"Role of Personalized Care and Patient Centered Counselling In Improving Compliance of Cancer Patient - An Experience from Tertiary Care and Research Centre of Poorvanchal, India"

JainRR[3],PataikuniSK,ShahiUP[1],ChiraranjanK,GovardhanHB[3],
,AzadSK[1],KerkattaM[2],FrancisD[3],SinghR[3],DewanganS,HishikarD,KesarP,JainI
ChoudharyV[1]

Dr Rajeev Ratan Jain Assistant Professor, Regional cancer centre Raipur (CG)
Corresponding author-Pataikuni SK, Regional cancer centre, Raipur (C.G)
1-Professor, 2-Associate Professor, 3-Assistant Professor

Abstract:-
Introduction: -*According to the world cancer report 2008 by the IARC, division of World Health Organization, the global burden of cancer has doubled during the last 30 years of the last century. In 2008, it was estimated that there were over 12 million new cases of cancer diagnosed, 7 million deaths from cancer and 25 million persons alive with cancer within five years of diagnosis. By 2030, it is estimated that there will be over 26 million incident cases of cancer annually. With this number of patient a personalized approach to patient is necessary to improve overall care*

"**Material and method:-***Patients of age 10-70 years attending the Radiotherapy Outpatient Department with histologically proven cancer were enrolled in the study. The patients were randomized into two groups- a study group and a control group. Both study and control were counseled regarding various aspects of treatment like toxicity, outcome, cost of treatment, modality etc. by treating doctor. Both groups were counseled on a personal basis by the doctor. All the patients were asked to fill quality of life questionnaire 'EORTC QLQ C-30' version 3.0. Study group patients were given comprehensive personalized care and support. They were subjected to individualized attention, care and support. All patients of study group were evaluated by the same doctor at each session up to third follow up from completion of treatment.*

Results:-*The mean age of patients were 47.5 years with a peak in age distribution in the 6th decade. Ninety four patients (58%) were females and remaining 42% were males.Among cervical cancer 86% of patients were on radical treatment. 112 of the total patients (70%) completed the prescribed treatment with 61 patients in the study arm and 51 in the control arm. 16 patients (10%) dropped out of treatment and 33 (20%) did not come back to Radiotherapy OPD to start treatment. The outcome in the study arm was better compared to the control arm; treatment completion was 78% vs. 61% (61 vs. 51); twelve percent of patients did not come for any treatment compared to 29% (29 patients) in the control arm. The number of patients failing to complete treatment were however similar in both (12% vs. 15%). Among the cancer types, patients of cancer cervix had the best outcome with 78% completing treatment, then head and neck cancer with 65% and last breast cancer 61%. The study arm had better outcome than the control arm.*

Head and neck cancer patients had the highest number of patients failing to complete treatment (21%) with an equal number in both arms;. Most patients who did not take treatment were those of breast cancer, with 20% in the study arm compared to 25% in the control arm (2 vs. 8 patients). The 8 patients of cancer cervix who did not start treatment all belonged to the control group.23 percent patients of cancer cervix experienced some interruption in their treatment with almost the same number of patients in either arms. In head and neck cancer, 9 out of 52 patients (17%) had to interrupt their treatment with 15% in the study arm vs. 19% in the control. No breast cancer patients experienced interruption in their treatment.

Conclusion: -*The use of personalized care approach, providing adequate and appropriate information, communication provision, and supportive care may improve the compliance in terms higher completion of treatment and lesser interruption of treatment and follow up. Information may be beneficial to both educated and less educated patients.*

Key words:-*Personalized health care, patient centered approach, EORTC QLQ C-30.compliance*

I. Introduction

Cancer was not been considered a major health problem in developing countries until recently, according to 2005 report by the World Health Organization (WHO).[1] According to the world cancer report 2008 by the IARC, division of World Health Organization, the global burden of cancer has doubled during the last 30 years of the last century. In 2008, it was estimated that there were over 12 million new cases of cancer diagnosed, 7 million deaths from cancer and 25 million persons alive with cancer within five years of diagnosis. By 2030, it is estimated that there will be over 26 million incident cases of cancer annually.[2]

The latest statistics from the WHO show that the number of death due to cancer accounts for around 13% of all deaths worldwide; more than 70% of all cancer deaths occurred in low- and middle-income countries.

UICC's scientific report published on 14 February 2010 focused on cancer that were caused by infectious agents and estimated that infections caused 22% of cancer deaths in low and middle income countries and 6% in developed countries. [3]

In low-resource settings, the great majority of cancers present at a stage when palliation is the only therapy which can be offered.

Knowing the burden of cancer and its variation in pattern between the regions is important for cancer control. In India, the National Cancer Registry Program (NCRP) was established to collect data on incidence and patterns of cancer through population based cancer registries in 1982. Until recent years NCRP reported cancer surveillance from five urban registries at Bangalore, Bhopal, Chennai, Delhi and Mumbai and only one rural registry at Barshi. These estimates were on the basis of defined populations and there were no adequate coverage from rural India [4, 5]

It is difficult to provide valid estimates of cancer in entire country, as over 70% of the population of India resides in the rural areas. Nonetheless, limited exercises have been carried out, by scientists in the NCRP, and these figures vary from 700-900,000 new cancer cases in India every year.[6]

Every year cervical cancer is diagnosed in about 500,000 women globally and is responsible for more than 280,000 deaths annually. Approximately 80 percent of the women who died of this disease globally resided in developing countries and 27 percent of total cases of cervical cancer were found in India. India has a population of 366.58 million women aged between 15 years and older and who are at risk of developing cervical cancer. [2] Current estimates indicate that every year 134,420 women are diagnosed with cervical cancer and 72825 die from the disease. Cervical cancer ranks as the first most frequent cancer among women in India, and the first most frequent cancer among women between 15 and 44 years of age. About 7.9% of women in the general population are estimated to harbor cervical HPV infection at a given time, and 82.5% of invasive cervical cancers are attributed to HPVs 16 or 18.

Personalized care is much more than simply educating patients about a diagnosis, potential treatment, or healthy behavior. It does not mean giving patients whatever they want; rather, patients want guidance from their care providers, but they expect that guidance to be provided in the context of full and unbiased information about options, benefits, and risks. By personalized care we mean to include patient centered care with individualized care and better communication provisions. "Patient-centered" means considering patients' cultural traditions, personal preferences and values, family situations, social circumstances and lifestyles, as used by the Institute of Medicine and Institute for Healthcare Improvement. The patient physician relationship has transitioned from being a paternalistic one to a patient-centered one. There are four common elements in this regard (1) being attentive of patients' psychosocial as well as physical needs,(2) enabling the disclosure of patients' concerns,(3) conveying a sense of partnership, and (4) actively facilitating patient involvement in decision making. By specifying human needs, the concept of autonomy support of physicians can be viewed as an orientation related to patient-centeredness. In order to be autonomy supportive it is necessary for the practitioner to elicit and acknowledge patient perspective, to support patient initiatives, and to avoid controlling the patient. [7, 8, 9]

With the above background the present study was conducted to see the impact of personalized care and support in management of cancer patients.

II. Material and methods

The present study was conducted in department of Radiotherapy and Radiation Medicine, Sir Sunderlal hospital, institute of medical sciences, Banaras Hindu University, Varanasi from January 2010 to January 2011.

Patient selection criteria
Inclusion criteria
Patients with histologically proven malignancy attending the Radiotherapy Outpatient Department of Sir Sunderlal Hospital, BHU during the period of January 2010 to January 2011 were considered for the study.

Exclusion criteria
- Patient age <10 year and age >70 years
- Patient too ill or moribund
- Patient considered mentally unsound
- Patient not giving consent

Patients attending the Radiotherapy Outpatient Department with histologically proven cancer were enrolled in the study. These patients were subjected to screening for above inclusion and exclusion criteria. Those patient fit for study where enrolled in study. All were subjected to thorough clinical examination and requisite investigations as per the requirements and patients were staged appropriately as found feasible. At this junction, the patients were randomized into two groups- a study group and a control group.

After randomization both study and control were counseled regarding various aspects of treatment like toxicity, outcome, cost of treatment, modality etc. by treating doctor. Both groups were counseled on a personal basis by the doctor.

Usually patients of both arms were called to the ward after the OPD hours and the interview/counseling was conducted in a quiet room. The patients were explained the purpose of the intervention and were informed that their participation in the study was entirely voluntary. Their consent was sought. They were reassured that their response to the interview would remain secret and also that non-participation in the study would have no consequences on their treatment and follow-up. The patients were usually accompanied by an attendant and each patient was subjected to finer details of intervention, where the personal details were noted. Each session took approximately 15 to 30 minutes.

All the patients were asked to fill quality of life questionnaire 'EORTC QLQ C-30' version 3.0.They were asked to fill the questionnaire individually. Those patients who were illiterates were helped to fill the form.

Study group patients were given comprehensive personalized care and support. They were subjected to individualized attention, care and support. Following this the patients of study group were given the treatment protocol sheet which had appropriate dates of interviews, overall cost of treatment both in wholesome and per session and approximate days of stay. Study arms patients were asked mobile no. or personal contact number and were given personal contact number of doctor. They were allowed to communicate with treating doctor according to need basis. All the patients of study group were asked to maintain a notebook. In this notebook they were asked to note down their daily inputs and output of food and water. They were asked to write the problems which they faced after each course of treatment as they reached home. These notebooks were checked before each session of treatment and patients were advised regarding basic management through which they can prevent complications during and after treatment hours. All patients of study group were evaluated by the same doctor at each session up to third follow up from completion of treatment. They were asked to report him whenever they need him. They can even call him when they need.

Patients of control arm were not given personalized health care and support. No personal attention was given. They were not given the contact number of treating doctor and asked to report complaints on regular follow up sessions. Controls were not asked to maintain a notebook but were verbally advised regarding diets and methods of coping toxicity. All controls were seen by different doctors on random basis and no individual attention was given. Those patients who were selected as controls were given information as per need basis, verbally and involuntarily. Treatment protocol was used as per standard NCCN guidelines.

Assessment of patients
- Patients on EBRT were seen on a weekly basis on the treatment unit and complications were sought and managed accordingly.
- Patients on chemotherapy were followed when they were admitted to the ward or weekly if on radiation. Complications were looked for and managed as per the departmental protocols.
- Patients were also assessed after completion of treatment-
I. After 2 weeks- Along with routine examinations patients were assessed for response. They were also assessed for quality of life and compliance.
II. After 3 month-patients were assessed for level of satisfaction and compliance
Compliance was assessed along following headings-
- Compliance to the scheduled plan in terms of the percentage of patients completing treatment and the frequency of interruptions during treatment.
- The percentage of patients who did not start treatment.
- The Percentage of patients had interruption in treatment.
- The number of patient on follow-up at the end of 3 months.

Data analysis: Collected data were entered in the Microsoft excel sheet and checked for its completeness and correctness before data analysis. The suitable statistical test was applied and p values < 0.05 was considered statistically significant.

III. Results

Table -1. Background Characteristics of Study Subjects

Background Characteristics	Control N-83	Study N-78	Total N-161
	No (%)	No (%)	No (%)
Age Group (In Years)			
<20	0	8(11%)	8(5%)
21-30	11 (14%)	4 (5%)	15 (9%)
31-40	20 (24%)	12 (15%)	32 (20%)
41-50	25 (30%)	15 (19%)	40 (25%)
51-60	17 (20%)	29 (37%)	46 (29%)
61-70	10 (12%)	10 (13%)	20 (12%)
Mean age- 47.5 yr			
Sex			
Male	30(36%)	37(47%)	67(42)
Female	53(64%)	41(53%)	94(58)
Cancer Site			
Head And Neck	26 (31%)	26 (33%)	52 (**32%**)
Cervix	32 (39%)	27 (35%)	59(**37%**)
Breast	8 (10%)	5 (6%)	13 (**8%**)
Brain	4(5%)	2(3%)	6(**4%**)
Git	8(9%)	3(3%)	11(**7%**)
Others	5(6%)	15(20%)	20(**12%**)

Table- 2. Distribution of Cases According to Cancer Staging

Head And Neck As Per TNM Stage	Control N-26	Study N-26	Total N-52
	No (%)	No (%)	No (%)
II	9(35%)	8(31%)	17(33%)
III	5(19%)	6(23%)	11(21%)
IV	12(46%)	12(46%)	24(46%)
Cervical Cancer As Per FIGO Stage	**Control N-32**	**Study N-27**	**Total N-59**
	No (%)	No (%)	No (%)
Ib1	2(6%)	2(8%)	4(7%)
IIa	1(4%)	0	1(1%)
IIb	8(25%)	8(30%)	16(27%)
IIIb	11(34%)	11(40%)	22(38%)
Postoperative With Stage Unknown	10(31%)	6(22%)	16(27%)

Table-3. Treatment modalities in patients with head and neck cancer who completed treatment

Treatment modalities	Control Arm N-17	Study Arm N-17	Total N-34
	No (%)	No (%)	No (%)
Radiotherapy	11(65%)	8(47%)	19(**55%**)
Chemo Radiation	6(35%)	8(47%)	14(**41%**)
Chemotherapy	0	1(6%)	1(**4%**)

Table- 4. Treatment Intent and Outcome in Control Vs Study Group

Treatment	Control (N-83) No. (%)	Study (N-78) No. (%)	Total (N-161) No. (%)
Intent			
Postoperative	19(23%)	17(22%)	36(22%)
Radical	60(72%)	54(69%)	114(71%)
Palliative	04(5%)	07(9%)	11(7%)
Outcome			
Treatment Completed	51(61%)	61(78%)	112(70%)
Did Not Come For Treatment After Work-Up	24(29%)	9(12%)	33(20%)
Did Not Complete Treatment	8(10%)	8(10%)	16(10%)
Compliance			
Treatment Interrupted	12(15%)	10(12%)	22(14%)

	44(53%)	54(69%)	98(61%)
Follow Up			

Table- 5.Various parametersin relation to different Cancer Categories

Cancer Site	Control	Study	Total
	No (%)	No (%)	No (%)
Treatment completion			
Head And Neck	17/26 (65%)	17/26(65%)	34/52(**65%**)
Cancer Cervix	22/32(69%)	24/27(89%)	46/59(**78%**)
Breast	4/8(50%)	4/5(80%)	8/13(**61%**)
Brain	2/4(50%)	2/2(100%)	4/6(**66%**)
Git	4/8(50%)	2/3(66%)	6/11(**55%**)
Other	2/5(40%)	12/15(87%)	14/20(**70%**)
Patients not completing treatment			
Head And Neck	5/26(19%)	6/26(23%)	11/52(21%)
Cancer Cervix	2/32(5%)	2/27(8%)	4/59(5%)
Breast	1/8(13%)	0/5	1/13(7%)
Patients not coming for treatment after workup			
Head And Neck	4/26(15%)	4/26(15%)	8/52(15%)
Cancer Cervix	8/32(25%)	0/27	8/59(13%)
Breast	2/8(25%)	1/5(20%)	3/13(23%)
Total	24/83(29%)	9/78(12%)	33/161(20%)
Treatment interruption			
Head And Neck	5/26 (19%)	4/26 (15%)	9/52 (17%)
Cancer Cervix	8/32 (25%)	5/27(20%)	13/59 (23%)
Breast	0/8	0/5	0/13(0)
Total	21/83 (25%)	9/78 (12%)	30/161 (19%)
Follow up during treatment			
Head And Neck	16/26(62%)	21/26(82%)	37/52 (71%)
Cancer Cervix	25/32 (78%)	24/27 (89%)	49/59 (83%)
Breast	2/8 (25%)	3/5 (60%)	5/13 (38%)
Total	48/83(58%)	59/78(76%)	107/161(66%)
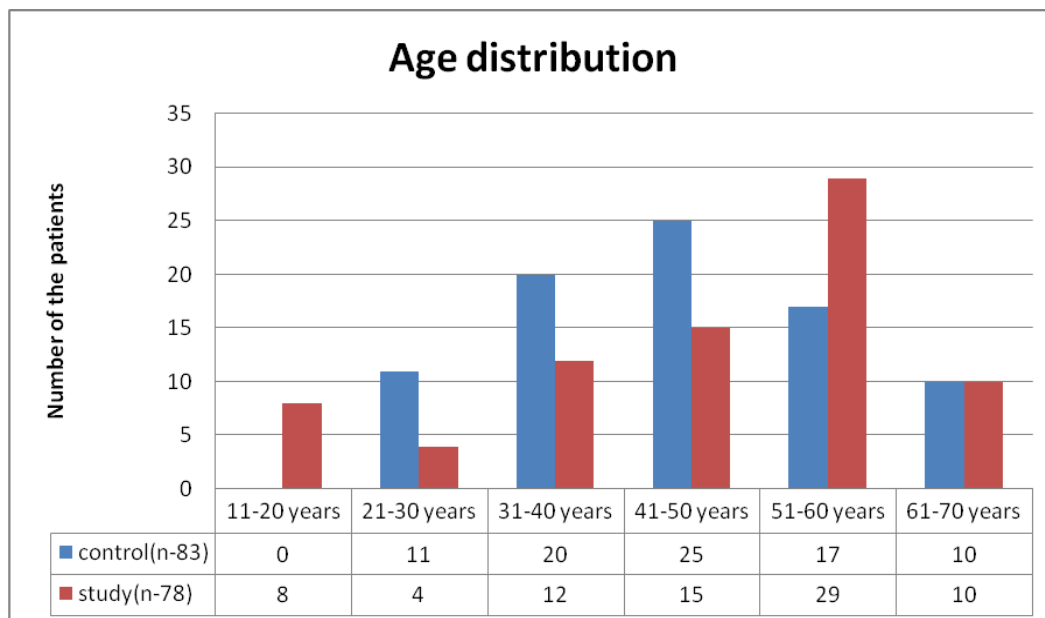
Figure 1 : Age distribution in the study.
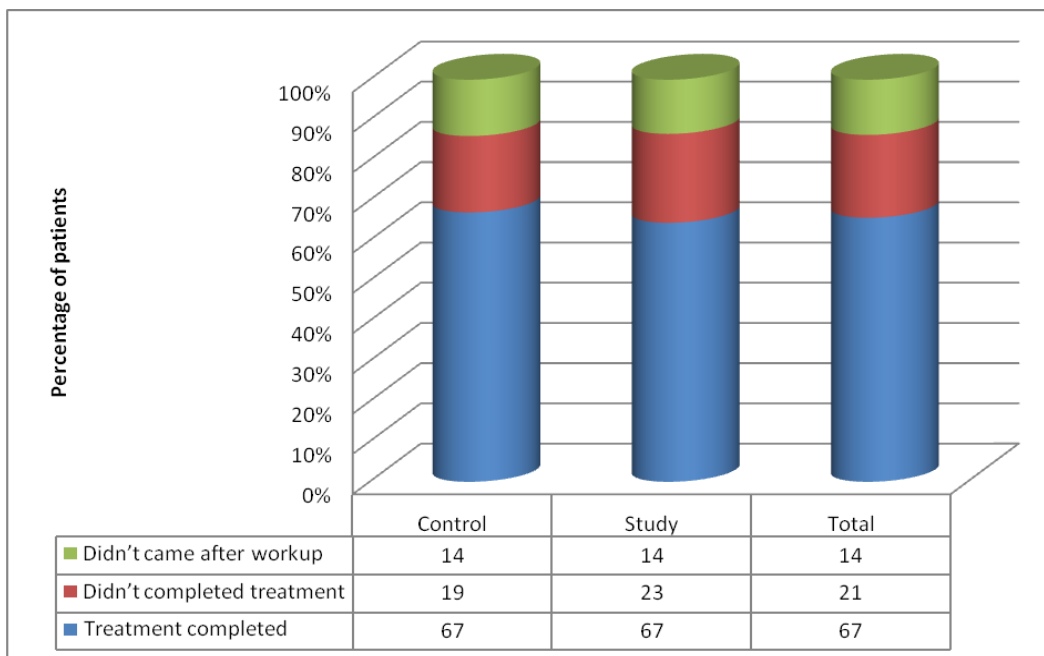
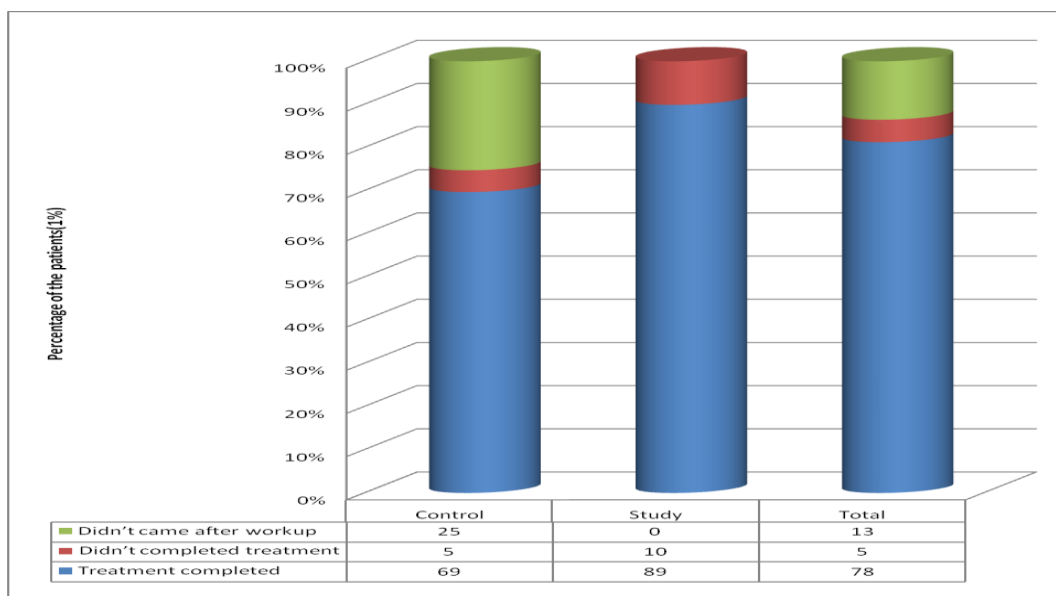**Figure 2: Treatment outcome among head and neck patients.**

	Control	Study	Total
■ Didn't came after workup	14	14	14
■ Didn't completed treatment	19	23	21
■ Treatment completed	67	67	67

Figure 3: Treatment outcome in cancer cervix patients

	Control	Study	Total
■ Didn't came after workup	25	0	13
■ Didn't completed treatment	5	10	5
■ Treatment completed	69	89	78

The mean age of patients were 47.5 years with a peak in age distribution in the 6th decade. Ninety four patients (58%) were female and the remaining 42% were males. Of the 161 patients, patients of head and neck cancer constituted 32%, cancer cervix 37%, breast cancer 8%, brain tumors 4%, GIT cancers 7% and others 12% of the total cancer patients. **[Table-1, Figure-1]**

Most patients in all the cancer types presented with stage III and stage IV disease.Twenty seven percent of cases of cancer cervix (16/59) were postoperative and the stage was not known for most of them. All the thirteen cases of breast cancer were post operative (100%) and for stage were known to all of them. **[Table-2]**

Fifty five percent of patients were treated by a combination of chemotherapy and radiation, either concomitantly or sequentially as in the case of breast cancer.Thirty patients (37% of total) received radiation either in the form of External Beam Radiotherapy alone or in combination with intracavitary radiation (ICR). Seven patients (9%) had palliative chemotherapy and all of them were found in the study arm. **[Table-3]**

Seventy one percent of patients were treated radically with curative intent. Seventy three percent of head and neck cancer patients were treated with curative intent. Among cervical cancer 86% of patients were on radical treatment.One hundred twelve of the total patients (70%) completed the prescribed treatment with 61 patients in the study arm and 51 in the control arm. Sixteen patients (10%) dropped out of treatment and 33

(20%) did not come back to Radiotherapy Outpatient Department to start treatment. The outcome in the study arm was better compared to the control arm; treatment completion was 78% vs. 61% (61 vs. 51); twelve percent of patients did not come for any treatment compared to 29% (29 patients) in the control arm. The number of patients failing to complete treatment were however similar in both (12% vs. 15%). The percentage of patients experiencing treatment interruption was slightly lower in the study group compared to the control group. Most patients were still under follow up 3 months after completing treatment.Among the cancer types, patients of cancer cervix had the best outcome with 78% completing treatment, then head and neck cancer with 65% and last breast cancer 61%. The study arm had better outcome than the control arm.

Head and neck cancer patients had the highest number of patients failing to complete treatment (21%) with an equal number in both arms;cancer cervix had only 5% of such patients.The drop-out rate was lowest in cancer breast with only one patient in the control arm failing to complete treatment.Most patients who did not take treatment were those of breast cancer, with 20% in the study arm compared to 25% in the control arm (2 vs 8 patients). Fewer number of patients of head and neck cancer failed to attend the hospital later on to start treatment, with 4 patients in each arm. The 8 patients of cancer cervix who did not start treatment all belonged to the control group.Twenty three percent patients of cancer cervix experienced some interruption in their treatment with almost the same number of patients in either arms.In head and neck cancer, 9 out of 52 patients (17%) had to interrupt their treatment with 15% in the study arm vs 19% in the control.No breast cancer patients experienced interruption in their treatment.Almost all patients of head and neck cancer and cancer cervix were on follow up compared to only 38% of breast cancer. **[Table-4, 5 and Figure-2, 3]**

IV. Discussion

The majority of patients in the study (69%) belong to fourth to sixth decades of life. The 2001 census of India estimates that the life expectancy of the population would turn around 67 and 72.6 years for male and female respectively. This supports high number of patients in 4th to 6th decade.**[10]**

In the present study, there is a female dominance with a ratio of male: female ratio 1.4: 1.

Thirty six patients out of the total 161 patients were postoperative, with 16 patients being those of cervical cancer, 10 of head and neck cancer patients, and 2 of cancer breast. Six out of six patients of brain tumor and seven patients of gastrointestinal tumors were for postoperative treatment. All postoperative cases of head and neck cancer were referred from within the hospital and all were staged properly. Sixteen out of the sixteen cases of cancer cervix were referred from private clinics with no proper staging and preoperative reports. 2 patients of cancer breast out of the 13 had a similar status of referral and stage. This illustrated the fact that breast surgery and gynecological procedures were commonly practiced in private whereas surgeries of the head and neck region represented more challenging procedures and were essentially confined to those departments having the required expertise.

Gender and literacy could be the reasons behind those patients who attended Radiotherapy OPD on their own; ten out of 19 patients (53%) were males and 11/19 (58%) were literate. As expected, majority of those who attended hospital on their own for consultation were cases of head and neck (10/19, 53%) bearing the highest literacy rate.

The majority of the total patients (55%) were treated by chemoradiation, 41% of patients of head and neck cancer and 78% of those of cancer cervix were treated with chemoradiation. Radiation as a sole modality was reserved for post-operative cases of either head and neck cancer, cancer cervix and breast cancer. Nine percent patients who had only palliative chemotherapy belonged to the study arm.

Most patients as pointed out earlier presented in advanced disease and warranted a multi-modality approach. The treatment protocol proposed in the study reflected the concepts found in different literatures (Rath (2002), Perez 5th edition, De Vita 8th edition).**[11, 12, 13]**

In the present study the outcome of treatment was defined in terms of (i) completion of planned treatment (ii) failure to complete the treament (drop out) (iii) failure to attend OPD after therapeutic decision and counselling given (iv) interruption in treatment (v) percentage of patients on follow up at the end of 3 months.

One hundred twelve out of 161 patients (70%) completed the planned treatment; thirty three patients failed to attend OPD a 2nd time; sixteen dropped out of treatment (10%) and 14% experienced some interruption during their treatment. The percentage of patients on follow up at 3 months was 61 (98 out of 161).

Mohanti et al in their study revealed that out of 2167 head and neck cancer, 56% started treatment and 44% withdrew after the first visit. An audit of cases done in PGIMS, Rohtak which revealed that 73% of patients were lost to follow up within 1 year of treatment. In Chittarajan National cancer Institute, Calcutta, during 1st January to 31st December 1991, out of 1003 patients of cancer cervix, the compliance was 40%. These studies showed that the compliance and follow up rate of patients are usually considered poor in India. **[11, 14]**

The present study had a similar trend as far as patients of breast cancer are concerned-61% of patients (8/13) completed treatment, 23% did not attend Outpatient department after first visit and 38% were on follow up after 3 months.

However encouraging results were observed for head and neck cancer and cancer cervix. Out of the 52 patients of head and neck cancer 34 (67%) completed the scheduled treatment, 11 (21%) did not; the remaining 8 (15%) did not come after their first visit. Most patients (37 out of total 52,60%) were available for follow up after 3 months.

In cancer cervix, 78% of patients (46/59) completed treatment, 13% withdrew after the first visit and 5% did not complete the prescribed treatment. 49 patients were available for follow up at 3 months.

One reason which can explain the difference between the studies of BD Das et al and Mohanti et al and the present one could be the fact that all patients in the latter study were counselled at the beginning of their treatment. Better outcome results in the study arm could be explained by the fact that patients were also given an information booklet. Another reason would be the short period of follow up (3 months) and the relatively small number of patients involved in the present study.**[11, 15]**

When both arms were compared,it was seen that the study arm had correspondingly better treatment compliance (78% vs 61%), more patients on follow up (69% vs 53%) and fewer patients not coming back after the 1st visit (12% vs 29%) than the control group. The number of cancer patients experiencing interruptions in their treatment was also lesser in the study group than in the control group (12% vs 15% patients).

One fourth of patients of breast cancer did not attending the hospital after their 1st visit (23%) with 2 out of 8 patients in the control arm and 1/5 in the study arm. In general, breast cancer patients were younger. Jones R et al (1999) conducted a cross-sectional survey of patients' satisfaction with information about cancer; out of the 525 patients, 309 had breast cancer and it was observed that though breast cancer patients were better provided with information than patients with other cancers, the former were not necessarily more satisfied. Treatment interruptions were lower in the study group compared to the control arm (12% compared to 25%). Hence patients in the study arm could be regarded as having experienced a better quality of life. Kerr et al (2003) observed that improved communication between patients and doctors resulted in a better quality of life for patients above the age of 50 years.**[16, 17]**

V. Conclusion

The use of personalized care approach, providing adequate and appropriate information, communication provision, and supportive care may improve the compliance in terms higher completion of treatment and lesser interruption of treatment and follow up.Information may be beneficial to both educated and less educated patients. The finding of the present study will be useful for oncologists during the management of these types of cases for effective outcome. The findings will be also useful for researchers in similar kind of study.

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