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Full Length Research Paper

Time trends, and survival of patients with oral and pharyngeal malignancies

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An accurate assessment of oral and pharyngeal malignancies in cancer treatment trends, and survival of the disease was missing in Egypt. Accordingly, all new cases treated in Alexandria and El Behira governorates during the last decade were studied retrospectively. Data were collected through all accessible archives using a special data collection sheet. The total populations of different governorates were obtained from the "Central Administration of Census and Statistics" reports, by gender, and residential selective distributions. The personal history, socio-demography, staging and site of the tumor, treatment and complications of treatment, response, as well as survival were explored. The mean age of 1254 investigated subjects was 52.02 ± 16.13 years, where 15% were educated. Pharyngeal cases represented 41.5%, while the oral were 58.5%. Those of stage 1 recorded 52%, while stage 4 was 47.7%. Surgery followed by irradiation was the line of treatment for 54.3% of cases. The estimated population for non-censal years was determined as the average value of both the "Arithmetic Progression" and the "Geometric Progression" technique estimates. The annual incidence rates through the period of study were plotted and analyzed using the relevant regression line to test significance (Di Bonito, 1983; Saunders and Trapp, 1990). Tracing trends revealed a decreasing incidence in all situations, except in females of El Behira governorate, which resulted in an increasing trend of El Behira as a whole, as all trends were not statistically significant. The 5-year survival was computed using the actuarial method, and presented graphically using the Kaplain Meier curve (Ederer and Cutler, 1958). The overall 5-year survival probability was 0.54%. Survival for stage 1 was 74.5%, while it was 46.38% for stage 4. Smoking showed an apparent adverse effect on survival. Stepwise logistic regression revealed that, the best predictor for overall survival was gender, as males have 1.74 times the risk compared to females, followed by stage, as stage 4 was the worst. Results of the present study suggest that, the database coded cases were quite important for treatment and follow up. Smoking should be prohibited in a decisive manner. Care is to be given for raising the socioeconomic status, especially for categories living under potentially higher stress. Early referral of cases to oncologists is highly mandatory, and whenever surgery is indicated; safety margin combined with alleviating complications is of great effect on survival.

Key words: Oral, pharyngeal, cancer, incidence, survival, quality of life.

INTRODUCTION

Malignant tumor is defined as a lesion arising from proliferation of cells, which is autonomous and persists after the initiating stimulus has been removed. It is a manifestation of an abnormality of the process involved in the control of all growth. The term "cancer" is a general term, which applies to malignant tumor of any type

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(Cawson and Odell, 1998)a. The ultimate definition of malignancy is the ability to metastasize. Metastasis is the spread of tumor cells from primary site to one or more separate distant secondary sites (Cawson and Odell, 1998b). In case of an epithelium, the cells are capable of invading through the basement membrane to make transition from *in situ* to invasive carcinoma (Cawson and Odell, 1998b).

Cancer is second to coronary artery disease as being the most common cause of death in the western world (Smyth, 1999). Oral cancer accounts for less than 1% of all cancer deaths among white females in the United States, and over 40% in various parts of India (Schottenfeld et al., 1993). The highest death rates from oral and pharyngeal cancer were in Hong Kong for both sexes followed by France and Puerto-Rico. The lowest mortality figures were reported for El-Salvador, Egypt, and Honduras in both sexes (Schottenfeld et al., 1993). Oral cancer registrations and incidence are increasing through Europe and in the United Kingdom (Schottenfeld et al., 1993). Worldwide 197,000 deaths from cancer of the oral cavity and pharynx occur per year, of which 74% are in developing countries (Pisani et al., 1999) Over 95% are well differentiated or moderately differentiated, arising from the mucosa, therefore classified as squamous cell carcinoma (SCC) (Cawson and Odell, 1998).

MATERIALS AND METHODS

Study setting

Study was conducted in Oncology Department, Faculty of Medicine, Maxillo-facial Department, Faculty of Dentistry, and Statistics Department, Medical Research Institute (Alexandria University), Oncology Department-Gamal Abdel Nasser Health Insurance Hospital and Damanhour Oncology Center (Ministry of Health and Population).

Study design

A retrospective study for 10 years (1991 to 2000) was conducted in oncology centers for all oral and pharyngeal malignancy records. A prospective study for survival and response was done up to the end of March 2002.

Target population

The target population was oral and pharyngeal cancer cases in Alexandria and El Behira region.

Data collection technique

Record review

a) Records of the “Cancer Registry” at the Medical Research Institute were studied for having an initial idea about the size and distribution of cases in the region.
b) All accessible files of oral and pharyngeal malignancies were reviewed in Alexandria University hospitals, Gamal Abdel Nasser Insurance hospital, and in Damanhour Oncology center.
c) Data about Alexandria and El Behira total population were collected from the Central Administration for Census and Statistics reports (Central Directory for Census and Statistics, 1998).

Follow up

Follow up was carried through the records and monthly regular clinic visits of the patients, also through telephone calls, letters, relatives, and home visits. Accessible cases of follow up were 852.

Data collection tool

Available data were collected, while missing data were tried to be completed by the researcher personal communications with patients or their families. Data available were collected using a pre-designed data collection sheet including:

1) Clinic name
2) Personal history: Patient name, phone number, address if available socio-demographic data (age, gender, residence, educational level, occupation, and marital status), smoking habit for number of cigarettes smoked daily, and duration of smoking (ex-smokers are those having a history of smoking before one year of diagnosis or more, and those smoke less than 10 cigarettes were considered light smokers).
3) Data about oral and pharyngeal cancer:

a. Date of diagnosis.
b. Site of cancer according to ICD-10 (World Health Organization, 1996) classification (including major salivary glands).
c. Stage of the tumor (TNM, 1997) according to TNM classification.
d. Grade of the tumor, including three grades according to degree of cell differentiation.
e. Main treatment line, broad lines of treatment were: surgical irradiation, chemotherapy, or their combinations. Also salvage or palliation were recorded as well.

4) Response, complete response, partial, no response, or progressive disease.
5) Data about survival.

Statistical design

Data were revised, coded, as a “Foxpro” database file. The “SPSS”-version 11 was used for data analysis.

Statistical analysis

Incidence and time trends of the disease

Reference population was estimated according to the official numbers of the “Central Directory of Census and Statistics”-Egyptian government (1986 to 1996). Screening showed that 173 cases were not from Alexandria or El Behira residents, so they were not included in the incidence analysis.

Estimation of the population: The estimated population was determined as the average of both figures obtained from the two methods.

1. Mid-year estimated population according to “Arithmetic Progression” method (Swaroops, 1960). This method assumes that, the population increases or decreases by constant value from year

to year between any two census years.
2. Mid-year estimated population according to "Geometric Progression" method (Swaroops, 1960) This method is more precise if the population is large, and it usually gives a higher estimate than the previous method. It assumes that the increase in population occurs at a constant rate throughout the period of estimation.

Incidence rates: Dividing the number of cases of every year by the estimated population, multiplying by 100000, incidence rates were calculated.

Trend analysis: The annual incidence rates throughout the period of study were plotted and analyzed using the simple regression line to test its significance (Di Bonito, 1983; Saunders and Trapp, 1990).

Survival analysis

Calculation of survival using the actuarial method: This method was based on information available for each case namely the date of diagnosis, and the cut off date of follow up. Computation was performed by recording the following for each one year interval follow up:

1. The number alive at the beginning of the interval.
2. The number who died during the interval.
3. The number lost to follow up during the interval.

Construction of life table

Registered cases survival during the 10 years was traced to 31st of March 2001.

Columns of this table were constructed according to the following scheme:

Column 1: Year of observation (x to x+1), time elapsed from date of diagnosis in intervals of one year.
Column 2: Alive at the beginning of interval (lx). The first entry in this column is the number of patients at diagnosis. Then the new entries are achieved as follows:
$l_x+1 = l_x – (d_x + w_x)$
Column 3: Withdrawn during interval (w_x).
Column 4: Died during interval (d_x).
Column 5: Effective number exposed to risk of dying l´x . It is assumed that patients lost or withdrawn from observation during an interval were exposed to the risk of dying, on average, for one half of the interval, $l´_x = l_x - ½ w_x$.
Column 6: Proportion dying during the interval (q_x).
Column 7: Proportion surviving during the interval: $p_x = 1-q_x$.
Column 8: Cumulative proportion surviving P_x. This is generally referred to as the cumulative survival rate, and is obtained by cumulatively multiplying the proportion surviving each interval:

$Px = p1 . p2 . p3 ……..p_x$

The successive entries in this column give the 1, 2 …..and 6-year cumulative survival rates (Saunders and Trapp, 1990; Ederer and Cutler, 1958).

Kaplain-Meier product limit estimates

This is a method for estimating the probability of survival at a distinct point of time. It is best presented graphically by the Kaplain-Meier curve (Beth, 1999). The significance of difference between survival curves was calculated by Breslow test (Generalized Wilcxon analysis) (Beth, 1999):

$$\bigcup = \sum_{i=1}^{K} W_1 (Oi - Ei)$$

where Wi is the weight for the time i (the weights are the number at risk at each time point). The test is based on computing the weighted difference between observed and expected number of death at each of the time points.

Multiple Cox-regression analysis: (Clayton and David, 1992; Christensen, 1987**)**

This standard statistical technique was performed using the stepwise method. It is used to discover the hazardous attributes for survival, where there are multiple covariates, and the additional complications of censored cases. This model allows the covariates (independent variables) in the regression equation to vary with time. The dependent variable is the years after diagnosis (Cox, 1999)

Cox regression model:

$H (T) = h_o (t) e (B_1X_1+B_2X_2+…….B_pX_p)$

Where: H (T) is the hazard rate of early death at time t.
h_o (t) is the baseline hazard at time t.
e is the well known constant.
B is the Cox regression coefficient which denotes the magnitude of the increase or decrease in the value of the independent variable while holding all other explanatory variables constant.
$B_1…..B_p$: the respective coefficient for each of the independent variables.

For each subject, two quantities were used to define the outcome survival. Binary model for death (Di Bonito, 1983), or otherwise which is called censoring (0). Also needed is an exposure time which is the length of observation for a patient from diagnosis date till death or last follow up whichever occurs first. The output of Cox Regression analysis is as follows (Ann and Sarabjot, 1998):

B: is the Cox regression coefficient that denoted the magnitude of the increase or decrease in the value of the independent variable.
SE (standard error): It estimates the variability in regression coefficient and can be used to construct confidence interval.
Wald test: is test to show the significance of the relation.
Exponentiation of the coefficient (B) estimates the hazard ratio of the outcome for each unit increase in factor (X).
P value: To test the null hypothesis (no association) between the exposure and survival.
Hazard ratio (HR) = e^B
95% CI= confidence intervals of HR = $e^{Bi \pm 1.96.SE (B)}$
If the confidence interval does not include the value of 1, null hypothesis could be rejected that the variable is not related to survival.

RESULTS

Frequency distribution of oral and pharyngeal cancer patients:

According to age; 59.5% were in the age of 30 to <60 years. Those below 30 represented 9.8%. The mean age was 52.02±16.13 years. Males represented 62%, and

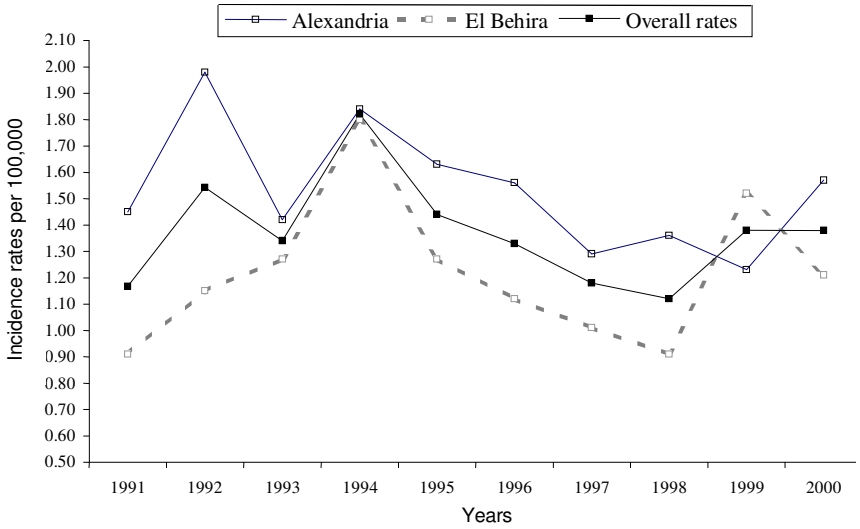

Figure 1. Incidence rates of registered oral and pharyngeal cancer cases "Alexandria and El Behira", 1991-2000.

Table 1. Incidence of registered oral and pharyngeal cancer cases rates per 100,000 persons in Alexandria and El Behira (1991 to 2000).

Year	El Behira	Overall rates
1991	0.91	1.17
1992	1.15	1.54
1993	1.27	1.34
1994	1.80	1.82
1995	1.27	1.44
1996	1.12	1.33
1997	1.01	1.18
1998	0.91	1.12
1999	1.52	1.38
2000	1.21	1.38

52.7% were urban. Married were 78.3%, where uneducated conformed to 85.1%. All types of workers represented 30%, as housewives and retired were nearly equal (26.3 and 26% respectively). Employee and professionals were 8.6%. Oral malignancies represented 58.5% of cases, as pharyngeal were 41.5%. Hard palate with cheek and retro-molar areas were affected in 19.6%, tongue was affected in 12.6%, followed by 9.6% in the major salivary glands. Lip cancer occupied 7.3%. Gum and floor of the mouth were the least (5.6 and 3.8% respectively). Naso-pharynx included 17.3% of the whole cases, and hypo-pharynx included 14%, while only 8.1% where for the oro-pharynx. Stages 1, 2, 3, and 4 were of an ascending trend (5.2, 14.1, 33, 47.7%).

Concerning grade; 296 patients (36.8%) had moderately differentiated tumors, followed by well differentiated (24.5%), then the least were the poorly differentiated and undifferentiated tumors (21.5 and 17.2% respectively). Distribution of patients according to the main line of treatment showed that, 54.3% received irradiation with surgery, and 14.4% were subjected to surgery only. Chemotherapy with irradiation and surgery were given to 19% of cases, as chemotherapy with surgery was the treatment of 5.6% of patients. Chemotherapy was afforded to only 1.2% of cases.

Trends of oral and pharyngeal cancer patients

Table 1 and Figures 1 and 2 display the incidence rate per 100,000 for Alexandria, El Behira, and both. The highest incidence rate in Alexandria and El Behira

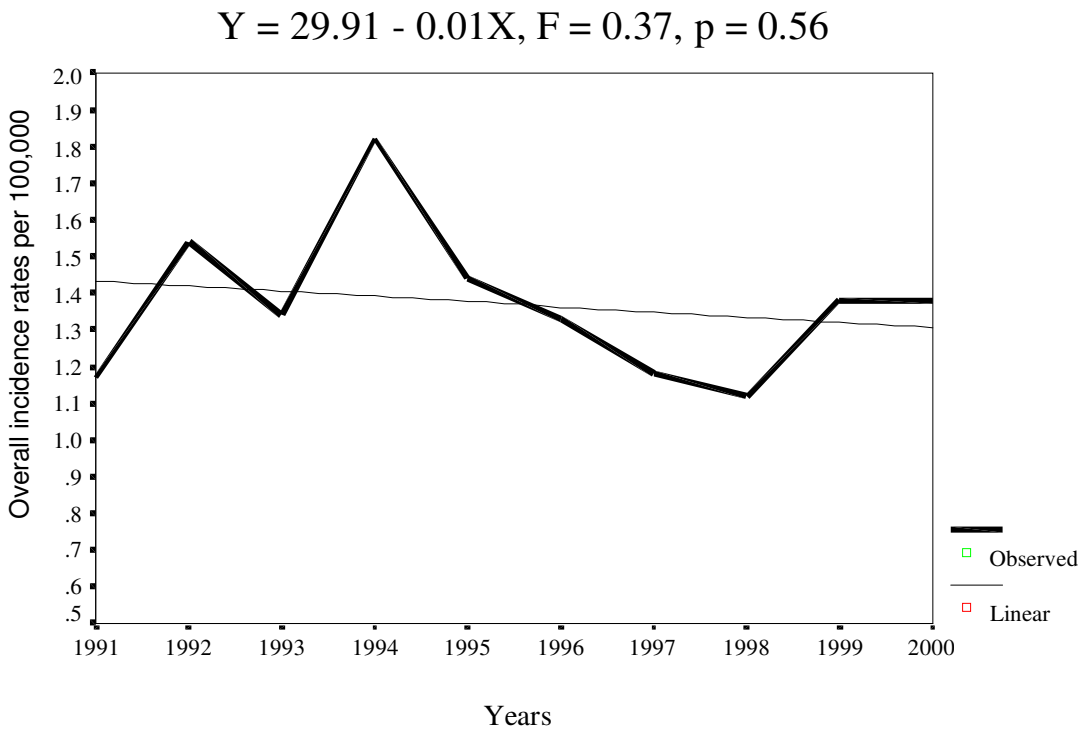

Figure 2. Trend of annual incidence rates of registered oral and pharyngeal cancer cases "Alexandria and El Behira", 1991-2000.

Table 2. Incidence of registered oral and pharyngeal cancer cases rates per 100,000 persons among total, male, and female in Alexandria and El Behira (1991 to 2000).

Years	Males	Females	Overall rates
1991	1.54	0.78	1.17
1992	1.88	1.19	1.54
1993	1.75	0.91	1.34
1994	1.86	1.77	1.82
1995	1.60	1.21	1.44
1996	1.57	1.07	1.33
1997	1.48	0.90	1.18
1998	1.28	0.95	1.12
1999	1.80	0.97	1.38
2000	1.59	1.15	1.38

governorates together lied in the year 1994 (1.82), followed by the year 1992 (1.54), as the lowest incidences were through the years 1998 and 1991 (1.12 and 1.17 respectively). Alexandria revealed its highest peaks of incidence rates in 1992 and 1994 also (1.98, and 1.84 respectively), where the lowest values of incidence rates were seen in years 1990 (1.23) and 1997 (1.29). El Behira, incidence rate was highest relatively also in the year 1994 (1.8), followed by the years 1993 and 1995 where incidence was 1.27 for each. During the years 1991 and 1998, El Behira had the lowest incidence rates (0.91 cases for each).

Table 2 display the incidence rated for the whole males, whole females, besides the overall rates. The highest incidence rates were shown among males in years 1992, 1994, and 1999 (1.88, 1.87, and 1.8 respectively), while the years 1998 and 1997, showed only 1.28 and 1.48 respectively. Females of Alexandria

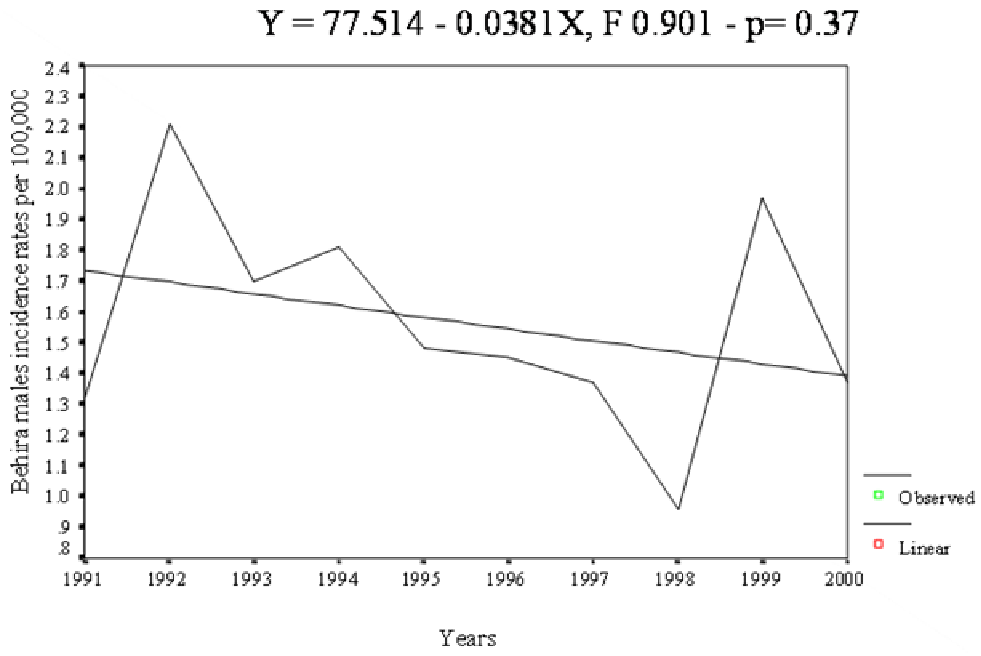

Figure 3. Trend of annual incidence rates of registered male oral and pharyngeal cancer cases " El Behira", 1991-2000.

and El Behira together showed their upper most value in 1994, that was 1.77 cases. The lowest incidence rate for females was shown through the year 1991 (0.78). A non-significant overall decreasing trend was seen. Figures 3 and 4 dismantle the only increasing trend which was in females of El Behira governorate, even though it was not significant.

Five year survival rates for oral and pharyngeal cancer cases

Table 3 summarizes cumulative probability of survival for 5 years of all variables of study. Knowing that the overall 5 year cumulative probability of survival was 53.4%, it was interesting to see the highest 5 year survival for those who received surgery alone (82.2%), followed by cases of stage 1 tumors in general (74.5%). The lowest rates of 5 year survival were seen in heavy smokers, and those received chemotherapy and /or irradiation (37.87 and 39.92% respectively). It may be worth noting that, the educated had 41.07%, workers had 40.24%, and widowed with divorced had 41.29% cumulative 5 year survival probabilities.

Cox-regression analysis

Table 4 shows the results of stepwise Cox's regression analysis of various independent factors on 5 year probability of survival. The Table 4 shows that, out of eight factors studied, only three were significantly associated with the probability of 5 year survival. The first predictor was gender. Males had higher risk of death than females (hazard ratio =1.741, 95% C.I. = 1.22 – 2.48).

Cases of stage 2 had higher risk of death compared to these with stage 1 (hazard ratio = 1.527, 95% C.I. = 0.586 - 3.978). Cases of stage 3 had about two times the risk of the first stage (95% C.I. = 1.215 – 6.759), while the risk in stage 4 was about three times (95% C.I. = 1.215-6.759). Studying the risk of death upon grade; grade 2 risk of dying was about 1.8 times (C.I. = 1.176 – 2.683), while grade 3 revealed only a risk of about 1.3 times the risk of grade 1 (95% C.I. = 0.765 –2.316); Model $\chi 2$ = 35.029; $p < 0.01$.

DISCUSSION

Over the past decade we have seen patients at a much younger age, in the third and fourth decades, suffering from head and neck cancer, especially cancer of the oral cavity and tongue. Around the world, oral age-standardized death rate through 46 countries revealed the least male or female value in Greece and Israel (Murphy et al., 1995). Incidence and mortality rates for oral and pharyngeal cancer have been increasing in several parts of the world, most notably in countries of central and Eastern Europe in the last two or three decades (Franceschi et al., 1999). From the present

Table 3. Summary of 5-year survival rates for registered patients with oral and pharyngeal cancer according to certain factors (Alexandria and El Behira, 1991 - 2000).

Variable		No. of cases	5-year survival
	Overall	852	0.5342
Gender	Male	516	0.5014
	Female	336	0.585
Residence	Urban	447	0.5504
	Rural	388	0.5011
Age	<30	85	0.5213
	30-<60	495	0.5544
	60-<75	229	0.5209
	>75	43	0.4151
Marital status	Married	503	0.4432
	Single	46	0.5502
	Widowed + divorced	104	0.4129
Education	Uneducated	518	0.4246
	Educated	88	0.4107
Occupation	Working	367	0.4024
	Not Working	338	0.5477
Site	Oral	516	0.5614
	Oro-pharygeal	72	0.5344
	Naso and hypo-pharyngeal	264	0.4823
Stage	1	39	0.745
	2	93	0.6065
	3	212	0.5062
	4	309	0.4638
Grade	1		0.6233
	2	322	0.4683
	3	97	0.605
Treatment	Surgery	60	0.822
	Chemo. and/or irradiation	49	0.3992
	Surgery+ irradiation	457	0.5604
	Surgery+ chemoth.	50	0.4477
	Surgery+ irradia.+ chemo.	177	0.4236
Type of surgery	Excisional	211	0.6602
	Safety margin	86	0.6927
	Radical neck dissection	95	0.5655

pharyngeal malignancy cases represented 58.5 and 41.5% respectively. The oro-pharynx, naso-pharynx, and hypo-pharynx accounted for 8.1, 17.3 and 14% respectively. The highest percent of occurrence was for

Table 4. Stepwise Cox regression analysis of the effect of various independent factors on 5-year survival probability (Alexandria and El Behira, 1991-2000).

Independent variables (covariates)	B	SE	Wald	P	Hazard ratio	95% CI LL - UL
Gender (male)	0.554	0.181	9.353	0.002	1.741	1.22 - 2.483
Stage of tumor		9.507	0.023			
Stage 2	0.423	0.489	0.749	0.387	1.527	0.586 - 3.978
Stage 3	0.795	0.441	3.256	0.071	2.215	0.934 - 5.254
Stage 4	1.053	0.438	5.787	0.016	2.866	1.215 - 6.759
Grade of differentiation		7.965	0.019			
Grade 2	0.574	0.211	7.444	0.006	1.776	1.176 - 2.683
Grade 3	0.286	0.283	1.023	0.312	1.331	0.765 - 2.316

$X_6^2 = 35.029$.

cases with stage 4, while one third had stage 3, and stage 1 represented the least percent. Regards grade; the highest percent was for those with moderately differentiated, but the lowest was for undifferentiated. About one half of all patients were exposed to surgery with irradiation treatment. Nearly one seven were subjected to surgical treatment only, and those received the three lines together were of less percent.

Although there was an ascending trend of incidence in El Behira governorate, but in general there was a decreasing trend of occurrence of oral and pharyngeal cancer in the years between 1990 and 2001, which was not statistically significant. Site and sex distribution of 6789 cases registered in “Cairo Metropolitan Registry” report for cancer (1987), showed that 5.8% of male malignancies was in the oral cavity and pharynx, compared to 3% only among female cases (The profile of cancer in Egypt, 1987). Incidence was quite different according to place, race, and time. As the average total incidence was 1.37 in our data; it is estimated with about 3 cases per 100,000 in U.S.A. in year 2001, where incidence of men was 2.6 times that of women (Silverman, 2001). In Catania (Italy), malignant tumors markedly prevailed in the males with an incidence that was 3 times that observed in females (Sortino and Milici, 1998).

Overall 5 year cumulative survival probability was 0.534, as it was 0.5 in males, and 0.585 in females. Male/female proportion of cases was 1.63, and this was matching that of Alexandria Registry (1.61) most recent reports, (Medical Research Institute, 2001) albeit “Cairo Metropolitan Registry” report was 1.8 male to females (The profile of cancer in Egypt, 1987). While male/female proportion of mean incidence in Alexandria Metropolitan region was 1.576; census male/female proportion in Alexandria and El Behira governorates ranged from 1.03 to 1.058 according to residential distribution. This survival rate was very impressive, as it was shown to be 49.8 in Scotland (1988 to 1992), (Information and Statistics Division, 2002). 52.5% for oral cancer in USA (1983 to 1990) and 33% for pharyngeal cancer (1981 to 1986), (Oral Cancer Background Papers, 2002) where it was 48% in Germany (Prevention of oral cancer, 2002). Finland showed 51% as 5 year cumulative survival rate in year 1978 to 1985 (Survival of Cancer Patients in Europe, 1995). A recent big research in Mumbai (India) showed a range of 20 to 43% as 5 year cumulative survival for oral cancer, and a range of only 8 to 25% 5 year survival in pharyngeal cancer (Rao et al., 1998).

The highest 5 years survival rate was found in patients age 30 to < 60, followed by those below 30 years, and 60 to <75 age groups. Urban cumulative survival probability was 55% in the 5th year, where it was 50.1/100 person in the rural areas. There was a significant statistical difference between 75+ age group and the other intervals. Educated patients recorded higher 5 year cumulative survival rate compared to uneducated. Those who did not marry had higher survival; and the same was seen with retired. Smoking revealed high statistical significance between any smoking rate and being a non smoker. The best cumulative survival rate was for oral sites, followed by oro-pharyngeal sites, as the worst survival was found in the other pharyngeal sites, and the difference was statistically different. Apparently, decrease of cumulative survival was there with the advance of age. Grade was not consistent with survival. The best cumulative survival rates existed in surgical treatment category, followed by surgery and irradiation, then surgery with chemotherapy, and this was statistically significant. Gender, stage, and grade were the most important predictors of survival. It is quite clear that stages 3 and 4 accounted for more than 80% of cases. TNM staging system, the most accurate prognostic variable in patients with oral carcinoma, (Noguchi et al., 1999) indicated that 80 to 90% of cases were presented with stage 3 or 4 malignancies in a recent research on a high-risk population of India (Rao et al., 1998).

RECOMMENDATIONS

1) Registration of malignancy cases must have a code

for every patient, which is to be used through a net covering all the oncology centers. This is a very beneficial regarding treatment of cases wherever they are, and provide an excellent database and a registry for such a disease. Planning and saving data would be available then, and also keeping the medico-legal dimensions. Stressing on the importance of meticulous and careful registration of patients data including the cause of death especially in the Ministry of Health is of prime importance.
2) Being a problem of non-controversial impact, a decisive fight against smoking must be launched. Intellectuals, politicians, and economists are to take their role in management of stopping such a bad habit.
3) Care is to be given for raising the socio-economic status, including the level of civilization and the infrastructure particularly in the rural areas (stressing on avoiding crowding and pollution). Life style and working circumstances seem to have an apparent impact on survival, hence care about occupational risk, and behavior therapy is mandatory.
4) Health education should be directed as the early referral to oncologists, as the earlier the surgery and /or stage were of significant higher survival feedback, thence it was the condition treatment modality.
5) Categories living potentially higher stress; are apt to develop malignancy; but have also lower survival rates comparatively. Those categories lie specifically within out-doors, uneducated, and males in addition to divorced or widow/widower females or males.
6) Whenever surgery is indicated, and patient is operable, safety margin is of great effect on survival.

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