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Survival Analysis on the Risk Factors of Women's with Cervical Cancer: A Case Study at Black Lion Hospital, Addis Ababa, Ethiopia.

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Abstract

Background: Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. The objective of this study was to identify factors associated with the survival time of cervical cancer patients in Black Lion Hospital Addis Ababa, Ethiopia. **Subjects and Methods:** A retrospective cohort study was conducted in Black Lion Hospital Addis Ababa, Ethiopia. Information on patients enrolled from December 2014 and had at least one follow-up until January 2017 time period in oncology center was used in this study. Kaplan-Meier survival curves and Log-Rank tests were used to compare the survival experience of different category of predictors. Semi-Parametric survival models were employed to examine the effect of explanatory variables on survival times. **Results:** A total of 518 cervical cancer patients in Black Lion Hospital were included in the study. Out of 518 cervical cancer patients, 49.04% were live in urban area and 50.96 % were live in rural area. The instantaneous risk of death for urban place of residence is 2.04 times the instantaneous risk of death for rural place of residence. The instantaneous risk of death for patients with hypertension has 2.15 greater risk of death than those patients without hypertension. Improved the survival of patients was an integral part of controlling cervical cancer. **Conclusion:** It has been found that 16% of the considered patients were died and the remaining 84% were censored at the end of the study. The median survival time of cervical cancer patients was 31months after diagnosis. The covariates those are more significant for cervical cancer patients are age, place of residence, hypertension, FIGO stage, histological type, and histological grade and HIV status.

Keywords: Transrectal Women, Cervical cancer; Risk factors, Survival model.

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Introduction

According to WHO report cancer is the second leading cause of death globally, and was responsible for 8.8 million deaths in 2015. Worldwide, nearly 1 in 6 deaths is because of cancer and from this number approximately 70% deaths of cancer occurring in low-income and middle-income countries.[1] Around one third of deaths from cancer are due to the 5 major behavioral and dietary risks: high body mass index, low fruit consume and vegetable intake, absence of physical activity, tobacco and alcohol intake. From the leading risk factors tobacco intake is the most leading risk factor for cancer and is responsible for approximately 22% of cancer deaths.[2] Cancers that exist in the female reproductive system includes cancer of the cervix, breast, ovaries, vagina, vulva and endometrial.[3]

Across the world 874 million women above or equal to 15 years are at risk of cervical cancer; 530,232 new cases of cervical cancer are diagnosed and 275,008 deaths occur due to cervical cancer annually. About 86% of the world cervical cancer risks occur in less developed countries.[4] The ASIR and ASMR were 18 and10 per 100,000, respectively, in developing countries and 9 and 3 per 100,000, respectively, in more developed countries. The incidence and mortality in sub-Saharan Africa are among the highest in the world and contribute for over 70% of the worldwide cervical cancer burden with 70,000 new cases annually. It is a health concern among women worldwide as it ranks as the second common cause of cancer among women.[5] The ACS predicts points out that there will be 12,900 new diagnoses and 4100 cervical cancer-related deaths in the United States in 2015.[6]

In Africa, which has a population of 267.9 million women aged above or equal to 15 years and older at risk of developing cervical cancer, approximately 80,000 women are diagnosed with cervical cancer each year, and over 60,000 women die due to the disease. However, cervical cancer incidence in Africa also varies considerably by place. The largest rates in Africa (ASIR >40 per 100,000) are all exist in Eastern, Southern, or Western Africa.[7] Cancer causing infections such as, Hepatitis C virus, HPV and infection with HIV substantially increases the risk of cervical cancer [2,8]. Infection with hepatitis and HPV, are responsible for up to 25% of cancer cases in low and middle-income countries.[8]

The rates of cervical cancer in developed countries have decline dramatically because of cytological screening and DNA testing for high-risk HPV types.[9] Basically, Sub-Saharan Africa has the highest incidence of cervical cancer in the world, with an incidence rate of 50.9 cases per 100,000 women's.[10] The risk of cervical cancer among women in sub-Saharan Africa including Ethiopia is very high. This is only in the fact that awareness and knowledge of patients on the continent are very poor and mortality still very high. Facilities for the prevention and treatment of cervical cancer are still very inadequate in many countries in the region.[11]

In Ethiopia according to the WHO estimates, there was 7,600 are diagnosed with cervical cancer and roughly 6,000 women die due to the disease annually.[12,13]But there is no national cancer registry in Ethiopia, reports from a retrospective review showed. In addition to this fact, very few women receive screening services in Ethiopia. Although there is no national cancer registry data base, reports from retrospective review of biopsy results have shown that cervical cancer is the major prevalent cancer among women in the country after breast cancer, and low level of awareness, lack of effective diagnosis programs, overshadowed by other health priorities (such as AIDS, TB, malaria) and inadequate attention to women's health are one leading determinant for the prognosis of cervical cancer.[14] Therefore, to prevent and control the risk factors that influence on the survival of cervical cancer patients for the future it is better to assess the determinants of cervical cancer cases, and this study assessed the survival time among cervical cancer patients and its determinants at Black Lion hospital using Cox proportional hazard model.

Subjects and Methods

Data

The target population of this study was being patients with cervical cancer at black lion hospital, Addis Ababa was enrolled from December 2014 to January 2017 time period in oncology center. In this retrospective cohort study the data was concerned all cervical cancer patients, diagnosed in between 2014-2017 and collect the data by reviewing follow-up charts of patients by using standardized structured questionnaire. This study considers all cervical cancer patients who were diagnosed and enrolled in BLH during the required time period (2014-2016) except those patients who have incomplete charts regarding to important variables, and patients who registered during the required period but their diagnosis is prior to that, for patients whose follow up time is less than two month was excluded from the study.

Variable of the study

The dependent variable (Y) is the survival time of cervical cancer patients, the length of time from diagnosis start date until the date of death/censored measured in months.

The independent variables: Age at diagnosis, Religion of patients, Place of residence, Parity (number of live birth), FIGO staging of the cervical cancer, Histological types of cancer, Histological grade cancer, Presence of diabetics, Oral contraceptive, HIV status of the patients, Presence of hypertension.

Survival analysis

Survival analysis is a statistical method for data analysis where the outcome variable of interest is the time to the occurrence of an event. The event can be death, occurrence of disease, married, divorce etc. Hence, survival analysis is also referred to as "time to event analysis", which is applied in a number of applied fields, such as medicine, public health, social science, and engineering etc. In medical science, time to event can be time until recurrence in a cancer study, time to death, or time until infection.[15]

Survivor Function

The survivor function $S(t)$; is the probability that the survival time of a randomly selected subject is greater than some specified time t or the probability of an individual being event-free beyond time t . In order to find the survival function, suppose $\mathbf{T}$ be random variable associated with the survival times, t be the observed value of the random variable T and $f(t)$ be the underlying probability density function of the survival time t. The cumulative distribution function $F(t)$ represents the probability that an individual selected at random will have a survival time less than or equal to the specified value$t$.

Kaplan-Meier estimator of the survival function

The Kaplan-Meier estimator proposed by Kaplan and Meier is the standard non parametric estimator of the survival function $S(t)$. Which is also called the product-limit estimator incorporates information from all observations available, both censored and uncensored, by considering any point in time as series of steps defined by the observed survival and censored times [16].

Suppose $t_1, t_2, \ldots, t_n$ be the survival times of n independent observations and $t_1 \leq t_2 \leq \ldots t_m, m \leq n$ be the m distinct ordered death times. Then the Kaplan-Meier estimator of the survivorship function (or survival probability) at time$t$, $S(t) = p(T > t)$ is defined as:

$$\hat{S}(t) = \prod_{t_j \leq t} \frac{n_j - d_j}{d_j} = \prod_{t_j \leq t} \left[1 - \frac{d_j}{n_j}\right]$$

Where, n_j is the number of individuals who are at risk of dying at time $t_j, j = 1, 2, \ldots m$with $\hat{S}(t)=1$ for $t< t_1$ and d_j is the number of individuals who failed (died) at timet_j. The variance of the K-M survival estimator which is also known as the Greenwood's formula is given by:

$$var\left(\hat{S}(t)\right) = (\hat{S}(t))^2 \sum \frac{d_j}{n_j(n_j - d_j)}$$

Cox Proportional Hazards Regression Model

Cox proposed a semi-parametric hazards model for the

survival data to see the effect of explanatory variables on the hazard function.[17,18,19] The Cox proportional hazards model is given by:

$$h(t;x) = h_o(t)\exp(\beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_p x_p) = h_o(t)e^{(\beta' x)}$$

Where $h_o(t)$ is called the baseline hazard function, which is the hazard function for an individual for whom all the variables included in the model are zero, $x = (x_1, x_2, \ldots, x_p)'$ is the values of the vector of explanatory variables for a particular individual, and $\beta' = \beta_1, \beta_2, \ldots, \beta_p$ is a vector of regression coefficients. The measure of effect is called hazard ratio. The hazard ratio of two individuals with different covariates x_1 and x_2 is

$$\widehat{HR} = \frac{\exp(X_1\beta)}{\exp(X_2\beta)} = \exp((X'_1 - X'_2)\beta)$$

This hazard ratio is time-independent, which is why this is called the proportional hazards model.

Estimation of Cox Regression Model

Suppose the survival data based on n independent observations are denoted by the triplet (t_i, δ_i, x_i) i=1, 2... $, n$

The full likelihood function for right censored data can be constructed as:

$$L(\beta) = \prod_{i=1}^{n} h(ti, Xi, \beta)^{\delta i} S(ti, Xi, \beta)$$

Where $h(ti, Xi, \beta) = h_0(ti)e^{\beta' Xi}$ is the hazard function for the i[th] individual.

$S(ti, Xi, \beta) = [s_o(ti)]^{\exp(\beta' X_i)}$ is the survival function for the i[th] individual.

It follows that:

$$L(\beta) = \prod_{i=1}^{n} [h_0(ti)e^{\beta' Xi}]^{\delta_i} [s_o(ti)]^{\exp(\beta' X_i)}$$

To avoid the specification of the base line hazard, Cox proposed a partial likelihood approach that treats the baseline hazard as a nuisance parameter and removes it from the estimating equation [19,20].

Partial Likelihood Estimation

The partial likelihood function is derived by taking the product of the conditional probability of a failure at time $t_{(i)}$, given the number of individuals who are at risk of experiencing the event at time $t_{(i)}$.

Then the probability that the j[th] individual will experience an event at time $t_{(i)}$ is given by: $L_p(\beta) = \frac{\exp(\beta' X(i))}{\sum_{j\in R(t(i))} \exp(\beta' Xj)}$

Where, the summation in the denominator is over all individuals in the risk set. Thus the partial likelihood is the product over all event time $t_{(i)}$ for $i = 1, 2, \ldots, r$ of the conditional probability (3.15) to give the partial likelihood function and can be expressed in the form:

$$LL_p(\beta) = \prod_{i=1}^{r} \left[\frac{\exp(\beta' X(i))}{\sum_{j\in R(t(i))} \exp(\beta' Xj)}\right]$$

The product is over the r distinct ordered survival times.

The corresponding log-partial likelihood function is given by:

$$\log L_p(\beta) = \sum_{i=1}^{r} \left\{\beta' X(i) - \log\left[\sum_{j\in R(t(i))} \exp(\beta' Xj)\right]\right\}$$

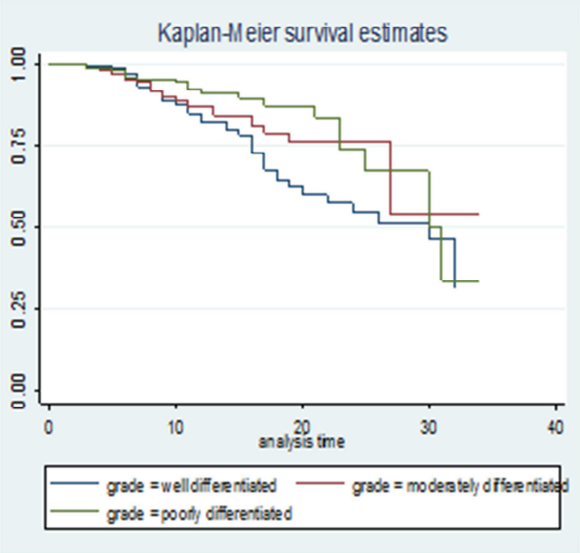
The partial likelihood derived above is valid when there are no ties in the data set. But in most real situations tied survival times are more likely to occur. There are three approaches commonly used to estimate regression parameters when there are ties. These are Efron, Breslow's approximation and Cox approximations. The most popular and easy approach is Breslow's approximation [19,21].

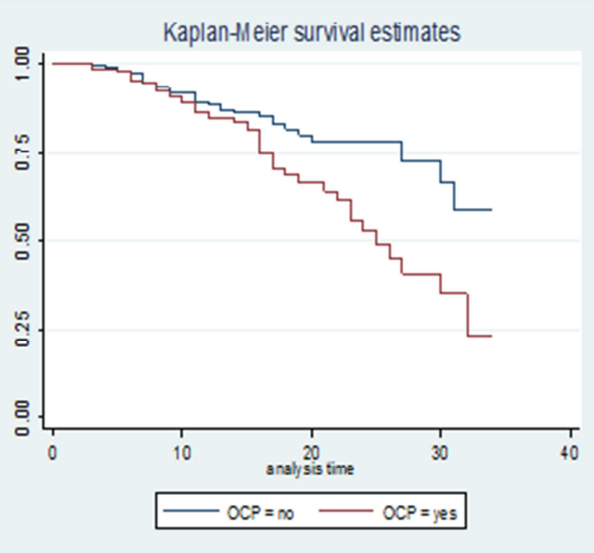
Model adequacy for Cox PH model

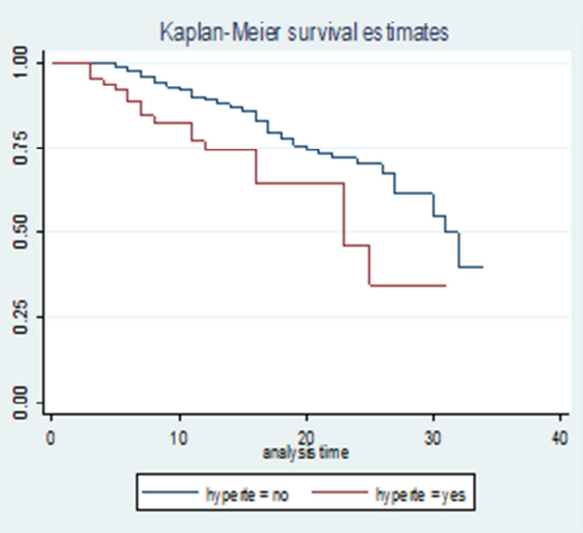
After a model has been fitted, the adequacy of the fitted model needs to be assessed. The model checking procedures below are based on residuals. In linear regression methods, residuals are defined as the difference between the observed and predicted values of the dependent variable. However, when censored observations are present and partial likely hood function is used in the Cox PH model, the usual concept of residual is not applicable. A number of residuals have been proposed for use in connection with the Cox PH model. We have describing three major residuals in the Cox model: the Cox-Snell residual, the martingale residual, and the Schoenfeld residual.

Results

From the total of 518 cervical cancer patients, the minimum age is 18 and the maximum age is 80. The mean age of the patients was 48.61 years with (SD=11.728). The descriptive summary shows a death proportion seems lower for urban women's (5.02%) than for rural women's (11.00%). The married group showed the highest percentage (10.04%) with respect to death proportions than the other three groups and patients whose religion are orthodox have highest percentage of death (9.27%) than the others religion groups. Stage III patients have the highest death proportion (7.72%) as compared to the other groups while stage I patients show the lowest death rate. The patient whose histological type has Squamous cell carcinoma was the highest percentage of death (12.36%) than the other types and well differentiated histological grade patients have highest death proportions (7.53%) than the other grades. A patient who took oral contraceptive was the highest death proportions (9.27%) and patients who have diabetic were lower death proportion (1.54%) than the patients who have no diabetics. The death proportion of patients who have no hypertension was highest (12.55%) than the patients who have hypertension and HIV negative patients have the highest proportion of death (10.62%) than the other groups.







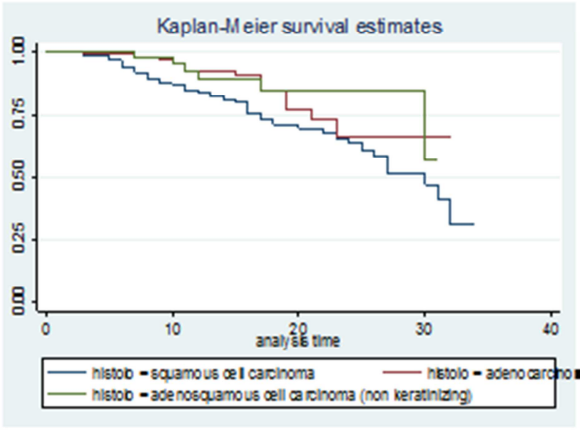


Figure 1: Kaplan-Meier curve for some covariate variables of cervical cancer patients, BLH, 2014-2017.

Patients who have not hypertension survive longer time than that of patients with hypertension. The cervical patients who don't use oral contraceptive stay longer times than that of patients use oral contraceptive (see figure 1 above).

According to the test results residence, FIGO stage, histological type, histological grade, OCP use, hypertension and HIV status were statistically not equal in experiencing the death event. The result has been presented in table 1 below

Table 1: Results of log rank test for the categorical variables in BLH, 2014-2017.

Variable	Chi-square	Pr>Ch-square
Religion	1.56	0.669
Presence of diabetics	0.66	0.417
Residence	11.28	0.0008
FIGO stage	9.72	0.0211
Histological type	8.02	0.0181
Histological grade	5.64	0.0591
Oral contraceptive use	7.16	0.0070
Presence of hypertension	9.56	0.0020
HIV status	13.45	0.0012

Cox proportional hazard model

Among the predicator variables considered for building multivariate Cox, the forward stepwise procedure picked up six variables age at diagnosis, place of residence, FIGO stage, histological type, histological grade and presence of hypertension. The multivariate Cox model based on this significant variable was summarized in table 2 below.

Table 2: Results of multivariate Cox regression model, BLH, 2014-2017.

Variable	Coef(β)	Haz. Ratio	Std. Err.	P-value	[95%Conf.Interval]	
Age	0.028	1.028	0.009	0.003	1.009	1.048
Residence(Ref. Rural)						
Urban	0.706	2.027	0.490	0.003	1.262	3.256
FIGO stage(Ref. Stage IV)						
Stage I	0.478	1.614	1.044	0.460	0.454	5.734
Stage II	0.979	2.661	1.617	0.107	0.808	8.761
Stage III	1.410	4.097	2.545	0.023	1.213	13.840
Histological						

type(Ref. Adenosquamous)						
Squamous cell carcinoma	-0.639	0.527	0.164	0.040	0.286	0.972
Adenocarcinoma	-0.768	0.464	0.201	0.075	0.199	1.081
Histological grade(Ref. Poorly differentiated)						
Well differentiated	-0.664	0.515	0.136	0.062	0.306	0.865
Moderately differentiated	-0.810	0.445	0.127	0.005	0.253	0.779
Hypertension(Ref. No)	0.804	2.236	0.615	0.003	1.304	3.835
HIV status(Ref. Negative)	0.749	2.115	0.302	0.013	1.171	3.820

Adequacy of the fitted model that is the assumptions of proportional hazards and the goodness of fit were assessed. We used the schoenfeld residuals to test the PH assumptions. The correlation (ρ) between schoenfeld residuals and survival time for each covariate was presented in table 3 below.

Table 3: Test of proportional hazards assumption based on schoenfeld residuals BLH, 2014-2017.

Variable	Rho(ρ)	Chi^2	DF	p-value
Age at diagnosis	0.13036	1.07	1	0.3008
Place of residence	-0.02107	0.04	1	0.848
FIGO stage	0.10068	0.83	1	0.364
Histological type	0.08839	0.69	1	0.4065
Histological grade	0.03967	0.14	1	0.711
Presence of hypertension	-0.09950	0.78	1	0.377
Global test		3.73	6	0.713

The plot of (1og (-log (survival))) plot versus log (survival time) were used to check the PH assumption for all the categorical variables included in the fitted model (see figure 3). The graphs for categorical variables display lines that appeared to be roughly parallel for place of residence. There was an interaction between FIGO stages. The results from table 3 indicate that all variables satisfied the PH assumption as the correlation between schoenfeld residuals and survival time is not significant at 0.05 levels. Plot of the cox-snell residuals was applied to test the overall fit of the model. In this method cox-snell residuals were plotted against the cumulative hazard of cox-snell residuals as shown in figure 2. The figure reveals that the overall fit of the Cox model is good. However there is little evidence of a systematic deviation from the straight line at the right, thus the result of the graph indicates the model fit the data well.

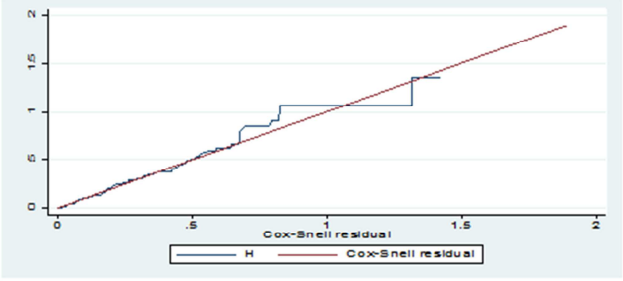
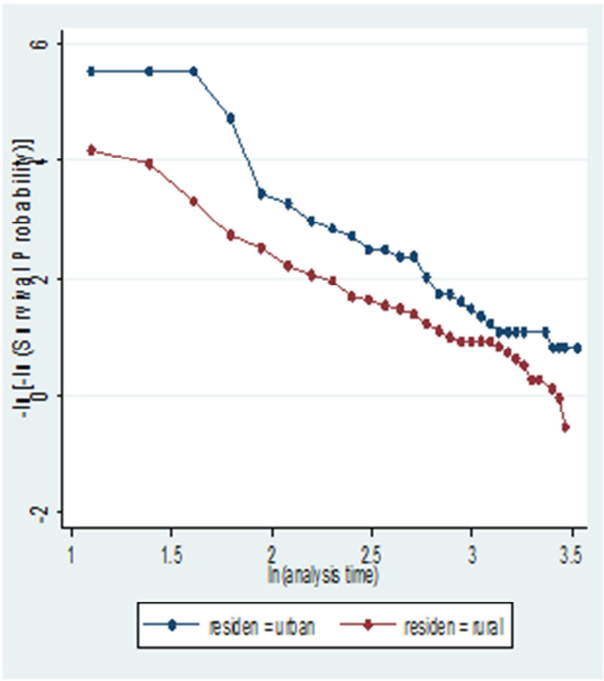


Figure 2: Cumulative hazard plot of the cox-snell residual for multivariate Cox PH model BLH, 2014-2017.



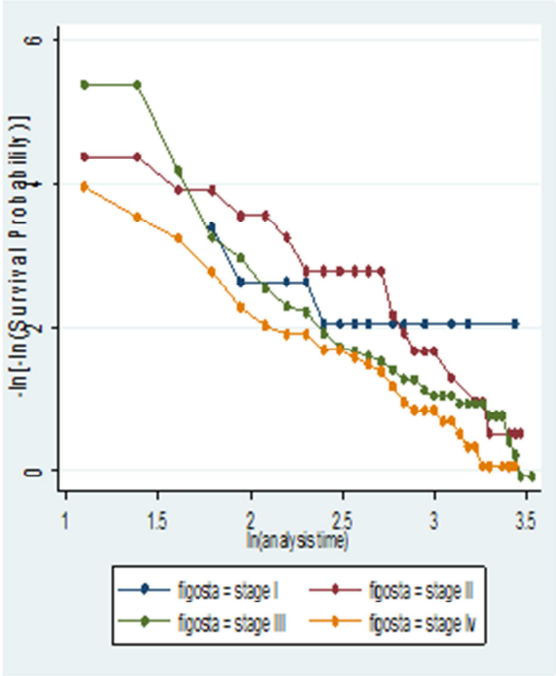


Figure 3: Cumulative hazard plot of the log(-log(survival)) plot for multivariate Cox PH model BLH, 2014-2017.

Discussion

The prevalence of death due to cervical cancer at Black lion Hospital at Addis Ababa was 16%. The median survival time is 31months after diagnosis. It is a very short time of survival after screening. This happened due to lack of health facility regarding to cervical cancer patients in the study area. In a related combined prospective and retrospective cohort study conducted in Mysuru, India for the purpose of estimating

prognostic factors for the survival of cervical cancer patients.The median survival time (14 months) was the highest among patients in the age group of 50- 64 years. Patients aged < 35 years as well as patients aged > 65 years had a median survival time of 6 months.[22] Other study employed Kaplan Meier analyses and log-rank test to determine the survival rates of Malaysian women with cervical cancer and associated factors, the median survival time was 65.8 months.[23] The age of the cervical cancer patients is a major factor to determine their survival time. When the age of the patient increased by one year; the instantaneous risk of death increased by 2.8%. A hospital-based retrospective study from Visakhapatnam City, conducted by Kumari revealed that aged women's have lower survival rate than the younger one.[24] Showalter conducted an observational cohort study in Virginia to evaluate receipt of quality cancer care and mortality after cancer diagnosis among patients with locally advanced cervical cancer, the study found that older age groups increased the mortality.[25]

Among cervical cancer patients the instantaneous risk of death for urban place of residence is 2.027 times the instantaneous risk of death for rural place of residence, after keeping all other covariates at some constant level. The cervical cancer patients death higher in urban area than that of rural area. This does suggest urban place of residence patients have excess risk of instantaneous death than their counterpart rural place of residence. Place of residence was significant for the instantaneous risk of death for cervical patients. The study supported by other researchers conducted in the previous time.[26]

The hazard ratio in table 5 shows that among cervical cancer patients the instantaneous risk of death for FIGO stage three is 4.097 times the instantaneous risk of death for FIGO stage four. Salem conducted a retrospective cohort study on treatment outcomes and prognostic factors of Cervical Cancer at South Egypt, revealed the same result.[27] The instantaneous risk of death for squamous cell carcinoma types are 43.3% less likely than that of the instantaneous risk of death for adenosquamous cell carcinoma. The risk of death due to cervical cancer for moderately differentiated grade 55.5% less likely than that of the instantaneous risk of poorly differentiated grade. A hospital-based retrospective study from Visakhapatnam City, Andhra Pradesh conducted by Kumari confirmed similar founding.[24]

The instantaneous risk of death for patients with HTN has 2.236 greater risk of instantaneous death than those patients without HTN, after keeping all other covariates at some constant level. This is may be occurred due to the complexity of patient health status. Cervical cancer patients live with HIV/AIDS the hazard of death 2.115 times higher than that of cervical cancer patients free from HIV/AIDS. This is may be occurred due to the complexity of patient health status.

Conclusion

This was a three-year (2014-2017) retrospective cohort study based on 518 cervical cancer patients in Black Lion Hospital Addis Ababa, Ethiopia. The purpose of the study was to identify factors associated with the survival time of cervical cancer patients in Black Lion Hospital Addis Ababa, Ethiopia. It has been found that 16% of the considered patients were died and the remaining 84% were censored at the end of the study. The median survival time of cervical cancer patients was 31months after diagnosis. The covariates those are more significant for cervical cancer patients are age, place of residence, hypertension, FIGO stage, histological type, and histological grade and HIV status. Survival time of cervical cancer through regular programs of women and prompt comprehensive treatment should be taken up to improve the overall survival of the patients. Further research on the survival time and the effect of treatment on the disease should be carried out to give more insight into the survival time of the disease and disease management.

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