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Original Article

Learning from Errors and Mishaps: An Audit of Hospital Morbidity Events from a Medical Oncology Unit

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Abstract

Introduction Morbidity, an unwanted and often preventable event, is an integral part of cancer treatment. Various morbidity events can contribute to significant toxicities and delay treatment. We intend to describe a novel morbidity data collection methodology to identify all possible morbidity events, learn from mishaps, and improve internal standards to prevent future occurrences.

Objective This article aims to understand the various morbidity events occurring during chemotherapy among patients undergoing treatment in the medical oncology unit.

Materials and Methods Data were collected from January 2019 to March 2020 from the department of medical oncology of a tertiary cancer center. The treating team notified the morbidity events via a closed WhatsApp group. These events were prospectively recorded by a nurse who updated various events from all work areas in a defined Excel sheet.

Results A total of 2,551 patients were registered for treatment from January 2019 to March 2020. A total of 864 morbidity events were recorded: 423 (48%) catheter-related events, 54 (6%) medical errors, 45 (5%) transfusion reactions, 210 (25%) miscellaneous morbidity events, and 31 (3%) unknown events. The median age was 26 years (1–70), with the majority of the events seen among adolescent young adult patients, 422 (48.9%). Catheter-related events were found in the majority, with central line–associated bloodstream infection being one of the significant causes of morbidity and catheter removal (13.3%). Hence, a catheter maintenance team was introduced. Catheter maintenance was successful in 36.8% (117/426).

Conclusion A structured, uniform, and prospective record of the morbidity events during treatment is essential to understanding errors, which can provide an opportunity to rectify future events. The periodic audit of events can help in establishing standardized operating procedures to minimize error and maximize safety.

Keywords
- morbidity
- chemotherapy-related toxicity
- central line-associated bloodstream infection
- transfusion reaction

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Key message Morbidity event definitions and recognition plus reporting are essential to understand and prevent future events.

1. **What is already known:** Mishaps and side effects occur concurrently with any patient care or treatment.
2. **What this study adds:** Novel method of data collection and reporting from all key areas of work, uniform definitions, and systematic categorization of events with emphasis on near and never miss events.
3. **How this study might affect research practice or policy:** Will enlighten on the major morbidity events possible and ways to prevent. Important teamwork and novel data collection methodology.

Introduction

Morbidity is "an untoward event or complication, which, under optimal conditions, is not a natural consequence of the patient's disease or treatment."[1] From the time cancer is diagnosed, patients are exposed to various chemotherapy drugs, supportive care medication, and transfusions, which are associated with multiple morbidities ranging from an anaphylactic or allergic reaction to prescription, dispersion, or administration error. To deliver chemotherapy and supportive care medications, patients might need a central venous catheter (CVC), which can be a source of immediate- or long-term complications. Before 2019, the morbidity events at our hospital were captured in the case files of individual patients and the respective ward records. This recording system used to be limited to the knowledge of only the treating or duty doctor at the time of the event. A structured format and uniform definition of event reporting were lacking. We formulated an internal standard proforma for reporting events, and with the latest technology, reporting events instantly was possible, reducing recall bias of the traditional event records. Treatment-related morbidity, preventable in certain circumstances, is an unseen yet significant cause of treatment interruptions or delays. Hence, this study highlights the various sources of morbidity among patients undergoing chemotherapy in the medical oncology unit in a tertiary-care center using the new internal standard format followed at our institution.

Materials and Methods

Data sources: Data were collected from the morbidity records from January 2019 to March 2020. These morbidity records were in Excel format and were prospectively maintained by a chemotherapy nurse and a minor operating theatre (OT) nurse, who regularly updated all the events recorded in various areas in a defined proforma.

On a daily basis, the nurse sought reports of morbidity events in the following categories encountered by the treating team. A reminder in the WhatsApp group was sought by the nurse designated for this purpose. The medical team of doctors and nurses updates events that occur. Minor OT and chemotherapy nurses maintained separate Excel sheets of events in their respective work areas. Minor OT procedure-related events and CVC-related events were recorded by a minor OT nurse and all other morbidities by a chemotherapy nurse. Both the Excel sheets of events were supervised and corrected by the physician in charge. The nurse weekly collates these, which were discussed in a department meeting. The number of patients admitted, patients undergoing chemotherapy, and the type and number of chemotherapies used from all the wards and daycare were recorded monthly.

Definition, classification, and methodology of data collection of morbidity events: For precise reporting of events, we divided morbidity into five broad headings: medication error, catheter-related, blood transfusion-related, drug-related, and miscellaneous events.

1. **Medication error**: Includes prescription, administration, and omission errors.
   Standard operating procedure for chemotherapy administration at our center: The Department of Medical Oncology has a daycare center with 12 beds and an inpatient unit of 20 beds. The daycare unit functions from 9:00 AM to 8:00 PM on weekdays and 9:00 AM to 1:00 PM on weekends and holidays. Around 30 to 40 patients were daily administered chemotherapy and other adjuvant drugs like antiemetics, antibiotics, or blood transfusions. The oncologist prescribed chemotherapy prescriptions and administration orders in a prestructured printed template with details of medication, dosage, premedication, method of administration, and time required to administer. The patients visit the pharmacy with the prescription, and the pharmacist receives the prescribed drugs. The prescription order was then submitted to the staff nurse at the daycare. The nurse administers the medications as instructed in the structured template. In the inpatient ward, the duty doctor prescribed and administered the medications.
   Identification of errors: During the process of chemotherapy prescription, dispersion, and administration, any identified error or reaction was noted in the morbidity diary with defined proforma (patient hospital number, age, diagnosis, chemotherapy protocol, name of the drug, dose, time and date of the event, treatment given at the time of the event). The same was updated in the department morbidity WhatsApp group, which was then entered into morbidity Excel weekly. The morbidity Excel was updated every week with the described events.
   Near-miss event was an incident that might have resulted in harm, but the problem did not reach the patient because of timely intervention by healthcare providers, the patient, or the patient's family. We defined certain

near-miss events to identify them cautiously, which are as follows:

- Administration of chemotherapy to the wrong patient.
- Wrong route and duration of chemotherapy administration.
- Omission of leucovorin rescue after high-dose methotrexate or mesna after ifosfamide.
- Maladministration of potassium infusion.
- Mismatched blood transfusion.
- Failure to monitor vitals among patients on chemotherapy, critically ill, or during transfusion.

Never event was a serious incident entirely preventable because safety recommendations provide a solid protective barrier

2. **Catheter-related events**: Early complications related to the catheter were defined as any event within the first week after CVC insertion.[2] Mechanical complications included failure of insertion, placement in the wrong vein, arterial puncture, hematoma, dislocation or obstruction, and accidental removal.[3] Central line–associated bloodstream infection (CLABSI) was defined according to the Centers for Disease Control and Prevention (CDC) criteria as culture-proven infection at least after 2 days of catheter use or the difference in time to positivity between central and peripherally drawn culture of more than 2 hours or more than three times the colony count of the mainline drawn blood sample compared to peripheral line.[4] Suspected infection was defined as unexplained fever among patients with CVC with no other evident focus of infection.[4] CVC-related thrombus was defined as any deep venous thrombus in the vein where the catheter was placed, visualized by ultrasound Doppler in a patient with symptoms suspicious of thrombus.[3]
   The minor OT nurse recorded the procedure date, type of CVC used, site of insertion, and any immediate complications. After the process, the patients were followed up twice weekly by the nurse in charge of maintaining CVC, with regular flushing and dressing, who also records the date of missed dressing and reasons for CVC removal. CLABSI, or unexplained fever due to CVC, is reported in the morbidity WhatsApp group. Details of positive blood culture, date and time of CVC removal, hospital number, and patient diagnosis were also mentioned for proper recording of events. The minor OT nurse maintains these events in Excel and updates weekly with the required details and date/time.
3. **Blood transfusion-related morbidity**: Allergic reaction was defined as fever, chills, or rashes during or immediately after transfusion. The anaphylactoid reaction was defined as fever, chills, or rashes associated with hypotension or bronchospasm.[5] Febrile non-hemolytic transfusion reaction was described as a body temperature rise of 1 °C or more, with or without chills and rigor occurring related to transfusion without any other explanation.[6] Transfusion-related acute lung injury was diagnosed in patients with acute respiratory distress within 6 hours with bilateral infiltrates on chest X-ray and was differentiated from transfusion-associated circulatory overload based on blood pressure, patient volume status, and the patient's response to diuretics.[7]
   All transfusion products were checked by the assigned staff at the blood bank, and compatible products were issued. Before the transfusion of blood products, the duty doctor would cross-check the issue number and blood group, and start the transfusion, monitoring from the start till the end. In the event of a transfusion reaction, a filled transfusion reaction reporting form would be sent to the blood bank along with the leftover blood product bag and posttransfusion patient blood and urine samples. Further workup for confirmation of transfusion reaction would be carried out in the transfusion medicine department. These events are updated in the morbidity Excel and the morbidity WhatsApp group.
4. **Chemotherapy or other drug-related allergic or anaphylactoid reactions** were defined as fever, chills, or rashes associated with bronchospasm or hypotension during or immediately after infusion.[8]
5. **Miscellaneous**: Extravasation was defined as the leakage of drugs from blood vessels into surrounding tissues. Fall, bedsore, deep venous thrombosis (except CVC related), and steroid-induced hyperglycemia were defined as an abnormal increase of blood glucose associated with the use of glucocorticoids in patients with or without a prior history of diabetes mellitus.[9] Tumor lysis syndrome, grade 4 febrile neutropenia, was defined according to common terminology criteria for adverse events as a drug-related reduction of peripheral neutrophils to less than 500 per 1 µL of blood.[10,11] Miscellaneous events were recorded during admission among admitted patients during the study period.
   All patients treated under the medical oncology department are registered and have a unique medical oncology number as an identifier. All patient details, including clinical, laboratory, imaging, and treatment, from the time of presentation, were maintained in the medical oncology case record file identified by the medical oncology number. Events encountered by the patient during the treatment are also recorded in the case record. Written informed consents were obtained from all patients registered under the Medical Oncology Unit before treatment or any procedure.

Analysis

Continuous variables were expressed in mean ± standard deviation or median (range) based on the distribution of data. The categorical data were expressed as frequency and percentages. Descriptive statistics have been used to summarize our data. All statistical analyses were done using IBM SPSS Statistics for Windows, version 19 (IBM Corp., Armonk, New York, United States). A $p < 0.05$ was considered statistically significant.

Ethical Approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Jawaharlal Institute of

Table 1 Baseline characteristics

Sl. no.	Feature		Total $n = 864$
1	Age	Median, range	26 (1–70)
2	Age group <18 18–49 >49 y	(*n*, %)	 325 (37.5) 423 (48.9) 116 (13.5)
3	Gender (M/F)	Ratio	1.64:1
4	Diagnosis Hematological malignancy Solid tumors	(*n*, %)	 725 (83.9) 139 (16.1)

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Results

A total of 2,551 patients were registered under medical oncology from January 2019 to March 2020. Among them, 864 morbidity events were recorded. The median age was 26 (1–70 years); the majority of the events were among adolescent young adult patients, 422 (48.9%). Around 724 (83.9%) morbidity events were recorded among patients undergoing chemotherapy for hematological malignancy compared to 139 (16.1%) events among patients undergoing chemotherapy for solid tumors (►**Table 1**).

Morbidity events were classified into five subtypes (►**Table 2**).

Medication error: The number of chemotherapy orders from January 2019 to March 2020 was 16,140. Out of these, 54 events related to medication errors were identified; 18 (33%) events were prescription errors, of which 3 were near-miss events; 12 (22%) were administration errors, of which one was a near-miss event; and 24 (45%) were associated with omission errors. The rate of events per 1,000 chemotherapy orders was 1.4. Allergic or anaphylactoid reactions during the study period were 101.

Table 2 Morbidity events

Sl. no.	Morbidity cause	Total events $n = 864$ (*n* %)
1	Catheter related	423(48)
2	Medical errors	54 (6)
3	Chemotherapy and supportive medication-related morbidity	101 (12)
4	Transfusion reactions	45 (5)
5	Miscellaneous events	241 (28)
	Extravasation Fall Bed sore Deep vein thrombosis Steroid hyperglycemia Tumor lysis syndrome Neutropenic colitis Malignant spinal cord compression Febrile neutropenia grade 4 Unknown	16 (7) 2 (1) 3 (1.5) 6 (2.5) 80 (33) 21 (9) 9 (4) 2 (1) 71 (29) 31(12)

Catheter-related events: A total of 432 CVCs were inserted during the study period, of which 73.9% (315 patients) were triple-lumen catheters, 26.1% (111) were peripherally inserted central catheter lines, and 1.5% (6) were Hickman. The most common site was the internal jugular vein (162; 56.8%), followed by the subclavian vein (119; 41.7%). Of all the morbidity events recorded during the study period, CVC-related events were the most common. The mean catheter days were 31 (3–250). The total catheter removal events were 175 (43.8%): accidental 41 (23.4%), suspected infection 40 (22.9%), proven infection 56 (32%), bleeding 14 (8.0%), and thrombosis 24 (13.7).

CVC-associated immediate morbidity events were 33 (7.8%), which included failed attempts (4%) and wrong placement (3.5%). There were no life-threatening events or complications during catheter insertion (►**Table 3**).

Catheter maintenance: Our catheter maintenance rate was evaluable in 426 patients. Among them, 23 patients died, and 11 were referred to another hospital. Catheter maintenance was successful in 119 (36.8%), who completed treatment without any events.

Transfusion reaction: During the study period, 502 packed cells, 5,768 random-donor platelets (RDPs), and 529 single-donor platelets were transfused. Among them, around 45 transfusion reaction–related events were recorded. All events of grade 2 or 3 anaphylactic reactions resolved after antihistaminic. None of the events was life-threatening.

Miscellaneous morbidity events: Among a total of 210 (25%) miscellaneous events, the significant events were of patients admitted with grade 4 febrile neutropenia, which accounted for 71 (33%) events and steroid-related hyperglycemia among 80 (38%) patients. Others included extravasation 16 (8%), fall 2 (1%), bed sore 3 (1.5%), deep vein thrombosis 6 (3%), tumor lysis syndrome 21 (10%), malignant spinal cord compression 2 (1%) (►**Table 2**).

Discussion

Morbidity during treatment is one of the most significant challenges faced. Early recognition of events might help in achieving the goal of reducing toxicity and improving outcomes.[8]

In this study, most morbidity-related events were CVC-associated, medication errors, and transfusion reactions. Central venous catheters have become an essential mode of chemotherapy delivery, but they carry significant morbidity of infection (24%) and thrombosis (6%), resulting in mean catheter days of 31. The complications associated with CVC were higher in our study than in the published literature. (►**Table 4**) An audit of CLABSI rates was performed, and a team of sisters was assigned to maintain the catheter by keeping a log of all inserted catheters, with twice-weekly

Table 3 Catheter-related events

Sl. no.	Catheter inserted	(*n*, %) (among 2,551 patients registered under medical oncology)	*N* (%)
1	**Site of central line placement (*n* = 432)**	(*n*, %)	
	IJV		162 (37.5)
	SCV		119 (27.5)
	Femoral		8 (1.9)
	PICC lines		111 (25.7)
	Hickman		6(1.4)
	Not available		26 (6.0)
2	**Failed catheter (reasons) (*n* = 33)**	(*n*, %)	
	Attempted but failed		17 (51.5)
	Wrongly placed/removed		15 (45.5)
	Not sedated fully		1 (3)
3	**Catheter removal (*n* = 399)**	(*n*, %)	
	Accidental		41 (10.3)
	End of treatment		119 (29.8)
	Suspected infection		40 (10.0)
	Proven infection (c/s positive)		56 (14.0)
	Bleeding or soakage		14 (3.5)
	Thrombosis		24 (6.0)
	Nonfunctional		10 (2.5)
	COVID-19		13 (3.3)
	Expired		23 (5.8)
	Discharge/AMA		11 (2.8)
	Missing reason for recorded morbidity		48 (12.0)

Abbreviations: AMA, against medical advice; IJV, internal jugular vein; PICC, peripherally inserted central catheter; SCV, subclavian vein.

dressing and flushing. Catheter maintenance was challenging among outpatients due to poor compliance with dressing schedules and multiple defaults. CVC care was successful in 119 patients (29.8%) without catheter-related events until treatment completion.

"To err is human,"[1] hence the need for internal checks to reduce error while prescribing or administering chemotherapy, which can lead to significant morbidity and mortality due to a narrow therapeutic index.[1,12,13] As reported in a few retrospective studies, medication errors account for 10 to 25% of all medical errors,[8] but is it just the tip of the iceberg? Identifying medication errors is a challenge, as it is multifactorial and involves multiple people, from prescription and dispersion to administration.[14] In a survey conducted in

Table 4 Central line–related events—comparison of literature with the present study

Sl. no.	Study	Morano et al[3]	Kim et al[4]	Baier et al[7]	Current data
	Trial design	**Retrospective**	**Prospective trial**	**Retrospective**	**Retrospective**
	Study period	**1999–2005**	**2007–2009**	**2017–2019**	**2019–2020**
1	Complications	26%	30.1%	NA	44%
2	Infection	17%	12.8%	18.2%	24% (14% proven CLABSI)
3	Thrombosis	2.6%	4.5%	NA	6.0%
4	Malposition and migration	9.2%	10.1%	NA	7.8%
5	Bleeding	2.4%	2.8%	NA	3.5%
6	Catheter days	131	45	17 (mean CVC days per patient)	31
7	Catheter removal rate due to comp	26%	41.9%	NA	44%

Abbreviations: CLABSI, central line–associated bloodstream infection; CVC, central venous catheter; NA, not available.

Turkey that included volunteer nurses from 18 chemotherapeutic centers, 83.4% of nurses reported one or multiple unintentional errors while preparing and administering chemotherapy.[14] This study's reported medication error rate is significantly less than that of the literature, probably due to structured and verified template-based prescription use. Among the chemotherapy toxicities, allergic and anaphylactic reactions were the most common. The significant morbidity event associated with chemotherapy was omission error compared to administration error described in other studies.[15,16] Omission of premedication and hydration was found commonly. There were three near-miss events in the prescription during the study period: a wrong capecitabine dose, an interchange of doses between epirubicin and cyclophosphamide in EC chemotherapy for breast cancer, and a docetaxel three-weekly dose prescribed as weekly. One administration error of a 5-FU bolus dose as an infusion was noted. All the near-miss events in prescription and administration were recognized by pharmacists and the duty doctor, respectively. There were no never-events.

Safe transfusion of blood products is an intrinsic part of treatment, especially in hematological malignancies. With modern cross-match techniques and good screening, transfusion-related reaction rates have decreased significantly.[6] Though transfusion-related life-threatening events are relatively minor, immediate transfusion-related events are still reported.[17] At our center during the study period, the average rate of transfusion reaction per 1,000 transfusions was around 1.9 for RDPs and 3.9 for packed cells. As described in various retrospective and prospective studies, allergic reaction rates are higher than other adverse transfusion reactions (ranging from 23% in Bassi et al to 51.4% in Saha et al).[6,17] The incidence of transfusion reaction reported in this study is comparable to the described literature.[17–20]

Among the miscellaneous events, two patients had a never-event of a fall while going to the washroom. The fall in both patients was probably associated with the sedative effect of morphine. Extra care of patients on morphine and caregiver education on possible impacts of sedation were made mandatory to avoid future events.

This study overviews a newer method of reporting various morbidities among chemotherapy patients. Instant event reporting enables us to audit patient care and treatment-related complications periodically. An audit of events helps understand multiple pitfalls and allows for rectifying them in the future. Our system of collecting data on all events using the latest apps readily available with centralized instant messaging has significantly increased reporting accuracy. The collection of denominators for the reported events was a challenge, which was meticulously done by our team from each area of patient care. Maintaining data prospectively adds further value by reducing missing data. However, self-reporting of events might lead to selective reporting and inconsistency in reporting events, which are a few limitations. Hence, a uniform contribution from all healthcare workers in event reporting without hiding facts is essential to improve patient care.

Conclusion

A structured, uniform, and prospective record of the morbidity events during treatment is essential to understanding errors, which can provide an opportunity to rectify future events. The periodic audit of events by the treating team can help establish standardized operating procedures to minimize error and maximize safety.

Data availability Statement

Data are available on request from the corresponding author.

Patients' Consent

Patient consent is not applicable. Waiver of consent is obtained from IEC, Jawaharlal Institute of Postgraduate Medical Education and Research.

Conflict of Interest

None declared.

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