CASE POSTER

PuraStat™
Beyond Haemostasis

EFFECTIVENESS OF A NEW HAEMOSTATIC AGENT IN ROBOTIC PARTIAL NEPHRECTOMY

Adapted from a poster originally presented at the 21st Annual Meeting of the EAU Robotic Urology Section, held from 11-13 September 2024 in Bordeaux, France.

Ahmed Sarhan [1], Aniruddha Chakravarti [2]

GOAL

This poster evaluates the safety and feasibility of RADA16 (i) in achieving haemostasis during partial nephrectomy procedures, compared to standard haemostatic agents previously used, including Floseal™ (Baxter), VeraSeal™, human fibrinogen (80 mg/mL), and human thrombin (500 IU/L) (Ethicon).

(i) PuraStat and PuraBond are both part of the RADA16 product family.

METHODOLOGY

Between 03/04/2023 and 18/05/2024, 68 cases underwent robotic partial nephrectomy for T1 renal cell carcinoma (RCC). Following renorrhaphy and early unclamping, three different haemostatic agent combinations (Floseal™ and VeraSeal™; Floseal™ and RADA16; RADA16) were applied to the resection bed in three subgroups of patients to reduce post-operative bleeding prior to the insertion of cortical sutures. In Group 1, Floseal™ was applied to the kidney resection bed, and VeraSeal™ was used on the cortical suture line. In Group 2, Floseal™ was applied to the resection bed, and RADA16 was used on the cortical suture line. In Group 3, RADA16 was applied to both the resection bed and the cortical suture line.

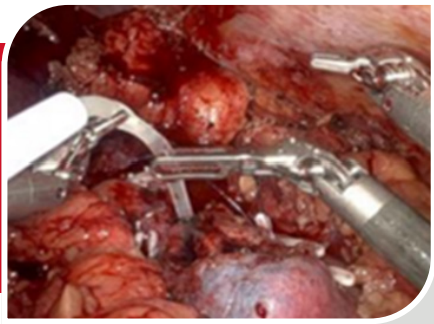

Fig.1 RADA16 applied to the resection bed after renorrhaphy suturing (Group 3)

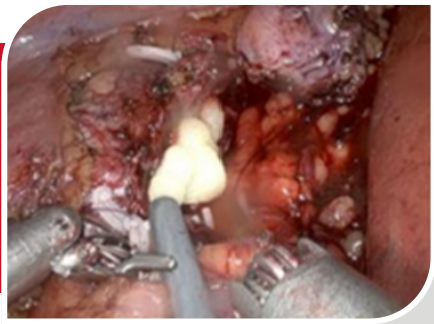

Fig.2 Floseal applied to the resection bed after renorrhaphy suturing (Group 2)

RESULTS

The study results showed that RADA16 (Group 3) achieved a Median Drop in Haemoglobin (*) of 14 g/L, compared to median drops of 21 g/L for the combination of Floseal with VeraSeal (Group 1) and 22 g/L for the combination of Floseal with RADA16 (Group 2) - (p = 0.06).
No statistically significant differences were observed in the remaining variables analysed, including the Mean Renal Nephrometry Score, Mean Warm Ischaemia Time, and the Median drop in eGFR.

(*) The median drop in haemoglobin, measured in grams per litre (g/L), indicates blood loss during and after surgery.

CONCLUSION

RADA16 demonstrated non-inferiority to other agents in **achieving effective haemostasis** following robotic partial nephrectomy. Its advantages over other agents include **ease of use** (it doesn't require freezing or thawing), **clear visibility** of the renorrhaphy bed due to its transparency and viscosity, which enables it to adhere effectively to the resection bed, and a lower cost.

PARTIAL NEPHRECTOMY

REFERENCES

- Sarhan, A., & Chakravarti, A. (2024, September). Effectiveness of a new hemostatic agent in robotic partial nephrectomy [Poster presentation]. 21st Annual Meeting of the EAU Robotic Urology Section, ERUS 2024, Bordeaux, France.

- VeraSeal™ - Instructions for use: https://www.jnjmedtech.com/en-GB/product/veraseal-solution-for-sealant

- Floseal™ - Instruction for use: https://www.baxterhealthcare.co.uk/healthcare-professionals/surgical-care/floseal-haemostatic-matrix-surgical-haemostasis

INDICATIONS FOR USE

RADA16 is indicated for haemostasis in the following situations encountered during surgery or endoscopic procedure, when haemostasis by ligation or standard means is insufficient or impractical(**):

- Bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs
- Oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues

(**) PuraStat IFU-007 Rev2 / IFU-011 Rev2

AFFILIATIONS

[1] - Specialty Doctor in Urology. The Royal Wolverhampton NHS Trust, United Kingdom

[2] - Consultant Urological. The Royal Wolverhampton NHS Trust, United Kingdom

PARTIAL NEPHRECTOMY

3-D Matrix Europe SAS
11 chemin des Petites Brosses, 69300 Caluire-et-Cuire-FRANCE.
+33 (0)4 27 19 03 40 | infoeu@puramatrix.com | www.3dmatrix.com
CH REP QUNIQUE GmbH Bahnhofweg 17, 5610 Wohlen CHRN-AR-20000058