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Original Research Article

An Evaluation of the Trigger Tool Method (TTM) in Detection, Monitoring, and Reporting of Adverse Drug Reactions (ADRS)

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Abstract

Aim: The aim of the present study was to evaluate the trigger tool method (TTM) in detection, monitoring, and reporting of adverse drug reactions (ADRs).

Methods: This was prospective, interventional, single center study conducted at department of Pharmacology, Darbhanga Medical College, Darbhanga, Bihar, India on a permanent basis, posted in Department of Medicine. A total 650 patients were admitted during the study period in the respective medicine unit.

Results: A total of 650 patients who fulfill the selection criteria were enrolled. 70% were male and 30% were females. The mean age of patients was 43.07 ± 16.4 years, and the mean length of hospital stay was 5.75 ± 3.12 days. Of the 650 patient cases, triggers were observed in 80 patients (12.30%). while 20 (25%) suffered one or more ADRs. A list of 17 triggers was given to 30 nurses for identification of ADEs. List of 17 triggers consists of 9 DT, 1 LT and 7 PT. Of these 17 triggers, 14 triggers were identified by nurses in the study population and 3 triggers were not observed. These 14 triggers were noticed 130 times, with an average 12.53 triggers observed per patient. These included DT (100 times), LT (0 times) and PT (30 times). Triggers were identified for a minimum once and maximum 3 times in 95 patients. Of the various triggers observed, 7 drug triggers and 4 patient triggers were related to ADRs. Hence 11 triggers (64.70%) were positive (related to ADRs), out of total 17 triggers under evaluation. A total 24 ADRs were observed in 25 inpatients during study period. One or more triggers were observed in these patients. The commonly detected ADRs were gastritis, thrombophlebitis, diarrhea and vomiting. Chills, cough, headache, joint pain, metallic taste, pruritus and weight gain were also observed.

Conclusion: The reporting system is operational at the study site and ADRs are being reported using a standard form. Patients recovering from the reactions following the withdrawal of the suspected drug, and the majority of ADRs were mild. TTM can be used as an add-on tool to existing methods like spontaneous method for the health-care professionals for better detection of ADRs in the pharmacovigilance program. However, further research is required to explore the feasibility and acceptability of TTM.

Keywords: Adverse drug reaction, adverse drug reaction monitoring, pharmacovigilance, surgery, trigger tool method

Introduction

Adverse drug reactions (ADRs) defined as "a response to drug that is noxious, unintended and occur in doses used in human beings for prophylaxis, diagnosis and therapy of disease or for modification of physiological function". [1] According to a study conducted in USA, about 2.9-5.6% of all hospitalizations were due to ADRs and as many as 35% of hospitalized patients experienced an ADR during their stay. [2] A study conducted in south India observed that while 0.7% of the hospital admissions were due to ADRs, 3.7% of the hospitalized patients experienced an ADR and 1.8% had fatal ADRs during hospitalization. [3]

There are several methods to monitor ADRs like voluntary reporting, record review, triggers, direct observation, interviews/surveys, targeted reporting, cohort event monitoring, EHR mining (electronic health record mining). [4] Voluntary reporting of ADRs is most commonly used method for reporting of ADRs. However, voluntary reporting has some

disadvantages like under reporting, reporting bias, difficult to detect delayed ADRs and capture only suspected ADRs. So, other methods needed to improve reporting of ADRs.4 One of them is trigger tool method (TTM).

A trigger is defined as an "occurrence, prompt or flag found on review of the medical record that 'triggers' further investigation to determine the presence or absence of an adverse event" a trigger may include Laboratory Trigger (LT), Drug Trigger (DT), and Patient Trigger (PT). An Adverse drug event (ADE) trigger tool makes chart review more efficient by identifying suspected AE via laboratory values, text phrases or automated 'values' available in medical records, which is more time effective than complete chart review and more sensitive than voluntary reporting. [4-6] In the 1990, the Institute for Healthcare Improvement (IHI) developed the IHI Global trigger tool to quantify AE. [7]

The aim of the present study was to evaluate the trigger tool method (TTM) in detection, monitoring, and reporting of adverse drug reactions (ADRs).

Materials and Methods

This was prospective, interventional, single center study conducted at department of Pharmacology, Darbhanga Medical College, Darbhanga, Bihar, India for one year on a permanent basis, posted in Department of Medicine. A total 650 patients were admitted during the study period in the respective medicine unit.

Inclusion Criteria

• Residents, who consent (written) to participate in the study, were included in the study.

Exclusion Criteria

• Residents not willing to participate in the study.

Study Period

Knowledge, attitude and practice questionnaire was given to each nurse at initiation of the study. It was pretested and validated questionnaire prepared by investigator. In 1st week they were sensitized about pharmacovigilance, methods of ADE reporting and details about trigger tool method (personal briefing, lectures). Also, a list of triggers was prepared from IHI Global Trigger Tool list[7] and list adopted by Abideen P (Indian study) and given to nurses.[6] By next 2 weeks, they were advised to report ADEs using trigger tool method under guidance of investigator. In following month, they were advised to report ADEs using trigger tool method. The investigator had evaluated all reported ADEs. Reminders to report were sent 1 SMS/week. After end of study KAP questionnaires were again given to evaluate knowledge, attitude and practice of ADR reporting.

Data was analyzed in Microsoft Excel sheet. All triggers and AEs reported were analyzed in terms of association between them, effectiveness of trigger in detecting an ADR. The Positive Predictive Value (PPV) was calculated for the sets of triggers and for each trigger. PPV was defined as number of patients for whom a trigger was indicating an ADE found, divided by the number of patients for whom a trigger was indicating an ADE found plus the number of patients for whom a trigger did not indicate an ADE. [8,9]

PPV = Number of medical records in which the trigger indicated an ADE × 100 / Number of medical records with triggers.

For ADRs causality assessment was done by investigator using WHO-UMC scale and Naranjo's algorithm. [10,11] Severity was assessed using modified Hartwig and Seigel while preventability was assessed using modified Schumock and Thornton scale. [12,13] All data are entered in Microsoft Excel 2007® and analyzed using appropriate statistical tests.

Results

Table 1: Demographic data

Gender	N%
Male	455 (70%)
Female	195 (30%)
Mean age	43.07 ± 16.4 years
Mean length of hospital stay was	5.75 ± 3.12 days

A total of 650 patients who fulfill the selection criteria were enrolled. 70% were male and 30% were females. The mean age of patients was 43.07 ± 16.4 years, and the mean length of hospital stay was 5.75 ± 3.12 days.

Table 2: Trigger tool list and positive predictive value (PPV) of triggers

Trigger	Trigger observed	Negative triggers (not related to ADRs)	Positive triggers (related to ADRs)	Positive predictive value (PPV%)
DT1- New drug administration	18	17	1	5.55%
DT2- Sudden stoppage of drug	7	4	3	42.85%
DT3- Antihistaminics	6	4	2	33.33%
DT4- Antiemetics	26	24	2	7.6%
DT5- Antidiarrhoeals	14	11	3	21.4%
DT6- Antacids	23	19	4	17.39%
DT7- Laxatives	0	0	0	-
DT8- Thrombophob gel	5	1	4	80%
DT9- IV fluid	1	1	0	0
LT1- Increased serum creatinine	0	0	0	-
PT1- Rash	7	5	2	28.57%
PT2- Pruritus	2	1	1	50%
PT3- Lethargy	3	3	0	0
PT4- Death	9	9	0	0
PT5- Transfer/reference to other department	0	0	0	-
PT6- Weight gain	1	0	1	100%
PT7- Other complain that are not relatedto the disease	8	4	4	50%

A list of 17 triggers was given to 30 nurses for identification of ADEs. List of 17 triggers consists of 9 DT, 1 LT and 7 PT. Of these 17 triggers, 14 triggers were identified by nurses in the study population and 3 triggers were not observed. These 14 triggers were noticed 130 times, with an average 12.53 triggers observed per patient. These included DT (100 times), LT (0 times) and PT (30 times). Triggers were identified for a minimum once and maximum 3 times in 95 patients. Of the various triggers observed, 7 drug triggers and 4 patient triggers were related to ADRs. Hence 11 triggers (64.70%) were positive (related to ADRs), out of total 17 triggers under evaluation.

Table 2: Detected adverse drug reactions

Detected adverse drug reactions	N
Gastritis	7
Thrombophlebitis	4
Diarrhea	2
Vomiting	2
Chills	2
Cough	2
Headache	1
Joint pain	1
Metallic taste	1
Pruritis	1
Weight gain	1

A total 24 ADRs were observed in 25 inpatients during study period. One or more triggers were observed in these patients. The commonly detected ADRs were gastritis, thrombophlebitis, diarrhea and vomiting. Chills, cough, headache, joint pain, metallic taste, pruritus and weight gain were also observed.

Discussion

An adverse drug reaction (ADR), is "a response to a drug that is noxious and unintended that occurs at doses normally used in male for prophylaxis, diagnosis, or treatment of disease, or for the modification of physiological function." Pharmacovigilance is "the science and activity relating to the detection, assessment, understanding,

and prevention of adverse effects or any other possible drug-related problems." [14] Epidemiological studies in India show that about 50% of all hospital admissions are associated with ADRs. [15] PPV, sensitivity, and specificity are the most commonly used parameters to assess the accuracy of the trigger tool. In the present study, the DT had a sensitivity of 100% and specificity of 11.48%. Pérez Zapata et al [16] found sensitivity (86%) and specificity (93.6%) of the DT in 350 surgical patients in Spain. However, difference in sensitivity and specificity of DT can be attributed to the difference in health-care setting.

A total of 650 patients who fulfill the selection criteria were enrolled. 70% were male and 30% were females. The mean age of patients was 43.07 ± 16.4 years, and the mean length of hospital stay was 5.75 ± 3.12 days. Of the 650 patient cases, triggers were observed in 80 patients (12.30%). Among 95 patient's cases with triggers, 60 (75%) patients did not suffer from an ADR, while 20 (25%) suffered one or more ADRs. A list of 17 triggers was given to 30 nurses for identification of ADEs. List of 17 triggers consists of 9 DT, 1 LT and 7 PT. Of these 17 triggers, 14 triggers were identified by nurses in the study population and 3 triggers were not observed. These 14 triggers were noticed 130 times, with an average 12.53 triggers observed per patient. These included DT (100 times), LT (0 times) and PT (30 times). Triggers were identified for a minimum once and maximum 3 times in 95 patients. Of the various triggers observed, 7 drug triggers and 4 patient triggers were related to ADRs. Hence 11 triggers (64.70%) were positive (related to ADRs), out of total 17 triggers under evaluation. The retrospective study conducted in Malaysia by Sam et al. observed nine triggers 45 times in 38 patients; 29 ADEs were detected using these triggers. [17] In all the above studies, DTs were more frequently detected than PTs and LTs. riffin and Classen [18] reported ADE rate (16 AE/100 patients) in a retrospective study similar to the present study. A much higher ADE rate (51.1 AE/100 patients) was observed in a study by Pérez Zapata et al [16] which can be because of the lack of causal association of reported ADEs. Matlow et al. [9] found high sensitivity (85%) and low specificity (44%) of the TT. Karpov et al. observed the sensitivity of the trigger tools to be between 2.6% and 15.8% and specificity varied from 99.3% to 100%. [19]

A total 24 ADRs were observed in 25 inpatients during study period. One or more triggers were observed in these patients. The commonly detected ADRs were gastritis, thrombophlebitis, diarrhea and vomiting. Chills, cough, headache, joint pain, metallic taste, pruritus and weight gain were also observed. Kennerly et al. using TTM observed PPV of triggers to be between 0% and 100% with an overall PPV of 17.1%. [20] Above findings reflects that PPV for predicting adverse events can be different for the same trigger in different clinical settings because the performance of the trigger may vary over time and is dependent on the existing diagnostic and therapeutic practices in the given health-care setting. Certain triggers occurring with a relatively lower frequency were more efficient in identifying ADE.

Conclusion

The reporting system is operational at the study site and ADRs are being reported using a standard form. Patients recovering from the reactions following the withdrawal of the suspected drug, and the majority of ADRs were mild. TTM can be used as an add-on tool to existing methods like spontaneous method for the health-care professionals for better detection of ADRs in the pharmacovigilance program. However, further research is required to explore the feasibility and acceptability of TTM.

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