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ORIGINAL RESEARCH

Evaluation of Adherence to Ready Reckoner on Management of Adverse Drug Reactions with Anti-Tubercular Drugs (2019) among Medical Officers

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ABSTRACT

Background: Adverse drug reactions (ADRs) with anti-tubercular treatment (ATT) are associated with substantial morbidity.Ready reckoner on management of ADRs with ATT was released by Govt of India for guidance of medical officers (MOs). Studies on evaluation of adherence on healthcare policies and guidelines are scanty in literature. It was planned to evaluate knowledge of management of ADRs with ATT among MOs in a tertiary hospital as per the Ready Reckoner. **Methods:** This was an observational and questionnaire-based survey designed from Ready reckoner involving 200 MOs.The score was noted based on the comments given on the questionnaire by the physicians. Total score: 10, Excellent knowledge: 08-10, Good knowledge: 07-05, Poor knowledge: <5. **Results:** Only 37.5% of MOs were having awareness about Ready Recknor.However, 73% of MOs were having excellent and good knowledge about management of ADRs with ATT. Poor knowledge was noted in 27% of MOs.Significant numbers of junior residents (JRs) from paraclinicaldepts had poor knowledge (43%) compared to JRs from clinical depts. **Conclusion:** The results of study emphasize the need for healthcareguideline awareness by MOs developed by Government by implementing measures like additional training and easy access to these guidelines. The healthcare policies and guidelines established by the Government and prominent academic bodies of India should be incorporated into the MBBS curriculum so that they are thoroughly acquainted with them.

Key words: Ready Recknor, medical officers, anti-TB drugs, adverse drug reaction

INTRODUCTION

Tuberculosis (TB) is one of the oldest diseases known to mankind and is responsible for huge death toll worldwide. India hasthe highest incidence of TB i.e. 28% in 2021.[1]Drugs have improved quality of life and increased life expectancy for millions of people. However, despite all these benefits, adverse reactions to drugs are common and cause illness, disability and even death. Importantlythese adverse reactions are often preventable.[2]The comprehensive ready reckoner on management of adverse drug reactions (ADRs) with anti-tubercular drugswas released in Aug'2019 and it is designed by Central Tuberculosis Division, Govt of India to guide the medical officers (MOs) and describes the processes for identification, management, recording and reporting of common and uncommon ADRs associated with use of anti TB drugs.[3]It is not known at the moment whether this ready reckoner on management of ADRs with anti-tubercular drugs that exists on paper and has been widely implemented in India. Although the treatment of choice for TB is taking anti-TB drugs, ADRs to first-line drugs (FLD) and second-line drugs ((SLD)) are associated with substantial morbidity. The overall prevalence of ADRs' with FLDs' and SLDs' are estimated to vary from 8.0% to 85% and 69% to 96% respectively. Most ADRs' are observed in the intensive phase as compared to continuation phase. Early recognition by active surveillance and appropriate management of these ADRs' is necessary for treatment success.[4,5,6]

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Healthcare policies including treatment and management policies are being developed and promulgated by Govt. time to time but studies on evaluation of adherence on these policies are scanty in literature. In view of this, it would be useful to evaluate knowledge of management of ADRs with anti-tubercular treatment (ATT) among medical officers in a tertiary referral centre as per the Ready Reckoner designed by Central Tuberculosis Division.

MATERIAL AND METHODS

The study was conducted at tertiary care hospital, Pune. The study was started after ethical clearance from the Institutional Ethics Committee. The study was conducted from 15 Nov 23 to 31 Jan 24.

Study design

This was an observational, cross sectional, questionnaire based survey. A total of 200 medical officers posted in various departments participated in the study. Consent was obtained from the participants. No formal size calculations have been made, but it is expected that this number will provide a reasonable indication of knowledge. Medical officers were selected as per feasibility and availability including resident doctors.

Study Tool

Medical officers were contacted and written consent was obtained. Total 10 questions were asked to assess their awareness relating to Ready Reckoner on management of ADRs with anti-tubercular drugs (2019). Copy of questionnaire to be used for the study is enclosed (Table I). The score was noted based on the comments given on the questionnaire by the physicians. Total score: 10, Excellent knowledge: 8-10, Good knowledge: 7-5, Poor knowledge: <5.

Statistical Analysis

The data obtained were entered in Microsoft excel spread sheet and evaluated. The completed questionnaire was analyzed using descriptive statistics. The correct answers of questionnaire were calculated as percentage (proportion). Subgroup analysis was done to assess knowledge score of resident doctors and other medical officers in tertiary hospital.All results attained were entered in Microsoft excel and the statistical calculations were executed using Graph Pad Instat. The p value less than 0.05 was considered to be statistically significant.

RESULTS

The demographic details of the participants with baselinecharacteristics are summarized in Table II. All 10 questionswere answered by medical officers.

Overall Assessment of Score on Awareness Relating to Ready Reckoner

Figure I depicts the overall score distribution of questionnaire designed(Table I) of MOs on knowledge of management of ADRs with anti-tubercular drugs as per the Ready Reckoner designed by Central Tuberculosis Division, Govt of India to guideMOs. Excellent knowledge (score of 8-10) was noted only in 18% of MOs while 55% of MOs were having good knowledge (score of 5-7). So overall, 73% of MOs were having excellent / good knowledge.Poor knowledge was noted in 27% of MOs.

Sub group Analysis of Medical Officers on Assessment of Score on Awareness Relating to Ready Reckoner

Out of 200 MOs, 132 included Junior resident (JR) doctors from clinical departments and 44 JRs included from paraclinical departments while 24 were MBBS physicians working in various OPDs of tertiary hospital.

Figure IA and 1B depicts score distribution of JR from clinical and paraclinicaldepartments, respectively on knowledge of management of ADRs with ATT as per the Ready Reckoner. Excellent knowledge was noted only in 18% of JRs from clinical depts while 16% of JRs from paramedical depts had excellent knowledge. More number of JRs from clinical depts had good knowledge (58%) versus only 41% of good knowledge score from JRs of paraclinical depts. 43% of JRs from paraclinicaldepts had poor knowledge while only 24% of JRs from clinical depts had poor knowledge ($P<0.001$).

The score distribution of MBBS physicians working in OPDs is shown in Figure IC. In these MOs, excellent knowledge was noted in 71% and 21% had good knowledge. Only 8% of MOs were having poor knowledge about management of ADRs on ATT while overall for all MOs, poor knowledge score was 27% ($P<0.001$).

Assessment of Individual Questions

Assessment of individual questions rightly attempted by MOs is shown in Table III in descending order as per the score obtained by MOs. The knowledge on awareness on Ready Reckoner was noted only in 37.5% of MOs.The question regarding baseline investigation prior to start of treatment is attempted correctly by 99% of MOs while only 19.5% of MOs could answer correctly the name of platform regarding the reporting of ADRs due to ATT. The question regarding the advice on orange colored urine following ATT was answered correctly by 91.5% of MOs whilethe questions on management of peripheral neuropathy and QT interval more than 500mm was answered correctly by less than 50% of MOs (35.5 and 35% respectively).The questions on management on acid indigestion, vomiting and elevation on liver transaminaseafter ATT were answered correctly by more than 50% of MOs (79.5%, 72% and 64.5% respectively).

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Table I:Score distribution as perReady Reckoner on management of ADRs with anti-tubercular drugs (2019)			
Sr. No.	**Questions**	**Comments**	**Score**
1.	Are you aware of ready reckoner (guideline) on management of ADRs associated with anti TB drugs issued by Central Tuberculosis division?	Yes	01
		No	00
2.	What is the name of platform which has in-built mechanism for recording, reporting and analyzing ADRs due to ATT	Nikshay	01
		Any other	00
3.	Are baseline investigations done prior to start of treatment?	Yes always	01
		Any other	
4.	Patient complaining of orange colored urine after start of ATT. What advise you will give to patient?	Orange/red discoloration of urine commonly encountered is caused due to rifampicin and is not an adverse reaction and patients should be made aware of this.	01
		Any other	00
5.	A 40 yrs male patient is taking 2nd line ATT containing ofloxacin, cycloserineand kanamycin He complained of acid indigestion. Which drug you will prefer?	Simple antacid will be effective	00
		Managed with H2 blocker/PPIs	01
6.	If patient develops nausea and single episode of vomiting after first dose of ATT. What will be your next step?	Counsel patient & reassure them that these symptoms resolve with time.	01
		Any other	00
7.	ECG as a baseline investigation is done before putting a patient on which medicines?	Bedaquiline, Delamanid, Fluoroquinolone, Clofazimine (any one answered)	01
		Any other drug	00
8.	If QTc interval is more than 500 ms, what will be your next step?	Wait and watch. Repeat ECGs daily (at least twice a week) and Check for S. electrolytes.	00
		Withhold culprit drugs (Clofazimine, Delamanid and Bedaquinile), Correct electrolytes if any, monitor QTc daily.	01
9.	If AST or ALT elevated but less <5x ULN with normal bilirubin. What will be next step/s?	Enquire about alcohol intake & other medications	01
		Continue the drugs with close monitoring (symptoms & lab test AST, ALT, Bilirubin every 2 weeks) till resolution	01*
		Any other	00
10.	Patient on ATT diagnosed with peripheral neuropathy. He is already on Tab pyridoxine 10 mg/day. Next line of management is	Give additional 100 mg Pyridoxine daily	01
		Divide or reduce the dose of offending oranti-TB drugs without compromising on the regimen	01*
		Any other	00
*Total score of 1 will be given for right answer for respective question			

Table II : Baseline characteristics of study population (n = 200)		
S. No	**Characteristics**	**Frequency (Number)**
1	**Gender**	
	Male	87
	Female	113
2	**Age Distribution in Years**	
	25-35	183
	36-45	17
3	**Subgroups of Medical Officers**	
	Junior Residents (Clinical)	132
	Junior Residents (Paramedical)	44
	MBBS Physicians	24

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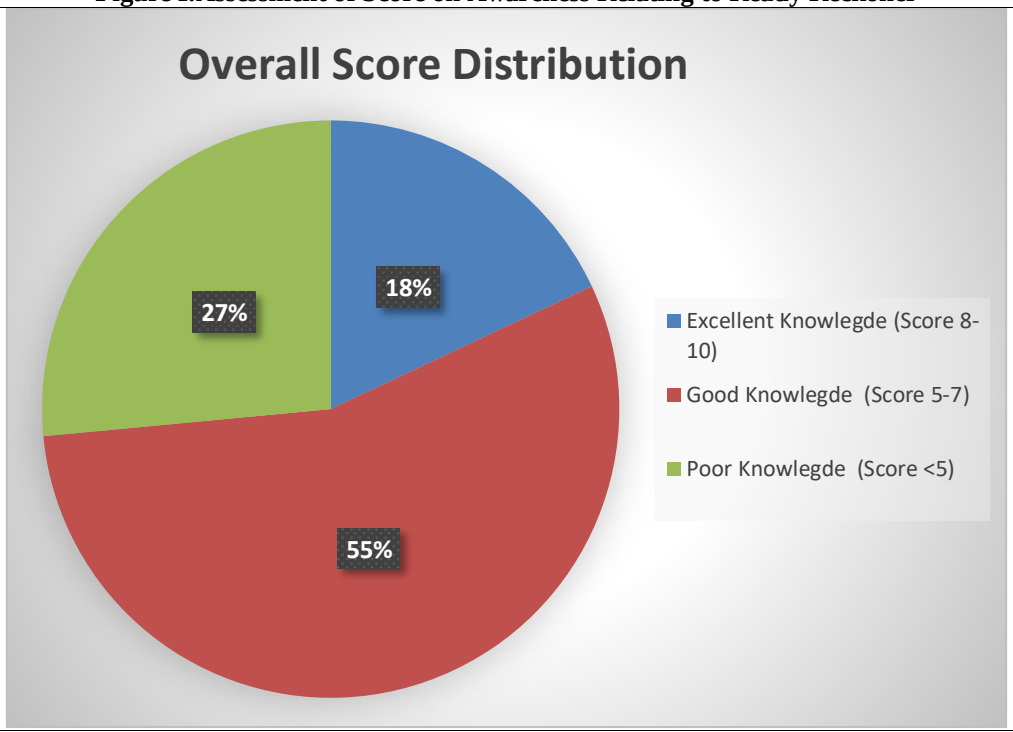
Table III. Assessment of Individual Questions Rightly Attempted by MOs (n= 200)

Sr No	Question	Right Answers attempted (%)*
1	Are baseline investigations done prior to start of treatment?	198 (99)
2	Patient complaining of orange colored urine after start of ATT. What advise you will give to patient?	183 (91.5)
3	A 40 yrs male patient is taking 2nd line ATT containing ofloxacin, cycloserine and kanamycin He complained of acid indigestion. Which drug you will prefer?	159 (79.5)
4	If patient develops nausea and single episode of vomiting after first dose of ATT. What will be your next step?	144 (72)
5	If AST or ALT elevated but less <5xULN with normal bilirubin. What will be next step/s?	129 (64.5)
6	ECG as a baseline investigation is done before putting a patient on which medicines?	85 (42.5)
7	Are you aware of Ready Reckoner on management of ADRs associated with anti-TB drugs issued by Central Tuberculosis division?	75 (37.5)
8	Patient on ATT diagnosed with peripheral neuropathy. He is already on Tab pyridoxine 10 mg/day. Next line of management is:	71 (35.5)
9	If QTc interval is more than 500 ms, what will be your next step?	70 (35)
10	What is the name of platform which has in-built mechanism for recording, reporting and analyzing ADRs due to ATT	39 (19.5)

*In descending order

Figure I:Assessment of Score on Awareness Relating to Ready Reckoner



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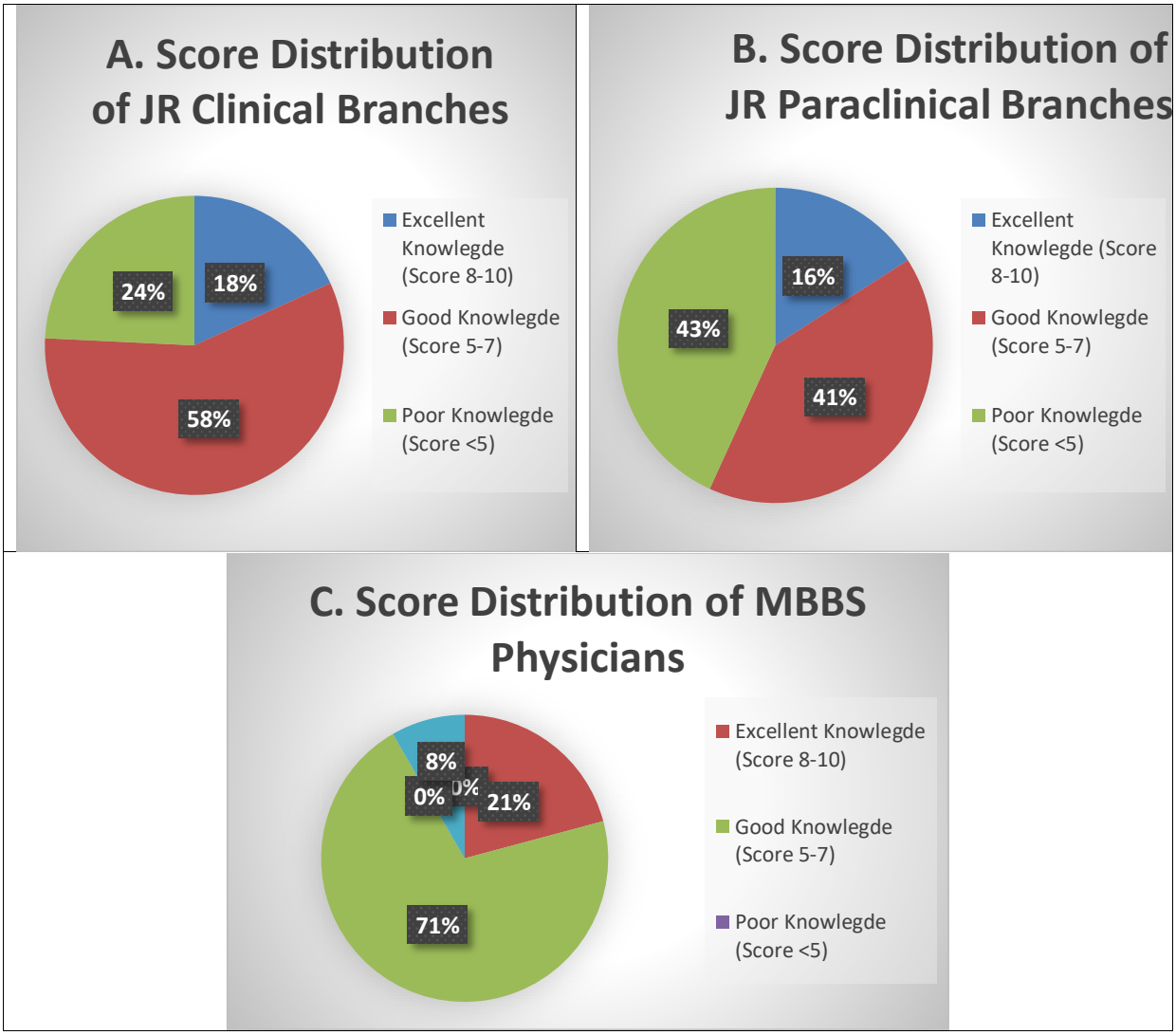

DISCUSSION

The findings from Figure 1 reveal a mixed level of knowledge among Medical Officers (MOs) regarding the management of Adverse Drug Reactions (ADRs) associated with anti-tubercular drugs, as assessed by the Ready Reckoner designed by the Central Tuberculosis Division, Government of India.

The presence of 27% of MOs with "poor knowledge" underscores the importance of targeted educational interventions or training programs to address gaps in understanding. Neverthless, there is considerable potential for improvement in almost 80% of MOs. More than half of MOs were not aware about the Ready Reckoner designed by the Central Tuberculosis Division, Government of India for management of ADRs with anti-TB drugs. However, only around one fourth of these MOs were having poor knowledge.The fact that some MOs answered correctly about managing ADRs without specifically being aware of the Ready Reckoner suggests a couple of possibilities. It's possible that the guidelines for managing ADRs are aligned with standard medical practices or protocols that these MOs are already familiar with. In other words, they may have a good understanding of how to manage ADRs based on their general medical knowledge and experience, even if they're not explicitly aware of the Ready Reckoner.Another possibility is that the Ready Reckoner guidelines are intuitively designed, making them easy to apply even without prior knowledge of the specific resource. If the guidelines are clear, concise, and easily accessible, healthcare professionals may be able to follow them effectively without needing to consult the Ready Reckoner directly.This suggests that the Ready Reckoner guidelines are well-designed and aligned with existing medical practices, allowing healthcare professionals to effectively manage ADRs even if they're not explicitly aware of the resource itself.

Study conducted by Karbach Ute et al[7] in 2011 assessed physicians' knowledge of the guidelinesfor the treatment of cardiovascular diseasesin primary care. As per this study, only 40% of physicians' knew the guideline adequately.Study was done by Mbogori T[8]on awareness and adherence to government guidelines on physical activity by American adults. In this study 36% of participants stated that theyhadnot heardabout government recommendations.Another study conducted by Hagemeister J et al [9]showed that

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awareness of national hypertension guidelines under Germanpractitioners was less than 25% and indicates the need for efficient strategies torelevantly improve guideline awareness.

The findings from the study shed light on the varying levels of knowledge among different categories of healthcare professionals (Figure 1A, B and C) regarding the management of ADRs associated with Anti-Tubercular Treatment (ATT). It is evident that MOs in clinical departments generally exhibited a higher level of knowledge compared to their counterparts in paraclinical departments. This difference could be attributed to the nature of their clinical exposure and direct involvement in patient care, which might provide them with more practical experience and opportunities to encounter ADRs firsthand. Conversely, Junior Residents (JRs) from paraclinical departments may have had less exposure to clinical settings and direct patient care, which could explain their lowerlevel of knowledge in managing ADRs with ATT. These findings underscore the importance of tailored educational interventions targeted at specific healthcare professional groups to address knowledge gaps effectively. Furthermore, the significantly higher proportion of MOs working in Outpatient Departments (OPDs) demonstrating excellent knowledge highlights the potential impact of clinical experience and specialization in enhancing ADR management skills. Overall, these results emphasize the need for continuous training programs to ensure that healthcare professionals across all departments are adequately equipped to handle ADRs associated with ATT, ultimately improving patient safety and treatmentoutcomes in tuberculosis management.

Watt S et al [10]analyzed barriers andfacilitators for implementation of a health care policy. This study concluded that policy enactment is inadequate to stimulate practice changes in health care and policy makersin any system must respect the knowledge and experienceof providers when developing policies that requirepractice change and physicians needs to be informed about policy.Study done by Qumseya B[11] identified barriers to clinical practice guidelineimplementation among physicians through survey. Authors identified several barriers to guideline implementation. These included complexity of guidelines, high number of conditional recommendations, and time constraints due to clinical responsibilities. They recommended that improved focus on guidelines during training and easy access to relevant guidelines at the point of care may be important to improve adherence to guidelines.

While our study provides valuable insights into evaluation of knowledge about Ready Reckoner among MOs, it is essential to acknowledge its limitations. Firstly, the research was conducted within a single hospital setting, which may limit the generalizability of our findings to other healthcare facilities. In addition, other factors that are associated with questionnaire-based studies such as accuracy of recall could also have affected the results of this study.

CONCLUSION

In conclusion,the Ready Reckoner guidelines are well-designed and aligned with existing medical practices which allowsMOs to effectively manage ADRs even if they're not well versed with this guideline.The results of this study emphasize the need for healthcareguideline awareness by MOs developed by Government time to time by implementing measures like additional training and easy access to these guidelines.This will additionally improve skills and knowledge to effectively manage ADRs associated with anti-tubercular drugs, ultimately contributing to better patient care and treatment adherence.The healthcare policies and guidelines established by the Government and prominent academic bodies of India should be incorporated into the MBBS curriculum, alongside authentic sources of these guidelines, to ensure that MBBS students become thoroughly acquainted with them.

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