion:
Our study has several limitations since it is a retrospective analysis without comparison with a control group. Furthermore, the lack of repeated endoscopy to assess the mucosal healing after several weeks is missing but corresponds to the clinical practice since second look endoscopy procedure is not recommended in Europe. The use of this novel SAP gel is a quick, easy to use and safe technique without any learning curve for trained physicians who perform endoscopic resections. It may help to reduce the post resection bleedings including in high-risk situations. Further studies are now scheduled to fully evaluate its effectiveness and its safety particularly in risky situations comparatively.

Abstract

Background:
Endoscopic resections remove superficial digestive neoplasia with low morbidity and mortality. Nevertheless, delayed bleeding has been reported in approximately 1 to 15% of cases, increasing with antiplatelet/anticoagulant therapy in case of high risk of bleeding. A self-assembling peptide (SAP) forming a gel in appropriate conditions of ionization could protect the mucosal defect during the early phase of healing. The aim of this clinical trial was to assess the safety and efficacy of the SAP to prevent delayed bleedings after endoscopic resections.

Methods:
Consecutive patients who underwent endoscopic resections for esophageal, gastric, duodenal or colic superficial lesions were enrolled in two tertiary referral centers. Patients with high risk of bleeding like patients with antiplatelet agent, anticoagulation drugs with heparin bridge therapy and cirrhosis with portal hypertension were also included. The SAP gel (Purassat, 3D Matrix, Ltd) was applied immediately after resection. The volume of gel depended on the resection's site measured and was applied with a catheter in order to cover the whole ulcer bed. Ease of use and safety were assessed.

Results:
65 patients were included with 65 lesions from different locations of the digestive tract (table 1) (esophagus n=8, stomach n=22, duodenum n=10, ampullary n=3, colon n=7, and rectum n=15) in two centers. Among those 65 lesions, 25 were resected in high-risk situations (9 pursued aspirin therapy, 6 heparin bridge therapies followed by anticoagulant drugs at day 1, 1 cirrhosis and portal hypertension, 1 both cirrhosis and heparin bridge therapy, 3 both cirrhosis and pursued aspirin therapy, 3 large duodenal lesions over 2 cm and 2 early introduction of clopidogrel at day 1). The resection technique was ESD 40 cases, en-bloc EMR in 16, piecemeal EMR in 6 and ampollectomy in 3. The mean lesion size was 7.9 mm (SD: 2.2) with a mean area of 6.3 cm² (SD: 3.5). No difficulty was noted during application. Four delayed overt bleedings occurred (6.2 %) (3 hematomea, 1 hematemesis) needing endoscopic hemostasis in 4 cases. The mean hemoglobin drop off was 0.6 g/dl (±0.5 to 3.1 g/dl). There were no adverse events related to the gel application.

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