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Short and long term response to argon plasma therapy for hemorrhagic radiation proctitis

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## ABSTRACT

**Introduction:** hemorrhagic radiation proctitis appears secondary to radiotherapy. Argon plasma is an effective, safe and easy-to-use technique with a relatively low cost. **Objectives:** to describe the short- and long-term response to argon plasma therapy in patients with hemorrhagic radiation proctitis.

**Method:** an observational prospective study was performed of a series of 82 patients with hemorrhagic radiation proctitis, attended at the National Center for Minimally Invasive Surgery between 2010 and 2016. Summary measurements and a comparison of means (paired Student's t-test) for the final and initial hemoglobin levels were used. In addition, the Kaplan-Meier method was used to determine the rectal bleeding recurrence free time.



**Results:** in the present study, 54.9% of cases required 1-3 argon sessions and 86.6% required 1-5 sessions to resolve the bleeding, with a median of 3.0 sessions. In addition, 4.9% of patients had proctalgia as a complication. There was an improvement in hemoglobin of 2 g/dl. Rectal bleeding recurrence occurred in 8.5% of the patients during the nine months after therapy. Bleeding recurrence free time at three, six and nine months was 98.8%, 96.3% and 91.5%, respectively. Short-term therapy response was observed in all patients and long-term response after one year of follow-up was 91.5%.

**Conclusion:** argon plasma coagulation shows a good short- and long-term response with few therapy sessions and a low rate of complications in patients with chronic hemorrhagic radiation proctitis.

**Key words:** Radiation proctitis. Argon plasma. Therapy response. Endoscopic therapy. Bleeding recurrence. Hematochezia. Rectal bleeding.

## INTRODUCTION

Radiation proctitis is a complication of radiotherapy that is applied to malignant tumors of the pelvic cavity (1-3). It has an incidence between 15 and 20%, although these figures are probably underestimated (3-4). The hemorrhagic form is the most common presentation (3-5). There are different treatments proposed to control this condition (5-11), although endoscopic therapies have better results. These include argon plasma coagulation (APC), which has a good efficacy, safety, ease of use and relatively low cost (1,2,6,12).

In Cuba, the National Center for Minimally Invasive Surgery has a decade of experience in the use of APC. They reported the first introduction of the technique in the country (13) and more recently published a study of the resolution of bleeding with a few sessions of APC and a very low number of complications (14).

This study was motivated by the health problems associated with this complication and the efforts made to establish guidelines in the health care algorithms of these patients. The objective of the study was to describe the short- and long-term response to argon plasma therapy in patients with chronic hemorrhagic radiation proctitis



(CHRP).

## METHODS

An observational, prospective study was performed of a series of 82 patients of both genders that were diagnosed with CHRP and assisted consecutively at the National Center for Minimally Invasive Surgery, between 2010 and 2016. Patients with more than three months of culmination of the radiant treatment who developed rectal bleeding, with an endoscopic diagnosis of radiation proctitis and no previous therapy for CHRP were classified as CHRP. Patients with doubtful endoscopic lesions or coexisting lesions which caused anemia and/or rectal bleeding such as inflammatory bowel disease, cirrhosis of the liver and HIV were excluded. Those patients with a neoplastic lesion and/or metastases were also excluded. Patients under platelet aggregation inhibitor and/or anticoagulant therapy that could not be discontinued due to a high risk of thrombosis were also excluded.

## Variables of the study

## **Group characteristics**

The following demographic variables were recorded: personal history of associated microvascular diseases (hypertension, ischemic heart disease and diabetes mellitus) and the item "Others" was used for other diseases; the reason for radiation (depending on the location of the irradiated malignant lesion); and the number of radiotherapy sessions and the initial post-radiation bleeding (time in months between the end of radiotherapy and the beginning of rectal bleeding).

Rectal bleeding was described based on its clinical features. According to the classification of Chutckan (15), bleeding intensity was graded in three groups: mild bleeding was Chutkan's grade 1 (scarce hematochezia on the toilet paper when wiping), moderate was grade 2 (bleeding in the toilet bowl) and severe was grade 3 (abundant bleeding, even staining clothes) and grade 4 (bleeding that required a transfusion).

Hemoglobin levels and those patients who needed a transfusion were specified within the analytical variables. The grade of proctitis was determined in three categories with



regard to endoscopic features: A (mild: 2 points), B (moderate: 3 points) and C (severe: 4/5 points). These were based on Saunders' score, taken from Zinicola R (16).

# Variables considered during the follow-up

– Number of therapy sessions required to achieve bleeding resolution.

 Complications (pain, tenesmus, colonic gas explosion, rectal strictures, deep ulcerations and necrosis).

- Check of hemoglobin parameters.
- Rectal bleeding recurrence.

This was determined as follows:

 Short-term therapy response: sustained bleeding control after one month or more or the same hemoglobin value as the initial result.

 Long-term therapy response: sustained bleeding control after 12 months of follow-up. Rectal bleeding recurrence free time was considered this way (time in months between the date of therapy discharge and the date of re-bleeding).

# Endoscopic technique and procedure

Previous sedation with propofol and a CV-260 SL videocolonoscope (Olympus, Japan) were used with the administration of air for assessment and endoscopic therapy. Flexible frontal probes (ERBE, Germany) and APC 300 equipment (ERBE, Germany) with an argon gas flow at 2 l/min and a power of 50 W were also used. Argon was applied using the stippling technique directly on telangiectasia, starting with the active bleeding and then from proximal to the distal sections. In every session, the technique was performed between a quarter and half of the circumference, with three week intervals between sessions until resolution of the clinical bleeding.

When the patient reported the cessation of bleeding, they were discharged from treatment and a clinical and hematologic follow-up was performed at one month, six months and one year.

# Statistical analysis



The statistical program SPSS version 21 for Windows (IBM, USA) was used to develop and process the database. Summary measures were used depending on the type of variable. The mean and standard deviation were used if there were symmetric distributions of variables. The median and interquartile range were used if this condition was not fulfilled for the quantitative variables and percentages for the qualitative variables. The statistical comparison of the mean test (paired Student's ttest) was used to contrast the initial and final hemoglobin values. The Kaplan-Meier method was used to analyze survival and thus determine the rectal bleeding recurrence free time. An  $\alpha$  statistical significance level lower than 0.05 was used to guarantee a 95% statistical test reliability.

## Ethical aspects

Informed consent of the patient was taken into consideration in order to carry out this study as well as the therapeutic procedures. The research was approved by the Ethics Committee of the institution.

#### RESULTS

The mean age of the patients was 62.8 (SD = 12.9) years and the majority were female: 60 cases (73.2%). Half of the patients reported a history of any disease that affected the microvasculature and hypertension was the most frequent with 19 cases (23.2%). Patients with a previous history of cervical cancer (64.6%) were most frequent, followed by prostate cancer (23.2%) and endometrial cancer (6.1%). The mean number of radiotherapy sessions was 28 (SD = 5.4) sessions and the mean time of the appearance of post radiation bleeding was 9.5 (SD = 4.8) months. Moderate and severe bleeding occurred in 39.0% and 36.6% of cases, respectively. Twenty-one patients (25.6%) required blood transfusions. Grade C proctitis was the most frequently reported, which occurred in 39 patients (47.6%) (Table 1).

The median (interquartile range) number of APC sessions was 3.0 (3). Of the 82 patients, 54.9% (45) achieved resolution of the bleeding with 1-3 sessions of APC and 86.6% (71) with 1-5 sessions. Proctalgia presented as a complication in four patients (4.9%) and rectal bleeding recurrence occurred in seven patients (8.5%). No other

complication was reported (Table 2).

The mean post-treatment hemoglobin level was significantly higher (11.7 g/dl; SD = 1.1) than before therapy (9.5 g/dl; SD = 2.0) (p = 0.000) (Table 2). Short-term therapeutic response was obtained in all patients and long-term response after one year of follow-up was obtained in 91.5%. Rectal bleeding recurrence occurred in seven patients (8.5%) in the first nine months after discharge from therapy. The bleeding recurrence free time at three, six and nine months was 98.8%, 96.3% and 91.5%, respectively. Subsequently, the absence of bleeding recurrence remained at 91.5% until the end of the study. The mean time of follow-up was 20.6 months (Fig. 1).

The median number of APC sessions (interquartile range) was 3.0 (3). Of the 82 patients included in the study, 54.9% (45) achieved bleeding resolution with 1-3 APC sessions and 86.6% (71) with 1-5 sessions. Proctalgia appeared as a complication in four patients (4.9%) and bleeding recurrence occurred in seven patients (8.5%). No other complications were reported (Table 2). Post-therapy mean hemoglobin levels were significantly higher (11.7 g/dl; SD = 1.1) than that reported prior to treatment (9.5 g/dl; SD = 2.0) (p = 0.000) (Table 2).

Short-term therapy response was obtained in all patients and long-term response after one year of follow-up occurred in 91.5% of cases. Bleeding recurrence occurred in seven patients (8.5%) during the first nine months following therapy discharge. Bleeding recurrence free time at three, six and nine months was 98.8%, 96.3% and 91.5%, respectively. The absence of bleeding recurrence remained at 91.5% until the study closed. The mean follow-up time was 20.6 months (Fig. 1).

# DISCUSSION

CHRP has a huge impact on the health and quality of life of an individual. The aim of APC therapy is to control bleeding, hemoglobin improvement, decrease the need for iron-deficiency therapy, blood transfusions and reduce hospital admissions. Thus increasing the quality of life of patients.

The mean age found in this study was similar to that of the reviewed studies (14,16-19). Only the age range in this series was somewhat broader due to the fact that gynecologic neoplasia presents at a younger age (20). In fact, this type of neoplasia

## REVISTA ESPAÑOLA DE ENFERMEDADES DIGESTIVAS The Spanish Journal of Gastroenterology

was the most frequently treated with radiotherapy. The prevalence of females also stands out. Nevertheless, there is a male tendency in international reports (18,21,22). Few studies, such as that of Sait (19), Chruscielewska-Kiliszek (23), De la Serna (24) and a previous study of the principal author of this study (14) have reported a greater number of female cases.

Patients with diseases that could compromise microcirculation have an increased predisposition to develop radiotherapy complications, with potentially more severe symptoms (12,25). La Torre et al. (26) state that 62.3% of their cohort presented with a microvasculature disease. In the present study, hypertension was most frequently reported and is the chronic disease with the highest incidence in Cuba (20). Other series report ischemic heart disease (17) and diabetes (21) as the most frequent diseases.

Moderate and severe bleeding predominated in this study, which is similar to that reported by Karamolis and his group (22) and La Torre et al. (26). Other studies only mention bleeding frequency and not severity. Dees et al. (27) express daily bleeding prevalence and Zinicola et al. (16) report frequent bleeding. Knowing the characteristics of bleeding prior to APC therapy is important as the improvement of bleeding is a marker for therapeutic efficacy (1,2,12,14). The results of the present study with regard to the need for transfusions are in accordance with other studies. The Tam group (28) reported that the percentage of patients that require transfusions varies between 10 and 25%.

Patients with a greater endoscopic involvement predominated in the current study. Karamolis et al. (22) reported a higher number of cases with moderate proctitis, followed by severe. Nevertheless, Zinicola (16) and Swan (28) reported a higher percentage of cases with milder grades of proctitis.

The current results show a median of around three APC sessions, which is very similar to that described previously in which a good therapy response was obtained with a mean of 2-3 sessions (17,26,29,30). Swan et al. (28) reported a mean of 1-3.7 sessions for therapy success, with a 68% and 96% improvement of rectal bleeding after the first and second session, respectively. Other authors reported means of 1.5, 1 and 1.7 sessions (16,18,32). Peng et al. (1) reported mean values between 1 to 3.7 APC

#### REVISTA ESPANOLA DE ENFERMEDADES DIGESTIVAS The Spanish Journal of Gastroenterology

sessions in a systematic revision of 33 studies.

In this way, it is clearly shown that a good therapeutic response can be achieved with few sessions, with a low incidence of complications. APC is considered a safe therapy (1,2,6,12). This is a non-contact electrocoagulation method that transmits the electric current to tissues using ionized gas, with a limited depth between 0.5-3 mm. This may explain the low risk of complications. Several authors have not reported any kind of complication in their studies (15,18,24,26,30). Some studies report a low incidence of post therapy rectal pain as an early complication (5,14,19,28,32,33). Rectal pain usually appears post-APC therapy near the dentate line. This may resolve spontaneously within a few days or with standard analgesic (1,14,32), as occurred in the current study. In two patients, it was self-limited and oral analgesics were administered in the other two cases. Late complications such as rectal ulcers and strictures have been reported in low numbers by some researchers. However, they did not appear in the studied series (16,21,29).

Hemoglobin improvement is also one of the parameters that indicate a good response to therapy. In fact, there are multiple studies that show an increase in hemoglobin levels after APC therapy. Some studies report a mean increase of around 1 g/dl (5,23,30) and others report similar results to this study, with an increase of over 2 g/dl (18,21,26,28,29). APC therapy had a high successful rate of hemostasis, which could help to improve hemoglobin levels (1,16,29,32). Despite the fact that better designed studies are required, this technique could be considered as a first-line therapy for CHRP (1), especially in patients with a mild-moderate condition (2).

Tam et al. (29) and Villavicencio et al. (32) report 100% hemostasis in their patients, which is similar to that in the current series. A systematic review published in 2012 showed the resolution of symptoms in 98% (range 51-100%) of patients treated with APC, which is similar to that presented in this report (10). The study by Hortelano et al. (21) had a mean follow-up of over 12 months, which seems a reasonable time to assess the efficacy of the treatment. This study showed very promising results, as 77% of patients had a complete response while 16.6% had a partial response. Thus, 93% of cases achieved a global response.



Karamolis et al. (22) found that 89.5% of patients had clinical remission, without bleeding recurrence during an average follow-up of 17.9 months (range 6-33). They also demonstrated that APC is a highly effective technique, with a long-term clinical remission.

The present study achieved a good short- and long-term response to therapy. This is consistent with the previous two reviews of APC efficacy and safety, which stated that rectal hemorrhage was improved in 80% to 90% of cases (1,12). Studies with long-term follow-up (2-60 months) have reported recurrences that perfectly respond to additional APC therapy sessions (6, 12).

## CONCLUSIONS

Argon plasma coagulation is an endoscopic technique with a good short- and longterm response, with a few therapy sessions and a low number of complications in patients with chronic hemorrhagic radiation proctitis.

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# Table 1. Characteristics of the study group

Demographic variables (n =	Frequencies			
Age (years)		Mean (SD)	62.8 (12.9)	
Gender, no. (%)		Male/Female	22 (26.8)/60 (73.2)	
Patient's personal history p	No. (%)			
Associated microvascular diseases	None		41 (50)	
	Hyperte	ension	19 (23.2)	
	Ischemic heart diseases		8 (9.8)	
	Diabetes mellitus		7 (8.5)	
	Others		7 (8.4)	
Cause of radiation	Cervix		53 (64.6)	
	Prostate	e	19 (23.2)	
	Endometrium		5 (6.1)	
	Rectum		3 (3.7)	
	Epidermal of the anus		1 (1.2)	
	Chordo	ma	1 (1.2)	
	Mean (SD)			
Number of radiotherapy se	28 (5.4)			
First post-radiation bleeding	9.5 (4.8)			
Clinical variables (n = 82)	No. (%)			
Rectal bleeding Gr		Mild	20 (24.4)	
	rade	Moderate	32 (39.0)	
		Severe	30 (36.6)	
Analytical variables (n = 82)	Frequencies			
Hemoglobin (g/l) Mean (S		an (SD)	9.5 (2.0)	
Need of transfusion, no. (%	21 (25.6)			
Endoscopic variables (n = 82	No. (%)			
	A		20 (24.4)	
Grade of proctitis	В		23 (28)	
	С		39 (47.6)	



SD: standard deviation.



# Table 2. Number of APC sessions applied for bleeding resolution, complications andevolution of hemoglobin

Number of APC sessions				Number of patients (%)			
1-3				45 (54.9%)			
4-5				26 (31.7%)			
6-8				9 (11%)			
9-10				2 (2.4%)			
Total number of sessions: 289							
Median (interquartile range) sessions: 3.0 (3)							
Complications (proctalgia): 4 (4.9%)							
Recurrence of bleeding: 7 (8.5%)							
Analytic	Mean (SD)	Mean		Paired	р		
	(g/dl)	differe	ence	Student's t-			
				test			
Initial hemoglobin	9.5 (2.0)	2.2		-12.83	0.000		
Final hemoglobin	11.7 (1.1)			12.00	0.000		

APC: argon plasma coagulation; SD: standard deviation.





Figure 1: Free time of recurrence of rectal bleeding