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Quality and Safety Improvement in Cancer Chemotherapy Using the Plan-Do-Check-Act Cycle

KEYWORDS: Chemotherapy; PDCA cycle; Hepatitis B reactivation

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ABSTRACT

The Plan-Do-Check-Act (PDCA) cycle has been effectively used to improve medical safety management. We selected six general items and two drug-specific items, all with a high risk in the chemotherapy process, and then checked the listed items for the patients who were administered antineoplastic agents. A risk assessment was implemented for each item to minimize the severe consequences of chemotherapy management errors. The first cycle of PDCA made it clear that full examination of hepatitis B virus (HBV) infection status was performed in only 30-40% of patients receiving anticancer drugs. Therefore, we disseminated the information of the risk of HBV reactivation induced by chemotherapy and changed the electronic medical records system to facilitate hepatitis B status testing. Application of the PDCA cycle successfully increased the check rate of HBs-Ab and HBc-Ab up to over 90 % in cancer patients before the commencement of chemotherapy.

Introduction

Cancer chemotherapy has become highly specialized to the individual patient, and sometimes requires genetic analyses and biomarkers to predict either therapeutic effects or adverse events[1]. The process of chemotherapy has very much increased in complexity, which requires the active participation of multiple disciplines[2, 3]. We organized a multidisciplinary chemotherapy team and conducted a prospective study to identify the high risk items related to the chemotherapy process. The Plan-Do-Check-Act (PDCA) cycle method[4] could be utilized for the quality management of cancer-related medical areas. We examined the effects of the PDCA methodology in cancer chemotherapy.

Materials and Methods

The study procedures were approved by the institutional review board (IRB) of our hospital. Inpatients undergoing the first cycle of a chemotherapeutic regimen were enrolled from January through September, 2014. With the aim of improving the quality and safety of chemotherapy, the chemotherapy team implemented risk assessment. We reviewed the medical records of patients receiving chemotherapy to check for 6 high risk items; informed consent, performance status (PS), hepatitis B virus (HBV) infection status (HBs-Ag, HBs-Ab, and HBc-Ab), laboratory data, alcohol hypersensitivity and history of drug allergy, and the washout period of antineoplastic agents. The items of genetic analyses and biomarkers were assessed for patients receiving specific anticancer agents (Table 1). Statistical analyses were performed with Bonferroni correction test using EZR (Saitama Medical Center, Jichi Medical University, saitama, Japan) [5], which is graphical user interface for the R Foundation for Statistical Computing (Vienna, Austria).

Results

At first 44 patients undergoing the initial cycle of cancer chemotherapeutic regimens were surveyed for the items listed in advance. The most common diagnoses were lymphoma (10; 23 %) and colorectal cancer (7; 16 %). Informed consent was obtained from 43 patients (98 %). Performance status was evaluated for all patients; 40 patients (91 %) had a PS of 0, 1, or 2, and 4 (9 %) had a PS of 3. HBs-Ag was examined in 42 patients (95 %), whereas HBs-Ab and HBc-Ab were examined in 17 (39 %) and 13 (30 %), respectively. For all patients, alcohol hypersensitivity and history of drug allergy were properly assessed. The indication and washout period of the proceeding regimens were properly implemented in all cases. As for drug-specific items, molecular target agents were found to be appropriately used; rituximab was infused in 9 out of 10 patients with anti-CD20 Ab positive lymphoma; anti-EGFR Ab was administered to 3 of 7 patients with colorectal cancer of wild-type ***KRAS***; and erlotinib was administered to 2 of 6 patients with lung cancer of EGFR mutation. Anthracyclines were administered to 14 patients. We made a system in the electronic medical records showing the updated accumulated dose of anthracyclines, since one patient was not entirely examined by echocardiography during the chemotherapy.

Because this survey revealed that the check rates of HBs-Ab and HBc-Ab were very low, the chemotherapy team recommended the doctors to strictly assess the status of HBV of all cancer patients before the commencement of chemotherapy. At the same time the team informed the staff such as nurses and pharmacists of the need to increase the check rate of HBV testing using the local area network. In addition to these measures, an easy check system for HBV status of the patients was created in the electronic medical records. The first cycle of PDCA application

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increased the examination rates of HBs-Ab and HBc-Ab to 54 % and 51%, respectively (March-15, Table 2). Repetitive PDCA improvement cycle significantly increased the check rates of HBs-Ab and HBc-Ab up to over 90 % in September, 2015, as compared to before PDCA (**p** < 0.05 **versus** Octber-14,) and after 1st cycle of PDCA (**p** < 0.05 **versus** March-15)

Discussion

A multidisciplinary chemotherapy team was organized in 2013. Based on the chemotherapy administration safety standards of American Society of Clinical Oncology /Oncology Nursing Society[6], the team performed ward rounds and then decided to create a list of high-risk items to assess during cancer chemotherapy management **(Plan)**. Concerning the items listed, we conducted the prospective survey of cancer patients who received chemotherapy **(Do)**. The examination rate of HBs-Ab and HBc-Ab was found to be very low prior to the start of antineoplastic agents **(Check)**. In cancer chemotherapy, HBV reactivation has become a serious problem, which might result in fulminant hepatic failure with an extremely high mortality rate[7, 8]. Therefore, it is highly recommended that the status of HBV including HBs-Ab and HBc-Ab should be strictly assessed before the commencement of chemotherapy. Along with disseminating information on the importance of HBV testing, we created an easy check system for HBV status in the electronic medical records **(Act)**. Application of the PDCA cycle method leads to that HBV screening tests are now performed in almost all of cancer patients prior to the commencement of chemotherapy.

Conclusion

Use of the PDCA methodology gradually facilitated the full examination of HBV status in cancer patients receiving chemotherapy. We are planning to share our experience of PDCA cycle with other institutes in order to mutually evaluate the utility of this method. We hope that it will further enhance the activity of our multidisciplinary team to improve quality and safety management in cancer-related medical areas.

Competing interests

The authors declare that they have no competing interests.

Table 1 Specific items related to molecular target or antineoplastic agents prior to the commencement of chemotherapy

(1) Genetic testing
Expression of CD20 for rituximab
Expression of HER2 for trastuzumab
KRAS status for anti-EGFR antibody agents

EGFR status for gefitinib and erlotinib
(2) Echocardiography for trastuzumab and anthracyclines

Table 2 Examined rates of HBs-Ag, HBs-Ab, and HBc-Ab in the patients receiving chemotherapy.

	October-14	March-15	September-15
Total	44	149	141
HBs-Ag			
examined(%)	42(95)	146(98)	140(99)
positive(%)	0(0)	1(0.7)	1(0.7)
negative(%)	42(100)	145(99.3)	139(99.3)
HBs-Ab			
examined(%)	17(39)	80(54)	130(92)[a,b]
positive(%)	2(12)	7(9)	18(14)
negative(%)	15(88)	73(91)	112(86)
HBc-Ab			
examined(%)	13(30)	76(51)	129(91)[a,b]
positive(%)	1(8)	11(14)	25(19)
negative(%)	12(92)	65(84)	104(81)

a; **p** < 0.05 **versus** Octber-14, b; **p** < 0.05 **versus** March-15

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