

Radiofrequency ablation: Solution for a long-time therapeutic dilemma of chronic radiation proctitis?



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ABSTRACT

Background and study aims Chronic radiation proctitis is a prevalent condition following pelvic radiation therapy, occasionally leading to significant blood loss. Although medical treatment and argon plasma coagulation (APC) are well-established options, endoscopic radiofrequency ablation (RFA) is an emerging treatment that has shown promising results in smaller studies. However, further research, particularly on long-term outcomes, is necessary. This study aimed to evaluate the treatment outcome of endoscopic RFA in patients with chronic radiation proctitis, with a particular focus on long-term outcome.

Patients and methods This retrospective study included all patients treated with RFA for radiation-induced chronic proctitis suffering from hematochezia at the Medical University of Innsbruck, Department of Visceral, Transplant and Thoracic Surgery, between 2018 and 2023.

Results Thirteen patients were included in the study, with RFA being the initial treatment in five cases. RFA sessions were performed once in nine patients, twice in three patients, and three times in one patient. After a median follow-up period of 58 months, 69.2% (n=9) remained still symptom-free and 30.8% (n=4) reported only mild rectal bleeding after hard stools.

Conclusions These data indicate that RFA is a highly effective and safe treatment option for chronic radiation proctitis, providing excellent long-term results.

Introduction

Radiation therapy is an important treatment modality for malignant diseases such as prostate cancer [1,2]. One of the most common complications of pelvic radiation is radiation proctitis, which occurs when the rectal epithelium is damaged by ionizing radiation.

Radiation proctitis is classified as either acute or chronic, depending on the onset of symptoms and the depth of tissue damage [2]. Acute proctitis typically manifests within 3 months of radiation therapy, presenting with symptoms such as tenesmus and diarrhea, and less frequently with hematochezia.

Chronic radiation proctitis, on the other hand, has delayed onset of symptoms, and rectal bleeding is a common symptom [3,4]. Chronic proctitis is usually more severe than acute proctitis, which is often self-limiting [2]. Incidence of chronic proctitis varies in the literature, generally ranging between 5% and 20% [4]. In severe cases, rectal bleeding can lead to significant drops in hemoglobin (Hb) levels, occasionally necessitating blood transfusion. However, even milder cases may impair quality of life, making rectal bleeding a symptom that requires treatment.

In general, medical treatment is used as first-line management for rectal bleeding due to radiation proctitis. Recommended medications include formalin application or sucralfate

retention enemas [1]. When medical therapy fails or in more severe cases, endoscopic therapeutic procedures such as argon plasma coagulation (APC) are typically employed [4].

APC is a common and effective therapy with rare serious complications. The most commonly described complications are pain caused by ulceration and bowel distention [3]. However, major complications such as perforation, colonic gas explosion, and extensive necrosis have been reported. In addition, effectiveness of APC may be limited in patients with extensive bleeding. In general, the efficiency of most treatment options, especially medical treatment, is limited.

Endoscopic radiofrequency ablation (RFA) is a more recent therapy that has shown promising results. The advantages of RFA include selective superficial ablation of the epithelium and muscularis mucosa without injuring the submucosa, allowing broad ablation, even circular application, without causing stenosis. According to American Society of Gastrointestinal Endoscopy guidelines, no serious adverse events (AEs) have been documented in the literature following RFA [3].

Nevertheless, the available data are insufficient and further studies are needed to evaluate the short-term and especially long-term outcome of RFA.

Patients and methods

This retrospective study included all patients who underwent endoscopic RFA for bleeding associated with radiation-induced chronic proctitis at the Medical University of Innsbruck, Department of Visceral, Transplant and Thoracic Surgery, between 2018 to 2023.

Data were collected from electronic health records (Klinisches Informationssystem, KIS, Powerchart, Cerner, Intl.), including medical reports and laboratory findings. Demographic variables, such as gender and age, were documented. Clinical variables included tumor diagnosis, duration and intensity of pelvic radiation therapy, as well as symptoms and laboratory findings. For the evaluation, RFA timing, intensity, and frequency of the procedure were documented.

Statistical analyses were performed with SPSS (IBM SPSS Statistics 20; International Business Machines Corporation; Armonk, New York, United States). Group correlations were performed using the Chi-squared test or Fisher's exact test for categorical variables, and the Mann-Whitney U test for continuous variables. Significance was defined as $P \leq 0.05$. Due to the limited number of patients and the resulting limited statistical power, significance level was not reported.

For bowel preparation, patients received rectal enemas. RFA was performed with Olympus-GIF-EZ 1500, Olympus-GIF-HQ-190, Olympus-CF-HQ-190 or Olympus-CF-Q-160 S endoscopes (Olympus Corporation; Tokyo, Japan) and the COVIDIEN Barrx Flex RFA Energy Generator (Medtronic; Minneapolis, USA). The RFA catheters used were COVIDIEN Barrx Channel RFA Endoscopic Catheter and Barrx 90 RFA Focal Catheter with 12 Joule.

The costs for the APC and RFA generators was roughly the same. Cost differences between the two methods were associated with from the probes. The APC probe can be used multi-

ple times, whereas the RFA catheter is for single use only and is about double the cost.

The local ethics committee approved the study (Votum 1078/2024).

Results

In total, 13 male patients with an average age of 75 years (range 68–85) were included. The average radiation dose was 97 Gy (range 63–128). All patients received radiation therapy for prostate cancer.

Before RFA, a drop in Hb was documented in two patients (15.4%), one (7.7%) of whom received a red blood cell (RBC) transfusion. In three patients (23.1%), previous Hb levels were unavailable for comparison. Six patients (46.2%) were taking an antiplatelet agent as blood thinning medication, one patient (7.7%) was taking new oral anticoagulants (NOAC), and one patient (7.7%) was taking both. Three patients (23.1%) were not taking any blood thinning medication, and documentation was missing for two patients (15.4%).

Initial treatment of proctitis included direct RFA in five patients (38.5%), APC in four patients (30.8%), medicinal therapy in three patients (23.1%), and APC with additional medical therapy in one patient (7.7%). Simultaneous with RFA treatment, no additional medical therapy was performed.

RFA sessions were performed once in nine patients (69.2%), twice in three patients (23.1%), and three times in one patient (7.7%). The average number of ablations in the first session was 41.0 (range 25–66), in the second session it was 21.3 (range 11–42), and in the third session it was 20, each at 12 Joules/cm². No complications were documented after RFA.

Due to the presence of only smaller existing lesions and significant endoscopic as well as clinical improvement, further endoscopic therapy was performed in four cases, using APC due to cost considerations.

After a median follow-up period of 58 months (range 8–65 months), 69.2% of patients (9/13) remained symptom-free. Four patients reported mild rectal bleeding after hard stools.

► **Table 1** lists patient characteristics and treatment. ► **Fig. 1**, **Fig. 2**, **Fig. 3**, **Fig. 4**, **Fig. 5**, and ► **Fig. 6** are endoscopic images of bleeding proctitis and the results after RFA treatment.

Discussion

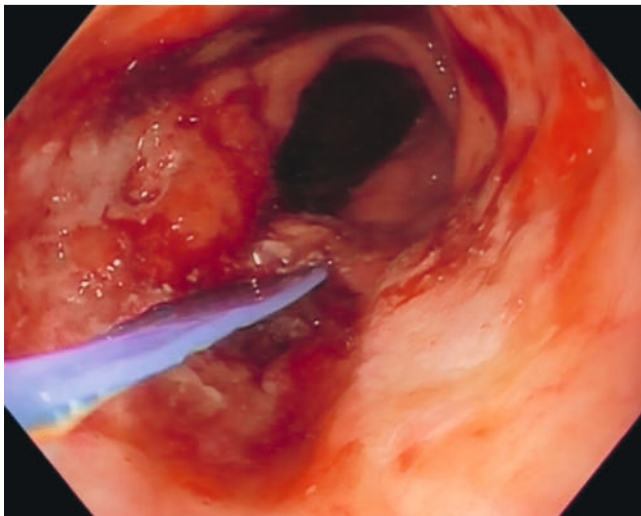
Chronic radiation proctitis is often inadequately managed with medical or supportive therapy alone, necessitating use of more effective endoscopic treatments, such as APC or RFA [3]. APC is frequently used due to its broad availability and manageable user costs. However, despite its effectiveness, APC can lead to AEs such as pain from ulcerations or excessive bowel distention [1, 3].

RFA is a well-established endoscopic treatment for conditions such as Barrett's esophagus. Although it has been medically approved, its application for chronic proctitis has been less common until recently. Studies have shown promising results with minimal side effects [3]. However, further studies are needed, especially of long-term results. To the best of our

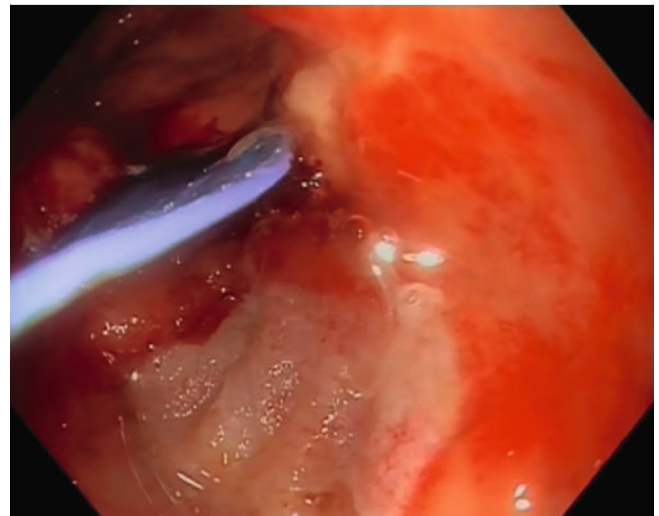
► **Table 1** Patient characteristics.

ID	Age	Blood thinning medication	Number of sessions	Symptoms after RFA	Follow-up (months)
1	84	Yes	1	None	35
2	71	Yes	1	None	59
3	69	NA	1	None	48
4	78	No	2	None	29
5	73	Yes	1	None	65
6	76	NA	1	None	48
7	71	No	2	Mild Hematochezia	59
8	68	Yes	1	Mild Hematochezia	64
9	81	No	1	Mild Hematochezia	65
10	70	Yes	2	None	58
11	85	Yes	1	None	40
12	76	Yes	1	Mild Hematochezia	63
13	75	Yes	3	None	8

NA, information not available; RFA, radiofrequency ablation.



► **Fig. 1** Broad application with the RFA catheter. RFA, radiofrequency ablation.



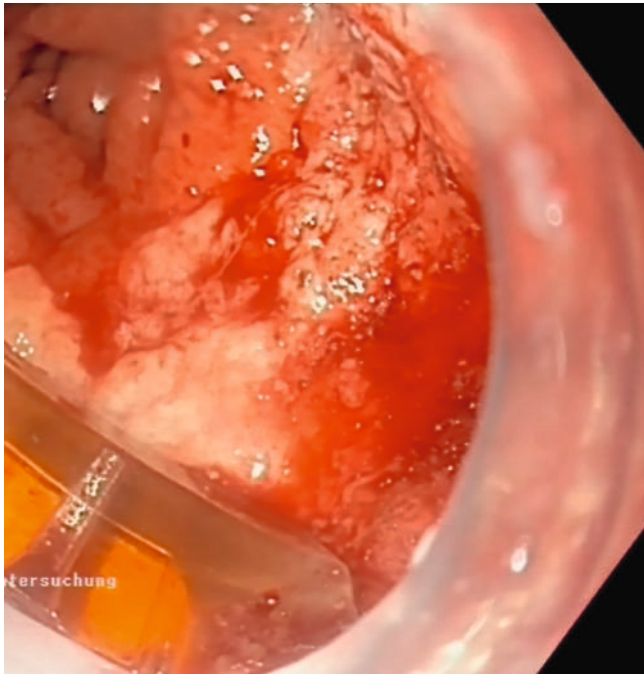
► **Fig. 2** Broad application with the RFA catheter. RFA, radiofrequency ablation.

knowledge, there are no extensive studies investigating long-term outcome of RFA for chronic radiation proctitis.

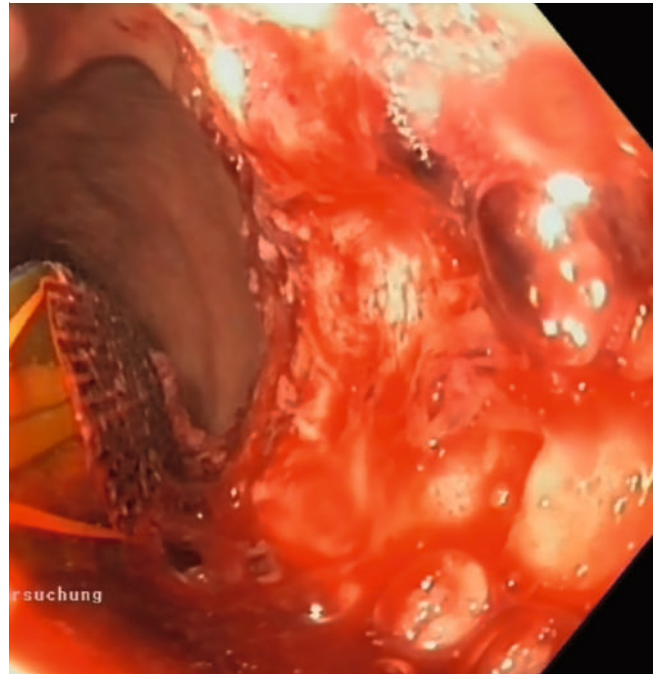
Because the primary indication for RFA treatment is radiation proctitis following therapy for prostate cancer, most patients are older and commonly on blood thinning medication [5]. In our study, the average patient age was 75 years, consistent with other studies [5,6]. In our cohort, the severity of bleeding due to proctitis was significant, with 15% of our patients experiencing a considerable decrease in Hb levels, and one patient requiring a RBC transfusion. This is lower than the 43% transfusion rate reported by Tang et al. [4]. Most studies describe a significant increase in Hb levels after RFA treatment

[5,6,7,8,9]. In our study, this parameter could not be evaluated because near-term Hb levels after the last RFA were missing. However, because the strong bleeding stopped after RFA, we believe that the Hb level increased as well.

When using RFA, costs have to be considered. Acquisition costs for generators for APC and RFA are about the same. However, the APC probe is reusable and about half of the cost of the RFA catheter, which is only for single use. Therefore, one session of RFA is more expensive than APC. However, RFA proved highly effective in our study, with nearly 70% of patients achieving satisfactory results after just one session. Other studies report even higher first-session success rates reaching up to 97%



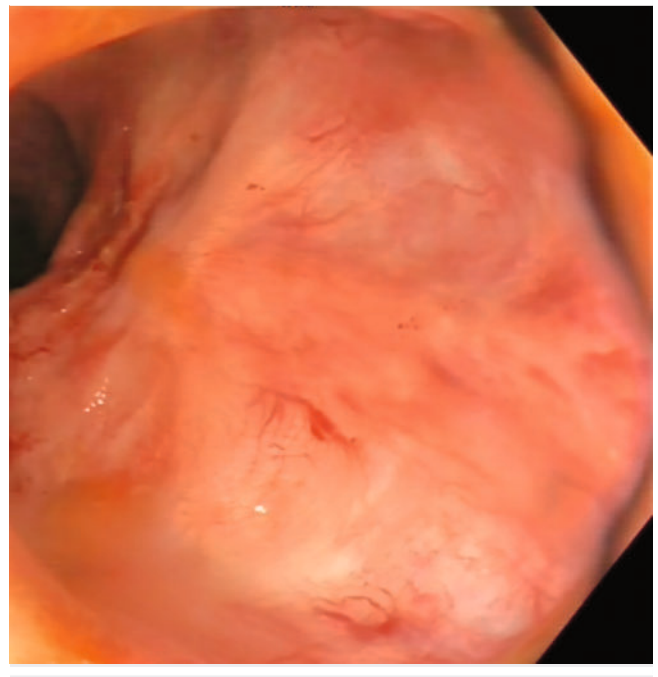
► **Fig. 3** Broad application with the RFA catheter in a more severe case. RFA, radiofrequency ablation.



► **Fig. 4** Broad application with the RFA catheter in a more severe case. RFA, radiofrequency ablation.



► **Fig. 5** Rectal mucosa after endoscopic RFA in a more severe case. RFA, radiofrequency ablation.



► **Fig. 6** Rectal mucosa after endoscopic RFA with only small remaining lesions. RFA, radiofrequency ablation.

[4,5,6]. Consistent with most other research, no serious AEs occurred in our investigation [4,6]. Possible complications include increased bleeding, pain, or incontinence. Because the ablation is superficial, more serious injuries such as perforation are unlikely. Therefore, RFA outcomes have been described as highly promising in previous studies, often achieving success rates close to 100%.

However, due to the follow-up times between 19 and 28 months, this outcome reflects only short-term outcome [3,4,5,6]. Our study with a median follow-up period of 58 months provides long-term outcomes data. Nearly 70% of the included patients remained asymptomatic after this extended follow-up period. The remaining four patients reported only mild symptoms, such as mild rectal bleeding after passing hard stools, not requiring further treatment. In total, RFA led to a significant improvement in all patients. Thus, RFA not only has favorable short-term outcomes, but also very good long-term results.

These findings demonstrate that RFA is a highly effective and safe treatment for chronic radiation proctitis, with a very favorable long-time outcome.

Limitations

This study's retrospective nature introduces inherent limitations. In addition, the small patient cohort and single-center setting limit generalizability of the results; however, large cohorts are difficult to acquire, given the limited number of treatments available for this condition, making it challenging to conduct multicenter studies.

Conflict of Interest

The authors declare that they have no conflict of interest.

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