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AN OBSERVATIONAL STUDY TO EVALUATE KNOWLEDGE AGAINST ADVERSE EFFECTS OF MEDICATIONS USED IN COVID-19 PATIENTS IN TERTIARY CARE HOSPITAL

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ABSTRACT

Purpose: With the currently growing spread of the COVID-19 pandemic, its affective treatment is also a major concern for the medical fraternity. At present there are no proven effective therapies for COVID–19 and the vaccine is also not available yet. The current treatments mainly focus on symptomatic relief and respiratory support. Various pharmacological treatments are currently being tested for patients with COVID–19. The elderly population and patients with underlying disease are at high risk of severe illness from COVID–19.These patients were more prone to experience adverse events (AEs) due to the use of concomitant medications and limited knowledge and inappropriate promotion of unproven therapies by the media and certain public figures leading to some severe ADRs. Thus, quality pharmacovigilance has become more important than ever. **Methods**: An Observational, non-interventional, questionnaire-based study was conducted by the Department of Pharmacology in the COVID ward of SKNMC & GH, Pune. This was a questionnaire-based study including 12 questions on adverse effects experienced due to medication in Covid-19 positive patients. **Results**: Out of the total, about 14% of patients suffered from ADR due to COVID medications while 76% experienced no ADR and 10% didn't know about any ADR. When asked about the severity of ADR; out of 14% of patients,6% wrote as they were having mild symptoms, 6% were moderate and 2% were severe. **Conclusions**: The study indicates that there are few ADRs related to the COVID 19 treatment. Those ADRs were not life-threatening ones.

KEYWORDS: COVID-19, ADR, AE.

INTRODUCTION

Coronavirus disease (COVID–19) is caused by a new coronavirus (CoV) SARS-CoV–2.The SARS-CoV–2 virus is a β coronavirus.[1] The β variant of the coronavirus can infect mammal. The novel coronavirus uses the same receptor, angiotensin-converting enzyme 2 as that for SARS CoV.[2] The pandemic of COVID–19 began in Wuhan, China, in December 2019, and has spread worldwide since then.

At present there are no proven effective therapies for COVID–19 and the vaccine is also not available yet. The current treatments mainly focus on symptomatic and respiratory support.[2] Oxygen therapy represents the major treatment intervention for patients with severe infection. Various pharmacological treatments[3] are currently being tested for patients with COVID–19. Although no antiviral treatment for COVID–19 has been approved, several treatment strategies have been proposed.[4] Primarily, broad-spectrum antiviral drugs like nucleoside analogs and HIV-protease inhibitors that could attenuate virus infection are currently being tested until a specific antiviral becomes available.[5] The most commonly used pharmacological interventions currently being tested for COVID–19 are remdesivir, chloroquine, tocilizumab, lopinavir/ritonavir, favipiravir. The elderly population and patients with underlying disease are at high risk of severe illness from COVID–19. The elderly patients are susceptible to greater frequency of decreased hepatic, renal, or cardiac function, and often have a concomitant disease or are on other drug therapy. All these conditions make COVID–19 patients more prone to experience adverse events (AEs) especially when various existing and novel pharmacological agent currently being tested in this population.[1]

The current COVID-19 crisis has brought about fear and uncertainty in many, resulting in an increased demand for effective antiviral therapies against COVID-19. Several potential therapies are emerging against COVID-19, however, patients and healthcare professionals must

understand that these are only preliminary trial results and they need more study to fully understand their efficacy and side effect profiles. Unfortunately, the media and certain public figures promote therapies that are not yet proven leading to people taking medications inappropriately and experiencing some severe ADRs. In an era where medication misinformation is rampant, quality pharmacovigilance has become more important than ever.[6]

The risk for drug-related adverse reactions is increased. Therefore, drug safety cannot be ignored while ensuring efficacy. Adverse drug reactions (ADRs) range from mild to life-threatening with short-term and long-term effects.

However, little is known about the incidence of ADRs in patients with COVID-19. It may partially solve the problems of under-reporting, undue delays, and miscommunication. Better reporting systems can also have a positive effect on rational drug use in medical institutions.[7]

Some of the main reasons for not reporting include lack of time, complex documentation, lengthy reporting procedures, failure to recognize an ADR, patient confidentiality concerns, and fear of blame. There is also a lack of routine, structured reporting, and shared motivation.[6]

The current study aims to evaluate the knowledge and severity of the adverse effects (AE)/ adverse drug reaction (ADR) occurring in patients with COVID-19 receiving active pharmacological treatment in COVID - 19 patients in tertiary care hospitals.

MATERIAL AND METHOD

An Observational, non-interventional, questionnaire-based study was conducted by the Department of Pharmacology in the COVID ward of Smt. Kashibai Navale Medical College and General Hospital, Pune. This Study included COVID positive patients admitted to the hospital.

- **Inclusion Criteria**

All COVID positive patients admitted to the hospital.

- **Exclusion Criteria**

Patients not willing to fill the consent form.
An incomplete questionnaire was excluded.

- **Study Design**

This was a questionnaire-based study including 12 questions on adverse effects experienced due to medication in Covid-19 positive patients. Sufficient time was given to participants to read, comprehend, and answer all the questions.

Questionnaire validation was done by the Faculty of Pharmacology to determine whether the questionnaire measured what it was designed to measure. Answer to each question was reviewed by experts and the requisite modifications and deletions were done.

The following validation criteria were used:

- The time required for completion of the questionnaire (10-15 min)
- Appropriateness of questionnaire for collecting data
- Repetition or inappropriate questions
- Logical order of questions
- Clear concise and unambiguous questions
- Easy and meaningful instructions

After getting the protocol approved by Institutional Ethics Committee (SKNMC No/Ethics/App/2020/650), the total number of COVID positive patients were provided a pre-validated questionnaire containing 12 questions and they were asked to fill up the questionnaire. Statistics was represented by percentage through a pie diagram and bar graph.

RESULTS

Out of the total of 50 patients enrolled, 20 were females and 30 were males. The mean age of the patients was 42.5 years.

When asked whether they are suffering from any disease, 4% gave a concomitant history of hypertension,4% of diabetes,4% of hypertension along with diabetes, 38% has no concomitant illness, while 50% did not answer the question.(Figure 1).

FIGURE 1

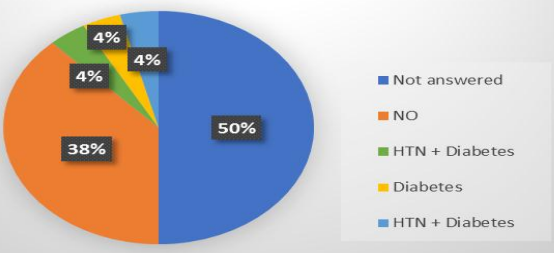

Figure 1: Are you suffering from any other diseases?.

Other diseases, 2 % had kidney stone, while 80% do not have any other disease and 18 % did not attempt the question (Figure 2).

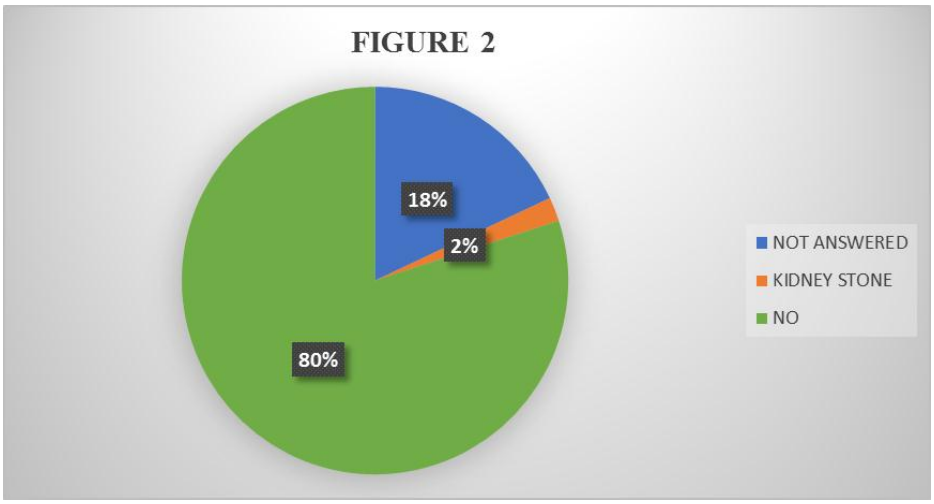

Figure 2: If any other disease?.

When asked about any other medication, only 4% of patients gave a history of medication but with no specification, according to 84 % they were not on any other medication and 12% did not attempt the question. (Figure 3).

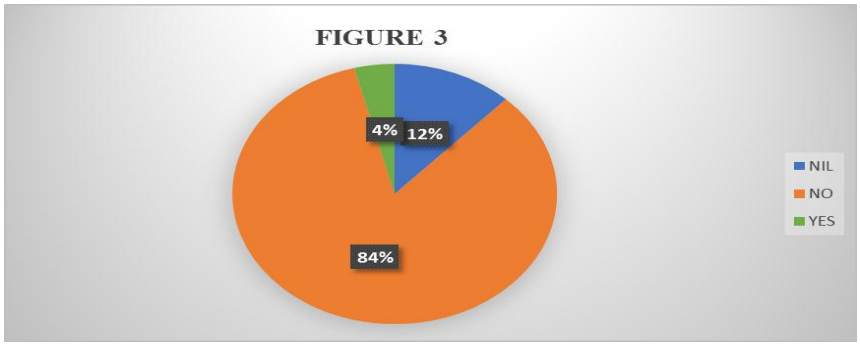

Figure 3: Are you on any other medication?.

Regarding taking any kind of supplementation, 5% were taking herbal preparation,8% on a multivitamin,9% were taking vitamin C, 25% were taking immunity boosters, 10 % were taking chawanprash, 11% were not on any supplementation and 32 % did not attempt the question. (Figure 4).

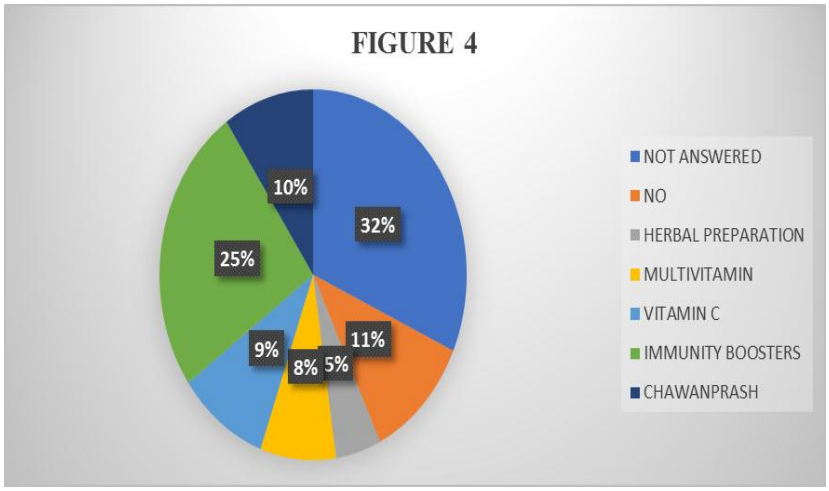

Figure 4: Are you taking any supplements?.

Out of the total, about 14% of patients suffered from ADR due to COVID medications while 76% experienced no ADR and 10% didn't know about any ADR. (Figure 5).

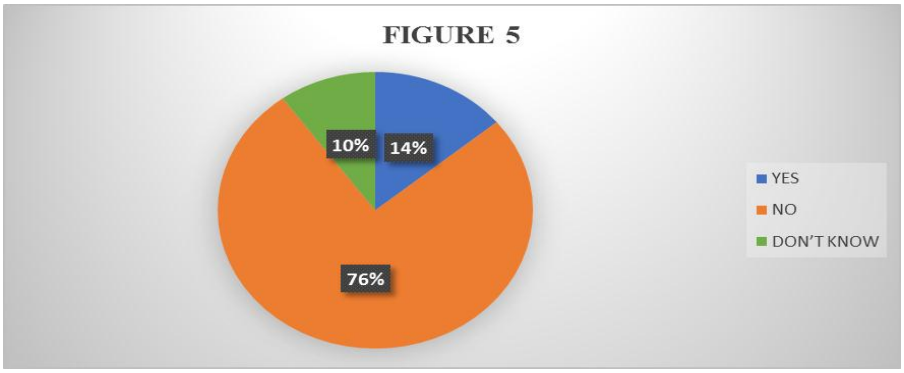

Figure 5: The adverse effect after taking medicines for coronavirus.

When asked about the severity of ADR; out of 14% of patients, 6%wrote as they were having mild symptoms, 6% were moderate and 2% were severe.(Figure 6)

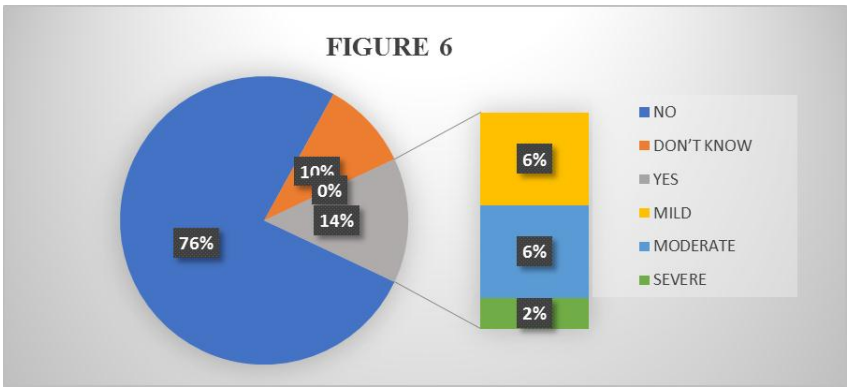

Figure 6: Adverse effects and its severity.

About adverse reactions, one patient was having altered taste sensation and anorexia while the second one was having gastric acidity, vomiting, and anorexia. The third patient experienced gastric acidity, anorexia & altered taste sensation. While the fourth and fifth patient experienced Vomiting and gastric acidity respectively. The sixth and seventh patient presented with an altered taste sensation.(Figure 7).

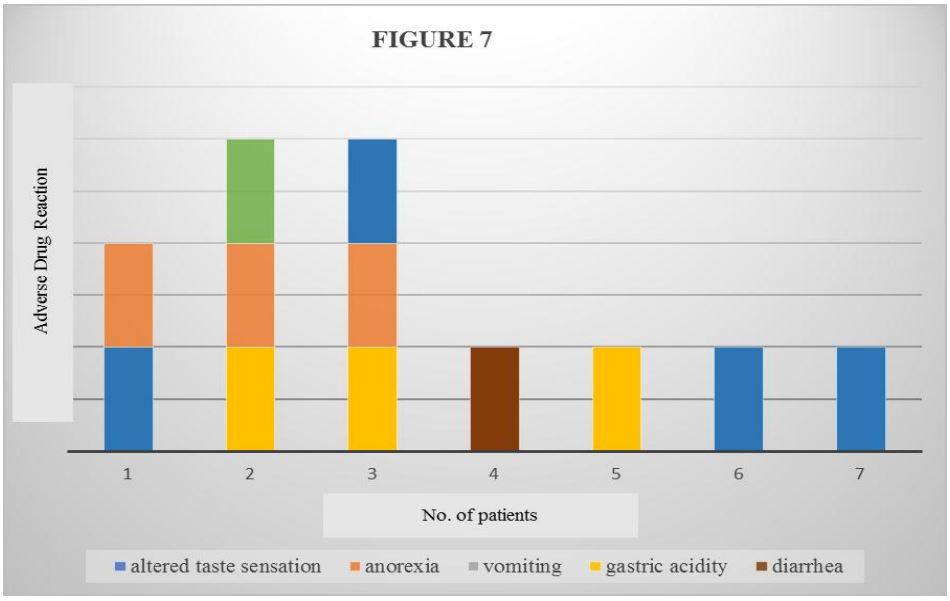

Figure 7: Different ADR experienced by the patients.

All 14 % of patients informed the doctor about the ADR.

Regarding the onset and duration of ADR, one patient doesn't know about it while five patients not attempted that question and one patient answered that reaction was present for 3 days but not mentioned about the onset of the reaction.

The reaction was subsided by the treatment given, according to all 14 % of patients.

None of 14 % of patients experienced the same reaction in the past.

DISCUSSION

There are few studies which are regarding drug safety monitoring. In other studies, ADR was monitored and the causative drugs were mentioned in COVID-19 positive patients. In the present study, we have focused on the knowledge of patients whether they were aware of the adverse effect caused by medication for COVID -19 or not.

A questionnaire covering various aspects was administered provided to the patients to check their knowledge regarding ADR caused by COVID-19 drug used. Many of them were having a co-morbid condition like hypertension and DM and for that, they were taking medication.

Very few patients were having knowledge of ADR that caused by COVID-19 medication.

Most of them experienced gastric acidity and altered taste sensation. Very few were having anorexia, vomiting, and Diarrhoea. They don't know about the onset and duration of the reaction.

So here it's difficult to interpret whether this anorexia and altered taste sensation are due to medication or they were signs of COVID -19 positivity.

Many times ADRs were not reported due to lack of knowledge, failure to recognized ADR, and miscommunication.

Our results showed that very few patients had knowledge about ADR. They show the symptoms but fail to recognized whether its due to medication or not.

Polypharmacy has been reported to be a strong risk factor for ADR in several studies.[8] The length of stay was reported to be significantly associated with the occurrence of ADRs in univariate analysis in the Kojima et al. study.[9]

Besides, there is also a significant association between the age and the occurrence of ADR, but this was not observed in our study. Although other studies have associated age as a risk factor for ADR,[10] our study did not show any association between age and ADRs.

The study was conducted with small sample size. Also, the onset, duration of adverse reaction was not known. The data about any other concomitant medication was not provided so the drug causing ADR cannot be pointed out. These are some major limitations of the study.

CONCLUSION

The study highlighted the need to have a sensitisation program so that everyone can know about ADR reporting. Also, this study indicates that there are few ADRs related to the COVID 19 treatment. Those ADRs were not life-threatening ones.

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