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Evaluating Safety And Efficiency Of Chemotherapy Among Patients With Advanced Colorectal Cancer

Dr.Aishwarya Dinakaran[1*], Shayestha Jabeen[2], Mohammed Abdul Mannan[2], Juweriya[2] & Ishrath Fatima[2,] Mohammed Salman[2]

[1*]*Associate Professor, Department of Pharmacy Practice, MRM College of Pharmacy, Chintapally guda, Hyderabad*
[2]*Department of Pharmacy Practice, MRM College of Pharmacy, Chintapally guda, Hyderabad*

***Corresponding Author:** Dr. Aishwarya Dinakaran*
**Associate Professor, Department of Pharmacy Practice, MRM College of Pharmacy, Chintapally guda, Hyderabad*

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Abstract

AIM:
Evaluating safety and efficacy of chemotherapy among metastatic colorectal cancer patients The cultural, social, and religious differences in parenting and child-parent relationships in families make parenthood a sensitive domain for the research study. Accordingly, the changing
nature of families, culture, and gender discrimination influence or affect parenting styles and
parent-child relationships. The current study explored the conceptual understanding of parenthood, such as beliefs, views, expectations, and parental well-being in Indian families, especially in the states of Tamil Nadu, Kerala, and Gujarat. The participants were nine parents living together and with children the age range between eighteen and thirty-five. The parents' age ranged from 41 to 63 (M = 50.8 years, SD = 6.05) (Mother's age M = 48.7 years, SD = 6.04; Fathers' age M = 52.9 years, SD = 5.28). They were selected based on purposive sampling. The method had an exploratory and qualitative design with multiple case studies. The researcher conducted in-depth, open-ended, semi-structured interviews using the online platform Google Meet and Zoom and face-to-face meetings. The interview transcriptions were analyzed using Braun and Clarke's inductive thematic analysis. The resulting six themes were:
Objectives:
Primary objective: To determine objective response rate of MCRC patients with chemotherapeutic regimen assessed as complete/ partial response/ stable/ progressive disease according to RECIST version 1.1. to evaluate the efficacy of chemotherapeutic regimen with in terms of objective response in accordance with response evaluation criteria in solid tumors RECIST version1.1.
Secondary objective: To asses patient's performance status using ECOG scale and to estimate percentage of all grade toxicities in accordance with CTCAE version 4.03.

MATERIAL AND METHODS:
It is a retrospective single centered empirical study conducted at the medical record department of oncology at a tertiary hospital for the duration of 6 months.

CONCLUSION:
MCRC is one of the major cause of death globally as the treatment involves complexities alongside much complications with chemotherapy are seen together with better outcomes. Entire data comprises of 109 subjects diagnosed with MCRC recorded in this retrospective study among which the no. of Male patients were 80 and Female patients were 29. The information extracted from the above data was that male subjects of age group between 50-70Y were more effected with colorectal cancer than female subjects of age group 40-70Y and patient specific treatment response rates were determined. The study revealed efficacy of chemotherapeutic regimen was found more with capox (capecitabine) and it came out as the most trending treatment among folfox (fluorouracil, oxaliplatin) and folfirinox (fluorouracil, irinotecan, oxaliplatin and capox is widely preferred by oncologists. Study revealed that among 109 patients with mcrc, the patients of age group 40- 70Y were more effected with repeatedly occurring adverse events of chemotherapy using CTCAE and determining the patient activity status.

Introduction: Cancer

The word cancer springs from the ancient 15renc word karkinoma which means crab is applied to enlarged tumors because bigger veins resemblance to the legs of crab. Oncology is the study of cancer including medical and surgical oncology.
It is a group of diseases and condition in which body's cells grow uncontrollably and spread to different body parts. There are trillions of cells within the human body following an orderly process which grow, multiply (undergo cell division) forms tissues and organs. The new cells replace the old and damaged cells. Any impairment during this normal process give rise to growth and multiplication of an abnormal or damaged cell and DNA changes leading to formation of lumps of tissue called tumor. Tumors are of two types cancerous (malignant) and non- cancerous (benign) then treatment is different depending upon the nature of tumor. Cancerous tumors invade into nearby tissues and can spread to distant sites in the body to from new cancer cells (metastasis). Benign tumors don't invade into nearby tissues and doesn't regrow when removed but some cases may be life threatening depending upon the location of tumor. Genetic factors, environmental factors, chemical carcinogens and a few drugs are contributing to formation of cancer.

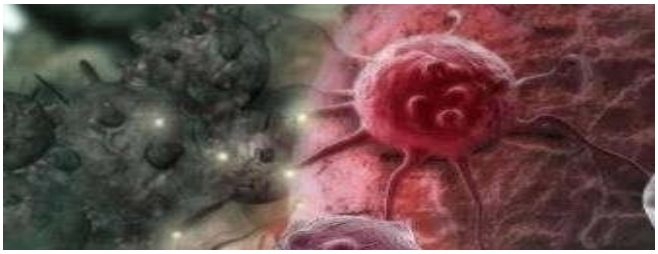

Fig 1: Cancer

ONCOGENES:

Proto oncogenes normally has the power to make the cells grow, divide and production of new cells. Any mutation to the normal cells leading to activation when it is not supposed to be, right at this point it is now an oncogene. Oncogene plays a crucial role in 15rench15son15 and induction of cancerous cell in the body. For example, oncogenes addiction may force cancer cells to depend on a certain metabolic pathway for

0 Growth.

TUMOR SUPRESSOR GENES

These are the normal genes having the ability to slow down the cell division process and any mutations can cause deregulation of cell signaling pathways (i.e., cells growing out of control causes cancer) eventually results in changes of gene expression. Tumor suppressor cells play crucial role in maintaining normalcy in cells, and mutation of those genes leads to classical condition that characterized cancer.

METASTASIS

Metastasis is an intricate process involving motion of cancerous cells from a localized region to distant organs which is the major complication in the cancer management contributing to deaths in patients of CRC as metastasis is usually from liver and others.

COLORECTAL CANCER

It develops in colon and rectum. It can be either called colon cancer or rectum cancer depending upon where it is initiated. Colon and rectum cancer are assembled together as it has common characteristics. Colon (large intestine) and rectum allows the passage connecting colon to anus. Polyps grows within the colon and rectum sometimes which may later on develop into cancers. Medical, surgical and radiation oncologists together plan the treatment schedules that varies individually to another depending upon the nature(benign/malignant) and size of tumour, stage of cancer, severity, location of tumour (colon/rectum/other), lymph nodes (present/absent) tailoring an appropriate regimen is important for better results. Regardless of numerous early diagnosis techniques late stage detection is common in colorectal cancer patients and poor prognosis is seen.

Fig 2: Colorectal Cancer

Colon is vital part of the body's gastrointestinal tract and together colon and rectum constitutes elimination of body's waste (1). There is 4-5% of probability of developing colorectal cancer which is often associated with personal habits, history, life style and other.

Types of Colorectal Cancer:

Adenocarcinoma, one among the prevalent cancer of colon and rectum which develops as cancer in cells lines inside tissues of rectum and colon.

Various other types develop very less often but benign in colorectalincudes (2)-

- gastrointestinal stromal tumour (GIST)
- neuroendocrine tumor of gastrointestinal tract
- small cell carcinoma
- lymphoma

METHODOLOGY STUDY DESIGN

This is a retrospective observational study evaluating safe and efficacious use of treatment among subjects confirmed with MCRC who underwent and undergoing cancer treatment within six months of the study.

Study site:

This study was carried out at CARE HOSPITALS, Hyderabad. Duration of study:

6 months Sample size:
109 cases of metastatic colorectal cancer were collected retrospectively. Study criteria:

INCLUSION CRITERIA:
- Male and female patients aged 18Y or above clinically confirmed with metastatic colorectal cancer.
- Subjects who already underwent and currently undergoing chemotherapeutic regimen.
- Subjects who are able to abide by the study protocol throughout the study, including treatment, visits, scheduled examinations and follow-up.
- Subjects willing and able to comply with all study requirements.

EXCLUSION CRITERIA
- Subjects with Psychiatric illness compromising understanding of information or completion of study.
- Inability to sign informed consent or to undergo medical follow-up of the study for social or psychological reasons.
- Pregnant (or) lactating women are excluded.
- All the subjects who were not compatible for inclusion in the study in the clinical judgment of the medical practitioner.

STUDY INSTRUMENTS:
Chemotherapy protocol forms MRI, PET CT Scan, ecog form, adr reports of patients Progress reports Patient medical records Previous medical records Laboratory investigations

STUDY PROCEDURE:
This study was carried out at the medical oncology department of the tertiary hospital and the needed data was extracted through medical record department of subjects diagnosed with metastatic colorectal cancer.

DATA COLLECTION:
Patient demographics:
- Age
- Sex
- Ethnicity
- Admission ID
- present chief complaints
- past medical history
- laboratory investigations
- previous MRI, CT, PET scan reports were collected.
- Chemotherapy regimen
- Chemo cycle number
- Ecog performance status form
- Adverse events form

GENDER WISE DISTRIBUTION

MALES	FEMALES
1	0
5	2
5	1
6	1
5	2
11	6
11	3
13	5

9	3
10	4
4	1
0	1
Total=80	29

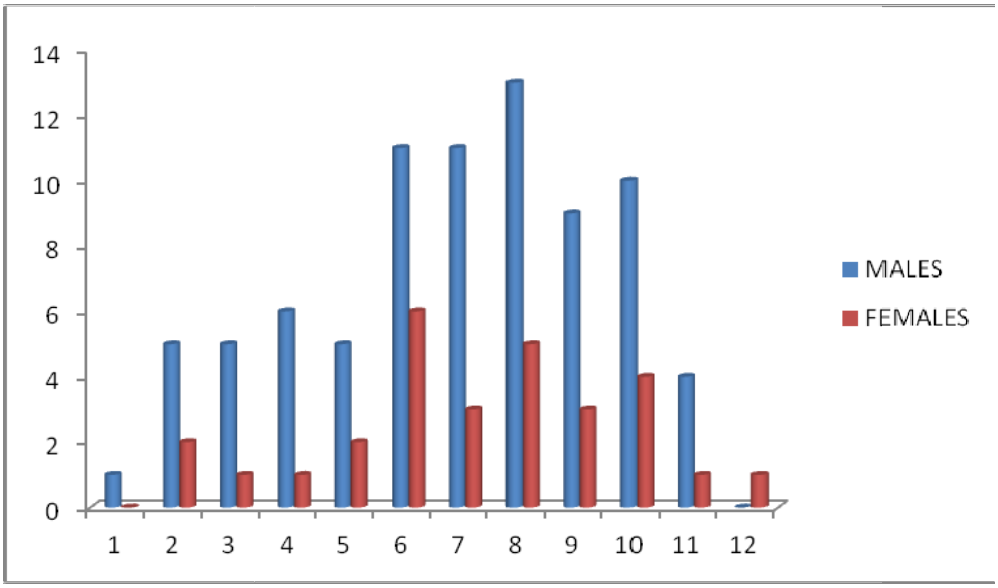

Fig 3: GENDER WISE DISTRIBUTION

Total no. of mcrc cases = 109 Males = 80 Females = 29

Age wise Distribution

Table 2: **Age wise Distribution**

A E GROUP	Total no. ofpatients
2 -25	1
2 -30	7
3 -35	6
3 -40	7
4 -45	7
4 -50	17
5 -55	14
5 -60	18
6 -65	12
6 -70	14
7 -75	5
7 -80	1
T tal=	109

1) Age wise distribution showing slight increase in number of cases with increase in age.
2) Age groups between 21 and 76 are being considered in the study.

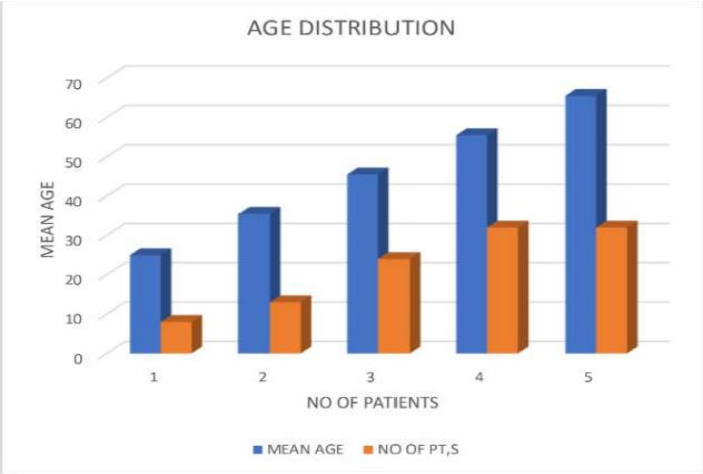

Fig 4: **Age wise distribution**

ADRs OF CHEMOHERAPEUTIC TREATMENT:

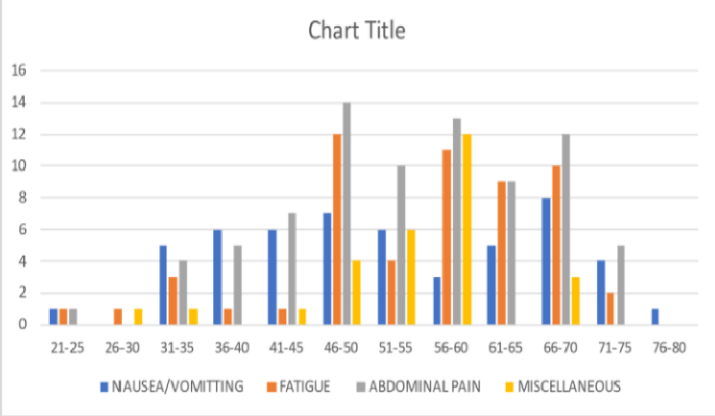

Fig 5: ADRs of Chemoherapeutic Treatment:

Adverse drug reactions of chemotherapeutic regimen showing most frequently occurred adrs among both males and females in this study which includes nausea/vomiting, fatigue, abdominal pain and miscellaneous seen mostly between the age group of 45-70Y during and after cycles of chemotherapy.

TREND OF TREATMENT AMONG CHEMOTHERAPEUTIC DRUG REGIMEN

capecitabine (capox), 5-fluorouracil & oxaliplatin (folfox), irinotecan & 5- (folfirinox). fluorouracil

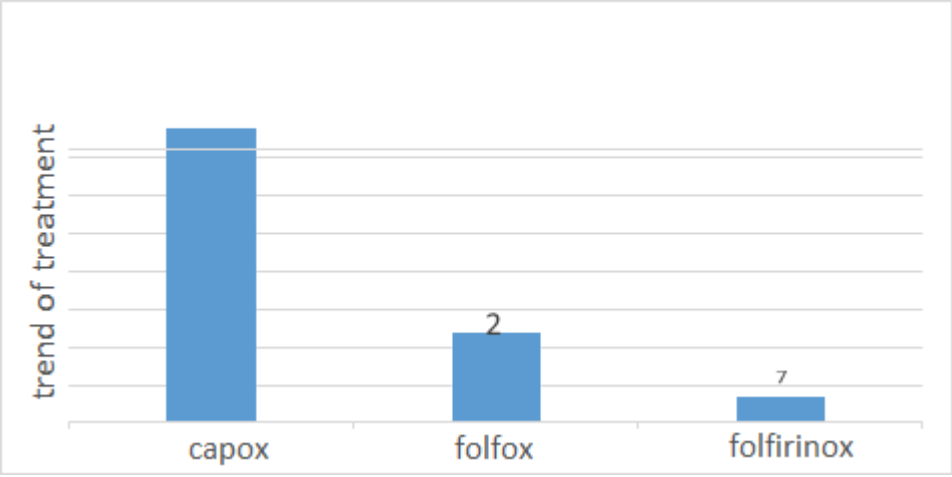

Fig 6: TREND OF TREATMENT AMONG CHEMOTHERAPEUTIC DRUG REGIMEN

The above graph illustrating that capecitabine (capox) is the mostly preferred chemotherapeutic drug regimen i.e., 78 among mcrc patients and leading the trend of treatment followed by 5- fluorouracil & oxaliplatin

(folfox) and the least irinotecan, 5-fluorouracil & oxaliplatin (folfirinox).

Table 3: T-TEST SHOWING MOREMALE SUBJECTS WITH MCRC AMONG 80 MALES AND 29 FEMALES.

X1	X2	$X1^2$	$X2^2$
1	0	1	0
5	2	25	4
5	1	25	1
6	1	36	1
5	2	25	4
11	6	121	36
11	3	121	9
13	5	169	23
9	3	91	9
10	4	100	16
4	1	16	1

0	1	0	1
X1=80	X2=29	$X1^2$ =720	$X2^2$ =107

Table 4: 2) KRUSKAL WALLIS TEST FOR RESPONSE USING RECIST 1.1

CR	PR	PD	SD
7	7	16.5	7
7	2.3	16.5	7
7	2.3	2.3	7
7	29.6	2.3	7
7	29.6	29.5	7
7	26.5	29.5	16.5
7	39	34	16.5
16.5	41.5	34	23
16.5	41.5	36.5	23
23	43	39	29.5
32	44	39	29.5
Total=139	357.5	320.5	173

$$H = \frac{12}{N(N+1)}\left(\sum_{i=1}^{k}\frac{R_i^2}{n_i}\right) - 3(N+1)$$

N= Total number of observations in all columns.K= Number of columns/variables.
R= Sum of ranks in the columns.R_1= Sum of ranks in 1st column.
R_2= Sum of ranks in 2nd column.R_3= Sum of ranks in 3rdcolumn. R_4= Sum of ranks in 4th column.
N_1= Number of observations in the 1stcolumn.N_2= Number of observations in the 2ndcolumn.N_3= Number of observations in the 3rdcolumn.N_4= Number of observations in the 4thcolumn.

DISCUSSION

- The experimental drugs mostly used as an effective chemo regimen are
- Capox, Folfox, Folfirinox and Bevacizumab is the drug combined with other regimen as a maintenance therapy.
- capecitabine and oxaliplatin (capox) had shown better outcomes in MCRC patients and known to be more efficacious when compared to other chemotherapeutic regimens.
- The folfox regimen has been compared in large observational studies with Capox regimen were priorly carried out on untreated patients with active malignancies for its efficacy and safety.
- Patients who underwent and undergoing chemotherapy are suffering minor to major adverse effects of the therapy and a compromised immune system and are known to be more prone to capture other

diseases.

- The incidences of the side effects are reported in the first and second cycle of chemo.
- Types of chemotherapy used for MCRC patients are Adjuvant therapy, palliative therapy, maintenance therapy and radiation therapy.

CONCLUSION

- In the last few years, colorectal cancer is the significant cause of death but preventable if diagnosed in early stages and chemotherapy improves the survival of patients. The incidence of colorectal cancer was higher in male than female.
- The risk factor like diet rich in high fat has no evidence for colorectal cancer.
- In this study 109 cases are recorded with 80 males and 29 females.
- Higher incidence of this disease was found in middle aged and above. In the last few years, adult age patients are also reported between age groups from (25-35).
- Among MCRC male and female patients the study shows that vomiting, nausea, fatigue and diarrhea reported more in male 80 cases than female 29 cases out of total 109 cases along with patient specific treatment response where the partial response of the therapeutic regimen was largely noted.
- ECOG status of mcrc patients was likely seen to be around 0-3 which is from active status to restricted activity status during and post chemotherapy.
- 2^{nd} and 3^{rd} grade toxicity was noted with most frequently occurring effects of therapy pertaining from nausea, vomiting, abdominal pain to miscellaneous.
- Surgery is the main procedure for colorectal cancer which is palliative, curative and more efficient either alone or in combination.
- The patient of middle age and elderly age presented with bleeding and altered bowel should be investigated with Sigmoidoscopy, CT-MRI and PET scan and patients with advanced stage having poor prognosis
- This study aims to identify adverse drug reaction like nausea, vomiting, fatigue, and safety and efficacy of chemotherapeutic agents along with pharmacist intervention.
- Hence patient must be educated about symptoms and etiology of disease and malignancies along with early diagnosis and routine investigations awareness should be made for prevention of late stage complications and better patient care.

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