

Treatment Patterns and Survival of Non-metastatic Anal Carcinoma at Tikur Anbessa Specialized Hospital, Addis Ababa Ethiopia: A 5 Year Retrospective Study

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Research Article

Keywords: Survival rate, CCRT, Anal carcinoma, treatment pattern, Ethiopia

Posted Date: April 24th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-9080015/v1>

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Additional Declarations: No competing interests reported.

Abstract

PURPOSE

Concurrent chemo-radiotherapy (CCRT) is the standard treatment of non-metastatic ASCC. However, there is a limited access to radiotherapy centers to delivery standard CCRT in resource constraint countries, like Ethiopia. We evaluate the treatment pattern, and survival of patients with non-metastatic anal squamous cell carcinoma at Tikur Anbessa Specialized Hospital (TASH), a tertiary teaching hospital in Addis Ababa, Ethiopia.

Methods

This retrospective study reviewed medical records of patients with non-metastatic ASCC between April 2019 and April 2024. Survival status and any missing data were addressed via phone calls. Data about socio-demographics, clinical presentations, treatments, and outcomes were collected. Descriptive statistics and Kaplan-Meier survival analysis were used to analyze the data. Factors influencing survival were identified using Cox proportional hazards.

Results

Median age of patients was 53.3 years, 66.7% were female, and 51.6% were living with HIV. Stage III disease accounts for 78.3%. Overall, 88% of patients were planned for primary radical treatment but only 45% received radical treatment, and the remaining received palliative treatment (34%), and did not receive any treatment (21.3%). The 5-year overall survival (OS) for the overall population was 28%. The 2 and 5 years OS of patients received radical RT and palliative RT was 100% vs 62% and 90% vs 0%, respectively ($p = 0.001$). Type of treatment was an independent risk factor for death. Patients received palliative RT had an inferior outcome than those received radical RT (HR = 13.3, 95% CI: 1.5–115). The mean radiotherapy waiting time was 27 weeks for radically treated patient.

Conclusions

The survival of non-metastatic ASCC in this study is unacceptably low. Factors contributing to poor survival include lack of treatment due to longer RT waiting times, a higher proportion of palliative treatment, and advanced stage. The findings emphasize the urgent need of strategies for management of ASCC, particularly in low-resource settings such as Ethiopia.

CONTEXT

Key Objective

What type of treatments are used, and survival outcomes of patients with non-metastatic anal squamous cell carcinoma at Tikur Anbessa Specialized Hospital?

Knowledge Generated

More than half of patients, among those patients planned to have radical treatment, received palliative treatment and without any treatment. Type of treatment was an independent risk factor for death. Patients received palliative RT had inferior outcome than those received radical RT but had superior outcome than those who did not received any treatment.

Relevance

Patients diagnosed with non metastatic ASCC should be received their radical treatment timely if not at least they should receive palliative treatment.

INTRODUCTION

Anal cancer is a rare cancer, accounts for 2% all gastrointestinal tract cancer. The most common type of primary anal cancer is anal squamous cell carcinoma. The global incidence of anal squamous cell carcinoma(ASCC) is rising ^{1,2}.

Treatment of anal SCC has evolved significantly in the past 4 decades. Historically, Abdomino-perineal resection(APR) was the primary treatment for ASCC³. However, this approach resulted in high rate of morbidity related due to the need for a permanent colostomy⁴. Since 1970s, CCRT is the standard treatment of non-metastatic ASCC^{5,6}. Majority of patients after CRT will have a clinically complete remission and do not require organ affecting surgery such as an APR. Nevertheless, APR still can play significant a role as salvage treatment^{7,8}.

Despite improved outcomes with definitive chemoradiotherapy (CCRT) for non-metastatic ASCC, there is a limited access to radiotherapy centers to delivery standard CCRT in resource constraint countries, like Ethiopia. Tikur Anbessa Specialized Hospital serves as the primary oncology center in Ethiopia. Due to longer radiotherapy waiting times, patients with non-metastatic ASCC at the hospital receive varied treatments from different clinicians. This leads to a situation including some patients receive induction chemotherapy (CT) while awaiting CCRT, and others are scheduled for CCRT but face delays in receiving the complete prescribed radiation dose. This lack of standardized treatment due to resource limitations creates uncertainty about the effectiveness of these alternative approaches compared to the gold standard CCRT.

Despite all these problems faced to treat anal cancer, no published studies in Ethiopia have investigated treatment patterns and survival outcomes for non-metastatic ASCC patients. Consequently, there a critical gap in knowledge regarding the treatment, and outcomes of non-metastatic anal SCC in the region. Research directed at addressing this gap requires, that can provide valuable insights into the

management and survival of anal SCC patients. The findings from this analysis will enhance the understanding of localized ASCC, and also inform clinical guidelines and policy decisions. Improved knowledge of treatment outcomes can lead to the development of tailored interventions that address the specific needs and challenges faced by anal cancer patients in low-resource countries. Additionally, it can guide resource allocation and capacity-building efforts to strengthen the healthcare system's ability to manage anal cancer effectively.

The goal of this study is to bridge this gap by assess the treatment pattern and survival outcome of non-metastatic anal SCC patients at Tikur Anbesa Specialized Hospital. The study seeks to contribute to the global understanding of non metastatic ASCC management and support the development of context-specific strategies to improve patient outcomes in Ethiopia and similar settings.

Materials and Methods

A retrospective study of non-metastatic ASCC patients at Tikur Anbessa Specialized Hospital Oncology department in Addis Ababa, Ethiopia, was conducted from April 1, 2019 to April 1, 2024. Tikur Anbesa Hospital is one of Ethiopia's leading tertiary care centers, serving as a national referral hospital for complex cases and providing specialized care to patients from across the country. At present, the majority of anal cancer cases are diagnosed and treated within adult Oncology units. The study population were all histologically confirmed anal squamous cell cancer patients who had adequately documented stage, and managed at oncology unit of TASH during the specified study period. Patients having another primary in addition to anal cancer, histology other than ASCC, and those whose diagnosis was only documented without detailed records to diagnostic and treatment criteria were excluded.

The data collection for this study was extracting from electronic medical record, and Eclipse for radiotherapy. Data was collected, regarding socio-demographic details, clinical data, diagnostic tests, Treatment details (surgery performed, type of surgery if available, chemotherapy received, specific chemotherapy drugs if available, radiotherapy received, radiotherapy dose, radiotherapy waiting time), and survival outcome. To address missing data, phone calls were made to the patients or their families to inquire. To ensure data accuracy and completeness, double data entry and cross-checking of records was implemented.

Statistical Analysis

The collected data were cleaned and transferred to SPSS version 27 for analysis. Descriptive Statistics was used to summarize patient demographics, clinical characteristics, and treatment patterns. Kaplan-Meier analysis was used to estimate the Overall survival (OS). Log-rank tests or Cox proportional hazards regression was used to analyze the association between patient demographics, disease characteristics, different treatment modalities on survival outcomes. Variables with a $p < 0.25$ on univariate analysis were considered as a candidate for the final analysis. Predictors for survival were declared at a p -value of < 0.05 .

Ethical approval

was obtained from the relevant Institutional Review Board (IRB) before initiating the study. Patient confidentiality was maintained throughout the study. All data was anonymized before analysis.

Result

Patient and clinical characteristics

Between April 2019 and April 2024, we identified 60 patients. The median age was 53.3 years (IQR = 41 – 60), and the vast majority of patients were female (66.7%). The anal SCC was most commonly diagnosed in those age older than 30 years (98.3%) (Table 1). The majority (51.6%) of patients were living with HIV. The CD4 count at diagnosis was available in only 12 (38.7%) patients with a mean CD4 count of 483.75 cell/m³ (SD ± 38.7). Most Patients (90%) at diagnosis had good performance status (ECOG 0 or I). The average tumor size was 6.34 cm (range 1 to 11 cm). Forty seven out of 60 patients had AJCC stage III (78.3%). Eighty percent of patients had been symptomatic for more than 6 months before diagnosis, and only 1.7% had symptoms for less than 1 month. The diagnosis of anal SCC was made by biopsy of the primary site in 96.7% of the study participants (Table 1).

Table 1
Baseline Patients' Characteristics

Patient characteristics (N = 60)	Frequency (No)	%
Age at diagnosis (years)		
Median age 53.3 (IQR = 41–60)		
<=30	1	1.7
30–50	28	46.7
> 50	31	51.7
Sex		
Female	40	66.7
Male	20	33.3
ECOG PS		
0,1	54	90
>=2	6	10
Duration of symptom(month)		
<=1	1	1.7
1–6	11	18.3
6–12	30	50
> 12	18	30
Tumor size in cm		
<=5cm	16	26.7
> 5cm	44	73.3
T-stage		
T1	3	5
T2	11	18.3
T3	20	33.3
T4	26	43.3
N-stage		
Abbreviations: ECOG PS, Eastern Cooperative Oncology Group performance status; LN, lymph node; CD4, clusters of differentiation 4; FNAC, fine needle aspiration cytology; HIV, human immune virus.		

Patient characteristics (N = 60)	Frequency (No)	%
N0	17	28.3
N1	43	71.7
Group staging		
Stage-I	1	1.7
Stage-II	12	20
Stage-III	47	78.3
HIV Positive	31	51.6
CD4 count		
Known	12	38.7
Unknown	19	61.3
CD4 level (cell/m3)		
<==200	1	8.3
200–500	6	50
> 500	5	41.7
Histology diagnosis		
Biopsy	58	96.7
FNAC	2	3.3
Site of histology diagnosis		
From LN	1	1.7
Primary tumor site	59	98.3
Abbreviations: ECOG PS, Eastern Cooperative Oncology Group performance status; LN, lymph node; CD4, clusters of differentiation 4; FNAC, fine needle aspiration cytology; HIV, human immune virus.		

Treatment patterns

The initial planned treatment after diagnosis of non metastatic ASCC was curative for 53 patients (88%), and palliative for 7 patients (12%). The most common planned curative treatment modalities were induction chemotherapy (CT) plus concurrent chemoradiotherapy (38.3%), CCRT alone (35%), Abdominoperineal resection (APR) followed by adjuvant RT with or without concurrent or induction chemotherapy for 5% of patients (Supplementary Table S1).

Despite being planned to receive the above treatments at diagnosis only 27 patients (45%) received their curative treatment according to the schedule, while 20 patients (33.3%) were treated with palliative intent and 13 patients (21.7%) did not receive any type of treatment(Supplementary Table S2).Among patients received curative treatment,the most common treatment modalities were definitive radiotherapy with or without concurrent chemotherapy (n = 19, 70.4%),and induction chemotherapy followed by RT with or without concurrent chemotherapy (n = 8, 29.6%).Among all patients received palliative treatment,the type of treatment were palliative CT alone (35%, 7/20), palliative RT alone (35%, 7/20) ,and combined treatment with palliative RT and palliative CT (30%,6/20) (Supplementary Table S2). Among stage I patients, who received radical intent of RT, palliative treatment and no treatment were 66.6%, 85% and 92% respectively.

Among 27 patients received radical radiotherapy(RT), mean dose of radiation to total target volume was 49.5 ± 5.5 Gray(Gy), with a range of 39.6Gy to 54Gy,and the radiotherapy technique used were 3DCRT (77.8%) ,VMAT (11%),and 2DRT (7.4%).The vast majority (88.9%) of patients received radical RT had one or more days of radiation therapy interruptions,with the mean radiotherapy interruption was 8.8 days (range : 1 to 24days). Approximately 25.9% of these patients had more than 10days of radiotherapy treatment interrupted (Supplementary Table S3).

Regarding concurrent chemotherapy, about half (51.9%, 14 out of 27 patients received radical RT) received at least one cycle of concurrent CT, while concurrent CT was planned but not given or not documented in 37% of patients. The commonest chemotherapy used as concurrent was cisplatin plus capecitabine accounting for 33.3% followed by capecitabine alone.

One third of patients in this study received a palliative or induction chemotherapy, the commonly used chemotherapy type was cisplatin /5-FU followed by carboplatin/taxane (Supplementary Fig.S1). The median number of cycles of induction or palliative chemotherapy given was 5 cycles, with a minimum of one cycle and a maximum of 6 cycles, respectively.

The mean RT waiting time from diagnosis to first fraction,was 26.8 weeks($SD \pm 32$ weeks) with a range of 0.57 weeks to 134 weeks for the over all population,and 27weeks($SD \pm 28$ weeks) for radical radiotherapy.The RT waiting times among patients treated with radical RT revealed that, 44.4% and 14.8% of patients had a 6 months and 1year and above waiting time, respectively(Supplementary Table S3).The mean chemotherapy waiting time was 21 weeks with minimum of 1 week and maximum of 61 weeks.

We also detected changes in the treatment modalities over the study period. The proportion of patients treated with radical intent of radiotherapy was increasing over the study period. However, the proportion of palliative RT remained relatively stable (Supplementary Fig.S2).

Treatment response

Among 21 patients received palliative and induction chemotherapy, only 60% of patients had a documented tumor response rate; Of those the response rate evaluation revealed that, at mid cycle of

chemotherapy 39.1% of patients had an overall response rate including 4.8% complete response rate, while at end cycles of chemotherapy 15% ,10% ,25%, and 20% of patients had an overall response, partial response, stable disease, and progressive disease, respectively(Supplementary Table S4).

Regarding radiotherapy treatment outcome, among 27 radically treated patients the treatment response evaluation at 3months and 6months post CCRT or RT was available in 17 and 23 patients,respectively.The response rate revealed that,at 3 months overall response rate was 62.9% with complete response rate of 29.6%,and these response rate at 6 months were increased to 81% with 63% of complete response rate.At 6months 3.7% of patients developed a progressive disease .The overall response rate at 3 month for palliative RT was 42.6%(Supplementary Table S4).

Survival

Median follow up time was 17.9 months (IQR 10-28.9) and 19 months for the overall population and for those patients treated with radical RT, respectively. For the overall population, the 2 and 5-year overall survival rate was 56% and 28%, respectively, with a median survival of 29 months (95% CI: 16–40.9) (Fig. 1). Patients with stage I and stage II disease had significantly longer 5-year OS compared to patients with stage III disease (Long Rank, $P = 0.028$).

The survival of patients receiving radical RT was significantly longer compared to those patients receiving palliative RT, with the 2 and 5- years OS of 100% vs 62% and 90% vs 0%, respectively ($P = 0.001$). The median survival was not reached for patients treated with radical RT,and the median survival was 32 months for patients treated with palliative RT with or with out palliative chemotherapy ($p = 0.001$) (Fig. 2).

The median survival of patients received palliative radiotherapy plus palliative chemotherapy (36 months, 95% CI 25–45), palliative RT alone (22 months, 95% CI, 10–42), palliative CT alone (20 months, 95 CI of 14–25) tended to be prolonged compared to those without any form of treatment (10 months, 95% CI 8.3–11.6). The 2 years OS of patients received definitive treatment, palliative treatment and no treatment was 100%, 42% and 0%, respectively (Fig. 3).

On uni variant analysis, intent of radiotherapy, stage and tumor size variables were a candidate for final analysis with $P < 0.25$. On multivariate cox-regression analysis patients treated with palliative RT was associated with 13.3 times increased chance of poor survival as compared to those treated with radical RT (aHR = 13.3, 95% CI:1.5–115, $p = 0.01$).

The probability of recurrence free survival for patient treated with radical intent of radiotherapy and having complete response at 6 months was evaluated from days of initiation of radiotherapy to diagnosis of recurrence or death. The estimated 5 years RFS was 72% (Fig. 4). The 5 years probability of colostomy free survival from first date of RT to date of colostomy, for those who had no colostomy before RT was 88%.

Discussion

To our knowledge, this is the first study conducted at the largest and only comprehensive cancer center in Ethiopia, to insight into treatment pattern and outcomes of non metastatic ASCC patients. The study found that a median age of patients was 53.3 years, which is a decade earlier than reported in Western data⁹. The majority of patients diagnosed with anal squamous cell carcinoma were female, and 51.6% were HIV positive. The incidence of HIV in this study is slightly lower compared to other Africa studies, which reported a prevalence of 64%¹⁰. In this study higher proportion of patient living with HIV presents at stage III disease than HIV negative patient (84% vs 71% respectively).

The current first line standard of care for anal squamous cell carcinoma is radiation therapy with concurrent 5-fluorouracil/capecitabine and mitomycin-C^{5,6,11}. In this study, different treatment strategies were planned at diagnosis, including CCRT plus induction CT (38%), CCRT alone (35%), and palliative treatment (12%). Despite these initial planned treatments, only 45% of patients received radical treatment, 33.3% received palliative treatment, and 21.7% didn't receive any type of treatment. Among those patients received radical treatment, 31.7% received RT with or without concurrent chemotherapy, and 13.3% received induction CT followed by RT with or without concurrent CT. The treatment trend shows an increment of the number of patients received radical radiotherapy over time. Only 3 patients were treated with definitive RT between a year 2019–2022, while the number of patients treated with definitive RT were increased to 16 in the year 2023. However no significant changes were observed in the treatment of palliative RT.

The proportion of patients treated with palliative RT or without treatments at all is higher than in another African study. A study conducted in Tanzania by Mduma et.al (2023), reported that patients treated with palliative RT was 27%¹⁰. The possible reasons for these discrepancies in treatment delivery could be longer RT waiting times. The average RT waiting time in our study was 26.7 weeks and 27 weeks for the overall population and for radically treated patients, respectively, and the mean chemotherapy waiting time was 21 weeks. Another study done in Nigerian by Tumba et.al (2020), the median RT waiting for cervical, prostatic and breast cancer was 40 day¹². A study done in Ethiopia on cervical cancer RT waiting time by Jilcha et.al (2023) revealed a median RT waiting time of 477days¹³.

The complete response and survival rates observed in this study are inferior to those reported in the literature^{5,6}. In addition to the longer RT waiting times several other factors, such as lower rate of concurrent chemotherapy use, the absence of concurrent mitomycine administration, and advanced disease stage presentation may contributes to these differences^{6,13}.

Patients received radical treatments the overall and complete response rate at 3 months was 62.9% and 29.6%, respectively. At 6-month follow-up, the overall and complete response rates increased to 81% and 63%, respectively. These findings are comparable to reports from another African study, in which complete response rate of 49%¹⁰. However, the response rate was lower than other western finding. In UK, ACT II clinical trial done by James et.al (2013), the complete response rate at 6 month was 84%⁵⁻⁷.

This discrepancy can be explained by the lower rate of concurrent chemotherapy use in our study, with only 51% of patients receiving concurrent CT; of those, none were receiving mitomycin.

The estimated 5-years OS was 28% and 90% for the overall population and radically treated patients, respectively. The estimated 2 years OS of patients received radical RT and palliative RT was 100% and 62%, respectively. The estimated 5 years RFS and CFS of patients received radical treatments were 72% and 88%, respectively. The OS and CFS in radically treated patients were higher than reported from western studies, which was 5-years OS rates of 65–79%, disease control rates of 68–84%, and colostomy free survival rates of 65–75%^{5,6}, the possible reason for this could be the shorter median follow up time in our study (19 months). In the RTOG 98 – 11 trial conducted in USA by Gunderson et al (2012), at a median of 5.1 years, 5 years OS, RFS and CFS were 78.3%, 67% and 71% in the 5FU/mitomycin arm, respectively⁵. In a retrospective study done in Tanzania by Mduma et al (2023), 2-years overall survival (OS) and local recurrence-free survival were 86.4% and 91.3%, respectively¹⁰.

In this study the median survival of patients received palliative RT alone, palliative CT and without any type of therapy was 22, 20 and 10 months, respectively. The lower OS rate in the overall population could be due to the higher proportion of non-metastatic SCC patients received palliative therapy (33.3%) and 21.3% of patients didn't receive any form of therapy. In this study the median survival of patients received palliative therapy has comparable outcome with metastatic anal SCC patients treated with systemic therapy (carboplatin/Taxol), while patients who did not receive any form of treatment has an inferior outcome. A phase II study, done by Rao et al (2020), to compare Cisplatin/FU vs carboplatin/taxol in metastatic anal SCC, showed median survival in carboplatin /taxol arm of 20 months¹⁴.

This study has some limitations. First, its retrospective nature, and this was affected by poor documentation of clinical information including outcome variables particularly, response assessment related information, that have limited the analysis. Second, the median follow up duration was short for patients treated with definitive treatment to assess survival.

In conclusion, this study highlights significant challenges in the management of non-metastatic anal SCC in TASH. Despite the global standard of care involving concurrent chemoradiation therapy, a significant proportion of patients in this study received suboptimal treatment, including palliative care or no treatment at all. The estimated 5-year OS for the overall population in this study was unacceptably low. Key factors contributing to this poor outcome include a substantial number of patients did not receive timely treatment due to longer waiting times for radiation therapy, higher proportion of patients received palliative treatment and advanced disease stage presentation, further exacerbating the poor survival outcomes. However, patients who received radical treatment demonstrated promising survival outcomes, potentially influenced by shorter follow-up times. The study also revealed that the 2-year OS for untreated or treated with palliative treatment non-metastatic anal SCC is comparable or inferior to that of metastatic anal SCC, emphasizing the critical need for timely and effective treatment.

Declarations

Author contributions

Conception/design: Birhanu T. Liyew, Sonia W. Semayneh

Provision of study material or patients: Birhanu T. Liyew, Sonia Semayneh

Collection and/or assembly of data: Birhanu T. Liyew, Feleke H. Maniso

Data analysis and interpretation: Birhanu T. Liyew, Feleke H. Maniso, Sonia Semayneh

Manuscript writing: Sonia W. Semayneh

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics approval and consent to participate

Ethical approval was obtained from Research and Ethics Committee of Addis Ababa University, College of Health Sciences, Ethiopia before we started the study. The study was conducted in accordance with the principles of 1964 Helsinki declaration and its later amendments. Due to the retrospective nature of the study and the use of anonymized patient records, the requirement for informed consent to participate was waived by Research and Ethics Committee of Addis Ababa University, College of Health Sciences.

Consent for publication

Not applicable

Data availability statement

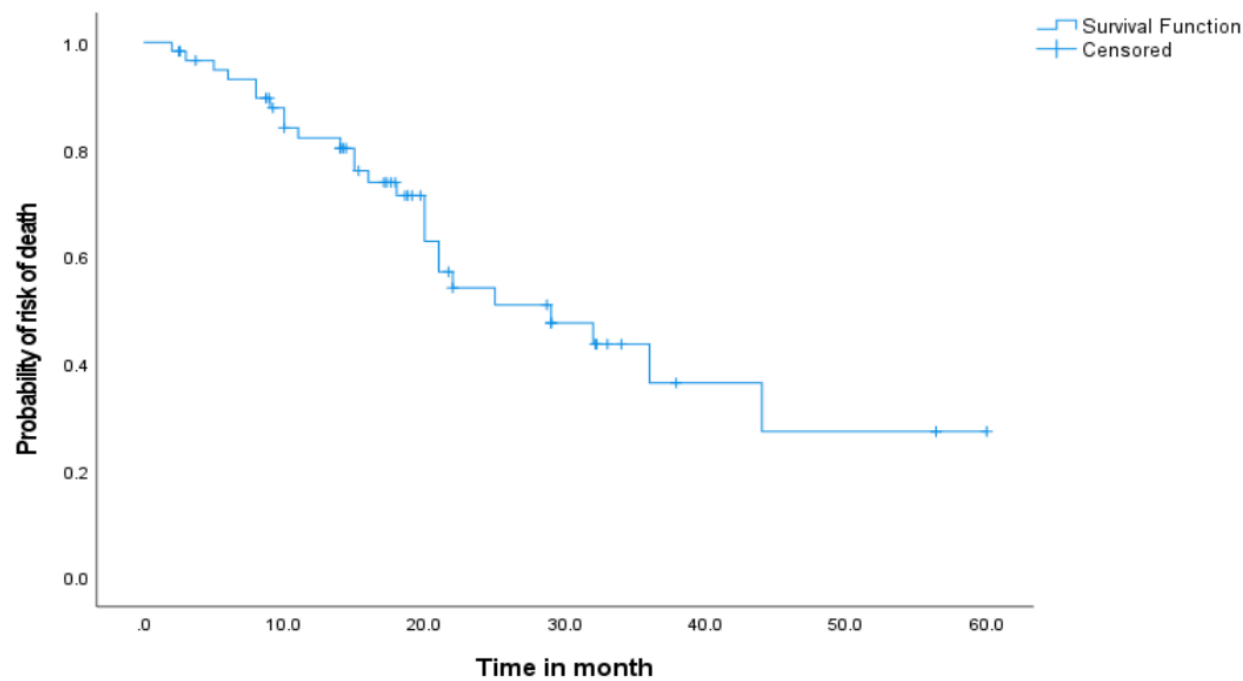
The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding author.

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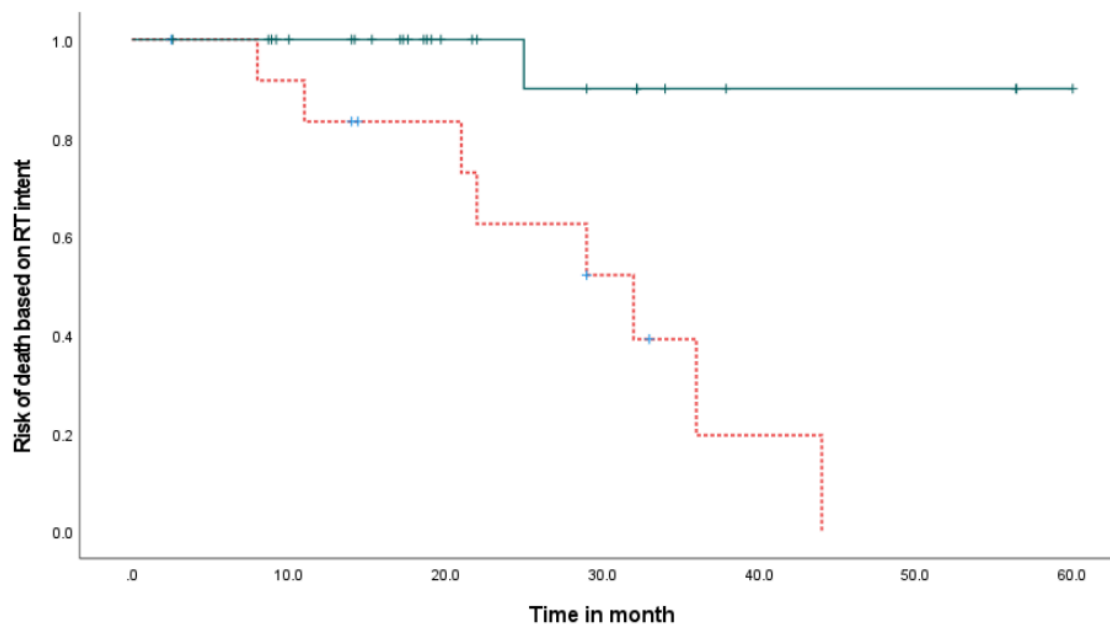
Figures



Time point (months)	10	20	30	40	50	60
Event/total at risk	8/40	8/22.5	2/9	1/4	0/2	0/0.5

Figure 1

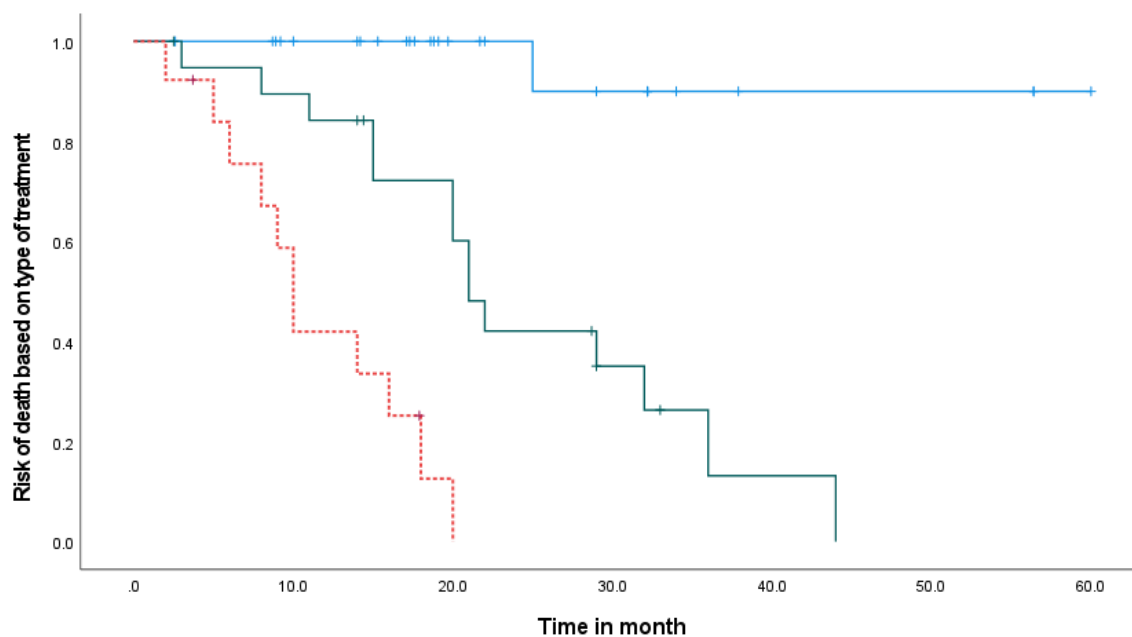
Kaplan-Meier survival curve for the overall patients with non-metastatic ASCC in TASH, Addis Ababa Ethiopia, 2024.



Time point (months)	10	20	30	40	50	60
Radical RT	0/25	0/17.5	1/10.5	0/5.5	0/3	0/0.5
Palliative RT	1/10	3/7.5	2/3.5	1/1	-	-

Figure 2

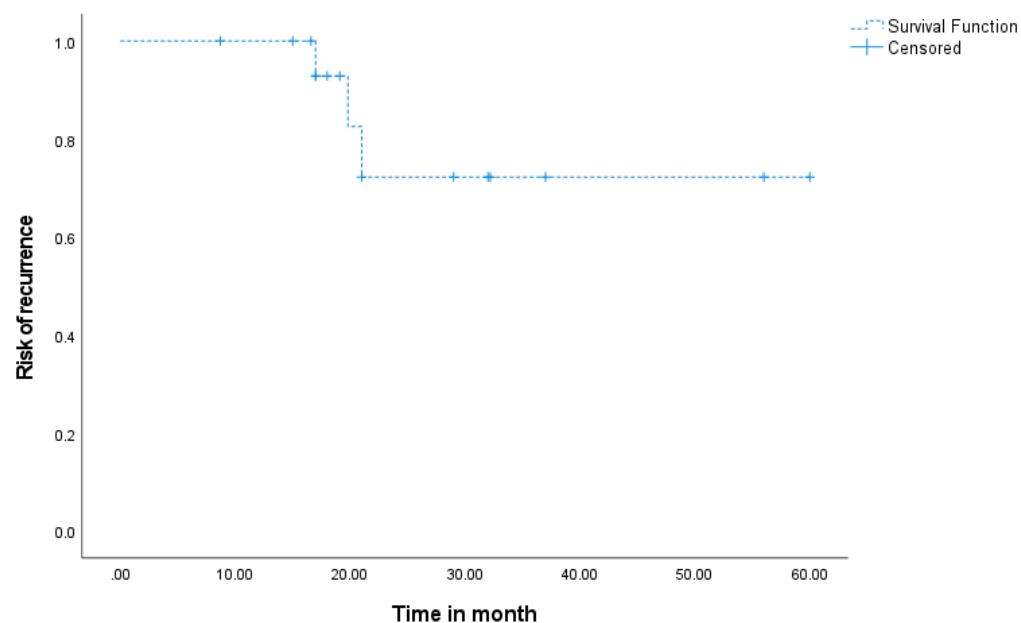
Kaplan-Meier survival curve radical and palliative intent of RT for patients with non-metastatic ASCC at TASH, Addis Ababa Ethiopia, 2024.



Time point (months)	10	20	30	40	50	60
Definitive Tx	0/17	1/10.5	0/5.5	0/3	0/2	0/0.5
Palliative Tx	3/16	6/11.5	2/3.5	1/1	-	-
No Tx	5/6.5	1/1	-	-	-	-

Figure 3

Kaplan-Meier survival curve for definitive treatment, palliative treatment and no treatment in patient with anal SCC at TASH, Addis Ababa Ethiopia, 2024



Time point (months)	10	20	30	40	50	60
Event/total at risk	2/13	1/7	/0/3.5	0/2	0/1.5	0/0.5

Figure 4

Estimated 5-years RFS for patients with non metastatic ASCC received a radical treatment and having complete response after 6months of treatment completion in TASH

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix.docx](#)