Radiofrequency ablation for the treatment of radiation proctitis

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Background and study aims: The main endoscopic therapy for radiation proctitis is argon plasma coagulation (APC); however treatment is not always successful. Radiofrequency ablation (RFA) is a possible treatment for radiation proctitis but data are scarce. The aim of this study was to report on the safety and efficacy of RFA in the treatment of radiation proctitis.

Patients and methods: This study was an open-label, retrospective, multicenter study of patients with chronic hemorrhagic radiation proctitis who were treated with RFA. Data included a three-item symptom score, the number of packed red blood cell transfusions, the lowest hemoglobin concentration, and complications, during the 6 months prior to and after RFA. Clinical success was defined as a decrease in the symptom score. Biological success was defined as an increase in the hemoglobin rate with equal or decreased number of transfusions required.

Results: A total of 17 patients underwent a median of 2 RFA sessions (range 1 – 4), without perioperative complications. Symptom scores decreased in 16 patients (clinical success 94 %), from a mean score of 3.6 (median 4) to 1.4 (median 1) ($P<0.01$). Two patients developed rectal ulceration, with no local symptoms. During the 6 months after RFA, hemoglobin concentration increased in all 17 patients (from mean 8.3 ± 2.8 g/dL [median 7.5] to 11.3 ± 2.2 g/dL [median 11.0]; $P<0.01$). Among 13 patients who were transfusion dependent prior to RFA (mean 7.2 ± 7.7 transfusions [median 4]), 9 patients (69 %) were weaned off transfusions after RFA. A significant increase in the hemoglobin level was observed in this subgroup of patients (from mean 7.2 ± 1.4 g/dL [median 7.3] to 10.7 ± 1.5 g/dL [median 10.5]; $P<0.001$). Biological success was 100 %.

Conclusions: RFA seems to significantly decrease clinical symptoms and increase the hemoglobin concentration, thus reducing the need for transfusions.

Introduction

Chronic radiation proctitis is a late complication following radiation therapy for pelvic malignancy, and affects up to 20 % of patients [1]. Patients with radiation proctitis often experience symptoms of rectal bleeding, with potential iron-deficiency anemia that requires blood transfusion [1]. The ablation of the pathological rectal mucosa containing the abnormal microvessels with subsequent re-epithelialization is currently considered the treatment of choice. As significant complications have been described with topical application of formalin [2], endoscopic therapy is considered to be the gold standard treatment for radiation proctitis. Because of its ease of use and safety profile, argon plasma coagulation (APC) is the most frequently used technique [3 – 5]. APC efficacy is greater than 80 % in most series. However, the efficacy of APC is limited in patients with active surface bleeding or extensive radiation proctitis, in whom multiple treatment sessions are often needed [3, 4]. Moreover, APC has a morbidity ranging from 19 % to 47 %, including colon distension, rectal pain, tenesmus, colonic explosion, perforation, ulceration, and stricturing [1, 5, 6].

Endoscopic radiofrequency ablation (RFA) has recently been proposed for the treatment of radiation proctitis, but the data available in the literature are scarce. This report describes a case series of patients who underwent RFA for the treatment of radiation proctitis.

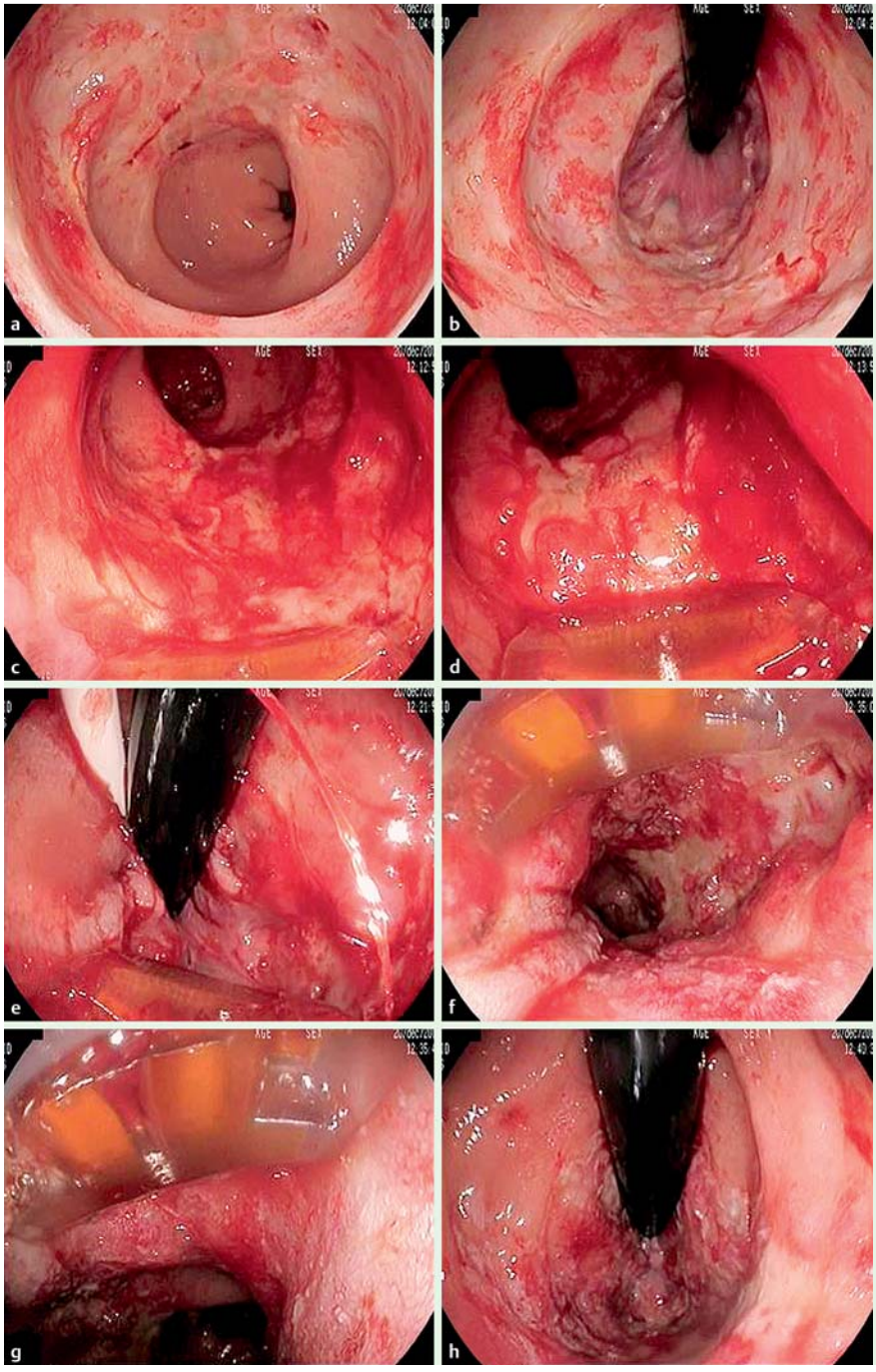

Fig. 1 A 77-year-old man (patient #4) with a history of radiation therapy for prostate cancer was referred for recurrent rectal bleeding under aspirin, despite one previous endoscopic treatment with bipolar electrocoagulation. **a** Endoscopic axial view of the rectum before treatment. **b** Endoscopic retrovision of the rectum before treatment. **c** Radiofrequency ablation (RFA) catheter placed in axial position before the first pair of pulses, with the Halo90 probe (Covidien GI Solutions, Sunnyvale, California, USA) placed in the 6 o'clock position. **d** Endoscopic axial view of the rectum after the first pair of RFA pulses had been applied. **e** Endoscopic retrovision of the rectum after the RFA pulses had been applied (whitish area on the left). **f** Endoscopic axial view of the rectum with the Halo90 probe placed in the 11 o'clock position. **g** Endoscopic axial view of the rectum with the Halo90 probe placed in the 11 o'clock position, after torquing of the endoscope. **h** Endoscopic retrovision of the rectum at the end of a RFA session (25 pulses total).

Patients and methods

Five centers performing RFA for the treatment of radiation proctitis were contacted for data collection. Included patients were aged over 18 years and had an endoscopic diagnosis of chronic hemorrhaging radiation proctitis with significant symptoms of rectal bleeding (blood in toilet bowl or heavy bleeding with clots, or bleeding requiring transfusion). Patients were excluded if they had nonsignificant bleeding (blood on toilet paper or in stool, with no transfusion requirement), a contraindication to endoscopy, or coagulopathy (international normalized ratio > 1.5 or platelet count < 50 000/mm^3). Demographic data and medical history were retrospectively collected, including details on pelvic cancer, symptoms of radiation proctitis, and previous treatments for radiation proctitis. Informed consent was obtained from all patients.

Antiplatelet agents and oral anticoagulants were discontinued 5 – 7 days prior to the procedure. Rectosigmoidoscopy was performed for diagnosis after bowel preparation with 4 L polyethylene glycol, water enema or both (depending on the physician choice). No antibiotic prophylaxis was given. Radiation proctitis was confirmed and areas of potential or active bleeding were identified.

RFA of pathological rectal mucosa was typically performed as follows (**Fig. 1**). The 13-mm electrode array residing on a pivoting cap (Halo90 or Halo60 systems; Covidien GI Solutions, Sunnyvale, California, USA) was mounted onto the distal end of the endoscope. After insertion of the device into the rectum, the operator deflected the endoscope in order to place the articulated electrode against the specific area of the rectal wall to be treated. The scope was torqued to target all lesions around the rectum cir-

cumference. In addition, when necessary, the electrode-pivoting cap was rotated to target all rectal lesions. Energy was delivered to the electrode using an energy generator (HaloFlex system; Covidien) in a pre-set and controlled manner, without moving the electrode or the endoscope. Treatment settings included an energy density of 12 – 15 J/cm^2 and a power density of 40 W/cm^2. To promote the hemostatic effect, the coagulum on treated areas was not scraped off. The device was moved to a new area and treatment was repeated. The device and endoscope were removed and cleaned every eight applications in order to maintain the effectiveness of the electrode surface for subsequent areas. The procedure was repeated as needed until complete ablation of the pathological rectal mucosa had been achieved. Antiplatelet agents and oral anticoagulants were resumed 5 – 7 days after the procedure.

The main outcome measures were recorded for both the 6 months prior to and after RFA: total symptom score (0 – 10 points) and subscores of diarrhea (0 – 3 points), bleeding (0 – 4 points), and tenesmus/rectal pain (0 – 3 points) (**Table 1**) [7,8]; endoscopic severity score of chronic radiation proctitis (**Table 2**) [9]; packed red blood cell (pRBC) transfusions (number of pRBC, number of patients weaned off transfusions); lowest hemoglobin concentration (g/dL). RFA-induced complications were also recorded. Clinical success was defined as a decrease in the symptom score. Biological success was defined as an increase in the hemoglobin rate with equal or decreased number of pRBC transfusions.

Nonparametric, two-tailed, matched-pairs, signed-rank tests were used to assess differences for continuous variables between the two treatment periods (i.e. during the 6 months prior to and after RFA) and to calculate the exact level of significance.

Table 1 Three-item symptom score for the assessment of disease severity in patients with chronic radiation proctitis, modified from Kochhar et al. [7] and Chruscielewska-Kiliszek et al. [8].

Symptoms	Score	Description
Diarrhea	0	Absent
	1	1 – 3 stools/24 hours
	2	4 – 6 stools/24 hours
	3	>6 stools/24 hours
Bleeding	0	No blood
	1	Blood on toilet paper or in stool
	2	Blood in toilet bowl
	3	Heavy bleeding with clots
	4	Bleeding requiring transfusion
Tenesmus/ rectal pain	0	Absent
	1	Mild tenesmus not requiring any drug
	2	Tenesmus requiring analgesics/antispasmodics
	3	Severe tenesmus requiring daily use of analgesics/ antispasmodics

Table 2 Endoscopic severity score of chronic radiation proctitis according to Gilinsky et al. [9].

Grade	Score	Description
Normal	0	Normal mucosa
Mild	3	Erythema and/or telangiectasia, edema, thickening, pallor of mucosa
Moderate	6	Friability
Severe	9	Ulceration and/or necrosis

Results

A total of 17 patients underwent RFA for the treatment of radiation proctitis (mean age 74 ± 6 years, median 75 years, range 63 – 87 years; 12 men) (**Table 3**). Medical history included cancers of the prostate (n = 11), cervix (n = 3), bladder (n = 1), anus (n = 1), and endometrium (n = 1). Six patients were treated with aspirin, one with warfarin, and one with both aspirin and warfarin. Six patients had received previous APC treatment (1 – 5 sessions), and one had undergone bipolar coagulation (1 session). Each center had managed 2 – 5 patients, and each individual endoscopist had performed (or supervised) 3 – 10 RFA sessions for radiation proctitis (**Table 4**).

Patients received a median number of 2 RFA sessions (interquartile range [IQR] 1 – 3; range 1 – 4) (**Fig. 2**). Seven patients underwent a single RFA session, five patients underwent 2 sessions, four patients underwent 3 sessions, and one patient had 4 consecutive sessions. Four rectal RFA sessions were performed without any sedation, and 10 followed rectal enemas rather than oral preparation (**Table 4**). The median duration of each session was 30 minutes (IQR 13 – 45 minutes; range 8 – 60 minutes). The median number of pulses per session was 50 (IQR 30 – 80; range 10 – 80).

No perioperative or inpatient postoperative complications were reported, including for the sessions performed without oral preparation. Two patients were referred for additional APC treatment at 1 month (patient #11) and 2 months (patient #15), respectively, after their last RFA session, due to persistent bleeding.

Symptom scores decreased in all but one patient (whose scores were unchanged), from a mean of 3.6 ± 0.8 (median 4, range 3 – 5) prior to RFA to 1.4 ± 0.9 (median 1, range 0 – 3) after RFA (P < 0.01), giving a clinical success rate of 94% (**Table 5**). An increase in hemoglobin concentration, with equal or decreased transfusion requirements, was observed in all 17 patients (biological success 100%) during the 6 months after RFA (from mean 8.3 ± 2.8 g/dL [median 7.5] to 11.3 ± 2.2 g/dL [median 11.0]; P < 0.01). Two patients developed rectal ulceration, with no local symptoms. Overall, there was no significant difference between patients who had experienced previous treatment failure (APC or bipolar coagulation) and those for whom RFA was the first-line treatment, including in terms of number of sessions performed, duration of treatment, and decrease in transfusion needs.

In the subgroup of 13 patients who were transfusion dependent during the 6-month period prior to RFA (mean 7.2 ± 7.7 pRBC packs [median 4], range 2 – 27), transfusion needs decreased after RFA (mean 0.9 ± 1.4 [median 0], range 0 – 4), with subsequent significant increase in the hemoglobin concentration (from mean 7.2 ± 1.4 g/dL [median 7.3] to 10.7 ± 1.5 g/dL [median 10.5]; P < 0.001) (**Table 5**). Indeed, 9 out of these 13 patients (69%) were weaned off transfusions completely during the 6 months after RFA. In the four patients (31%) who remained transfusion dependent after RFA, the hemoglobin concentration had increased in all four patients (+2.3 to +3.3 g/dL over the 6-month period), but transfusion requirements had decreased in only one patient (from 8 to 3 pRBC packs), and remained unchanged in the three other patients (2, 3, and 4 pRBC packs over the two 6-month periods, respectively).

Table 3 Clinical data of 17 patients treated with radiofrequency ablation for chronic radiation proctitis.

Patient #	Age at first RFA session, years	Sex	Initial cancer site	Age at radiation therapy, years	Radiation dose, Gy	Past treatment type × number of sessions	Co-morbidities	Antiaggregant or anticoagulation treatment
1	75	F	Cervix	74	45	APC × 2	Dyslipidemia	None
2	63	F	Cervix	61	45	APC × 4	Poliomyelitis	None
3	71	F	Endometrium	70	50	APC × 3	Alcoholic cirrhosis, type 2 diabetes, diverticulitis	None
4	77	M	Prostate	71	72	BEC × 1	Confusion	Aspirin
5	67	M	Prostate	66	80	None	Hypertension, dyslipidemia	None
6	64	M	Prostate	61	35	None	Hypertension, ischemic heart disease, chronic renal failure	None
7	75	M	Prostate	74	72	None	Hypertension, colorectal cancer, breast cancer	None
8	72	M	Prostate	71	70	None	Hypertension, ischemic heart disease, diabetes	Aspirin
9	82	M	Prostate	72	72	None	Diabetes	Aspirin
10	69	M	Prostate	67	45	None	Ischemic heart disease, atrial fibrillation	Aspirin, warfarin
11	79	M	Bladder	87	45	APC × 1	None	None
12	87	M	Prostate	85	50	APC × 5	Severe neutropenia secondary to aminosalicylates, arteriopathy	Aspirin
13	77	M	Prostate	76	70	None	Ischemic heart disease	Aspirin
14	83	M	Prostate	81	78	None	Lower limb arteriopathy	Aspirin
15	86	F	Cervix	66	60	None	Ischemic heart disease	None
16	79	F	Anus	78	65	None	None	None
17	73	M	Prostate	70	70	APC × 2	Atrial fibrillation, stroke	Warfarin

RFA, radiofrequency ablation; M, male; F, female; APC, argon plasma coagulation; BEC, bipolar electrocoagulation.

Table 4 Treatment procedure in 17 patients treated with radiofrequency ablation for radiation proctitis.

Patient #	Endoscopist initials[1]	Total number of RFA sessions	Preparation	Number of RFA sessions without sedation	Time between first and last RFA session, weeks	Highest power delivered, J/cm^2	Type of probe used	Total no. pulses	Total duration for all RFA sessions, minutes
1	PG	2	Oral only	0	26	12	Halo90	95	80
2	PG	2	Oral + enema	0	21	12	Halo90	78	70
3	XD	1	Oral only	0	–	12	Halo90	15	50
4	XD	1	Oral only	0	–	12	Halo90	25	60
5	XD	1	Oral only	0	–	12	Halo90	10	60
6	AR	2	Oral only	1	9	15	Halo90	152	N/A
7	AR	3	Oral only	1	17	15	Halo90	240	N/A
8	AR	2	Oral only	1	10	15	Halo90	148	N/A
9	AR	3	Enema only	1	10	15	Halo90	240	N/A
10	DW	3	Oral + enema	0	32	12	Halo90	160	N/A
11	DW	4	Oral + enema	0	10	12	Halo90	120	N/A
12	DW	2	Oral + enema	0	17	12	Halo90	80	26
13	GB	1	Enema only	0	–	12	Halo60	N/A	30
14	GB	3	Enema only	0	12	15	Halo60	N/A	27
15	GB	1	Enema only	0	–	15	Halo60	N/A	25
16	GB	1	Enema only	0	–	12	Halo60	N/A	21
17	GB	1	Enema only	0	–	15	Halo60	58	30

RFA, radiofrequency ablation; N/A, not available.
[1] Performing or supervising endoscopists: XD, Xavier Dray; GB, Gorgio Battaglia; DV, Dov Wengrower; PG, Pedro Gonzalez; AR, Alessandro Repici.

Discussion

In this series of 17 patients, RFA was feasible in all patients. Significant reduction in clinical symptoms and the need for pRBC transfusions, with an increase in the hemoglobin level was noted, not only in patients for whom RFA was the first-line treatment, but also in patients who had previously been treated with other techniques.

RFA is mainly used for the treatment of Barrett's esophagus with dysplasia [10], although its effectiveness has also recently been reported in the management of gastric antral vascular ectasia (GAVE) [11]. Trunzo et al. first suggested the use of RFA in the

Table 5 Outcomes of 17 patients treated with radiofrequency ablation for chronic radiation proctitis.

Patient #	Symptom scores, before and after RFA[1]								Endoscopic score, Total (0–9)[1]		RBC packs transfused[1]		Lowest hemoglobin level, g/dL[1]	
	Diarrhea (0–3)		Bleeding (0–4)		Pain/tenesmus (0–4)		Total (0–10)							
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
1	0	0	3	0	1	0	4	1	6	3	18	0	7.5	10.2
2	0	0	2	0	2	0	4	1	3	3	2	0	7.3	11.2
3	0	0	4	0	0	0	4	0	6	N/D	10	0	7.4	8.3
4	0	0	4	0	0	0	4	0	6	N/D	4	0	7	11.8
5	0	0	2	0	0	0	2	1	3	0	0	0	16.3	17.3
6	0	0	3	1	1	1	4	3	6	3	8	3	7.2	10.5
7	0	0	2	0	2	0	4	1	6	3	0	0	8.7	11.0
8	0	0	3	0	2	1	5	2	6	3	0	0	8.2	10.8
9	0	0	4	0	1	0	5	1	3	3	10	0	6.8	9.8
10	0	0	3	1	0	0	3	2	6	N/D	0	0	13.4	14.4
11[2]	0	0	3	1	0	0	3	2	6	3	2	0	9.5	13.6
12	0	0	4	1	0	0	4	2	6	3	27	0	7.2	9.3
13	0	0	3	3	1	0	4	3	3	N/D	4	4	7.7	10.0
14	0	0	2	2	0	0	2	2	3	9	2	2	8.5	11.7
15[2]	0	0	3	0	0	0	3	0	3	0	2	0	3.7	11.5
16	0	0	4	1	0	0	4	1	3	3	3	3	5.6	8.4
17	0	0	2	1	1	0	3	1	3	9	1	0	8.4	12.5
Mean ± SD	0	0	3.0 ± 0.8	0.6 ± 0.8	0.6 ± 0.8	0.1 ± 0.3	3.6 ± 0.8	1.4 ± 0.9	4.6 ± 1.5	3.5 ± 2.6	5.5 ± 7.1	0.7 ± 1.3	8.3 ± 2.8	11.3 ± 2.2
Median	0	0	3	0	0	0	4	1	6	3	2	0	7.5	11.0
P value[3]		> 0.99		< 0.01		< 0.01		< 0.01		< 0.01		< 0.01		< 0.01

RFA, radiofrequency ablation; RBC, red blood cells; N/D, not determined.

[1] In the 6 months before/after RFA treatment.

[2] Patients had one argon plasma coagulation treatment 1 month (patient #11) and 2 months (patient #15) after last RFA session.

[3] Nonparametric, Wilcoxon 2-tailed, matched-pairs, signed-rank tests.

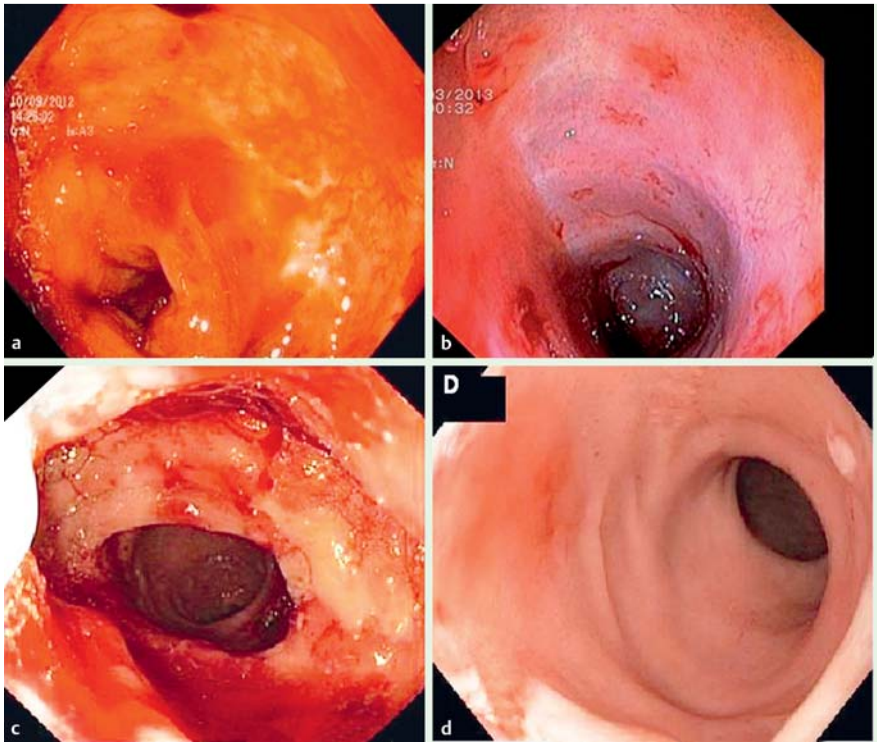

Fig. 2 Endoscopic views before and after radiofrequency ablation (RFA) treatment. **a** Endoscopic axial view of the rectum before treatment in patient #12. **b** Endoscopic axial view of the rectum 6 months after the last RFA treatment in patient #12. **c** Endoscopic axial view of the rectum before treatment in patient #13. **d** Endoscopic axial view of the rectum 6 months after the last RFA treatment in patient #13.

colon and rectum [12]. The authors histologically assessed 51 focal RFA areas created in normal segments of the colon and rectum in delimited surgical resection specimens of 16 patients undergoing colectomy. Their main conclusion was that the deepest ablative effect was limited to the muscularis propria when no more than two ablations were applied in the same location, regardless of the energy density used (12 – 20 J/cm^2) [12]. The use of RFA in radiation proctitis was then described in 11 patients from five different series [13 – 17]. In all cases, the procedure was well tolerated, and hemostasis was effectively achieved after one or two RFA sessions. A multicenter, retrospective, open-label study including 39 male patients with hemorrhagic radiation proctitis has recently been published [18], including 14 patients who had undergone previous endoscopic treatment (APC in most cases). Patients underwent 1 – 4 RFA sessions. Up to 270° of the rectum circumference was treated in the same session, with great use of the retroflexion position of the scope. Bleeding symptoms stopped in all 39 patients, with subsequent increase in hemoglobin level from a mean of 11.2 g/dL to 12.9 g/dL. A total of 11 out of 12 patients (92 %) were weaned off pRBC transfusions, and 14 of 17 patients (82 %) stopped iron therapy. One patient experienced a significant arterial bleed, which was controlled by endoscopic treatment.

The use of RFA as endoscopic therapy for the treatment of radiation proctitis has several benefits. The RFA unit delivers a consistent amount of energy to the surface using well-defined and reproducible increments of energy. This limits the radiofrequency energy penetration to the superficial mucosa, and reduces the possibility of operator dependence and over-treatment that could lead to perforations or ulcerations. RFA seems particularly suited to avoiding deep injury in relatively ischemic tissues. However, the procedure requires caution because two rectal ulcerations were observed in the current series. Moreover, RFA enables the simultaneous treatment of broader tissue areas than the point-by-point approach required with heater or bipolar probes, or APC. The median duration of each session in the current series was 30 minutes, and this could probably be shortened with increasing experience.

Some disadvantages of this technique should be discussed. The electrodes required repeated cleaning causing time-consuming exchanges, which are not needed with APC and bipolar coagulation probes. New through-the-scope, small (1.2 cm^2) flexible RFA catheters, allowing 120 pulses, are now available and may be of interest to treat rectal folds and avoid repeated scope withdrawals and insertions. The higher cost of RFA devices (compared with APC) should also be taken into account. The efficacy of a limited number of RFA sessions (even in patients refractory to APC), with subsequent reduced symptoms, blood transfusion need, and hospitalizations, could overcome this limitation, particularly in patients in whom APC has failed.

The study has several limitations. First, it was a case series study rather than a clinical trial. Second, a direct comparison of RFA and APC was not performed. Third, it was a retrospective case series, with potential selection bias. Indeed, clinical decisions for transfusions, re-treatment (with RFA or any other treatment), laboratory work-up, and techniques were not standardized, making any formal conclusions difficult to draw. Thus, endoscopic techniques were quite different between operators. For instance, one operator (G.B.) used the Halo60 catheter (rather than the Halo90 used by others) for all patients for its better maneuverability (smaller and potentially less traumatic probe). Another operator (X.D.) delivered a significantly lower number of pulses (10 – 25 pulses in one single session compared with 58 – 240 pulses in 1 – 3 sessions for other operators), but still produced satisfactory outcomes. Other parameters (power, preparation, sedation, time intervals between two sessions) were highly variable between operators. Techniques for RFA of radiation proctitis may be better standardized and evaluated in future prospective studies. Fourth, the follow-up period was limited to 6 months, whereas longer-term follow-up is ideal for identifying complications such as stricturing. Fifth, the number of patients included (n = 17) was limited. Despite these limitations, this case series suggests that RFA is fea-

sible, safe, and effective for the treatment of radiation proctitis, and does not seem to be strongly operator dependent because findings were consistent between the five different academic and nonacademic study centers.

RFA could be an alternative option in patients with radiation proctitis in whom APC has failed. These findings should encourage the prospective assessment of RFA for the treatment of radiation proctitis, which would be of particular interest in patients who are refractory to other endoscopic treatments.

Competing interests: Dr. Dray has received lecture and consultancy fees from Given Imaging, Mayoli Spindler Norgine, and Covidien.

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