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Risk factors and clinico-pathological profile of female genital tract malignancies at BPKIHS

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ABSTRACT

Aims: To evaluate the risk factors and clinico-pathological profile of patients with female genital tract malignancy.

Methods: It was a prospective descriptive study of female genital tract malignancy conducted from December 2019 to December 2020 in the Department of Gynaecology, BPKIHS.

Results: Out of 61 cases, cervical cancer was the most common cancer (56.0%) followed by ovarian cancer (21.0%) and gestational trophoblastic neoplasia (13.0%). The mean age of patients was 50.82±12.81 years. 38 (62.3%) were postmenopausal; 59 (96.7%) had good performance status at presentation (ECOG 1 and 2); 41 (67.2%) had early stage disease (stage I and II). 36 (59.0%) were referred outside for further treatment and majority belonged to cervical cancer (n=29;80.5%) for radiotherapy services. Eight (13.1%) patients had disease recurrence and one patient (1.6%) had death during the study duration. Among patients with cervical cancer, the mean age at marriage and at first pregnancy were 17.24±2.32 years and 19.47±2.51 years respectively. Majority of them had poor local hygiene (n=27; 79.4%). The most common presentation was post menopausal bleeding (n=29; 85.3%) and most common histology was squamous cell carcinoma (n=30; 88.3%).

Conclusions: Cervical cancer is the most common female genital tract cancer followed by ovarian and gestational trophoblastic tumor.

Keywords: clinico-pathological, female, genital tract, malignancy, risk factors.

INTRODUCTION

Globally over 40.5 million deaths accounting for 71.0% were related to Non-Communicable Diseases (NCDs) in 2016.[1] Among the major NCDs, cancer ranked second globally and fifth leading cause of death in Nepal with an estimated 11,525 deaths in 2015.[2] Cancer is a major public health problem in Nepal.[3] There is country-wise wide variation in the distribution of various cancers which is largely due to exogenous factors rather than the inherited differences

between populations.[4]

According to the GLOBOCAN 2020, the top three common cancers among the females globally were breast cancer followed by colorectal and lung cancer with cervical cancer at fourth place. In Nepal, the top three frequent cancers were cervical cancer (19.4%) followed by breast (17.1%) and lung cancer (7.7%) with ovarian cancer (5.1%) at fifth position among the females.[5] The factors influencing the rising burden of cancer incidence and deaths in developing countries includes modifiable risk factors like dietary habits, smoking, alcohol consumption, sedentary lifestyle, obesity, sexual behaviour, environmental pollution, chemicals, radiation, low level of awareness, poor socio-economic status, low screening rate etc. and non-modifiable risk factors like - genetic factors, increased life expectancy, sex and racial predisposition, geographical distribution etc.[6] With such a high frequency and mortality, there is paucity of knowledge regarding the risk factors, clinical and pathological characteristics of cancers in developing countries like Nepal.

This study was aimed to evaluate the risk factors, clinical and pathological profile of female genital tract malignancy.

METHODS

It was a prospective descriptive study conducted in the Department of Gynaecology, B. P. Koirala Institute of Health Sciences (BPKIHS), Dharan, Nepal from December 2019 to December 2020 using purposive sampling technique among sixty-one patients with diagnosis of female lower genital tract malignancies. The study was undertaken after the ethical approval from Institutional Review Committee, BPKIHS, Dharan. Women with cytological and/or histological and/or biochemical proven gynaecological cancers [cervical, ovarian, endometrial, vulval, vaginal, tubal, gestational trophoblastic neoplasia (GTN)] at BPKIHS (both inpatients and outpatients) requiring curative or palliative treatment were included in the study. Those patients who were referred outside for further treatment after diagnosis at BPKIHS were also included in the study. Those who lost follow up or suspected malignancy but no definitive histological diagnosis were excluded from the study. Socio-demographic characteristics of the patients including the outcome variables like age, menopausal status, parity, risk factors, medical illness, tumor markers, performance status, body mass index, histological patterns, laboratory parameters, stage, modes of treatment, disease course like recurrence and death were recorded. After treatment completion (surgery and/or radiotherapy and/or chemotherapy), they were followed up as per the hospital based surveillance protocol.

All the relevant data were recorded and entered into the excel sheet as per the proforma and statistical analysis was done using SPSS version 16.0. Categorical variables were interpreted using frequency and continuous variables using mean±SD or median (IQR/Range) in the forms of tables and pie charts.

RESULT

There were a total of sixty-one patients who were diagnosed with female lower genital malignancy during the study duration. The mean age was 50.82±12.81 years and the average number of children was 3.39±1.9. More than half belonged to cervical cancers (n=34; 56.0%) followed by ovarian cancers (n=13; 21.0%) and gestational trophoblastic neoplasia (n=8; 13.0%) [Figure-1].

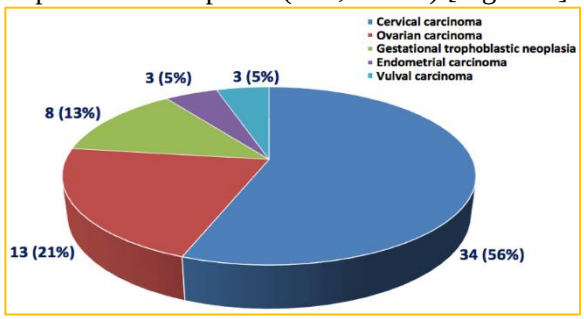

Figure-1: Disease distribution based on the site of malignancy (n=61)

Among cervical cancer patients, the mean age at marriage and at first pregnancy were 17.24±2.32 years and 19.47±2.51 years respectively. The median patient delay (onset of symptoms to the first medical consultation) in the care pathway was 3 months (Range=1-18 months). The most common symptom was postmenopausal bleeding (n=29; 85.3%) followed by vaginal discharge (n=21; 61.8%) and pelvic pain (n=17; 50.0%). Only two (5.9%) patients had undergone cervical cancer screening in their lifetime.

Table-1: Baseline characteristics of patients with female genital tract malignancy (n=61)

Characteristics	Sub-groups	Frequency	Percent
Age groups (years)	<40	16	26.2
	40-60	32	52.5
	>60	13	21.3
Body mass index (BMI)	<18.5	4	6.6
	18.5-24.9	45	73.8
	25-29.9	11	18
	≥30	1	1.6
Educational level	Illiterate	53	86.8
	Literate	8	13.1
Socio-economic status	Poor class	24	39.3
	Medium class	35	57.4
	High class	2	3.3
Menopausal status	Premenopausal	23	37.7
	Postmenopausal	38	62.3
Performance status (ECOG)	1	54	88.5
	2	5	8.2
	3	1	1.6
	4	0	0
	5	1	1.6
Stage of disease (FIGO)	I	26	42.6
	II	15	24.6
	III	18	29.5
	IV	2	3.3
Course of disease	Recurrence	8	13.1
	No recurrence	53	86.9
Complications of disease (Recurrence excluded)	None	47	77.0
	Anemia and uremia	5	8.2
	Anemia	4	6.6
	Uremia	3	4.9
	Myelosupression	1	1.6
	Death	1	1.6
Referral pattern for treatment	Referral outside	36	59.0
	No referral	22	36.1
	Refused further treatment	3	4.9

NB. ECOG=Eastern Cooperative Oncology Group, FIGO=International Federation of Gynaecology and Obstetrics, BMI=Body Mass Index

Among the patients with ovarian cancer, the mean age and Body Mass Index (BMI) were 57.54±12.12 years and 23.38±3.86 respectively. The average number of children of these patients was 3.77±1.96. The most common clinical presentation among ovarian cancer patients was

abdominal pain and discomfort (n=11; 84.6%). The median pretreatment CA125 value was 260 (Range=56-5000) U/ml.

Among patients with Gestational Trophoblastic Neoplasia (GTN), the mean age was 34.88±9.03 years. The median pre-evacuation beta-Human Chorionic Gonadotropin (β-hCG) value was 1,55,200 (IQR=29,873-2,71,162) mIU/ml. The median number of children of these patients was 2.5 (Range=0-10). The most common presentation of these patients was persistently elevated serial β-hCG value (n=8; 100%) followed by irregular menses (n=7; 87.5%). Almost half of the patients (n=32; 52.5%) belonged to the age group of 40-60 years. Most of them (n=53; 86.8%) were illiterate. More than half (n=38; 62.3%) were postmenopausal. Most of them (n=59; 96.7%) had good performance status of ECOG ≤2. Only eight patients (13.1%) had disease recurrence during the study duration. Two-third of them (n=41; 67.2%) had early stage

Table-2: Risk factors and Clinico-pathological profile of patients with cervical malignancy (n=34)

Characteristics		Sub-groups		Frequency	Percent
Risk factors	Education level	Illiterate		30	88.2
		Literate		4	11.8
	Socio-economic status	Poor class		15	44.1
		Medium class		19	55.9
	Local hygiene	Poor		27	79.4
		Good		7	20.6
	Menopausal status	Premenopausal		12	35.3
		Postmenopausal		22	64.7
Clinical and pathological profile	Performance status (ECOG)	1		30	88.2
		2		3	8.8
		3		1	2.9
	FIGO Stage	≤IB2		7	20.6
		IB3		4	11.8
		IIA1		1	3.0
		IIB		12	38.2
		III		8	23.5
		IVA		2	5.9
	Gross look of the lesions	Exophytic		24	70.6
		Ulcerative		10	29.4
	Histological type	SCC	Keratinizing	7	20.6
			Non-Keratinizing	12	35.3
			Not specified	11	32.4
		Adenocarcinoma		2	5.9
		Adenoma malignum		1	2.9
		Cervical melanoma		1	2.9
	Modality of treatment	Primary chemoradiation		25	73.5
		Dual treatment		3	8.8
		Radical hysterectomy		5	14.7
		Radical hysterectomy abandoned		1	2.9
	Course of disease	Recurrence	Nodal	4	11.8
			Parenchymal	2	5.9
		No recurrence		28	82.3

NB. ECOG=Eastern Cooperative Oncology Group, FIGO=International Federation of Gynaecology and Obstetrics

disease (stage I and II). Thirty-six patients (59.0%) were referred outside for further treatment (radiotherapy and/or chemotherapy). [Table-1]

The commonly associated risk factors among the cervical cancer patients were illiteracy (n=30; 88.2%), poor local hygiene (n=27; 79.4%), postmenopausal status (n=22; 64.7%) and poor socio-economic status (n=15; 44.1%). Almost all them (n=33; 97%) had good performance status (ECOG ≤2). The most common histological type of cervical cancer was squamous cell carcinoma (n=30; 88.3%). Most of these patients (n=26; 76.4%) had locally advanced cervical cancer at diagnosis. Majority of them (n=25; 73.5%) were directly referred for primary chemoradiation for treatment at initial presentation. Most of the cervical cancer patients (n=28; 82.3%) were free of disease after treatment during the study duration while six patients (17.7%) had recurrence (4 nodal, 2 parenchymal). [Table-2]

Table-3: Risk factors and Clinico-pathological profile of patients with ovarian malignancy (n=13)

	Characteristics	Sub-groups		N	%
Risk factors	Prior hysterectomy	Yes		1	7.7
		No		12	92.3
	Menopausal status	Premenopausal		2	15.4
		Postmenopausal		11	84.6
	Education level	Illiterate		11	84.6
		Literate		2	15.4
	Tubo-ligation	None		13	100
	Use of OCPs	None		13	100
Clinical and pathological profile	Performance status (ECOG)	0	Asymptomatic	1	7.6
		1	Symptomatic	10	77.0
		2		2	15.4
	Stage of disease (FIGO)	I		5	38.5
		II		1	7.7
		III		7	53.8
	Histological types	HG serous carcinoma		6	46.1
		Adenocarcinoma		2	15.4
		Mucinous carcinoma		2	15.4
		Endometrioid carcinoma		1	7.7
		Adult granulosa cell tumor		1	7.7
		Missing		1	7.7
	Treatment modality	Interval surgery		7	53.8
		Primary surgery		6	46.2
	Course of disease	Recurrence		2	15.4
		No recurrence		11	84.6

NB. OCP=Oral Contraceptive Pills, ECOG=Eastern Cooperative Oncology Group, FIGO=International Federation of Gynaecology and Obstetrics, HG=High Grade

Among ovarian cancer patients, all of them had no any oral contraceptive pills (OCPs) use and no tubal ligation (n=13; 100%). Only one patient (7.7%) had history of hysterectomy and most of them were postmenopausal (n=11; 84.6%). All of them (n=13; 100.0%) had good performance status of ECOG ≤2. Seven patients (53.8%) had advanced stage disease. The most common histological type among the ovarian cancer

Table-4: Risk factors and Clinico-pathological profile of patients with GTN (n=8)

	Characteristics	Sub-groups		Frequency	Percent
Risk factors	Extreme of age>40 years	Yes		2	25.0
		No		6	75.0
	Past history of molar pregnancy	Yes		5	62.5
		No		3	37.5
Clinical and pathological profile	Types of GTN	Invasive mole		2	25.0
		Choriocarcinoma		2	25.0
		Post-molar GTN		4	50.0
	Performance status (ECOG)	1		6	75.0
		2		1	12.5
		5		1	12.5
	Stage of disease (FIGO)	I		6	75.0
		III		2	25.0
	FIGO/WHO prognostic risk score	Low risk		6	75.0
		High risk		2	25.0
	Chemotherapy regimen	Single agent	Methotrexate	4	50.0
			Actinomycin-D	2	25.0
		Multi-agent (EMACO)		2	25.0
	Complications of disease/treatment	None		4	50.0
		Anemia (P/V bleeding)		2	25.0
		Severe myelosupression		1	12.5
		Death		1	12.5

NB. GTN=Gestational Trophoblastic Neoplasia, ECOG=Eastern Cooperative Oncology Group, FIGO=International Federation of Gynaecology and Obstetrics, WHO=World Health Organization, EMACO=Etoposide, Methotrexate, Actinomycin-D, Cyclophosphamide, Vincristine.

patients was high grade serous carcinoma (n=6; 46.1%). Seven (53.8%) patients had interval surgery after neoadjuvant chemotherapy (NACT). Most of them (n=11; 84.6%) had no recurrence till the study duration. [Table-3]

The associated risk factor among these patients was prior history of molar pregnancy (n=5; 62.5%). Four patients (50.0%) had post-molar GTN, two patients (25.0%) had choriocarcinoma and two patients (25.0%) had invasive mole. One patient (12.5%) had disease related death. Six patients (75.0%) had stage one as well as low risk disease so were managed with single agent chemotherapy i.e. methotrexate or Actinomycin-D (n=6; 75.0%). Half of them (50.0%) had disease or treatment related complications (2 anemia, 1 severe myelosupression, 1 death). [Table-4]

DISCUSSION

In this study, cervical cancer (56.0%) was found to be the most common female genital tract malignancy followed by ovarian (21.0%), GTN (13.0%), endometrial (5.0%) and vulval cancer (5.0%). Squamous cell carcinoma (88.3%) and high grade serous carcinoma (46.1%) were the most common histological type among cervical cancer and ovarian cancer patients respectively. The findings of this study are similar to the study done by Jha et al at Paropakar Maternity and Women's Hospital, Kathmandu, Nepal in which cervical cancer (71.0%) was the commonest followed by ovarian (14.0%), endometrial (8.0%) and choriocarcinoma (3.0%). Also, squamous cell carcinoma and high grade serous carcinoma were the commonest histological type among cervical cancer and ovarian cancer patients seen in 93.0% and 44.1% patients respectively.[7] Similarly result was seen in the study by Mohammad et al done in Kathmandu University Teaching Hospital, Dhulikhel, Nepal where cervical cancer (n=16; 59.25%) was the

commonest cancer among all the malignancies of female reproductive system and squamous cell carcinoma (100%) as the commonest histology among the cervical cancer patients.[8] A similar trend of distribution of these cancers of female genital tract was also seen in the study done by Pokhrel et al back in 2007 at BPKIHS with cervical cancer (67.3%) as the commonest followed by ovarian cancer (17.0%), endometrial (10.0%), choriocarcinoma (3.4%) and vulvo-vaginal cancer (2.8%).[9]

Annually, around 6,00,000 new cases of cervical cancer are diagnosed globally and 2,244 new cases diagnosed in Nepal making it the commonest cancer among women above breast cancer in Nepal.[7] It is the second most common cause of cancer incidence and deaths among all cancers in Nepal after lung cancer accounting for a total death of 1,493 in 2020.[7] The commonly associated risk factors associated with cervical cancer in this study were illiteracy leading to lack of awareness (88.2%), poor local hygiene (79.4%) and poor socio-economic status (44.1%). The lack of awareness regarding Human Papilloma Virus (HPV) infection, need of screening and proper hygiene and availability of vaccination against cervical cancer for its prevention among general populations as well as other cultural and social barriers has led to the presentation of cervical cancers in advanced stages in the developing countries like ours.[9-13] Screening for cervical cancer in the developing countries is a real challenge, because of the paucity of resources, health awareness amongst the women and inadequate treatment of precursor lesions of cervical cancer. Simple screening techniques like visual inspection with acetic acid (VIA) may be helpful in reducing the incidence and mortality from cancer cervix in developing countries like ours.[14] The missed opportunity to diagnose the cervical cancer in time has really proved fatal in our country. This has huge negative impacts not only on family life but also in the economical and social cost. Peripheral Teaching Hospital like ours, has initiated the national or regional community-based cervical cancer screening program in integration with primary health care and district health services along with effective manpower production for effective screening programs in support from Provincial Level Government. In developed countries, the incidence rates of invasive cervical cancer have declined steadily over the past few decades. In contrary, it is rising in developing countries. The decrease in the incidence of cervical cancer in developed countries is presumably as a result of the widespread use of cervical screening and effective vaccination programs. The reason that Papanicolaou smear screening is so effective in reducing the incidence of cervical cancer by 70.0% is that the majority of cancers are detected at precancerous state. This lesion may exist in the noninvasive stage for as long as 20 years and shed abnormal cells that can be detected on cytologic examination.[15] Besides the mortality, invasive cervical cancer has a huge adverse impacts in the quality of life like dyspareunia, reproductive, bladder, defecatory and sexual dysfunction, chronic pelvic pain, renal failure, fistula and vaginal discharge.[13] The burden of advanced cases of cervical cancer is increasing. In our study, a small proportion (14.7%) of cervical cancer patients were treated with surgery only for early stage while 8.8% patients required adjuvant radiotherapy after surgery (Dual treatment). 32.4%, 41.2%, 23.5% and 5.9% patients had stage I, stage II, stage III and stage IV disease at presentation. Most of these patients (n=26; 76.4%) had locally advanced cervical cancer at diagnosis so they were referred to other cancer centres especially for primary chemo-radiotherapy services. Similar results were seen in the study by Pokhrel et al with 9.3% managed with surgery alone for early stage cervical cancer and rest (90.7%) were referred to the cancer centre for chemoradiation.[9] Afroj et al. in their study reported 19.4%, 47.8%, 31.3% and 1.5% patients as stage I, stage II, stage III and stage IV disease[16] and the findings of this study is similar to our study.

In our study, the mean age among the patients with ovarian cancer was 57.54±12.12 years. Seven (53.8%) patients had stage III disease at presentation and high grade serous carcinoma was the most common histology (46.1%). In the

study by Paes et al[17], the mean age of the women with ovarian cancer was 54.67±13.84 years and serous carcinoma was the most common histology (30.1%) which is similar to our study but 23.9% patients had stage III disease at presentation which is in contrary to the finding of our study. In our study, ovarian cancer constitutes 21.0% among the female lower genital tract malignancies. The most common clinical presentation among them was abdominal pain and discomfort (84.6%). In contrary; ovarian malignancy constituted only 5.6% of all malignancies of women and 75.0% of them presented in advanced stage (stage III-53.6%, stage IV-21.4%) in the retrospective study by Prasad et al.[18] Similar results are noted in other Indian studies too regarding the presentation of the disease at advanced stage.[19-21] However, in the study by Prasad et al[18], the median age at presentation was 51 years, most common presenting symptoms were pain abdomen (39.0%) and abdominal distension/ bloating (16.0%) and most common histology was serous cystadenocarcinoma (32.0%) which are similar to the findings of our study. Majority of the patients with ovarian cancer usually presented with vague nonspecific abdominal complaints mimicking other common ailments and also there is delayed referral by the primary care clinicians which may be the reasons for the delay in diagnosis leading to the presentation of the disease in advanced stage.[22] Early diagnosis is difficult due to its asymptomatic nature, inaccessible site, limited benefits of tumor markers and ultrasonography and limited use of various new techniques like cytology and biopsy.[23] It has been shown that patients with ovarian cancers may have symptoms for at least few months to several months before their diagnosis[24]. Few studies done by Saini et al[20] and Basu et al[25] from India too mention mean age of ovarian cancer patients as 48.8±11.2 and 55.98±9.24 years respectively which is in consistent to the finding of our study. Similar result was highlighted by Kumar et al[26] regarding the age at presentation of ovarian cancer with their incidence more commonly in older women, between the ages of 45 and 65 years. In our study, six patients (46.2%) had undergone primary surgery and seven patients (53.8%) had undergone interval surgery. It is in contrast to the findings of the study by Prasad et al[18] in which primary surgery was done in twenty-three patients (27.3%) with 87.0% inadequately staged and sub-optimally cytoreduced and neoadjuvant chemotherapy was initiated in five patients (6.0%) for interval surgery in the latter sitting. In our study, most of the ovarian cancers were of surface epithelial origin (84.6%) which correspond to the finding of the study by Mondal et al[27] (90.0%) but contradict to the findings by Vaidya et al[28] (43.5%) and Karki et al[29] (47.3%).

Among the patients with gestational trophoblastic neoplasia in our study, the mean (±SD) age was 34.88 ±9.03 years. In the study done by Pariyar et al[30], the mean age of the patients was 29.1 years which is similar to the finding of our study. In our study, past history of molar pregnancy was seen in 62.5% patients with invasive mole and choriocarcinoma in 25.0% patients each. Pariyar et al[30] in his study reported history of previous molar pregnancy in 15.5%, invasive mole in 13.3% and choriocarcinoma in 48.8% patients which is in contrast to the findings of our study. But in the study by Tamang et al[31], prior history of molar pregnancy was reported in 60.0% patients with gestational trophoblastic neoplasia with 33.3% belonging to gestational choriocarcinoma. These findings are similar to the findings of our study. The most common presentation in our study was persistently elevated β-hCG (100%) followed by irregular vaginal bleeding (87.5%) and 25.0% patients had anemia. But in the study by Pariyar et al[30], the most common presentation was vaginal bleeding (82.2%) and 57.8% patients had anaemia which are in contrast to the finding of our study. Similarly, in our study 75.0% patients fell in the WHO low risk group and were treated with single agent (Methotrexate or Actinomycin-D) while 25.0% patients fell in the high risk group and were treated with multi-agent chemotherapy. This is similar to the findings by Tamang et al[31] in which 66.7% patients with low-risk GTN responded to single agent methotrexate regimen and remaining 33.3% received multi-

agent regimen due to resistance. All these patients (100.0%) achieved complete remission after chemotherapy and there was one mortality (12.5%) due to the disease related complication. Pariyar et al[30] in his study reported 48.8% patients in World Health Organization (WHO) low risk and 52.2% patients in high risk group. Among them, 33.3% patients received single agent chemotherapy and 42.2% received multi-agent chemotherapy respectively which are in contrast to the findings of our study. Similarly, in the study by Tamang et al[31], 60.0% fell in low-risk and 40.0% in high-risk group which is in contrast to the finding of our study. In our study, 75.0% patients belonged to stage I and 25.0% belonged to stage III which is in consistent to the findings by Tamang T et al[31] in which 73.3% patients belonged to stage I and 26.7% patients to stage III. Single agent methotrexate resulted in complete remission in 86.6% patients and multi-agent chemotherapy in 73.7% patients with 6.6% mortality in the study by Pariyar et al[30] which are in contrast to the finding of our study. Cure rates of 90-100% have been reported in patients with non-metastatic and low-risk metastatic gestational trophoblastic neoplasia if treated appropriately[32,33] Overall cure rate achieved in our study is similar to that of other studies.

Our study is a prospective study but we had recruited sixty-one patients over the duration of one year which is comparatively a small sample size to draw conclusions. The study duration is also limited to discuss on the outcomes like recurrence and death. Further, we had limited access for treatment outcomes among some of the patients who were referred outside for further treatment and had lost follow up.

CONCLUSIONS

Cervical malignancy is the most frequent cancer of female lower genital tract by 56.0% followed by ovarian cancer (21.0%) and gestational trophoblastic neoplasia (13.0%). Ovarian cancer usually presents in advanced stage due to its vague nonspecific abdominal complaints leading to delay in diagnosis and poor outcomes. There is need to scale up mass awareness programmes about risk factors, recognition of symptoms and available care measures against cancers.

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