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FULL PAPER

Pharmacovigilance and radiologists: How well do they get along?

¹OZLEM CELIK AYDIN, MD, ²SONAY AYDIN, MD and ¹HAKKI ZAFER GUNEY

¹Department of Medical Pharmacology, Gazi University, Faculty of Medicine, Ankara, Turkey

²Department of Radiology, Dr. Sami Ulus Training and Research Hospital, Ankara, Turkey

Address correspondence to: Ozlem Celik Aydin

E-mail: ozlemclk_89@hotmail.com

Objectives: Considering the growing use of imaging modalities and contrast agents, radiologists are prone to encounter adverse drug reactions (ADR). In the current study, we mainly aim to evaluate the knowledge of radiologists regarding pharmacovigilance (PV). Also, we intend to gather information about their previous ADR experiences. Secondly, we hope to increase the awareness about contrast-medium-related ADRs and attract attention to the importance of properly reporting these ADRs.

Methods: A survey was generated by using an online survey webpage, and the relevant link was e-mailed to radiologists and radiology residents. The survey begins with a short explanation about the study. The second section contains questions about PV knowledge level, and the final section aims to gather information about the experienced ADRs.

Results: The survey was completed by 202 participants. 65.3% stated that they were aware of PV. 24.8%

of the participants said that they know the national PV program. 97% told that they knew the term ADR. 66.3% of the participants encountered an ADR. 53.7% of them reported these ADRs. 70.8% of them reported these ADRs to a clinician.

Conclusions: Radiologists encounter ADRs almost as frequently as the other doctors. Their awareness about PV is similar with other healthcare professionals. They have fewer information about TUFAM and PvCPs. Radiologists generally prefer to communicate with a clinician about an ADR. Overall condition of radiologists about PV is quite similar with other healthcare professionals and education can improve it, as for the others.

Advances in knowledge: Radiologists encounters ADRs almost as frequently as the other doctors. Overall condition of radiologists about PV is quite similar with other healthcare professionals and education can improve it, as for the others.

INTRODUCTION

Pharmacovigilance (PV) encompasses both the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any drug-related problem. The World Health Organization (WHO) created a program for international drug monitoring following the thalidomide disaster of 1961. WHO also encourages countries to create national PV programs. At the end of 2010, 134 countries were included in WHO PV program. The main aims of PV are to enhance safer medication use and to support public health by providing reliable information about the risk profile of medicines.¹

In Turkey, PV activities started in 1985, and Turkey joined the WHO PV program as an official member in 1997. The first PV regulation, "Regulation on the Monitoring and Assessment of the Safety of Medicinal Products for Human Use" was created in 2005, and since that date, the "Turkish Pharmacovigilance Center" (TUFAM) has been

monitoring and assessing national adverse drug reaction (ADR) reports.²

Adverse drug reactions (ADR) are defined by WHO as "noxious and unintended responses to drugs occurring at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function". In Turkey, national ADR reports can be delivered to TUFAM via two main routes, from healthcare professionals or from marketing authorization holders. Healthcare professionals can send these reports to TUFAM either directly or via PV contact points (PvCPs). PvCPs are physicians or pharmacists who collect ADR data and deliver these data to TUFAM, and organize training sessions to enhance PV activities in their hospitals.^{2,3}

Over the last decades, there has been an increase in the use of imaging methods, especially CT, and MRI. In parallel with this increase, there has also been an increase in the

use of radiocontrast agents. Although very useful, radiocontrast agents can cause serious ADRs.⁴ These ADRs must be properly reported to the PV programs to create reliable knowledge, as well as awareness about the proper and necessary use of these agents.

Creating awareness about PV and proper notification of ADRs has recently become a widely studied subject. Studies have been conducted to define and increase the level of knowledge about PV for different healthcare professionals, such as nurses, dentists and doctors.^{5–10} Previous studies have provided information about the PV knowledge of doctors from different branches, mainly clinicians. However, to the best of our knowledge, there is no study in the English literature which has evaluated the awareness of PV of radiologists.

Considering the growing use of imaging modalities and relatedly contrast agents, radiologists are prone to encounter ADRs associated with radiocontrast agents. In the current study, we mainly aim to evaluate the current knowledge of radiologists regarding PV and PV program. Also, we intend to gather information about their previous ADR experiences. Secondly, we hope to increase the awareness about contrast-medium-related ADRs and attract attention to the importance of properly reporting these ADRs.

METHODS AND MATERIALS

The study protocol and questionnaire were approved by the Ethics Committee of the Institutional Review Board. Consent for participation was acquired before the questionnaire. The data were collected between January and May 2020.

A focus group consisting of 10 radiologists with different levels of experience reviewed the questionnaire in terms of content, language, and comprehensibility of the questions. The final questionnaire was created in accordance with this feedback.

The questionnaire was generated using an online survey webpage, and the relevant link was e-mailed to radiologists and radiology residents. E-mail addresses were obtained from the websites of relevant institutions. Occasionally, we managed to reach names of the radiologists; however, we could not find e-mail addresses of these radiologists on webpages of their institutions. In that case, we tried to reach these radiologists through social media platforms (Facebook, Instagram, Twitter, WhatsApp). The responses were collected anonymously and repeated completion of the questionnaire by the same participant was prevented by Internet Protocol (IP) address limitation.

The questionnaire consists of three parts. The first section gives a short explanation of the subject and aim of the study. It is also stated that participation is completely voluntary and responses will be anonymous. Consent for participation is given at the end of the explanation. The second section contains questions about PV knowledge level, and the final section aims to gather information about the ADRs that the participant has experienced. The experience level of the participants (year of experience as a radiologist/radiology resident) is also asked ([Supplementary Material 1](#)).

The potential correlation between the PV knowledge and the experience level of the participants was also evaluated; since PV education has been gaining interest amongst institutions in the last decade,^{10,11} and as a result younger/less experienced participants were expected to have a better knowledge of PV.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) for Windows. 20 software (IBM SPSS Inc., Chicago, IL, USA). Conformity of the data to normal distribution was evaluated with the Kolmogorov-Smirnov test. Distribution of the responses were shown as percentages. Correlations between the experience level and PV knowledge, encountering an ADR, reporting an ADR were analyzed with Spearman correlation analysis.

A two-tailed value of $p < 0.05$ was considered statistically significant.

RESULTS

The survey link reached 613 radiologists and 202 completed the survey.

Of the total respondents, 68 (33.7%) were radiology residents with <5 years of experience and 134 (66.3%) were radiology specialists. The median level of experience of the respondents was 13 years (range, 1–35 years).

Awareness of the term, PV, was stated by 132 (65.3%) respondents, whereas 70 (34.7%) reported no knowledge of PV. Only 50 (24.8%) radiologists stated that they knew about the national PV program, only 40 (19.8%) knew of the Turkish PV Center (TUFAM), and 12 (5.9%) stated that they knew the PV contact points (PvCPs) in their hospital.

The term, ADR, was reported to be known by 196 (97%) respondents, and 172 (85.1%) were able to define all the signs of serious ADR. A total of 236 responses were collected about the components of serious ADR. The distribution of the responses is shown in [Figure 1](#).

A total of 188 respondents (93.1%) correctly stated that ADR covers adverse events occurring when the medication is used under licensed conditions, and 88 (43.6%) correctly stated that adverse reactions occurring under non-licensed conditions were also considered as an ADR. Adverse reactions caused by occupational exposure were considered as an ADR by 98 respondents (48.5%).

A total of 124 respondents (61.4%) correctly defined where to report an ADR, with 90 (44.6%) selecting PvCPs, and 34 (16.8%) TUFAM. The distribution of the responses is shown in [Table 1](#).

An ADR was reported to have been previously encountered by 134 (66.3%) respondents. Of these, the ADR was reported by 72/134 (53.7%) and of those 72 radiologists, 51 (70.8%) reported the ADR to a clinician. The distribution of the responses is shown in [Figure 2](#).

Figure 1. The distribution of answers about the components of serious adverse drug reaction.

Of the previously encountered ADRs, 98 (48.5%) were related with an iodinated contrast medium, 4 (2%) were related with a gadolinium-based contrast medium, and 32 (15.8%) were related with both iodinated and gadolinium-based contrast agents. The 134 respondents who had previously encountered an ADR defined the symptoms of these ADRs according to systems, giving 352 responses about affected systems (Supplementary Material 1). The distribution of systems affected by previous ADRs is shown in Table 2. In 128 of 134 (95.5%) cases of previously encountered ADR, the contrast medium had been administered intravenously/intra-arterially, in two cases, it was administered orally, and in two cases, no information was given about the administration route.

No significant correlation was determined between the experience level of the respondents and PV knowledge. A positive correlation was determined between the level of experience of the respondent and experience of ADR resulting from a

Table 1. Distribution of answers about to whom to report an ADR

Answers	Number of participants (%)
Clinician	10 (5%)
PvCPs	90 (44.6%)
TUFAM	34 (16.8%)
Manufacturer	0 (0%)
I do not know	68 (33.7%)

Figure 2. Distribution of answers about reporting previously experienced adverse drug reactions.

radio-contrast medium (Spearman's $r = 0.63$, $p = 0.00$) and the rate of reporting these experiences (Spearman's $r = 0.57$, $p = 0.04$).

DISCUSSION

The aim of this study was to evaluate the awareness of radiologists about PV. Approximately one-third of the radiologists did not know the term PV and its content. Very few radiologists (24.8%) knew about the national PV program and even fewer were aware of TUFAM or PvCPs. A significant number of radiologists knew the term ADR and its major components, with more than half of the respondents (61.4%) correctly defining where to report an ADR. However, the rate of having reported a previously encountered ADR to TUFAM or PvCPs was low (19.3%).

ADRs are one of the most serious health problems, and a leading cause of mortality and morbidity. PV has recently been gaining more and more importance, as a good PV system will identify the risks of drug-related problems, so that it can reduce drug-related harms.¹² Despite the importance of an effective PV system, the rate of reporting ADRs has not yet reached a desired level worldwide.^{7,13,14}

Table 2. Effected systems in previously experienced ADRs

Systems	Number (%)
Gastrointestinal	63 (17.8%)
Dermatologic	103 (29.2%)
Respiratory	66 (18.7%)
Urinary/Renal	40 (11.3%)
Cardiovascular	28 (7.9%)
Neurologic	38 (10.7%)
Immunologic	14 (3.9%)
Total	352 (100%)

With the increasing use of radiocontrast agents has been increasing, radiologists are becoming more likely to encounter an ADR. To the best of our knowledge, there has been no previous study in literature that has evaluated PV knowledge and ADR reporting experiences of radiologists. Previous studies have mainly concentrated on the reasons for under reporting, and reporting rate differences between healthcare workers (doctors, nurses, pharmacists etc.).^{14,15} These studies have generally not included any radiologists, as radiologists do not usually prescribe drugs or follow patients under medication. Consequently, it is difficult to find recent and reliable data about the PV knowledge of radiologists, even although there is the possibility of encountering an ADR as a result of contrast medium use. The main aim of this study was to define the level of PV awareness of radiologists, to be able to increase awareness of radiocontrast-related ADRs and the proper reporting of these ADRs.

The results of this study demonstrated that 34.7% of the radiologists participating in the study did not know about PV. This rate is similar to that of other recent studies from Turkey, conducted with doctors from different specialisms. In a study by Ergun et al,¹⁵ 25% of the participating doctors stated that they did not know about PV, and this rate was 35.5% in a study by Guner et al.¹⁰ Similar rates have been reported from other countries; a recent study from India¹⁶ stated that 37.6% of the participating healthcare workers did not know about PV, and this rate was similar for doctors in India.⁶ When the current study results are evaluated together with the findings in literature, it can be concluded that awareness of radiologists about PV, although not at a satisfactory level, is similar to that of other specialists or healthcare workers. An awareness level between 60 and 70% is generally considered insufficient and PV training is recommended.^{10,15,16} It can be said that together with other healthcare professionals, radiologists should be included in these training activities.

Awareness of doctors about national PV program changes between 41–77% in the previous studies from different countries (Turkey, Uganda, India, Iraq).^{9,14,16,17} 24.8% of the radiologists stated that they were aware of national PV program, a relatively low percentage in comparison with the other specialists. However, there is also a similar rate (29%) was stated in Ergun et al.'s study, performed in Turkey. Also awareness rates about TUFAM is similar between our study and Ergun et al.'s¹⁵ (19.8% vs 25%, accordingly). Only 5.9% of the participating radiologists knew PvCPs in their institutions; this awareness rate changes between 21.5 and 44% in the literature.^{14,15,17} It can be inferred that; even although radiologists are familiar with PV, they do not have sufficient information about the components of PV and national PV system. The awareness about PV and ADR was questioned separately in the questionnaire, considering the possibility that ADR is a more widely used term than PV. The results confirmed this hypothesis as 97% of the respondents stated that they knew the term ADR, and 86.1% of those were able to define the components of a serious ADR, a significantly higher rate in comparison with awareness of PV. A problematic point about ADR knowledge is that more than half of the radiologists did not consider that adverse events occurring under non-licensed usage or as a result of occupational exposure, were

ADRs, contrary to the fact that these are defined components of ADR.

The main reason for higher rates of awareness rates of ADR than PV can be considered to be that ADR is a more widely used term both in daily life and practice, and is an older term taught during basic medicine education. It might be inferred that, as previously stated, proper training about PV could increase the rate of awareness rate, close to that of ADR. No similar study could be found in English literature that has evaluated the awareness of ADR and PV, separately.

The ADR experiences of the respondents were also evaluated, and it was seen that 66.3% of the radiologists had previously encountered an ADR. In previous studies of other healthcare branches, this rate has been reported to vary between 54.4–70%.^{6,9,16} Therefore, it can be inferred that radiologists encounter ADRs just as often as other specialists.

According to the data obtained in this study, 53.7% of the radiologists reported these ADRs, although 70.8% of those reported to a clinician, instead of PvCP and/or TUFAM. Only 19.3% of the radiologists reported these ADRs to PvCP or TUFAM. However, when the radiologists were asked about the proper person/institution to report an ADR to, 61.4% correctly selected PvCP or TUFAM (44.6%, 16.8%, respectively). It can be understood that most of the radiologists knew the proper way to report an ADR, but in practice, they found it sufficient to communicate only with a clinician. Under reporting of ADRs is also a current and widely known problem for other doctors/healthcare professionals. The rate of reporting an ADR has been reported as 16.6–32% in previous studies conducted on doctors and other healthcare professionals.^{6,9,16,17} The rate of correct reporting of an ADR by radiologists was seen to be similar to that of other healthcare professionals. Similar to the current study results, doctors in a recent study¹⁵ most frequently chose TUFAM and PvCPs to report an ADR theoretically, but the rate of spontaneous reporting of ADRs tended to be 8%, which was even lower than the current study results.

Evaluated with the previous results; both radiologists and other health care professionals know the proper ways to report ADRs, however spontaneous reporting rates are inadequate. In the literature from Turkey and abroad, most frequent reasons to prevent proper reporting is stated as lack of time and lack of knowledge about national PV system.^{10,15,17} According to data obtained from Ministry of Health of Turkey, ADR reporting rates has been increasing annually since 2009 among both clinicians and pharmacists. Unfortunately government data do not contain any detail about the reporting rates according to the branches of the clinicians.^{2,18} As far as we know, our study will be the first one to offer a nationwide information about PV knowledge and attitude of radiologists.

Reporting ADRs has been an important matter for safety concerns among radiologists. Unpleasant effects caused by radiocontrast agent use, such as nephrogenic systemic fibrosis or gadolinium deposits in tissues, have all been defined by correct PV signaling

and effective ADR reporting.^{19–21} Even its proven importance, considering our results and literature data together; reporting rates of ADRs has not still reached an adequate level. As for other health care specialist, training programs about reporting ADRs and PV can increase reporting rates among radiologists.

In the current study, ADRs were stated to have occurred most frequently with iodinated contrast medium and after administration via intravascular route, which was consistent with previous findings in literature.^{22,23} The ADRs reported as previously encountered most frequently created dermatological, respiratory and gastrointestinal symptoms, which was similar to findings in literature.²³ The consistency of the ADR experience data with previous studies can be interpreted as a sign of the reliability of the other responses.

No significant correlation was determined between the experience level of the respondents and PV knowledge. Since 2013, PV training has been gaining importance and is more often included in the routine education syllabus of medical students.¹⁴ As these students become a part of the active workforce of healthcare professionals, the levels of awareness and rates of reporting should increase, and it may be seen in future studies that young radiologists will have more awareness and higher rates of reporting than more experienced colleagues.

In conclusion, the results of this survey study show that radiologists encounters ADRs almost as frequently as other doctors.

Their awareness of PV, although not at a sufficient level, is similar to that of other doctors/healthcare professionals, and they have less information about the major components of the national PV system such as TUFAM and PvCPs. Radiologists generally prefer to communicate with a clinician about an ADR, instead of properly reporting it. The overall situation of radiologists about PV is quite similar to that of other healthcare professionals and, as for all other branches, training can improve this.

CONTRIBUTORS

Study Design: Ozlem Celik Aydin, Data collection: Sonay Aydin, Statistical analysis: Sonay Aydin, Data Interpretation: Sonay Aydin, Hakki Zafer Guney, Manuscript Preparation: Ozlem Celik Aydin, Hakki Zafer Guney, Literature Research: Ozlem Celik Aydin.

COMPETING INTERESTS

All authors declare that they have no conflict of interest. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The local institutional review board approved the current prospective study. Informed consent was acquired from all of the participants.

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