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Patients' reports of chemotherapy adverse reactions in regular medical treatment: A Cohort research of prevalence and severity

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ABSTRACT

Background: Despite frequently reporting these problems in clinical studies, there needs to be more data on the Frequency (F) of adverse effects of chemotherapy under regular clinical care.

Aim: This study aimed to outline how frequently and severely patients at treatment facilities in India reported experiencing side effects from chemotherapy during routine visits.

Materials and Method: We performed prospective cohort research on people receiving lung, breast, or colorectal cancer chemotherapy. The side effects such patient's encountered move reported through patients. For dividing a side effects' frequency, occurrence and incidence rates on kind and severity of each malignancy, cumulative incidence curves for each adverse outcome were generated. Secondary impact analysis using chi-squared statistics frequency was examined across demographic categories.

Result and Conclusion: Side effect information remains available for eligible patients with a 5.7 2-months median follow-up. During the trial period, 87% of individuals had at least one adverse effect and 28% of them, most frequently tired, experienced a grade IV side effect. Constipation (76%), diarrhea (75%) and fatigue (86%) were the most prevalent adverse effects overall 459. Different cancer types and side effects have comparable prevalence and incidence rates. Older adults are less likely to report age was only demographic and adverse impact characteristics linked to occurrence of side effects. The findings of this study are the first self-reported frequency of adverse effects from chemotherapy in standard clinical treatment to be estimated in India. Treatment side effects are frequent, persistent during treatment and even life-threatening in regular care. This study supports the idea that observational data are crucial for giving decision-makers information that is pertinent to clinical practice.

Keywords: chemotherapy, breast cancer, lung cancer, chi-squared statistics, cohort

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INTRODUCTION

Radical surgery and chemotherapy with platinum and taxane-based agents are used as first-line treatments. The majority of patients have side effects from their treatments, which can include cognitive impairment, anxiety, depression, and physical signs such as nausea, vomiting, hair loss, exhaustion, also peripheral neuropathy. Some of these could last after treatment and impact long-term quality of life [1]. Neo Adjuvant Chemotherapy (NAC) is followed by Pre-Radical Cystectomy (pre-RC), a primary curative therapy for Muscle Invasive Bladder Cancer (MIBC) for medically healthy patients. When chemo tolerance is anticipated to be improved before RC, its goal is to remove systemic micro-metastatic illness [2].

Clinical trials at present concentrate on combinations of death-ligand 1(PD-L1) inhibitors and randomized clinical studies showed increased overall survival and progression-free survival [3]. There hasn't been much study about its status, chemotherapy tolerance, and effectiveness in individuals with diabetes. Diabetic individuals appear to be more susceptible to Adverse Events (AEs), according to reports of colorectal cancer. Due to their possible comorbidities, individuals with diabetes can experience more chemotherapy-related Adverse Events (AEs) and experience treatment delays, which might result in less effective cancer treatment [4]. Among those with metastatic cancer, Chemotherapy (CT) can be administered during the maintenance phase, after the surgical treatment, before or after a surgical procedure (adjuvant CT), or even in a comforting setting. Xerostomia, dysphagia, dysosmia, dysgeusia, fatigue, nausea, vomiting, anorexia, and diarrhea are common adverse effects of CT. Different definitions of dysgeusia include a strange or compromised perception of taste, a disagreeable change in taste experience, and perversion or distortion of the sense of taste [5].

With better screening and advancements in chemotherapy, the death rate has fallen over time. As a result, less harsh therapies like breast-conserving surgery are made possible by neoadjuvant chemotherapy. Unfortunately, there are several side effects linked with chemotherapy. Chemotherapy-related peripheral neuropathy is particularly intriguing. According to an experimental model, chemotherapy medicines impact autonomic nervous system neurons [6]. Chemotherapy only provides small overall survival advantages for most familiar solid tumors at metastatic stages. The most significant therapeutic benefit of chemotherapy is diminished by its toxicity and developed

resistance. In recent years, Immune Checkpoint Inhibitors (ICIs), combined with chemotherapy, have entirely changed how several advanced cancers are treated [7].

Surgery, radiation, chemotherapy, and immunotherapy are cancer treatment's 4 primary therapeutic modalities. It is vital to note that chemotherapy is given to 2/3 of neoplasm patients at some time throughout their treatment to eradicate tumor cells. Although technological advancements enable increasingly tailored treatments, chemotherapy-free difficulty also has unfavorable consequences affecting other body sections [8]. Chemotherapeutic-Induced Peripheral Neuropathy (CIPN) is a prevalent and difficult side effect of several widely used chemotherapy medications. The growth of CIPN can lead to extended infusion durations, dose decreases, or an early conclusion to chemotherapy, all of which can have a negative impact on the survival of patients and treatment efficacy. A meta-analysis that combines cohort studies and randomized controlled trials revealed that almost half of all patients have CIPN while undergoing therapy [9].

Chemotherapy is a medical procedure that destroys cancer cells by administering anti-cancer medications. Chemotherapy has many side effects and disadvantages, in addition to its potential for curing cancer. The following are a few of the most frequent side effects of chemotherapy: Chemotherapy medications can produce nausea and vomiting, which might be so severe as to call for anti-nausea medicine. Extreme weariness and weakness brought by chemotherapy might interfere with everyday activities and quality of life [10]. The Ketogenic Diet's (KD) ability to suppress appetite, half of patients should follow a KD for six days before each modified Short-term Fasting (mSTF) phase. At each treatment, toxicities brought by the chemotherapy, pain from fasting, body composition, lifestyle, test findings, and compliance were evaluated [11].

Related works

Paper evaluated risk factors for dose modification, Adverse Events (AEs) and severe chemotherapy-related damage in elderly cancer patients [12]. The paper investigated the effectiveness of individuals with bladder cancer that is Not Muscle-Invasive Bladder Cancer (NMIBC) and Bacillus Calmette-Guérin (BCG) resistance using Hyper-thermic Intra-VEsical Chemotherapy (HIVEC) [13]. Paper observed patients obtaining self-assess of routine adjuvant chemotherapy for functional breast cancer, and assessed the severity of Treatment-Related Side Effects (TSEs) using a survey based on the National Cancer Center's Common Terminology Criteria for Adverse Events (CTCAE) v4.0 [14]. Paper assessed whether all levels of cumulative toxicity, including Adverse Events (AEs), are more indicative of patient Quality of Life (QOL); individuals with colorectal cancer that has spread should receive first-line chemotherapy rather than the cumulative toxicity caused by high-grade AEs [15].

Paper examined risk variables for Cisplatin (CP)-induced nephrotoxicity following Hyperthermic Intraperitoneal Chemotherapy (HIPEC) [16]. Paper investigated a way that all distinct regimens based on docetaxel and long-term effects on patient features Peripheral Neuropathy (PN) patient-reported outcomes and the effect of PN on long-lasting Quality of Life (QOL) [17]. The paper investigated a current situation about Chemotherapy-Induced Nausea and Vomiting (CINV) using an anticipated multicenter cohort study [18]. Paper included patient without a breast cancer history of disease or chemotherapy, goal was to determine a frequency about taste changes after Epirubicin and Cyclophosphamide (EC) treatment [19]. Paper examined instances in advanced colorectal cancer patients that underwent first-line systemic chemotherapy and a correlation Overall Survival (OS) or toxicity and cancer cachexia [20]. Paper investigated an association between breast cancer patients' quality of life in terms of health and adverse effects of chemotherapy [21].

Breast cancer patients were enrolled into retrospective cohort research and data on chemotherapy dosage reductions or interruptions and side effects were gathered [22]. Paper discussed variables that could increase the incidence pericardial effusion in patients with esophageal cancer getting definitive concurrent chemotherapy and Intensity Modulated Radiotherapy (IMRT) [23]. Paper investigated a Permanent Chemotherapy-Induced Alopecia (PCIA) in a cohort of breast cancer patients: long-term incidence hair density and volume was assessed before treatment [24].

Paper suggested Supportive Care Medications (SCMs). The regularity of need-based SCMs, trips to neighborhood doctors, also hospitalizations (if any) during an inter-cycle period were also noted by the patients [25]. The study investigated the prediction of chemotherapy side effects and death in older patients with primary lung cancer using a pre-chemotherapy frailty assessment according to common laboratory results [26]. Paper investigated a connection between clinicopathological factors and a dysphagia score at diagnosis, such as adverse events associated with Docetaxel, Cisplatin and 5-Fluorouracil (DCF) treatment, tumor response coupled with the survival [27]. Chemotherapy based on cisplatin frequently has ototoxicity as a side effect. However, there aren't many studies evaluating its incidence in groups with clearly identified risk factors [28]. Paper examined prevalence of Weight Loss (WL) and connection among WL and adverse events or Overall Survival (OS) [29]. The paper compared the efficacy of intense chemotherapy alone with intensive chemotherapy in combination with venetoclax [30].

MATERIALS AND METHODS

The cancer care elements research

Research design has been discussed as an Element of Cancer Care (EOCC), a nutshell project following patients with Non-Small Cell Lung Cancer (NSCLC), undergoing chemotherapy, breast and colorectal cancer, which are other kinds of cancer. It used data interviews, connected administrative data along with medical and chemotherapy records. Patients were included in research of 12 cancer treatment centers in India, which represented urban and rural areas as well as public and private hospital systems. Patients were to be at least 18 years old and literate in English orally and in writing. To be eligible, one must not participate in a clinical trial and be able to give informed permission.

Every study field worker trained to conduct a research interview performed monthly patient interviews and evaluations of medical records as important data collecting methods. Data were gathered on various parameters, including the treatment of cancer, use of healthcare services, socioeconomic position and alternative therapies. When chemotherapy was stopped without being restarted within 30 days, a patient withdrew but data collection

and follow-up continued. Unless one of the requirements above was satisfied, interviews continued for another 6 months following hiring. Although a lot of primary data were gathered, only data points mainly related to side effects are used in this research. Participants were asked about side effects monthly face-to-face and if they had ever suffered nausea, diarrhea, or chest discomfort. These adverse effects were chosen because they are typical ones associated with chemotherapy and can be usefully described from a patient's perspective. The quality-of-life tool recorded depression and anxiety; these findings have been published elsewhere. Version 4 of the National Cancer Institute (NCI) Common Toxicity Criteria was translated into simple English structured questions and gave a list of harmful consequences with illustrations for each grade. There is evidence that modified Common Toxicity Criteria for patient completion produce ratings consistent with those supplied by their doctors, despite a fact that instrument still needs to be fully validated. The patient signed informed permission acquired through in-person interviews with research field staff. The primary data collection was authorized. Each of participating centers provided site-specific permissions.

Analysis

The entire sample and each form of cancer underwent analysis. The number of sample patients and participants provided information about each selected adverse any grade and at least once during their academic career follow-up duration were used to calculate the total frequency of adverse reactions. The prevalence obtained was established by considering the percentage of visits during each listed negative consequence. The frequency rate of adverse reactions was determined by dividing every number of people encountered for selected adverse effects by a total follow-up period of person months. After having discovered a particular side effect, they were censored. Using a lowest possible rating for each adverse consequence a person encountered during an observation period, side effects frequency by grade was determined. This aligns with how adverse effects are frequently described in medical trial literature.

Cancer type was classified using chi-squared tests of independence and frequency of side effects was compared among sociodemographic subgroups for age, gender, amount of education, social standing, and cancer stage. Each side effect's cumulative incidence curve per grade was graphed to show trends. Considering the length of follow-up, the likelihood of noticing a side effect at that grade was determined using Statistical Analysis System (SAS) version 9.4's Cumulative Incidence (CUMINCID) macro.

RESULTS

Statistical information and medical characteristics

The demographic, cancer and treatment information on 486 eligible participants recruited to EOCC research has already been published. Incomplete or missing data were present for remaining 450 people, who had side effect information accessible for 450 of them. There were, on average, 15% fewer visits missed among 450 people. Individuals had 3 interviews, median duration between interviews was 38 days and median overall follow-up period was 5.72 months. The group for which data on side effects were available is described in table 1 by its clinical and demographic characteristics.

The participants were mostly over 50 years old and there were more women than men. Around half of the sample had metastatic disease and more than 50% had breast cancer.

Tab. 1. Elements of cancer care cohort demographic and clinical characteristics

Demographic	Colorectal Cancer(n=146)	Breast Cancer(n=245)	Lung Cancer(n=59)	Total(n=450)
Gender F (%)				
Male	88(60.2)	4 (2.0)	28(46.4)	120(26.6)
Female	58(39.7)	241 (98.3)	31(52.5)	330(73.3)
Age Group (years)				
<45	10(6.8)	44(17.9)	1(1.6)	55(12.2)
46–65	72(49.3)	155(63.2)	30(50.8)	257(57.1)
66+	60(41.1)	37(15.1)	27(45.7)	124(27.5)
Missing	4	9	1	14
Socio-Economic is an Advantage				
High	15(10.1)	25(10.2)	13(22)	53(11.7)
Moderate	50(34.2)	73(29.6)	20(33.8)	143(31.8)
Low	80(54.7)	146(59.5)	26(44)	252(56)
Missing	1	1	0	2
Higher Education				
No	47(32.1)	57(23.2)	23 (38.9)	127(28.2)
Yes	83(56.8)	143(58.3)	26(44.1)	252(56)
Missing	16	45	10	71
Stage of Cancer				
Stage I	0	23(9.3)	5(8.4)	28(6.2)

Stage II	8(5.4)	80(32.6)	3(5.1)	91(20.2)
Stage III	41(28.1)	42(17.1)	15(25.4)	98(21.7)
Stage IV	97(66.4)	100(40.8)	36(61)	233(51.7)

Side effects' frequency, occurrence, and prevalence

Table 2 displays the frequency and prevalence of each adverse event that occurred throughout the data-collecting period. Almost all patients (87%) had at least one side effect; this was the case for all disease categories (87% for colorectal cancer, 80% for NSCL, and 84% for breast cancer). 11% of individuals overall indicated a maximum of three adverse effects and 11% of them reported up to five adverse effects and throughout the research, 68% of participants experienced at least 6 adverse effects. This trend held true throughout all cancer types (10%, 6%, and 68% for breast cancer, 10%, 17%, 60% for colorectal cancer, and 10%, 6%, 64% for NSCL cancer).

Tab. 2. Side effects that patients have self-reported for first time while undergoing treatment

	NSCL Cancer		Colorectal Cancer		Breast Cancer		Overall		p-value†
Side Effect	Frequency (%)	Incidence Rate	Frequency (%)	Incidence Rate	Frequency (%)	Incidence Rate	Frequency (%)	Incidence Rate	
Any side effect	47(80)	-	128 (87)	-	206 (84)	-	382 (87)	-	0.45
Constipation	42(71)	0.51	105 (72)	0.45	186 (76)	0.52	337 (75)	0.55	0.72
Dyspnea	41(70)	0.47	101 (69)	0.39	178 (73)	0.48	325 (72)	0.47	0.84
Chest pain	11 (19)	0.09	18 (12)	0.05	28 (11)	0.07	58 (13)	0.05	0.54
Diarrhea	42 (71)	0.51	109 (75)	0.47	182 (74)	0.51	339 (75)	0.53	0.87
Mucositis	42 (71)	0.46	103 (71)	0.44	178 (73)	0.47	325 (72)	0.5	0.92
Fatigue	50(85)	0.81	124 (85)	0.85	202 (82)	0.82	388 (86)	0.82	0.33
Rash	42 (71)	0.51	94(64)	0.36	183 (75)	0.52	324 (72)	0.48	0.15
Pain	45 (76)	0.55	111 (76)	0.46	181 (74)	0.56	343 (76)	0.52	0.78
Vomiting	38 (64)	0.11	84 (58)	0.29	164 (67)	0.43	288 (64)	0.39	0.23
Anemia†	46 (77.9)	0.62	120 (82.1)	0.32	188(76.7)	0.62	354 (78.6)	0.56	0.25

Incidence rates for all events were 0.24 per person every follow-up month (0.24 for breast, 0.23 for colorectal and 0.25 for NSCL). The incidence of adverse effects did not vary substantially throughout cancer types. With the exception of vomiting and chest discomfort, at least 71% of subjects reported experiencing some degree of each side effect. The most frequently reported adverse effect (87%) was tiredness, which also had the greatest incidence rate 82 people reporting fatigue for every 100 people who had not previously reported fatigue during the subsequent month. In general, 56% of sample had side symptoms. The prevalence was equal across all cancer types, with chest discomfort having a lower majority and exhaustion having highest rates. For information, view figure 1.

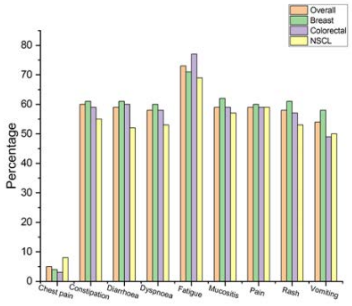

Fig. 1. Self-reported side effect frequency across cancer categories from the essentials of cancer treatment time frame

Chi-square analysis of any negative impact during a time of demographic characteristics failed to show a socioeconomic disadvantage (p=0.49), gender (p=0.12) and education (p=0.60) all have significant relationships. They were insufficient samples to evaluate whether education and a place of birth were related to adverse consequences. When their malignancy was considered, older people reported fewer side effects before (p=0.014) and after (p=0.020).

Adverse effects' magnitude and general frequency

The majority of adverse effects, as shown in table 3, had been Grade I or Grade II and fewer reports of more serious problems were received. The few exemptions to this rule include fatigue, pain and dyspnoea, when Grade (G) III or IV occurrences happen more often. Overall, most common adverse effect grade was moderate (grade (G) I or II) for 25% of individuals, sensible for (grade (G) III) 36% and (Grade (G) IV) severe for 28% of people. These findings are only shown for combined cohorts since they weren't discernible variations of unfavorable effects by kind and Frequency (F) of malignancy.

Tab. 3. During the elements of the cancer care research period, self-reported side effects received the worst rating

Trial (t)	G -0		G -I		G -II		G - III		G - IV	
Side effect	F (%)		F (%)		F (%)		F (%)		F (%)	
Diarrhea	120	27	210	47	101	22	23	5	7	2
Fatigue	70	16	53	12	96	21	166	37	74	16
Chest pain	397	88	36	8	18	4	6	1	2	0
Mucositis	131	29	186	41	94	21	42	9	6	1
Constipation	120	27	180	40	113	25	33	7	13	3
Dyspnoea	131	29	179	`40	62	14	51	11	35	8
Pain	113	25	159	35	68	15	84	19	35	8
Vomiting	168	37	201	45	36	8	22	5	6	1
Rash	133	30	227	50	72	16	46	10	7	2

Figure 2 shows cumulative frequency of each adverse consequence about six months following an initial interview. The six-month graph's apparent increase is caused by a lower percentage of individuals that received all 6 months of follow-up. These findings solely apply to this combined cohort because neither existed discernible variations in frequency of adverse cancer-type impacts. Fatigue has most significant cumulative incidence, whereas chest discomfort has most minor. Vomiting and diarrhea are noticeable, as a considerable number of grade one incidents but comparatively a few more grave incidents, although weariness was widespread at each stage throughout time.

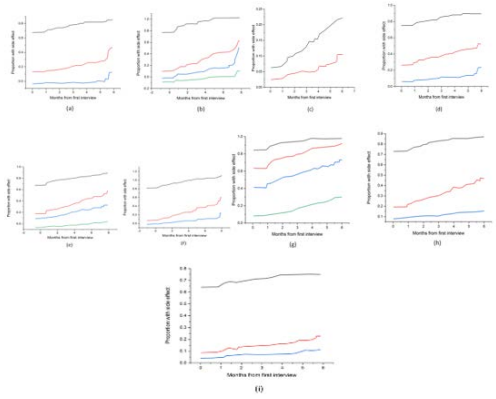

Fig. 2. Self-reported adverse events cumulatively documented over trial phase for cancer care components; **(a)** Diarrhoea, **(b)** Dyspnoea, **(c)** Chest pain, **(d)** Constipation, **(e)** Pain, **(f)** Rash, **(g)** Fatigue, **(h)** Mucositis, **(i)** Vomiting

DISCUSSION

Results in context

In a clinical practice setting, as opposed to a clinical trial, this study calculates a prevalence of typical chemotherapy side effects. In an initial survey of its kind to be conducted in India, we find that more than 26% of persons receiving several adverse side effects will occur as a result of chemotherapy, also more than 61% of these side effects be significant (grade III or IV). These statistics provide insight into side-effect patterns seen throughout chemotherapy by displaying cumulative incidence. Many persons experienced moderate adverse symptoms such as vomiting, mucositis, diarrhea and constipation throughout a follow-up period. A disproportionately large number of participants also experienced severe exhaustion.

These studies have also examined specific chemotherapy regimens. The length of follow-up varies between researches, making it challenging to contrast their rate of some adverse effects with those found in earlier investigations. Within five days of receiving highly or moderately emetogenic chemotherapy, 36.6% of patients reported experiencing nausea and vomiting, according to community research on chemotherapy-related side effects, although reveals that 65% of patients suffer nausea and vomiting at some time throughout a mean of 5.72 months were monitored after therapy. Every more significant incidence effect in long-term findings might suggest that many patients have side effects that lingered after chemotherapy. For specific individuals, after a few months of treatment, these adverse effects start to become apparent. Only a tiny percentage of people experience significant adverse effects, emphasizing its observing side effects is essential during therapy. Every decreased number of those underwent all 6 months of follow-up is to blame for any apparent spikes in cumulative incidence is shown in figure 2. Therefore, caution should be used when interpreting findings from later months.

The approach used to gather self-reported side effects can also be

blamed as a discrepancy between this study's and prior research's incidence of adverse effects. That is proof that a patient claims damaging property agrees with doctor evaluations, but there is additional proof that time and methodology used to gather side effect data might have an impact on the final findings. In contrast to being asked open-ended questions, participants' instances of each negative consequence on level were provided, inspiring participants to report side effects that were both more varied and less severe. A "Patient Reported Outcomes (PRO) Version of a CTCAE (PRO-CTCAE) is a recently improved patient version of a CTCAE that offers a verified method as gathering patient reports of toxicities during therapy that is currently available and can be used in future studies.

Because trial participants tend to be healthier and younger than average patients encountered in clinical practice, they could be physically more capable of handling chemotherapy, making them less likely to experience side effects. Additionally, most clinical trials are conducted at sizable, top-notch teaching hospitals where best-practice side effect management, monitoring and follow-up unique to an investigation will reduce the rate and severity of any adverse effects. However, findings indicate that younger patients were more inclined to have negative outcomes therefore, was not taken into account. This might mean that elderly individuals often receive fewer chemotherapy dosages in clinical settings, avoiding side effects but perhaps at expense of therapeutic efficacy.

Additionally, policymakers frequently decide for the entire population. Even though the study's tiny sample size emphasizes the significance of empirical data's higher external validity than clinical trials, yet it is not large enough to directly impact national strategy and accuracy compared to administrative data. Observational information collection takes a lot of time and resources. Even though it is not practical to conduct an observational study for every economic evaluation, execution of sizable, carefully planned, prospective observational studies with requirements about decision-makers along with modelers might benefit financial models and health policy decision choices.

Possibilities and constraints

Indians with cancer were part of observational research conducted in this very sizable, prospectively planned research; instead of focusing on particular chemotherapeutic protocols used in previous literature, it looked at side effects seen across a variety of malignancies. However, the few people with NSCLC in the sample that could have distinct adverse effects seen by people with colorectal and breast cancer limit the generalization of these findings. Additionally, humans cannot distinguish between those participating in a program for hospice care. Likewise, individuals with different forms of cancer could undergo alternative forms of chemotherapy as part of a documented palliative care program. They cannot identify what percentage of these adverse effects may not be attributable to chemotherapy without a cancer-free control group with cancer but no chemotherapy. For instance, specific cancer-related symptoms could have been misdiagnosed as chemotherapeutic side effects. Additionally, more prevalent in elderly persons, fatigue and constipation may not be connected to therapy.

The fact it is uncertain that treating professionals would react to reported adverse effects is another drawback. While some of negative effects that were reported could have been handled, others might have gone unreported. These changes could have led to persistent side effect experiences that differed from those recorded in current research. Additionally, participant replies probably contained memory bias due to monthly intervals of retrospective self-reporting of adverse effects. In the future, it would be beneficial to do more extensive, country-wide, prospective, observational research on individuals with a wider variety of malignancies and investigate alternate ways of reporting side effects.

CONCLUSION

The frequency of side effects that chemotherapy patients in a specific environment experience of standard medical treatment as opposed to a clinical trial is estimated in this research, adding to a body of literature. By examining a variety of malignancies and treatment plans, it outperforms earlier research in this regard. Among those in this group, 61% had less than one major negative outcome and most suffered several negative effects. Many individuals continually had moderate side effects throughout the therapy time recorded in study. Both physicians and policymakers can benefit from this knowledge since they frequently base judgments about financing and treatment for accepted practices on clinical research that may not be accurate. This research also underlines the value of using observational, supplying decision-makers with data, with information pertinent to a clinical practice setting and it reinforces the necessity of collecting side effects through patient-reported techniques and monitoring them during chemotherapy care.

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