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Technique used for PuraStat® application in urinary bladder bleeding

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ABSTRACT

Objectives: Persistent bleeding of the bladder is one of the side effects of radiotherapy. At present, there is no treatment to reliably cure the persistent bleeding caused by the radiation cystitis. PuraStat® (a haemostatic agent) has been successfully used to stop bleeding during endoscopy, and to control rectal bleeding after radiotherapy (post-radiation proctitis). We aimed to develop and describe the technique of using the PuraStat® for radiation cystitis.

Methods: For this procedure, we use a single use cystoscope. After assessment of bleeding using cystoscopy grading (TABS – score), a 50 mls (luer-lock) syringe is attached to the cystoscope, urine is aspirated. A three-way adaptor is placed on the flexible cystoscope fluid channel and air is instilled into the bladder, approximately 150 mls with the exact quantity depending on the bladder capacity. Next, an air cystoscopy is performed. Over the bleeding areas, a small amount of PuraStat® is applied by connecting the PuraStat® syringe to the flexible cystoscope and injecting it through the irrigation port. The same procedure is repeated approximately one month after the initial procedure. After another month, a further cystoscopy can be performed to assess clinical outcomes.

Findings: The technique was feasible to perform and is easy to duplicate. In our previous published case report on this novel technique, the results were promising with the bleeding stopped completely after the second application of PuraStat®.

Conclusions: The application of PuraStat® in the bladder is feasible, and in our single case experience, very effective. More cases are now needed to be able to assess the true effectiveness, and whether any adverse events may occur subsequently.

KEYWORDS

Hemorrhagic cystitis; haemostatic; PuraStat®, air cystoscopy

1. INTRODUCTION

Radiation Cystitis occurs owing to inflammation and subsequent destruction to the normal anatomy of the urinary bladder at the cellular level after the use of radiation in the treatment of multiple cancer types, such as, pelvic cancers [1]. Acute radiation cystitis occurs during or soon after radiation treatment. It is usually self-limiting and is generally managed conservatively. Late radiation cystitis, can develop from 6 months to 20 years after radiation therapy. The main presenting symptom is hematuria, which may vary from mild to severe, life-threatening hemorrhage. While some clinical management procedures are available for severe late radiation cystitis, such as selective embolization or ligation of the internal iliac arteries, at present these treatments do not reliably cure the persistent bleeding caused by the radiation cystitis.

PuraStat® is a synthetic haemostatic material in the form of a prefilled syringe. PuraStat® is indicated for haemostasis in the following situations encountered during surgery, when haemostasis by ligation or standard means is insufficient or impractical, including: a) bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs; b) oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues; and c) bleeding from small vessels and oozing from capillaries of the GI tract and surrounding tissues [2].

Previously, PuraStat® has been successfully used to stop bleeding during endoscopic procedures, and to control rectal bleeding after radiotherapy (post-radiation proctitis) [3]. The potential use of this product looks promising for patients with persistent hematuria post radiation cystitis who otherwise, have no other option. We have previously conducted a case report where a 73-years old male patient was emitted to a hospital emergency unit several times with gross hematuria leading to urinary clot retention and was diagnosed with radiation cystitis. After initial clinical management, a cystoscopic application of PuraStat® was administered which led to the remission of the urinary bleeding in the short-term. We continue to monitor the effects in the medium and long-term. The present paper aims to clearly outline the procedure to support radiation cystitis with severe hematuria clinical treatment and management.

2. METHODS

To develop the technique of using the PuraStat® for radiation cystitis, one of the challenges is the need for PuraStat® not to be exposed to urine, even for a limited period of time.

The technique: For this procedure we use a single use cystoscope. Before performing the cystoscopy, we need to make sure we can transfer the PuraStat® through the cystoscope. To be able to deliver the hemostatic via the cystoscope, the PuraStat® is transferred from the recipient into a 20 mls Luer lock syringe in a sterile manner and the syringe is kept secure on a sterile drape (Figure 1).

Figure 1. Preparing the PuraStat to be applied

After the preparation for cystoscopy in the usual manner, cleaning of the area and instillation of local anesthetic, flexible cystoscopy is performed. The extent of the bleeding is assessed.

To assess the bleeding, we propose a classification system to facilitate the standardization of the approach and the subsequent use of PuraStat®.

Cystoscopic grading: We propose patients should be classified with a new endoscopic score for radiation cystitis, comprising three factors: telangiectasia presence, surface area involved (number or distinct area), and presence of fresh blood (**TABS - score**):

- grade 0 – normal
- grade A – single, small area of telangiectasia with no fresh blood

- grade B - single, small area of telangiectasia with fresh blood
- grade C - single, large area (> 1 cm2) or more than a single area separated by 1 cm between the centers' of the lesions telangiectasia with no fresh blood
- grade D - single, large area (> 1 cm2) or more than a single area separated by 1 cm between the centers' of the lesions telangiectasia with fresh blood

The bladder neck should be assessed properly as that is the usual place of bleeding.

After the bladder is inspected and the bleeding point identified, a 50 mls (luer-lock) syringe is attached to the cystoscope, urine is aspirated, and the bladder emptied (Figure 2).

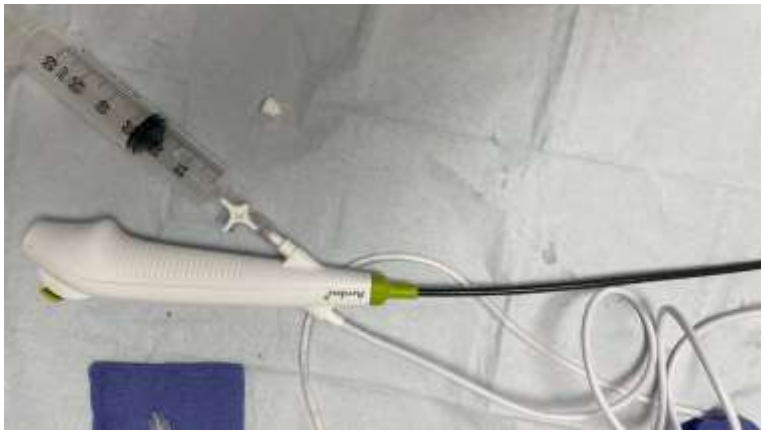

Figure 2. Emptying the bladder followed by air instillation for air cystoscopy

After the urine is evacuated, a three-way adaptor is placed on the flexible cystoscope fluid channel and air is instilled into the bladder, approximately 150 mls, depending on the bladder capacity. Next, an air cystoscopy is performed (Figure 3).

Figure 3. Air cystoscopy

PuraStat® is applied sparingly to cover the entire bleeding areas by connecting the PuraStat® to the flexible cystoscope and injecting it through the irrigation port of the cystoscope (Figure 4). During this, the 3-way connector is in place to allow a change from the 50 mls bladder syringe to the 20 mls pre-preprepared Luer-lock syringe without losing the air injected previously to allow visualization. If needed, more air can be injected to improve visualization.

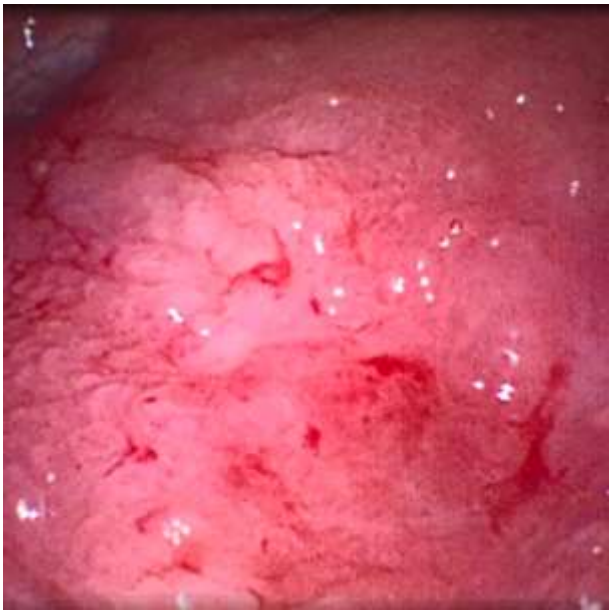

Figure 4. Application of a small layer of PuraStat

Once all the bleeding area points are controlled, the cystoscope is removed.

Successful voiding should be assessed with a bladder scanner before discharge.

The same procedure should be repeated approximately one month later if required.

The patient should be warned that the air will leave the bladder with a relatively loud sound and that is expected after air cystoscopy.

3. RESULTS

The technique allowed inspection of the bladder with no fluid inside and an easy application of the PuraStat® with the cystoscope in slight contact with the bleeding areas. In our case report, the patient ongoing bleeding was corrected with no further need for hospital stay. We repeated the procedure after 30 days and identified another very small area of radiation cystitis that was treated with PuraStat® again. At the third cystoscopy, at 2 months, there was no further bleeding and no area needed to be treated.

4. DISCUSSION

Radiotherapy alongside other treatment modalities may be used to treat pelvic neoplasms, such as prostate, bladder, uterus, ovary, cervix, and rectal malignancy.

Patient outcomes indicate 23% to 80% of complications associated with pelvic radiotherapy are related to radiation-induced haemorrhagic cystitis (RHC), with severe haematuria occurring in 5% to 8% of the patients, sometimes requiring multiple hospitalisations [1].

Beyond bladder irrigation and washout, proposed treatment options for RHC, include hyperbaric oxygen therapy, corticosteroids, oestrogens, intravesical alum, formalin and hyaluronic acid, pentosan polysulfate sodium, epsilon-aminocaproic acid, and factor VIIa/factor VIII. Embolization or ligation of the internal vesical and iliac arteries or even cystectomy with urinary diversion may be required [4].

PuraStat® has been successfully used as a haemostatic agent following endoscopic resection in the gastrointestinal tract, refractory acute gastrointestinal bleeding, anastomotic bleeding in vascular surgery and in cases of haemorrhagic radiation proctopathy [3, 5].

In this article, we describe the technique as we have found the cystoscopic application of PuraStat® technically simple, and it did not clog or block the cystoscopic channel. PuraStat® is broken down by enzymatic activity over 30 days into its constituent amino acids and then excreted. During this time, it remains transparent and flexible, in a viscous gel state reducing the risk of migration which may make it a suitable agent for bleeding points within the urinary bladder [2].

We acknowledge that to date, we have carried out one isolated case report of using PuraStat® in the management of RHC, and more evidence is needed to replicate the results we have observed. In the future, if our results are supported clinically by other studies, cystoscopic application of PuraStat® could be recognised as an appropriate option for RHC.

5. CONCLUSIONS

The application of PuraStat® in the bladder is feasible and very effective, at least in our single case experience. However, more cases are needed to be able to assess the effectiveness of the haemostatic agent for this indication.

6. REFERENCES

1. Browne C, Davis NF, Mac Craith E, et al. A narrative review on the pathophysiology and management for radiation cystitis. Adv Urol. 2015;346812.
2. 3-D Matrix. [Internet]. Purastat. [cited 26.11.2023]. Available from: https://3dmatrix.com/products/purastat
3. White K, Henson CC. Endoscopically delivered Purastat for the treatment of severe haemorrhagic radiation proctopathy: a service evaluation of a new endoscopic treatment for a challenging condition Frontline Gastroenterology 2021;12:608-613.
4. Martinez DR, Ercole CE, Lopez JG, et al. A novel approach for the treatment of radiation-induced hemorrhagic cystitis with the GreenLight™ XPS Laser. Int Braz J Urol. 2015;41:584-587.
5. Subramaniam S, Kandiah K, Chedgy F, et al. A novel self-assembling peptide for hemostasis during endoscopic submucosal dissection: a randomized controlled trial. Endoscopy. 2021;53(1):27-35.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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