PuraStat®

gastrointestinal case report | Vol. 1

Mode of Action

PuraStat is a slightly viscous solution of synthetic peptides. Contact between PuraStat and blood causes the acidic peptide solution to be neutralized and exposed to ions, resulting in the formation of β-sheets that then form a 3-dimensional scaffold structure. PuraStat provides a physical barrier to stop bleeding in a variety of surgical indications.

Indication For Use (1)

PuraStat is indicated for haemostasis in the following situations encountered during surgery, when haemostasis by ligation or standard means is insufficient or impractical:

- Anastomosis to native or artificial vessel
- Coronary bypass
- Femoral bypass
- Surgery of the aorta or any peripheral arteries
- Endoscopic mucosal resection (EMR) of GI tract
- Endoscopic submucosal dissection (ESD) of GI tract
- Laparoscopic resection of GI tract organs

PuraStat is also indicated for the reduction of delayed bleeding following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon.

Please read carefully the Instructions for Use for indications and contra-indications.

References:
(1) PuraStat IFU-002 Rev 2.2
(2) Data on file (Swell Report 2018, Eun Seok Gil 12/06/2018)
(3) Biological Safety Report - current version

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KEY FEATURES

- Transparent soft gel
- No preparation required
- Synthetic peptide
- Non-swelling (2)
- Biocompatible (3)
Experience of PuraStat® During Resection of a Large Circumferential, Recto-Sigmoid Polyp

CASE PRESENTATION

DIAGNOSIS  
Carpet adenoma of rectum (Size: Circumferential lesion from dentate line to 17 cm in rectum)

PROCEDURE

- Knife Assisted snare Resection (KAR): An ESD knife was used for marking the edges of the polyp and performing circumferential mucosal incision around the lesion with some submucosal dissection before snare resecting it in multiple pieces. An electro-surgical coagulation forceps was occasionally used for haemostasis.
- PuraStat was applied, with the catheter specially designed for the syringe, a total of 4 times to the bleeding vessels in the EMR base during procedure and good haemostasis was observed. Approximately 8.5 ml of PuraStat was used in total.
- Histology: Adenoma with low grade dysplasia.

POSTOPERATIVE COURSE  
Repeat endoscopy at 2 weeks showed very healthy, almost healed EMR scar with mild narrowing of the lumen. Prophylactic dilatation was performed twice with no recurrence at 3 months.

FEEDBACK ON PURASTAT USAGE

“PuraStat is very easy to deliver and to handle. PuraStat stops oozing and slows down brisk bleeds. It is a transparent gel which does not compromise endoscopic views after application as compared to other spray powders. This allows endoscopist to apply additional haemostatic therapy if necessary. The standard therapy for haemostasis control such as electrocautery introduces a thermal injury to the bowel wall and carries the risk of causing perforation. Furthermore, it requires precise targeting of the bleeding vessel which can be very difficult during active bleeds.”

PuraStat can be applied in the general area of bleeding and does not require precise application to the exact point of bleeding. It was really surprising to see enhanced healing and formation of soft scar at the EMR site, 15 days post procedure.”

Pradeep Bhandari, Professor  
Queen Alexandra Hospital, Endoscopy Department  
Portsmouth, United Kingdom
**PuraStat**

**Mode of Action**

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<table>
<thead>
<tr>
<th>Example</th>
<th>Bleeding from small blood vessels and oozing from capillaries of the parenchyma of solid organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myomectomy</td>
<td>・Myomectomy</td>
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<tr>
<td>Nephrectomy</td>
<td>・Nephrectomy</td>
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<tr>
<td>Pancreactectomy</td>
<td>・Pancreactectomy</td>
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<tr>
<td>Partial hepatectomy</td>
<td>・Partial hepatectomy</td>
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<tr>
<td>Prostatectomy</td>
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<tr>
<td>Splenectomy</td>
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<tr>
<td>Femoral bypass</td>
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PuraStat is also indicated for the **reduction of delayed bleeding** following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon.

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Haemostasis with PuraStat® During ESD/EMR Procedure

**CASE PRESENTATION 1**

**DIAGNOSIS**
Barrett’s oesophagus C0M5 (Circumferential extent and Maximum extent of metaplasia) and a neoplastic lesion within the Barrett’s segment

**PATIENT DEMOGRAPHICS**
Male, 63 years old

**PROCEDURE**
- Underwent ESD for 40 mm nodule
- Mucosal oozing and bleeding from a visible vessel encountered during procedure and haemostasis achieved with 4 ml of PuraStat
- Post ESD histology:
  - Residual tumor (R) classification: R0
  - Well differentiated intramucosal cancer (tumor extension: pT1aM2) with no lympho-vascular invasion

**POSTOPERATIVE COURSE**
Uneventful
No delayed bleeding or perforation

**CASE PRESENTATION 2**

**DIAGNOSIS**
A 20 mm sigmoid polyp scarred from previous unsuccessful attempts at resection

**PATIENT DEMOGRAPHICS**
Female, 71 years old

**PROCEDURE**
- Knife Assisted snare Resection (KAR) was performed following 80% circumferential dissection
- Mucosal bleeding encountered during dissection
  Haemostasis achieved with 2 ml of PuraStat

**POSTOPERATIVE COURSE**
Uneventful
No delayed bleeding or perforation

**FEEDBACK ON PURASTAT USAGE**

"Haemostatic control offered by PuraStat made Barrett’s ESD safer by reducing the need for coagulation current on the esophageal ESD base."

"Scarred polyps can be very difficult to resect with significant risk of bleed and perforation. PuraStat is helping reduced the immediate risk."

Pradeep Bhandari, Professor
Queen Alexandra Hospital, Endoscopy Department Portsmouth, United Kingdom
PuraStat®
Clear haemostatic control (1)

Mode of Action

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Bleeding from small blood vessels and oozing from capillaries of the parenchyma of solid organs

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Haemostasis with PuraStat® During Polyp Resection in Patients Using Anti-Aggregants

CASE PRESENTATION 1

**DIAGNOSIS**
Sigmoid polyp in patient receiving dual antiplatelet therapy.
Restenosis after prior stent placement 6 months ago. Patient requiring urgent surgery due to caecum neoplasia (Fig. 1).

**PATIENT DEMOGRAPHICS**
Male, 72 years old

**PROCEDURE**
- Injection of diluted adrenalin in the base of the lesion and then resection with a braided polypectomy loop
- 1.5 ml of PuraStat was applied over the bleeding scar, achieving a good haemostasis (Fig. 2)
- Histology: Tubular villous adenoma with high grade dysplasia and foci of intramucosal carcinoma

**POSTOPERATIVE COURSE**
The patient showed good progress without manifestation of bleeding and anemia. Endoscopic follow up after 2 months without alterations.

CASE PRESENTATION 2

**DIAGNOSIS**
Active bleeding polyp in left colon (Fig. 3)
Patient suffering from anemia and episodes of angina pectoris. Antiplatelet medication due to stent placement after heart attack 4 months ago

**PATIENT DEMOGRAPHICS**
Male, 54 years old

**PROCEDURE**
- Resection with polypectomy loop
- After application of 2 ml PuraStat haemostasis was achieved in the resected area (Fig. 4)
- Histology: Tubular villous adenoma with high grade dysplasia

**POSTOPERATIVE COURSE**
The patient was discharged showing good progress without anemia or active bleeding having occurred. Endoscopic follow up after 2 months without complications.

**FEEDBACK ON PURASTAT USAGE**

“Due to the transparency and the fact that it is easy-to-use, PuraStat is well applicable to treat and prevent bleedings in the sub-mucosa due to possible residual lesions”

Dr. Víctor M Aguilar Urbano
Hospital El Ángel (Málaga), Spain
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Haemostasis with PuraStat® in Papillectomy

**CASE PRESENTATION**

**DIAGNOSIS**
Adenoma of the major duodenal papilla

**PATIENT DEMOGRAPHICS**
- Male, 54 years old
- Incidental finding of an adenoma of major duodenal papilla (Fig. 1)
- Histology: tubulo-villous adenoma with low grade dysplasia

**PROCEDURE**
- Endoscopic resection of the adenoma with snare papillectomy and prophylactic implantation of a pancreatic stent (Fig. 2)
- Hemorrhagic shock on the following day caused by an arterial bleeding at the resection site occurred (Fig. 3)
- Injection of 6ml adrenaline (1:10000) and implantation of a stent in the bile duct was consecutively performed (Fig. 4)
- Because of persistent bleeding 1ml PuraStat was applicated and hemostasis could be achieved after 45 seconds (Fig. 5); (Fig. 6)

**POSTOPERATIVE COURSE**
2 days after following application of PuraStat a clear resection site was observed an both stents could be removed

**FEEDBACK ON PURASTAT USAGE**

“PuraStat is very helpful new tool in haemostasis that allows successful application also in such special bleeding sites as the duodenal papilla where clipping is very difficult/dangerous because of the orifice of pancreatic and bile duct.

PuraStat is very easy to use.”

Professor Jens Tischendorf, M.D.
Department of Internal Medicine und Gastroenterology
Rhein-Maas Hospital, Würselen, Germany
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Available in 1 mL (621-013), 3 mL (621-014) and 5 mL (621-015)

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A recto-sigmoidoscopy was immediately performed, showing a 3cm dehiscence caused by impaired or delayed wound healing.

During the same procedure, PuraStat was applied to the dehiscence area. This allowed the creation of a film, protecting the submucosal layers. 3mL of PuraStat was used.

No during or post-procedural bleeding or other complications were observed.

Four weeks after the first treatment, the patient underwent a new recto-sigmoidoscopy. This showed a complete mucosal healing of the dehiscence. Patient reported no recurrence of rectal bleeding or tenesmus.

"PuraStat is very easy to use endoscopic device, with a quick haemostatic effect and a full transparency allowing a clear vision on bleeding or tissue. Transparency of PuraStat maintains a clear view and full control, increasing accuracy and safety. Our case shows a new possible field of application for PuraStat. This peptide-based matrix seems to have tissue regenerative properties, as demonstrated on cell cultural media and in dental bone."

Dr Claudio Zulli
GI and Endoscopy Staff, Endoscopy Unit, AOUI San Giovanni di Dio e Ruggi d’Aragona, Mercato San Severino, Salerno, Italy