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Challenges in the implementation of a high-resolution anoscopy clinic for people with HIV in an oncologic center in Mexico City

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Abstract

Background Anal cancer incidence is increased in people with HIV (PWH), up to 60 times higher in men who have sex with men, and almost 15 times higher among women with HIV. Screening and treating high-grade lesions (HSIL) have proven to reduce the incidence of invasive anal cancer. In 2020, we started implementing a high-resolution anoscopy (HRA) clinic at INCan, a tertiary care oncologic center, as part of a screening program for PWH from the HIV clinic.

Objectives We describe the barriers and difficulties in implementing an HRA Clinic from January 2020 to April 2021, including physician training, the certification process, discrepancies between cytology and histopathologist results, and the lack of experience of gastrointestinal pathologists in HPV-related lesions.

Results During the first 18 months of the HRA clinic implementation, 124 studies were performed, and 85 biopsies were done. The prevalence of HSIL was 22%. Initially, when a gastrointestinal pathologist reviewed anal canal biopsies, a second opinion was requested from a genitourinary pathologist who examined 72 of the biopsies; there were discrepancies in the diagnosis in 61% of the cases, with more advanced intraepithelial lesions in 43% of cases. Specifically, gastrointestinal pathologists missed 68% of HSILs. The difficulties we faced were not having access to adequate anoscopes. Training and certification are a long way to go. Also, women's reachability was low.

Conclusions Diagnosis and management of anal HSIL have become a standard of care in the prevention of Anal Carcinoma in PWIH, the population with the highest incidence of this neoplasia. Implementing HRA programs requires correct supplies and equipment, which are not always locally available; investing in physicians' training and an experienced pathologist in HPV-associated lesions interpretation is also imperative. More advocacy is needed for HIV programs to incorporate and invest in anal cancer screening.

Keywords Anal cancer, Human papilloma virus, High-grade squamous intrepithelial lesions, HIV, Cancer screening, High-resolution anoscopy

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Introduction

Anal cancer is increased in people with HIV (PWH), especially men who have sex with men (MSM), where the incidence can go from 40 to 60 times higher than the general population [1]. It results from persistent human papillomavirus (HPV) infection, and its primary precursor is high-grade squamous intraepithelial lesions (HSIL) [2, 3]. HPV16 is the most frequent oncogenic virus found in precursor and invasive cancer lesions, although other oncogenic types of HPV have been described. Vaccination is the most effective primary prevention measure for anal cancer (ideally before sexual activity initiation). Secondary prevention consists of screening and treating HSIL, the precursor lesions [3]. The ANCHOR study, a randomized clinical trial, demonstrated a 57% reduction in anal cancer when treating men and women with HIV older than 35 years with biopsy-proven HSIL. This trial underscores the relevance of screening, diagnosis, and ablative therapy of anal HSIL [4]. In the latter study high-resolution anoscopy (HRA) and biopsy were performed. Although anal cancer screening can be initiated with anal cytology, the test most frequently used, the sensitivity ranges from 50 to 80%. HRA is the most specific test for diagnosis but is expensive and requires adequate training, which hinders its implementation as a universal screening tool. Current recommendations rely on annual anal cytology and digital examination with referral to HRA for abnormal results [5–7].

In 2020, an HRA clinic was put into operation at Instituto Nacional de Cancerologia (INCan), a tertiary care oncologic center, as part of a screening program for PWH admitted to the HIV/AIDS cancer Clinic. The HPV and anal precursor lesions prevalence in the HRA performed during 2021–2022 has been published elsewhere [8]. We report here the initial results of HRA performed during the first 18 months of its implementation, during physicians' training and certification, and describe the barriers and difficulties in building an HRA program.

Methods

Setting

INCan is a 148-bed oncological hospital located in Mexico City. It serves adult patients with cancer and no social security. The HIV/AIDS Cancer Clinic was created in 1990 and receives PWH with confirmed or suspected cancer. In 2022, the clinic included 829 active patients with HIV-associated and non-HIV-associated malignancies under control (583 70.3% men and 244 29.4% women). Patients are followed up by an infectious disease (ID) practitioner and hemato-oncologist for patients with hematologic malignancies.

In 2020, an HRA clinic was created at INCan to screen all PWH with anal cytology and HRA ± biopsy. Public Health Service Grant No UM1CA121947 partly supported the implementation of the HRA program, and the National Cancer Institute, National Institutes of Health (NIH), and the Department of Health and Human Services, provided training, certification, and specialized supplies. Clinicians attended the International Anal Neoplasia Society (IANS) HRA course and then received on-site and remote training through the AIDS Malignancy Consortium (AMC) training grant. Clinicians were required to maintain procedure logs and were certified by the AMC trainer to provide HRA examinations.

Study population

During the first 18 months of the HRA clinic implementation (between January 2020 and April 2021), all patients from the HIV/AIDS Cancer Clinic on antiretroviral therapy, were consecutively referred for HRA, where they underwent anal evaluation, collection of specimens for anal cytology, followed by HRA with directed biopsy if needed. Patients with a prior diagnosis of anal cancer were excluded."

Procedures

HRA was performed by a team that included one gynecologist and two proctologists. During the ID consultation, the physician informed the patients of the importance of HRA as part of follow-up. Patients were then referred to the HRA clinic and scheduled for screening with no age restriction.

The protocol established a three-step approach on the same day. An initial anal sample was obtained with cytobrush for conventional anal cytology. We used a national product, soft bristle cytobrush, provided by DL Medica SA de CV. Subsequently, a digital anal rectal examination was performed. On the same day, this was followed by an HRA in all patients. According to standards, if the HRA provider identified any anal lesions during the procedure, an HRA-directed biopsy was done. The anoscopist reported their findings, according to the WHO classification of tumors [9]. Biopsies and cytology samples were processed and reported by the histopathology department of INCan. If multiple biopsies were performed, patients were classified by the highest histopathologic result [9]. Patients' treatment and follow-up depended on the biopsy results. See Fig. 1 for the algorithm of patients' care.

During the first 12 months, a gastrointestinal (GI) pathologist reported the biopsies. However, after discordant results were observed between the anoscopy impression and pathology results, a Genitourinary pathologist reassessed the biopsies.

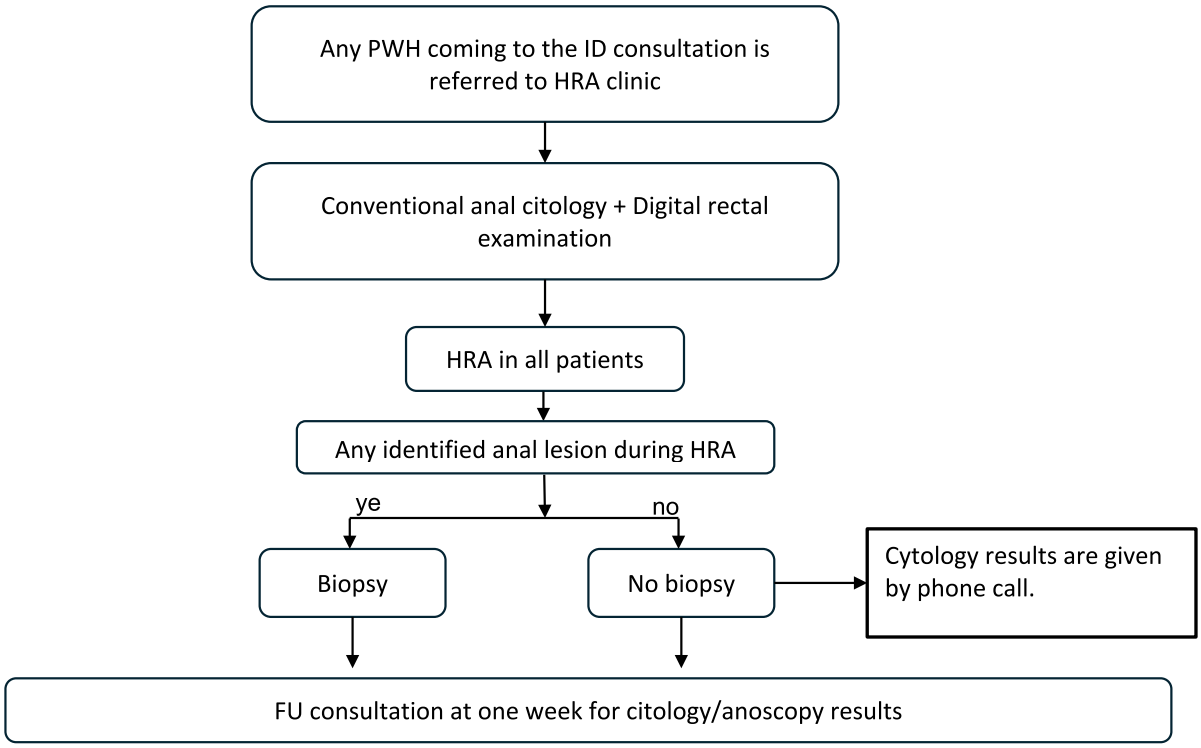

Fig. 1 Patients' flow to the HRA clinic. *PWH* people living with HIV, *ID* infectious diseases, *HRA* high resolution anoscopy, *FU* follow up

IRB committee

The Institutional Ethics and Research Committee approved the protocol (IRB) of the Instituto Nacional de Cancerología (009/006/IBI) (CEI/529/09).

Data collection and analysis

HRA, cytology, and biopsy results are reported for patients from January 2020 to April 2021. We reviewed electronic files for sociodemographic data and HIV characteristics, including baseline CD4 and viral load. We also describe the difficulties found during the implementation.

Results

Prevalence of HPV-associated lesions:

During the first 18 months of the HRA clinic implementation (January 2020 to April 2021), 124 patients from the HIV/AIDS Cancer Clinic were evaluated at the clinic. Table 1 describes the main characteristics of the patients. Most patients were men (87%). Kaposi Sarcoma was the most common cancer (64%) (active or in remission), followed by non-Hodgkin lymphoma (11%). In nine patients, the cancer diagnosis was not confirmed. All patients had an HRA performed, and 85 biopsies were done; at the first biopsy evaluation (done by the gastrointestinal pathologyst), 17 patients (20%) had HSIL, and 2 (2%) had invasive anal cancer. Table 2 describes the histopathologic results.

When comparing the anoscopist's clinical impression to the initial histopathologic report, the impression was correct in 31% of cases. The anoscopist identified 48% of the LSIL, 24% of the HSIL, and one of two invasive cancer lesions.

Difficulties in the implementation process

Certification of the HRA providers

The AMC of the NIH provides training and certification for anoscopists. Training providers must perform and register in logs between 200 and 250 HRAs for certification, which should meet certification criteria showing acceptable metrics. Also, for the accreditation of diagnostic HRAs, it is needed at least 8 to 10 assessments with biopsies of anal HSIL by the AMC instructor through an in-person certification visit to evaluate progress. The onsite training visits were deferred for nearly two years due to the COVID-19 pandemic. Anoscopy exams began without mentoring, which may have delayed progress to adequate exams. There were 2–3 training and certification visits per clinician. To certify therapeutic procedures for anal HSIL, a log with at least 50 procedures was required for each in-training provider; after that, one or

Table 1 Characteristics of the patients

	N **= 124** ***N*** **(%)**	**Men* (*n* = 108)**	**Women* (*n* = 16)**
Age in years, median (IQR)	38 (32–49)	36(31–44)	51 (39–54)
Age at onset of sexual life, median (IQR)	18 (16–19)	18 (16–19)	17 (15–19)
Number of sexual partners, median (IQR)	6 (3–10)	8 (4–10)	3 (2–4)
HIV diagnostic time in years, median (IQR)	5 (2–14)	4 (2–9)	17 (12–25)
Smoking history	72 (58)	67 (62)	5 (29)
Previous alcohol intake	21 (17)	20 (19)	1 (6)
Cancer diagnosis: Kaposi sarcoma Non-Hodgkin lymphoma Hodgkin lymphoma Invasive cervical cancer Other gynecological tumors[a] Other cancers No cancer confirmation	80 (64) 13 (11) 7 (6) 3 (2) 8 (7) 4 (3) 9 (7)	80 (74) 11 (10) 7 (7) 0 0 2[b] (2) 8 (7)	0 2 (13) 0 3 (19) 8 (50) 2[b] (13) 1 (5)
Baseline CD4+ T cells/mm^3, median (IQR)	97 (39–232)	84 (38–200)	213 (132–357)
Baseline HIV Viral load, $\log_{10}$ copies/mL	5.2 (4.6–5.7)	5.3 (4.7–5.7)	4.6 (4.1–5.6)
CD4+ T cells/mm^3 count closest to the procedure, median (IQR)	331 (190–498)	307 (184–605)	498 (364–617)
ART at the moment of the procedure	123 (99)	107 (99)	16 (100)

*Sex at birth

[a] Includes intraepithelial vulvar (3), vaginal (1), and cervical SIL lesions (4)

[b] Includes one multiple myeloma, one head and neck cancer, one breast cancer, and one skin cancer

ART antiretroviral therapy

Table 2 Cytologic and histopathologic results

	N **(%)**
Digital rectal examination (*n* = 124)	17 (14)
Adequate anoscopy (*n* = 124)	18 (14)
HRA findings (*n* = 124): Normal Condyloma LSIL HSIL Invasive cancer	 51 (41) 19 (15) 40 (33) 13 (10) 1 (1)
Adequate cytology (*n* = 124)	104 (85)
Cytology results (*n* = 104): Inflammation LSIL HSIL ASCUS	 47 (45) 33 (32) 8 (8) 16 (15)
Number of anal biopsies, median (IQR) (*n* = 85)	1 (1–2)
First biopsy result[a,b] (*n* = 85): Inflammation Condylomas LSIL HSIL Invasive cancer Other (proctitis, hemorroides)	 8 (9.5) 19 (22) 31 (37) 17 (20) 2 (2) 8 (9.5)

LSIL low-grade squamous intraepithelial lesion, *HSIL* High-grade squamous intraepithelial lesion, *ASCUS* Atypical squamous cells of unknown significance

[a] Interpretation by gastrointestinal pathologist

[b] Highest histopathologic result if multiple biopsies

two in-person mentor visits to evaluate at least eight adequate treatments were needed.

Availability of materials

The anoscope available in Mexico had a notch that caused discomfort to patients, hindering adequate visualization. New ones had to be imported. This impacted the quality of many HRAs performed, which delayed the certification process and the inclusion of patients. Cotton swabs were also unavailable, and the table height had to be modified by blankets to accommodate the provider's comfortable ergonomics. Some of these problems were unknown until the trainer came for a site visit. (Fig. 2).

Accuracy of histopathology interpretation

Initially, the 85 perianal biopsies were sent to the gastrointestinal area of the pathology department and reviewed by a pathologist trained in gastrointestinal pathology. After a genitourinary pathologist reviewed 72 of the 85 biopsies, we found discrepancies in the diagnosis in 44/72 samples (61% of the cases). In 31/72 samples (43%), the new interpretation reported more advanced intraepithelial lesions (see Table 3). The gastrointestinal pathologist missed 47% of LSIL and 68% of HSIL. The two cancer diagnoses were accurately reported by both pathologists (see Tables 3 and 4).

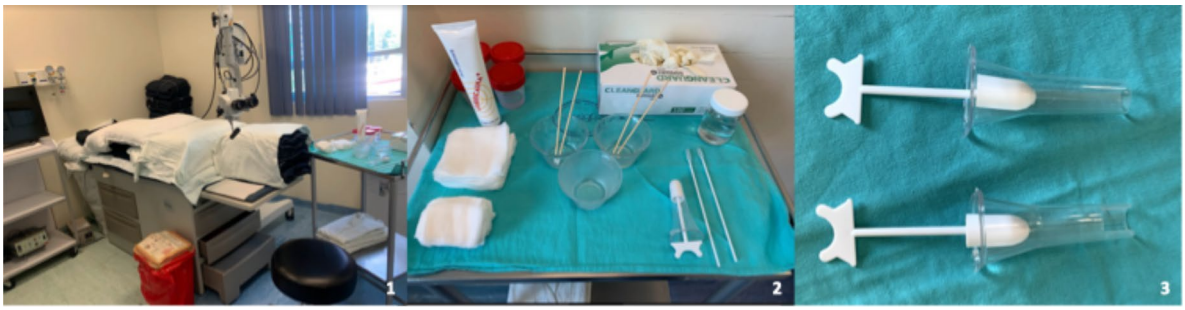

Fig. 2 Supplies to set up an HRA clinic. **1** The office must have a high exploration table. A high-resolution colposcope, an adequate visual system, and a comfortable chair. **2** The supplies must include acetic acid, Lugol, swabs, and containers for each biopsy. **3** There are two types of anoscopes, with and without notch. The preferred anoscopes must not have a notch

Table 3 Final histopathology evaluation*, *n* = 72(%)

Inflammation	2 (3)
Condylomas	3 (4)
LSIL	32 (44)
HSIL	25 (35)
Invasive cancer	2 (3)
Insufficient sample	8 (11)

*Genitourinary pathologist

Outreach to women

Although women were informed of the importance of the HRA study by the ID consultant and referred for HRA, few of them made an appointment for screening, and our sample only included 12.9% women, although cisgender women represent 29.5% of the PWH follow-up at the HIV/AIDS Cancer Clinic. Of the 16 cisgender women included, four had a history of invasive cervical cancer, and eight had precursor lesions: four had vulvar, two had vaginal, and two had cervical HSIL. Two women had non-Hodgkin lymphoma, and two had breast cancer. Some women had multiple cancer diagnoses overtime during their HIV control follow-ups.

Discussion

We present the first data from a recently implemented HRA clinic in an oncologic center in Mexico. The clinic reached patients living with HIV, with a high-risk profile: they had a very low CD4 count nadir, most had been diagnosed with an AIDS-defining malignancy or had a history of HIV advanced disease. The high proportion of high-grade lesions underscores the relevance of screening in this population.

The importance of early diagnosis of high-grade anal lesions has been recognized for more than a decade.

Table 4 Comparison of gastrointestinal and genitourinary pathologists' evaluation

		Gastrointestinal pathologist evaluation					
		Inflammation	**LSIL**	**HSIL**	**Condylomas**	**Cancer**	**Proctitis**
Genitourinary pathologist evaluation	Inflammation, (%) *N* = 2	0	0	2 (100)	0	0	
	LSIL, (%) *N* = 32	1 (3)	**17 (53)**	1 (3)	11 (35)	0	2 (6)
	HSIL, (%) *N* = 25	1 (4)	9 (36)	**8 (32)**	6 (24)	0	1 (4)
	Condylomas, (%) *N* = 3	0	2 (67)	0 (24)	**1 (33)**	0	0
	Invasive cancer, (%) *N* = 2	0	0	0	0	**2 (100)**	0
	Insufficient sample, (%) *N* = 8	3 (37)	0	0	0	0	5 (63)
	Total *N* = 72	5 (7)	28 (39)	11 (15)	18 (25)	2 (3)	8 (11)

LSIL low-grade squamous intraepithelial lesion, *HSIL* high-grade squamous intraepithelial lesion

Cells in bold: concordance between both pathologists

However, recently, it was acknowledged as an essential part of the clinical-preventive management of PWH. The management of HSIL has been shown to reduce the risk of progression in MSM living with HIV [4], and HRA is a procedure that allows identification and treatment of HSIL more efficiently to avoid the development of anal cancer [4]. Previous studies have reported the positive impact of implementing an HRA program on the incidence of anal cancer and the implications for advanced disease. In a cohort study, Barnell et al. compared the incidence of anal cancer in PWH, at a population level, before and after the implementation of an HRA program, showing a 65% reduction in the incidence of anal cancer and a 77% reduction in advanced anal cancer [10].

To improve the diagnosis and management of anal HSIL in PWH, many steps must be considered, including an adequate cytology sample, screening with HRA and HRA-guided biopsies, pathology interpretation of the biopsy and the timely and complete treatment of the HSIL. Our experience highlights the importance of mentoring and training with an experienced HRA trainer, as well as a trained pathologist familiar with HPV lesions, to identify the histopathologic grades of disease correctly. In this study, 68% of HSIL would not have been diagnosed and thus not treated if a second pathologist had not reviewed the biopsies.

In June 2021, HPV typing was included, and a genitourinary pathologist reviewed all biopsies. Of 155 patients studied, 100% were HPV infected, 89% had high-risk HPV (HR-HVP), and the median number of HR-HPV per patient was four. More biopsies were performed (108), with an abnormal result in 70% of cases, 38% HSIL, and 32% LSIL, which may also reflect the increased experience achieved by the anoscopists. This second analysis has been reported elsewhere [8].

Outreach to women was low; they represented only 12% of people screened. This is partly the result of a concentrated epidemic in the country. In Mexico City, men represent 80% of the PWH [11]. However, women in our cohort represented 30% of active patients in 2022, more than twice the proportion of women screened.

Although less common, anal cancer is also increasing in women, more specifically in women with previous HPV-related lesions in the genital tract [12]. The recently published IANS guidelines recommend screening in all women with vulvar lesions [7]. Prior literature has reported barriers to anal cancer screening in women, such as anticipated pain and discomfort increased. However, familiarity with the procedure and knowledge regarding the utility of the study could improve acceptability [13, 14]. New strategies need to be considered to increase anal cancer screening uptake in women.

As part of the implementation, describing the patient's acceptability is essential. We do not provide details on the patient's refusal to come to the HRA clinic, especially for women with HIV. We also do not report adverse effects related to the procedure. This could be evaluated through a patient survey for patients who underwent HRA and those who refused to go. Moreover, further evaluation of the patient's risk perception and response to the procedure is needed. One study from Maryland reported surveys done to HIV providers and patients to evaluate anal cancer knowledge and risk perception. More than 50% of patients were aware of cancer risk factors, with a general perception that cancer screening was good for their health (89%) [15]. Another qualitative study evaluated knowledge, attitudes, and beliefs around anal cancer in MSM with a history of HSIL through focus groups and reported that most participants found HRA to be stressful (71%) and uncomfortable (79%) but not scary (79%). Most participants thought it was necessary for anal cancer prevention (93%) and genital wart prevention 57%. Internalized stigma and physical discomfort were barriers to adequate adherence to HRA follow-up. In contrast, beliefs about HPV-related diseases worked mostly as facilitators [16].

During this initial period of HRA implementation, two invasive anal cancer in male patients were diagnosed and sent to treatment, reflecting that our population is at a very high risk for anal cancer. Nonetheless, the prevalence of HSIL by biopsy initially observed in this implementing period (17%) is below the ANCHOR study prevalence of 53.9%. This lower prevalence may reflect an incomplete mastery of the anoscopy technique since, during the first 12 months of the COVID pandemic, HRAs were performed before training. The prevalence of HSIL improved by 38% in the second year, more than double the first year [8]. The same happened with the cytology study that initially showed an even lower prevalence of HSIL (5%). This prevalence has remained low (8%) in the second year, with a high percentage of inadequate samples, almost 15%. This has been addressed by changing cytobrush to moistened polyester swabs that produce less discomfort, allowing more pressure in the canal to obtain a better sample, a recommendation of the training specialist NJ, as well as virtual training sessions involving the INCan cytologist with the AMC head gyn-cytologists.

Conclusions

Anal carcinoma stands today as a severe menace to PWH; diagnostic and therapeutic intervention can reduce the risk of occurrence. Implementing a HRA faced many difficulties at INCan. Training and certification are a cornerstone in this goal, and experienced

genital pathologists are also essential to interpret HPV lesions. More advocacy is needed for HIV programs to incorporate and invest in anal cancer screening. More high-resolution anoscopy capacity must be built in the country to extend the service beyond a national referral center.

Abbreviations

PWH	People living with HIV
MSM	Men who have sex with men
HSIL	High-grade squamous intrepithelial lesions
HRA	High-resolution anoscopy
GI	Gastrointestinal
HPV	Human papilloma virus
ID	Infectious diseases
IANS	International anal neoplasia society
AMC	AIDS Malignancy Consortium

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Author contributions
PV, SB, NJ and AMO study conception; VL and MJM: data collection and curation, data analysis; PV and AMO: draft; SB and NJ: data analysis, manuscript review and edition; SB, PM and MM performed the anoscopies and obtained the samples. DP: histopathologic examination of the samples; PM, MM and DP: manuscript review. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The Institutional Ethics and Research Committee approved the protocol (IRB) of the Instituto Nacional de Cancerología (009/006/IBI) (CEI/529/09).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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