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Original Research Paper

An Observational Pharmacovigilance Study of Patients Receiving Dots at Ashok Nagar District Hospital of Madhya Pradesh, India

Pharma

KEYWORDS : Pharmacovigilance, DOTS, Tuberculosis

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ABSTRACT

Vigilant assessment of the risks and benefits of medicines applies throughout the life cycle of a medicine. India had a National TB Programme to combat the problem of TB. India's National Tuberculosis Programme (NTP) was initiated as a truly integrated Programme , instigated through District Tuberculosis Centers (DTCs). It was a hospital based prospective observational study. A total of 47 patients were registered. Among these, 38 (80.85%) patients were showed adverse drug reaction due to any therapeutic agent. Twenty six (68.42%) patients were male and 12 (31.57%) were female. Most common age group affected, was between 10-30 years (55.26%). Most common adverse drug reaction experienced was nausea and vomiting (developed among 27 patients). Chest pain was present in 10 persons. Loss of appetite in 9, Loss of communication in five patients, 5 patients experienced cough, three patients experienced constipation, two patients had restlessness, another two patients suffered from fever, headache. Only one patient had skin rashes. Metallic taste was seen in one patient. Drowsiness was experienced by one patient. Causality assessments by Naranjo's causality assessment scale showed, possible causality in 28 patients (73.68%), probable in 7 patients (18.42%), definite in 2 patients (5.26%) while doubtful in 1 patient (2.63%).

INTRODUCTION

Pharmacovigilance has been defined by the World Health Organization (WHO) as: "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem"[1]. Vigilant assessment of the risks and benefits of medicines applies throughout the life cycle of a medicine - from the preapproval stage to use by patients[2]. WHO defines Adverse Drug Reaction (ADR) as "any response to the drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for modification of physiological function" [3]. Tuberculosis (TB) is a contagious infection caused by an airborne bacterium, Mycobacterium tuberculosis[4]. India accounts for one-fifth of the global TB cases [5].

It is estimated that annually around 330,000 Indians die due to TB [6]. The World Health Organization (WHO) declared TB as a global emergency in 1993 and the rank of India in TB is first [7]. India had a National TB Programme to combat the problem of TB. India's National Tuberculosis Programme (NTP) was initiated as a truly integrated Programme, instigated through District Tuberculosis Centers (DTCs)[8]. The Government of India progressively replaced NTP by the DOTS strategy/programme in 1993 and it is now recognized as the Revised National Tuberculosis Programme (RNTCP)[9]. Antitubercular treatment has exhibit greater level of efficacy with a satisfactory degree of toxicity; however combination treatment, especially during the intensive phase of therapy may produce severe adverse events[9].

Present study was conducted for Detection, assessment and reporting of Adverse Drug Events (ADEs) in TB patients undergoing therapy for TB and treated with DOTS therapy in a Govt. Distt. Hospital, Ashok nagar (M.P) India.

MATERIAL & METHOD

The study was carried out in the Department of Tuberculosis, In Govt. District Hospital, Ashok nagar (M.P), India, from October, 2013 to May, 2014 (eight months). It was a hospital based prospective observational study with follow up during the study period.

Among the patients receiving dots therapy, those who developed at least one Adverse drug reaction, were included in the study. The patients who did not show any ADR except urine discoloration were excluded from the study.

Tools that were used to detect and assess the adverse effects were as follows:

- CDSCO Adverse Drug Reaction Event reporting Form. [10]
- One separate questionnaire regarding socio-demographic characteristics was developed and used in the study.[11]
- Naranjo Causality Assessment Scale.[11]

After collection of data, it was compiled in Microsoft Excel sheet. Identification of signals (i.e., possible causal relationships between an adverse event and a medicine) of ADRs of concern following the introduction of a new drug or drug combination.

RESULTS

A total of 47 patients were selected in the tuberculosis ward of Govt. District Hospital. Among these 47 patients, 38 (80.85%) patients were showed adverse drug reaction due to any therapeutic agent. It was found that among these 38 patients, 26 (68.42%) were male and remaining 12 (31.57%) were female. Most common age group affected, was between 10-30 years (55.26%). Only 3 patients (7.89%) were aged below 10 years. 10 (26.30%) patients were between 31 -50 years, 4 (10.52%) patients were between 60-69 years. Most common patients had 31-50 kgs (65.78%). Others above 50 weights have 9 patients (23.68%) show adverse drug reactions. Most of the study population (55.26%) belonged from lower middle socio-economic status.

Category-I was the treatment regime in 37 patients, while 8 patients were on category-II and only 2 patients were receiving treatment of MDR-TB.

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Most common adverse drug reaction experienced was nausea and vomiting (developed among 27 patients). Chest pain was found to be second most common adverse drug reaction experienced by 10 persons. Loss of appetite showed by 9 patients Loss of communication was developed among five patients, five patients experienced cough, three patients experienced constipation, two patients had restlessness, another two patients suffered from fever, headache. Only one patient had skin rashes. Metallic taste was seen in one patient. Drowsiness was experienced by one patient (Table No. 1).

There were mild adverse effects, observed in 31 patients of DOTS therapy. Six patients showed life threatening adverse effect. There were six patients who had to hospitalize. Only two patients showed disability and 2 patients showed teratogenicity.

Table No. 1: Causality assessments among the patients show adverse drug reactions.

Adverse effects	No. of patients	Percent (%)
Nausea and vomiting	27	71.05
Chest pain	10	26.32
Loss of appetite	9	23.68
Loss of communication	5	13.16
Cough	5	13.16
Constipation	3	7.89
had restlessness	2	5.26
fever, headache	2	5.26
skin rashes	1	2.63
Metallic taste	1	2.63
Drowsiness	1	2.63

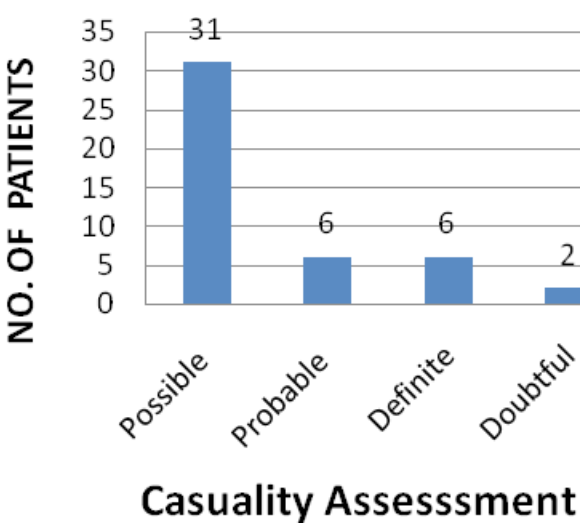

Figure No. 1: Causality assessments among the patients show adverse drug reactions.

Causality assessments were calculated by Naranjo's causality assessment scale. In this study, 28 patients showed possible (73.68%), 7 patients showed probable (18.42%), 2 patients showed (5.26%), 1 patient showed doubtful (2.63%) results (FigureNo. 1).

DISCUSSION

Pharmacovigilance study was conducted at Govt. Distti. Hospital, Ashok nagar (M.P.), this hospital have different TB ward and provided in patients facilities and also have dots therapy providers. There were 80.85% patients received dot therapies developed ADRs in the TB ward. Only 9 patients did not have any events except urine discolouration after taking Dot therapy regimen. As urine discolouration has no major problem (only drug colourinduced problems), so this effect was not considered as adverse effect in the present study.

Higher incidence of ADRs had showed by male patients and patients belonging to the age group 10-30 years. ADR was experienced most commonly by married people and who belonged to lower middle socio-economic status or middle lower socioeconomic status. Nausea and vomiting are the commonest ADRs reported. Rifampicin was the common drug causing the ADRs. Causality assessment of ADRs was done using Naranjo's scale. [12]In this study founded that 28 patients showed possible (73.68%), probable result showed by 7 patients (18.42%), 2 patients showed definite (5.26%) and 1 patient (2.63%) was founded doubtful.

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