Original Article

Comparison of anal cancer outcomes in public and private hospital patients treated at a single radiation oncology center

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Objective: To compare clinical and treatment characteristics and outcomes in locally advanced anal cancer, a potentially curable disease, in patients referred from a public or private hospital.

Methods: We retrospectively reviewed 112 anal cancer patients from a public and a private hospital who received definitive chemoradiotherapy at the same cancer center between 2004 and 2013. Tumor stage, radiotherapy delay, radiotherapy duration, and unplanned treatment breaks ≥10 days were compared using *t*-test and χ^2 test. Overall survival (OS), disease free survival (DFS), and colostomy free survival (CFS) were examined using the Kaplan-Meier method and compared with the log-rank test. Cox proportional hazard models for OS and DFS were developed.

Results: The follow-up was 14.9 months (range, 0.7-94.8 months). Public hospital patients presented with significantly higher clinical T stage (P<0.05) and clinical stage group (P<0.05), had significantly longer radiotherapy delays (P<0.05) and radiotherapy duration (P<0.05), and had more frequent radiation therapy (RT) breaks ≥10 days (P<0.05). Three-year OS showed a marked trend in favor of private hospital patients for 3-year OS (72.8% *vs.* 48.9%; P=0.171), 3-year DFS (66.3% *vs.* 42.7%, P=0.352), and 3-year CFS (86.4% *vs.* 68.9%, P=0.299). Referral hospital was not predictive of OS or DFS on multivariate analysis.

Conclusions: Public hospital patients presented at later stage and experienced more delays in initiating and completing radiotherapy, which may contribute to the trend in poorer DFS and OS. These findings emphasize the need for identifying clinical and treatment factors that contribute to decreased survival in low socioeconomic status (SES) populations.

Keywords: Anal cancer; radiotherapy, socioeconomic factors; public hospitals; treatment outcome

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Introduction

Despite significant advances in the diagnosis and treatment of the disease, cancer remains the 4th leading cause of death in adults in the United States. Socioeconomic status (SES) has been demonstrated to be associated with both cancer incidence and prognosis, with patients of low SES bearing a disproportionately large portion of the public health burden of the disease (1-3). However, the specific drivers of poorer outcome have not been fully elucidated, impeding our ability to act on these inequalities (4). In fact, while our understanding of cancer biology, screening techniques, and treatment has improved significantly over the past 20 years, SES disparities in cancer mortality have remained constant (5).

Anal cancer is an uncommon malignancy, with 7,210 new cases and 950 deaths yearly (6). Locally advanced anal cancer treated with chemotherapy and radiation has a survival outcome approaching 80%. Although there is a clear association between HPV infection and the development of anal cancer, molecular and biologic outcome predictors for survival are not well understood. Furthermore, because of its association with a transmittable virus, the incidence of this disease is rising worldwide (7-9). Most research into factors associated with anal cancer incidence and prognosis focuses on pathologic features of the disease (10-12). Since the largest gaps in survival based on SES has been found among the most treatable cancers, identifying and minimizing SES disparities in diagnosis and treatment among anal cancer patients is particularly valuable (1).

Many SES studies have used large national databases of multi-institutional trial data to assess disparities in cancer outcomes (13,14). One potential limitation of this approach is the confounding factor of variable treatment patterns between institutions. This study compares patients referred from either a private, not-for-profit hospital or a public safety net hospital to a single clinical cancer center, with hospital type serving as a surrogate for SES. Our public hospital primarily comprises uninsured or Medicaid-insured patients, many of whom are of racial and ethnic minorities, and/or do not speak English as a first language (15). We compared anal cancer clinical and treatment characteristics between patients referred from these two hospitals to a single cancer center where they received radiation therapy (RT) from the same treatment staff.

Methods

Study sites and patient inclusion criteria

We conducted a chart review on all patients from a private and public hospital who received RT anal cancer at the same clinical cancer center. Both facilities are located in midtown Manhattan. The private hospital is an integrated, not-for-profit academic medical center. The public hospital is an urban safety net hospital that largely serves underinsured patients. Thirty-one percent of clinic patients at this institution are uninsured and 45% are insured through Medicaid (15). In the primary service area of the public hospital, 57% of residents do not speak English as a first language, and 22% of families live below Federal poverty guidelines (15). The clinical cancer center is based at the private hospital, but is affiliated with the public hospital and provides RT for patients referred from both institutions. The NYU Department of Radiation Oncology routinely treats all patients referred from both institutions at the clinical cancer center. Thus, all patients in this review were treated with a unified protocol administered the by the NYU Radiation Oncology faculty, residents, and staff.

Between December 2004 and December 2013, 112 patients with locally advanced anal cancer were treated definitively with chemoradiation (CRT). Patients were excluded if CRT was delivered for patients with stage IV disease, recurrent disease, or if histology revealed anything but an epithelial cancer of anal canal. Three patients from the public hospital were excluded due to insufficient treatment data. We performed a retrospective analysis of the remaining 109 patients, with institutional review board approval.

Diagnosis and treatment

Patients were clinically staged with CT imaging. External beam RT was delivered as either 3-dimensional radiation therapy (3D RT) or intensity modulated radiation therapy (IMRT) with continuous standard fractionation. A minimum dose of 30.6 Gy was delivered to electively treated lymph nodes and a minimum dose of 45 Gy was delivered to the gross tumor. RT was delivered in 1.8 Gy fractions for all patients. Most patients also received continuous infusion of 5-fluorouracil 1,000 mg/m^2/d IV on days 1-4 and 29-32 of treatment, and mitomycin C 10 mg/m^2 IV bolus on days 1 and 29 of treatment.

Data

Data were collected on patient age at diagnosis, gender, race, insurance, HIV status, histology, and clinical stage at presentation. Date of pathologic diagnosis, dates of RT, RT dose, presence of unplanned RT breaks, chemotherapy regimens, and RT toxicities were recorded. Radiation toxicities were graded according to the Radiation Therapy and Oncology Group (RTOG) common toxicity criteria.

Statistical analysis

Outcome measures were tumor size stage at presentation, RT delay, RT duration, unplanned treatment breaks greater than or equal to 10 days, overall survival (OS), disease free survival (DFS) rate, and colostomy free survival (CFS). RT delay was defined as the interval from date of pathologic

diagnosis to the first day of RT. OS was defined as time from initiation of CRT to death due to any cause or most recent follow-up. DFS was defined as time from initiation of CRT to the occurrence of local, regional, or distant recurrence, death, or most recent follow-up. CFS was measured from initiation of CRT to diverting colostomy or salvage abdominoperineal resection (APR), death, or most recent follow-up without surgery.

The associations between referral hospital and outcomes were examined using Student's *t*-test to compare means and χ^2 test to compare frequency, as appropriate. Survival curves for OS, DFS, and CFS for private hospital and public hospital were created using the Kaplan-Meier method and compared with the log-rank test. Confidence intervals (CIs) were calculated using the formula "95% CI = mean ± standard error ×1.96". Unadjusted and adjusted hazard ratios for referral hospital, insurance status, and race were calculated using the Cox proportional hazards model. All statistical analyses were carried out using SPSS version 20 (IBM Corp., Armonk, NY, USA). Statistical tests were two-sided and P values <0.05 were considered significant.

Results

Patient population and characteristics

In our cohort, the charts of 109 patients undergoing CRT for anal cancer at the public and private hospital were reviewed. Seventy-seven patients were from the private hospital and 32 patients were from the public hospital. Demographic and clinical variables of the patients are reported in *Table 1*. The mean age of patients overall was 59.5 years (range, 24.4-93.2 years), with no significant difference between private hospital and public hospital patients (P=0.222). A total of 60.6% of patients were male, and the gender distribution was the same between the private and public hospital (P=0.554).

The majority of private hospital patients were non-Hispanic White (76.6%), while the majority of public hospital patients were Black (34.4%) or Hispanic (34.4%) (P<0.001). There were more patients with private insurance and Medicare at the private hospital, and more with Medicaid or uninsured at the public hospital (P<0.001). There were more HIV positive patients in the public hospital group compared to the private hospital group (50% *vs.* 31.2%, P=0.063, respectively).

Of 109 patients, 105 (96.3%) were found to have squamous cell carcinoma, one patient from each hospital had cloacogenic carcinoma, and one patient from each hospital had adenocarcinoma. Patients from the public hospital presented with higher T stage and AJCC stage group (P=0.004 and 0.029, respectively). There was no difference in N stage between the groups.

Treatment

The distribution of RT treatment course characteristics is described in *Table 2*. Most patients received 3D RT prior to 2009, and IMRT after 2009. There was no significant difference in the rate of IMRT, dose to electively treated lymph nodes, or dose to gross tumor. RT course was truncated in two patients from the private hospital and one from the public hospital. Concurrent chemotherapy was given in 99 patients (97.1%), with similar rates between the two hospitals. Eight patients received 5-fluorouracil only; 18 patients received alternative chemotherapy in addition to 5-fluorouracil, most commonly capecitabine (n=8) and cisplatin (n=5).

Public hospital patients had longer RT delay (103±105 *vs.* 50±38 days, P<0.001), and experienced significantly longer RT duration (57±26 *vs.* 50±16 days, P=0.03). More patients from the public hospital had a treatment interruption greater than or equal to 10 days (43.8% *vs.* 23%, P=0.031, respectively). When stratified by RT technique, there was no difference between the hospitals in RT duration (P=0.440) or presence of treatment breaks (P=0.655) among patients receiving 3D RT. Among patients receiving IMRT, public hospital patients experienced longer RT duration (62.8±8.3 *vs.* 43.0±33.6 days, P<0.001) and were more likely to have a break of 10 days or greater (50% *vs.* 10.6%, P=0.001). The duration of RT delay was not associated with the presence of unplanned treatment breaks (P=0.439).

Toxicity

The incidence of grade 3-4 dermatitis was greater in the public hospital group, while the incidence of fatigue and diarrhea was similar between the two hospitals (*Table 3*). There was no difference between the hospitals in the percentage of patients requiring growth factor support (P=0.646) or platelet or red blood cell transfusion (P=0.556) during CRT. There was no difference between the private and public hospitals in absolute neutrophil count nadir (1.8±1.0 *vs.* 1.7±1.1, P=0.726), white blood cell nadir (2.8±1.5 *vs.* 2.5±1.5, P=0.390), platelet nadir (98.5±56.9 *vs.* 128.3±99.4, P=0.154), or hemoglobin nadir (10.1±1.9 *vs.* 15.3±31.2, P=0.395).

Table 1 Demographics of anal cancer radiotherapy patients by referral hospital

Characteristics	Total (n=109) (%)	Private hospital (n=77) (%)	Public hospital (n=32) (%)	P value
Age (y)				0.222
Mean	59.5	60.5	57.1	
Standard deviation	13.2	13.7	12.1	
Range	24.4-93.2	24.4-93.2	33.2-90.2	
Gender, male	66 (60.6)	48 (62.3)	18 (56.2)	0.554
Race				<0.001
Non-Hispanic White	67 (61.5)	59 (76.6)	8 (25.0)	
Black	24 (22.0)	13 (16.9)	11 (34.4)	
Hispanic	16 (14.7)	5 (6.5)	11 (34.4)	
Asian	1 (0.9)	0 (0)	1 (3.1)	
Insurance				<0.001
Private	48 (44.0)	48 (62.3)	0 (0)	
Medicare	33 (30.3)	26 (33.8)	7 (21.9)	
Medicaid	20 (18.3)	3 (3.9)	17 (53.1)	
None/self	8 (7.3)	0 (0)	8 (25.0)	
HIV positive	40 (36.7)	24 (31.2)	16 (50.0)	0.063
T stage				0.004
1	25 (22.9)	25 (32.5)	0 (0)	
2	59 (54.1)	36 (46.8)	23 (71.9)	
3	21 (19.3)	14 (18.2)	7 (21.9)	
4	3 (2.8)	1 (1.3)	2 (6.2)	
x	1 (0.9)	1 (1.3)	0 (0)	
N stage				0.583
0	71 (65.1)	53 (68.8)	18 (56.2)	
1	14 (12.8)	9 (11.7)	5 (15.6)	
2	20 (18.3)	12 (15.6)	8 (25.0)	
3	4 (3.7)	3 (3.9)	1 (3.1)	
M stage				N/A
0	109 (100.0)	77 (100.0)	33 (100.0)	
1	0 (0)	0 (0)	0 (0)	
Clinical stage				0.029
I	18 (16.5)	18 (23.4)	0 (0)	
II	52 (47.7)	34 (44.2)	18 (56.2)	
IIIa	15 (13.8)	10 (13.0)	5 (15.6)	
IIIb	24 (22.0)	15 (19.5)	9 (28.1)	

Data are reported as number of patients unless otherwise noted. HIV, human immunodeficiency virus.

Patients with a treatment break of greater than or equal to 10 days were more likely to have grade 3-4 dermatitis toxicity (52.2% *vs.* 27.1%, P=0.027). There was no statistically significant correlation between treatment break and fatigue, diarrhea, or hematologic toxicity.

Clinical follow-up

Following CRT, patients were followed with palpation of the inguinal lymph nodes, digital rectal exam, and anoscopy every 3-6 months for 5 years, and with chest, abdominal,

Table 2 Treatment characteristics by referral hospital

Characteristics	Total (%)	Private hospital (%)	Public hospital (%)	P value
Radiation technique				0.186
3D RT	44 (40.4)	28 (36.4)	16 (50.0)	
IMRT	65 (59.6)	49 (63.6)	16 (50.0)	
RT dose to elective LNs (Gy)				0.628
Median	36	36	34.2	
Range	10.8-45	14.4-45	10.8-45	
RT dose to boost volume (Gy)				0.947
Median	54	54	54	
Range	10.8-64.8	14.4-63	10.8-64.8	
RT delay				<0.001
Mean	64.2	50	103	
Standard deviation	67.5	38	105	
Range	12-564	12-262	23-564	
RT duration (days)				0.030
Mean	50.6	50	57	
standard deviation	19.8	16	26	
Range	14-174	14-153	31-174	
RT interruption ≥10 days				0.031
Yes	31 (28.4)	17 (23.0)	14 (43.8)	
No	75 (68.8)	57 (77.0)	18 (56.2)	
Concurrent chemotherapy	99 (97.1)	69 (97.2)	30 (96.8)	0.910

3D RT, 3-dimensional radiation therapy; IMRT, intensity modulated radiation therapy; RT, radiation therapy.

Table 3 RTOG toxicity by referral hospital

Characteristics	Total (%)	Private hospital (%)	Public hospital (%)	P value
Diarrhea				0.449
Grade 0-2	94 (97.9)	73 (97.3)	21 (100.0)	
Grade 3-4	2 (2.1)	2 (2.7)	0 (0)	
Fatigue				0.208
Grade 0-2	67 (69.8)	50 (66.7)	17 (81.0)	
Grade 3-4	29 (30.2)	25 (33.3)	4 (19.0)	
Dermatitis				0.036
Grade 0-2	64 (66.7)	54 (72.0)	10 (47.6)	
Grade 3-4	32 (33.3)	21 (28.0)	32 (33.3)	

RTOG, radiation therapy and oncology group.

and pelvic imaging annually for 3 years. The median duration of follow-up was 14.9 mos (range, 0.7-94.8 mos), with no difference in follow-up time between the hospitals (P=0.150). At the time of this review, 80 patients (73.4%) were alive and 24 patients (22.0%) were dead. Five patients were lost to follow-up.

Patient outcomes

The Kaplan-Meier curves for OS, DFS, and CFS are

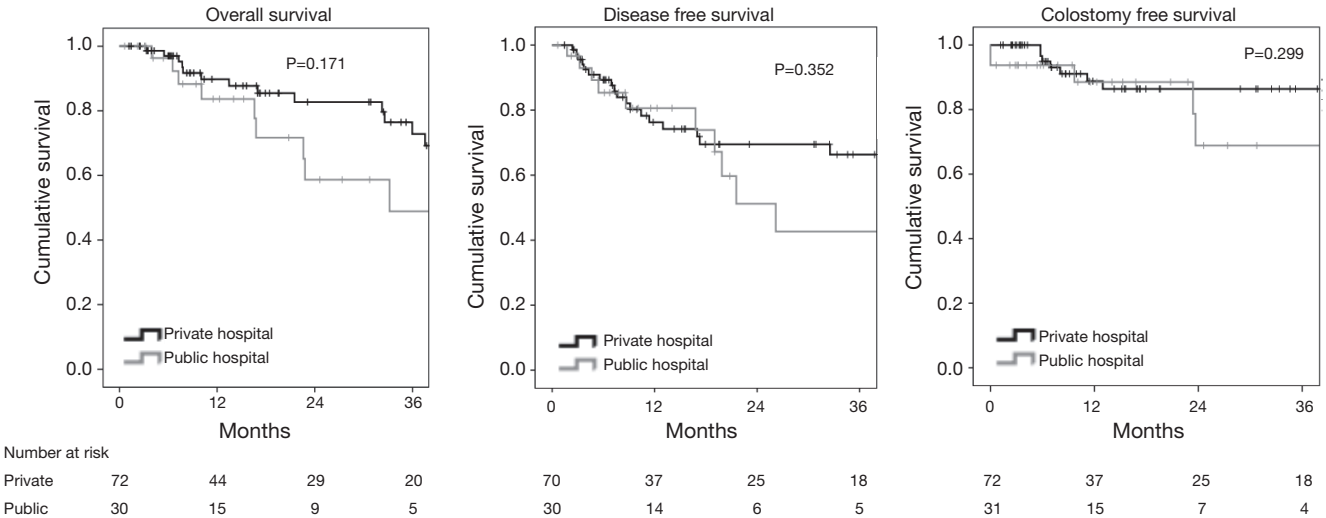

Figure 1 Kaplan-Meier survival curves for OS, DFS, and CFS stratified by referral from the private, not-for-profit hospital (solid line) or the public hospital (grey line). The number of patients at risk from each group is presented below the curves. There is no statistically significant difference in survival between patients referred from the private hospital compared to the public hospital on log-rank test for all three outcomes (P values shown). OS, overall survival; DFS, disease free survival; CFS, colostomy free survival.

Table 4 Multivariate cox proportional hazards model for OS and DFS

Covariate	OS			DFS		
	HR	95% CI	P value	HR	95% CI	P value
Referral from public hospital	1.32	0.503-3.463	0.573	0.869	0.359-2.106	0.757
HIV positive	1.459	0.558-3.812	0.441	1.626	0.726-3.640	0.237
T stage 3-4	2.879	1.112-7.455	0.029	2.223	0.997-4.957	0.051
RT as IMRT	0.245	0.079-0.765	0.015	0.569	0.262-1.232	0.152
RT duration (days)	1.013	0.998-1.028	0.081	1.01	0.991-1.028	0.315
RT delay (days)	0.999	0.990-1.009	0.872	0.999	0.991-1.007	0.770

OS, overall survival; DFS, disease free survival; HR, hazard ratio; CI, confidence interval; HIV, human immunodeficiency virus; RT, radiation therapy.

presented in *Figure 1*. The three-year OS was 72.8% (95% CI, 63.4% to 76.6%) for private hospital patients and 48.9% (95% CI, 22.8% to 75.0%) for public hospital patients, hazard ratio (HR) 1.77 (95% CI, 0.77-4.07). The 3-year DFS was 66.3% (95% CI, 53.0% to 70.1%) for private hospital patents and 42.7% (95% CI, 16.6% to 68.8%) for public hospital patients, HR 1.41 (95% CI, 0.68-2.94). The three-year CFS was 86.4% (95% CI, 76.8% to 90.2%) for private hospital patients and 68.9% (42.8% to 95.0%) for public hospital patients, HR 1.82 (95% CI, 0.58-5.74).

Multivariate analysis showed that referral from the public hospital did not confer a statistically significant increased risk of death or recurrence when potential confounders were controlled for (*Table 4*).

Discussion

In the study presented here, public hospital patients presented at more advanced stages and were more likely to have delayed RT, increased RT duration due to unplanned treatment interruptions, and treatment breaks greater than or equal to 10 days. RT courses were otherwise comparable between the two populations, as the patients received care at the same RT center. While the private hospital patients' survival was similar to nationally and internationally reported statistics, OS and DFS was substantially lower

for public hospital patients (7,16). It is critical to note that the patient size is small and the Kaplan-Meier curves cross, limiting the interpretation of the survival analysis in this retrospective review. However, a decreased survival is consistent with poorer outcomes associated with the observed differences in presentation and RT course.

On review of the literature, few studies have examined the effect of SES on anal cancer survival as a primary objective. One study analyzing the National Cancer Data Base (NCDB) found that income <$36,000 and Black and Hispanic race were associated with increased risk of death from anal cancer (17). An analysis of the Surveillance, Epidemiology, and End Results Program found poorer survival in Black patients between 1994 and 2000 (8). However, a more recent analysis of the NCDB between 2004 and 2014 found that race was not predictive of salvage APR (18). Our study is the first to compare differences in clinical presentation and treatment course between two different SES populations, allowing for the identification of potentially reversible inequalities in treatment characteristics that may contribute to poorer survival in low SES patients.

In the United States, anal cancer incidence is higher in females, however in this study the majority of patients were male (6). This discrepancy may reflect an increased prevalence of genital/anal HPV infections and sexual practices in our urban population, particularly given the high rate of HIV infection in our study. Of note, since the introduction of HAART, the incidence of anal cancer has been rising, particularly among men who have sex with men and those who are HIV-positive (9,17,19). Our study population may be reflective of this demographic shift, and increasing education and screening in this population may be appropriate.

A strength of our study is that all patients were treated at the same RT center, and hence RT treatment quality was the same despite differences in patterns of care. This allowed us to evaluate the effect of RT quality on SES disparities. It is well documented that patients treated at safety net hospitals and those insured through Medicaid are less likely to receive standard of care treatment (20,21). Particularly in the case of rare cancers, access to standard treatment provided by high volume, centralized cancer centers such as the one in this study is an important determinant of outcome (22,23). At this RT center, all patients are treated by the same staff in the same facility and are discussed at multidisciplinary tumor boards. Access to quality RT and careful coordination of care should mitigate differences in outcome between the two hospitals, but other factors come into play. More intensive care coordination and patient navigation may be required in low SES populations to improve survival.

The T-stage differential between the two hospital populations is the most apparent reason for the trends in DFS and OS favoring the private hospital patients. Advanced local stage at presentation is a known risk factor in anal cancer, and was associated with increased risk of death and disease recurrence in this study. More advanced presentation in low SES patients has been observed in other malignancies (5,24). These findings may be due to logistic, financial, language, cultural, and health literacy barriers to screening and care among low SES populations (25,26). Since anal cancer is generally symptomatic even at early stages, increasing community awareness of the warning signs for anal cancer may be a particularly effective way to improve anal cancer outcomes in low SES populations.

Multiple studies have reported longer delays to RT initiation in racial minorities in prostate, breast, and cervical cancer (27-29). These findings are consistent with the delay in RT observed in the public hospital patients. In addition to the barriers mentioned above, one explanation for this finding is that public hospitals are resource-limited, and therefore tend to have longer waits to obtain the necessary clinical appointments and imaging studies prior to treatment. In breast and head and neck cancer, longer time from diagnosis to RT initiation has been associated with increased risk of local recurrence and poorer survival (30-32). To the best of our knowledge, the prognostic significance of treatment delays has not previously been examined in anal cancer. Further investigation into its effect on outcome is warranted to clarify its role in anal cancer outcome disparities.

The etiology of the increased incidence of unplanned RT breaks in the public hospital population is likely multifactorial. First, public hospital patients were more likely to experience severe dermatitis, which is likely explained in part by the higher proportion of HIV-positive individuals in this group (33). Further, patients from racial and ethnic minorities report poorer physician information-sharing than white patients, potentially contributing to decreased compliance with RT (34). Additionally, navigating cancer treatment is difficult for all patients, and may be especially challenging for public hospital patients who face financial, language, and health literacy barriers (15). In 2010, Ben-Josef *et al.* analyzed data on 644 anal cancer patients from the RTOG 87-04 and RTOG 98-11 trials, and found that total treatment time, but not RT duration, negatively impacted local control and colostomy-free rate (11).

While several small, retrospective studies have also demonstrated a trend toward poorer survival with RT interruption (35,36), others have not (37,38). Though the prognostic significance of RT breaks requires further study, low SES patients appear to be particularly vulnerable to treatment interruptions, and increasing compliance may improve outcomes in this population.

This study has several limitations that should be considered when interpreting the data. We were unable to collect information on income and education status, and therefore may have overlooked subsets of the low SES population that experienced poorer outcomes. We also did not have data on reasons for RT delay and RT interruptions, limiting our ability to identify specific drivers of treatment disparities. Additionally, it has been postulated that higher rates of medical comorbidities among low SES patients may contribute to poorer outcomes (4). Low SES populations, and in particular those treated at safety net hospitals, have significantly more comorbidities than the average population (39). It is possible that higher comorbidities in the public hospital patients may have contributed to RT delay and RT breaks, as well as differences in survival. Finally, the median follow-up time of 14.9 months is suboptimal. Historically, it has been difficult to achieve long-term follow-up in the public hospital population, as these patients have increased socioeconomic stressors that make long-term follow-up challenging. Finally, the small sample size limits our power to detect differences in survival. Nevertheless, the results are suggestive of a clinically meaningful difference and justify further study.

Conclusions

Despite receiving the same high-quality RT as the private hospital patients, the public hospital patients had poorer survival than expected in this study. We identified discrepancies in stage at diagnosis, treatment initiation, and compliance during RT between the two populations, suggesting that addressing these disparities may improve survival in low SES populations. Resources should be directed towards interventions that address these inequities, and outcomes should be studied prospectively. In the future, larger studies with longer follow-up may be needed to better understand the impact of SES on anal cancer survival.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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