

Drug Related Problems in Radio and Nuclear Pharmacy

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Background: Radiopharmaceutical plays a critical role in modern medicine primarily for the diagnostic purpose, but also for monitoring disease progression and response to treatment. Identification, resolution and prevention of medication related problems is a vital role of healthcare professionals Drug related problems are an important challenge that may affect morbidity and mortality, as well as the patient's quality of life. The Drug Related Problems recorded by the pharmacists were found to be of clinical significance lends support to actively including clinical pharmacists in the therapeutic health care team. **Method:** Data was collected in data collection form using patient's medication file. Patients visiting department of nuclear medicine Gujarat Cancer and Research Institute, Ahmedabad were recruited in study. Data was collected in data collection form By reviewing patient's medication file. **Result:** Total 65 patient included in the study and 146 DRPs identified in 56 (15.47%) patients. The frequency of Drug Related Problem was 2.60 per patient. Most common problems came to know were logistic problem(35.38%), repetition of report (35.38%), Imagine problem (37.69%), patient identifying problem (27.69%), dose selection problem (24.62%), administration problem (87.69%) and vein identifying problem (12.31%). **Conclusion:** It is concluded that apart from general medicines, Drug Related Problems also presented in nuclear and Radio Pharmaceutical product. Moreover there is a need to develop specific classification system to identify the Drug Related Problems associated with radio and nuclear pharmacy.

Key words: Nuclear Pharmacy, Pharmacist, Drug Related Problems, Radio Pharmacy.

INTRODUCTION

Radiopharmaceutical plays a critical role in modern medicine primarily for the diagnostic purpose, but also for monitoring disease progression and response to treatment.¹ Radio pharmacy is integral part of clinical pharmacy so pharmaceutical care is applied in the specialty area of nuclear medicine. Clinical pharmacy and role of Radio pharmacy is in infancy.² There has been Reported Drug Related Problems (DRPs) with the clinical use of radiopharmaceutical. Identification, resolution and prevention of medication related problems is a vital role of healthcare professionals.³ Drugs are a dualistic therapeutic tool. They are intended to cure, prevent or diagnose disease, signs or symptoms, but the shadow side is that improper use can be the cause of patient morbidity and even mortality. In general, problems related to the use of approved

drugs can be summarized with the term "Drug Related Problems".⁴ DRPs can originate when prescribing, dispensing or taking /administering medicines. Drug use problems by the patient are probably the most frequent, but are not always noticed.⁵ The DRPs recorded by the pharmacists were found to be of clinical significance lends support to actively including clinical pharmacists in the therapeutic health care team.⁶ It has been reported in literature that Pharmacist's involvements in patient counselling and pharmacist's willingness and abilities to detect solve and document DRPs in every day routine and categorize and analyze the different types of DRPs in community pharmacies. Pharmacist's role in safe and efficient use of medicines in daily practice in the pharmacy practice.⁷ In the case of most diseases drug therapy

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will enhance health-related quality of life. However, inappropriate use of harmful drugs could evoke new adverse symptoms. This has been known for centuries but, it was first when the reports of aplastic anaemia following treatment with chloramphenicol⁸ and of birth defects after use of thalidomide⁹ that the interest in DRPs increased dramatically. Since then, research in this field has been intensified. The increasing number of available drugs and drug users, as well as more complex drug regimen led to more side effects, drug interaction, and complicates follow-up. DRPs leads to substantial increase health care expenditure, affects both society and patient.¹⁰ The DRP may differ in pharmacologically, pathologically, epidemiologically, and legal respects and may have different consequences, for examples, regards scientific study, regulation or rational use.¹¹ ADRs have been the focus of studies on the drug related morbidity, but they form only small part of DRPs. Medication error, over dosage, Drug dependence, Noncompliance and Therapeutic failure are other examples of problems associated with drug use. Therefore, it may be more appropriate to use the term “DRPs”.¹² There has been reported drug interaction with use of radiopharmaceuticals.¹³⁻¹⁴ Important risk factors included insufficient pharmacological knowledge of health professionals, errors in patient charts or documentation by nurses and inadequate pharmacy services.¹⁵ Nuclear medicine has been associated with radiation exposure from the administration of radionuclides for diagnostic imaging.¹⁶ The incidence of DRPs and hospitalizations in the elderly can potentially be reduced by improving medication use. Enhanced communication, particularly between hospital and community pharmacists and their patients, may be a key mechanism.¹⁷ The documentation of DRPs is regarded as an essential component of pharmaceutical care. Many pharmacists are working to the best practice and to create tools that support their way of practicing.¹⁸ Optimum therapeutic outcome is a term that has been used to describe “the right drug, to the right patient, at the right time.” Optimal therapeutic outcome has been expanded to include the absence of DRPs.¹⁹ It is important to identify and avoid or minimize DRPs as they may cause morbidity and mortality, reduce quality of life and increase health expenses for the patients and for society specially in radio and nuclear – pharmacy. Awareness of the various DRPs and of predictors of the DRPs, should be an important part of high standard drug therapy.²⁰ Non UK studies have reported DRPs to be the cause of 3-16 % of hospital admissions at emergency departments.²¹⁻²³ Studies have been conducted on DRPs,²⁴ but still a need for more thorough knowledge about their nature and the reasons for their occurrence in radio and nuclear pharmacy. Some studies shows the importance

of pharmacist in identification of DRPs.²⁵⁻²⁷

MATERIALS AND METHODS

The study had been conducted at Gujarat Cancer and Research Institute, Asarwa, Ahmedabad during December 2013 to May 2014 for 6 months. Gujarat Cancer and Research Institute, Ahmedabad is located middle of India's/Gujarat's largest city and awarded as Asia's first biggest hospital for a span of many years. Nuclear medicine department and pharmacy that had specifically appointed healthcare professional (doctor, radiologist, technician, radiation officer, patient and facilities) had been selected for participation and study. Researcher pharmacist (i.e. is the trained data collector cum trainee pharmacist visited the ward/working place/ laboratories frequently on routine basis (weekend/ Holidays also included). The study is designed primarily to investigate occurrence of drug related problems (DRPs) in general patients visiting radio and nuclear medicine department/nuclear pharmacy. Thus, study can described as a prospective observational study. Patients of Nuclear Medicine Department included in study. Inclusion criteria of study were patient on nuclear medicine for the diagnostic purpose, patient on nuclear medicine for the therapeutic purpose, age through 18 to 65 years either of sex, patient along with co-morbid condition. An exclusion criterion of study was pregnant woman. Data Collection and study was started after the prior permission of ethics committee, institution permission and specific protocol prescribed by BARC, Bombay.

Data collection Method

For present piece of study to find out DRPs, mechanical problem and problem related to radio and nuclear pharmacy had been collected from appropriate sources by suitable techniques. The patient file and sources approached or reviewed individually. Trainee pharmacist had collect the data from medical charts, medical records, physicians, clinical note, multidisciplinary meeting interprofessional discussion and careful observation of procedures and protocols where each issues for patients were discussed, devised /planned.. On the use of radio pharmaceuticals with regard to diagnosis, management, treatment and follow up.

Drug Related Problems

DRPs is defined an according to definition of PCNE. Operational classification was perform according to Hepler and strand. Hepler and strand defines DRPs as “A drug related problem is an event or circumstances involving drug treatment that actually or potentially

interferes with the patient's experiencing an outcome of medical care". For present piece of work DRPs had been evaluated as per the standard guidelines prescribed by PCNE, Hepler and strand and by Abood. The pharmacist assessed present of DRPs is by using explicit criteria published in standards sources of information.

Most of DRPs were evaluated with the help of standard literature and by multidisciplinary team who may made or guide/decide/accept about acknowledgement DRPs and what action should be taken. Some specific drug may exhibit and introduce more than one DRPs and some of them may interdependent.

Assessment of DRPs

DRPs classified by PCNE and Hepler and strand have been assessed with the help of standard text. The multidisciplinary consultation approach was acted for the quality assessment of DRPs and independent quality assessment had been performed with the help of standard text and if necessary expert/specialized in relevant area were be approached for quality assessment trainee or researcher pharmacist was assessed clinical significance of DRPs and categorized both on PCNE classification and clinical significance.

Statistic analysis

Treatment and analysis (management) was performed with help of computer facilitated Microsoft Windows (Microsoft version 7, USA) and statistical analysis was carried out by using SPSS (Version 22.0, Chicago USA). Descriptive analysis had been represented in mean with standard deviation, frequency, percentage, range to present preliminary data. Fisher exact test was used to test level of significance at 95 % confidence interval at 5% α . Result was considered as significant when p is < 0.05 obtained.

Follow-up had been taken on routine basis.

RESULT AND DISCUSSION

Characteristic of the study population

Study conducted through 16th January to 25th March in Gujarat Cancer and Research Institute, Ahmedabad. During period, Total 420 patients visited either for diagnostic purpose or therapeutic purpose of nuclear medicine department. During this period, file of 85 patients were reviewed. Of the all, 65 patients included as per inclusion and exclusion criteria. 146 DRPs found in 65 patients. In the literature considerable difference

in DRPs frequency have been reported. Rianne reported 442 DRPs in 228 patients in study,²⁵ this showed 736 DRPs in 196 patients.²⁶ The lack of standardized method for identifying DRP restricts the possibility in such area. Much of Such controversy can be explained by differences is the definition and operationalization of team. However, DRP were solely depicted through file/chart review and sometime all attending on ward round. It is likely that attention on ward round in impossible in this discipline as like other medicine which could be on explanation for the lower DRPs prevalence seen in our study. The mean age of the study sample was 43.82 ± 13.65 years. (range 18 - 65 years). There were 16 (24.62%) of patient belongs to age group 18 - 30 years subsequently 15 (23.08 %) patients were in age group 41 - 50, and 51 -60 years respectively. Majority of the patients belongs to age group 41 - 60. There were 36 female (55.38 %) and 29 male (44.61 %) in the sample population. 19 (29.23 %) of the men and 20 (30.76 %) of the women were aged belongs to age group of 18 - 40 and 41 - 65. There was statistically significant difference ($P < 0.0001^*$) between age and gender of the population. There are two main application and use of radiopharmaceutical diagnostic application and therapeutic application. Application of diagnostic radio and nuclear pharmacy was 52 (80 %) while 13 (20 %) were used for therapeutic purpose. Out of the 65 patients with drug related problems, Patients 72.30 % ($n=47$) having the medical condition like cancer, Patients followed by 6.15 %, ($n=4$) were having non cancerous medical condition and Patients 21.53 % ($n=14$) having undiagnosed medical condition however there were higher number of cancerous patient 47 compared to noncancerous patients 4. However there was no statistical significant difference found between medical condition and age ($P = 0.7473$).

Handling of identified DRPs is not straight forward procedure in this area and clinical setting due to underdeveloped clinical pharmacy services in our setting. DRPs in this area of specially are probably handled most successfully by multidisciplinary team. In the setting of Radio and nuclear pharmacy medicine, we found that it is difficult for the patient to achieve adequate understanding of therapy. Therefore, patient run away/ went to home even after injecting a drug. Therefore it is sensible that professional discussion on the optimal drug therapy and in turn handling of DRPs be held with the department after which therapeutic or diagnostic option can be prescribed to the patient or care taker. The research clinical pharmacist had a specific task of searching a DRP and discusses the Radio and Nuclear pharmacy and its problems with other healthcare provider and safety officer available at site. Even through included in teaching curriculum of pharmacy graduate and certificate course

(B. Pharm / D. Pharm) Radio and Nuclear pharmacy subject and its application are under estimated. We found that the most of the medicine were handled exclusively as per criteria laid down by BRIT/BARC/IAEC. Setting infrastructure and procedure was exclusively strengthen concept of Radio and Nuclear Pharmacy application. In such environment, we identified DRPs and were discussed in the team/ mentor indicating that the pharmacist is active and eager to learn and contribution. The participation of clinical pharmacist in this learning and multidisciplinary approached implies stronger focus on us contribution towards DRPs in Radio and Nuclear pharmaceutical products.

One element of the discussion concern whereas the definition show include potential DRPs of radio and nuclear pharmacy but definition on DRPs are still present in limitation. Closeness of problems have been called drug related problems, inappropriate drugs, suboptimal prescribing and so on.

Incidences of DRPs

DRPs in present studies 146 in 65 patients and incidence rate are 15.47 %. This compares more favour with 41.3 % in a large study of Barbara J,¹⁷ Patients hospitalized with internal medicine and a study of Ding-Cheng Chan,²⁸ Tommy W,²⁴ Leanne S.²⁹ in which found DRPs prevalence 78 %, 3-7 %, 30 %. Above studies defined and reported DRP prevalence already to PCNE system as in the current study. Total of 65 patients, 21.54 % (n=14) patients had one DRP, 18.46 % (n=12) patients had two DRPs, 26.15 % (n=17) patients had three DRPs, 13.84 % (n=9) patients had four DRPs, 6.15 % (n=4) patients had five DRPs, while rest of patients (13.85 %, n=9) had no any DRPs.

DRPs in Gender

Account of DRPs outdated in more in female than in male. Female had more DRPs (2.59 per patient) than Male patients (2.54 %) per patient. The highest DRPs (2.66 DRPs per patient) found in the age group of 41 - 65 years patients which was followed by age group of 18 - 40 (2.56 DRPs per patient).

Types of DRPs and its frequency

In line with other studies, inconvenience of drug use, administration, patient related, imagine problems were frequently occurring DRP in our study, had not been subject of assessment in other same studies. It is necessary to the drugs within highest robustness and those with most frequently expose risk when administering drugs on the other hand, it is also necessary to be aware of frequently use of drugs with lower drug dose or high drug dose because direct relationship with DRPs. Low doses

of the drugs were given to 9 patients (13.85%) and higher doses of the drugs were administered to only 7 patients (10.77%). The area and concepts of DRPs overlaps with area and concepts of medication/ medical error. Both these area are of significant and great concerns. Plethora of Journal published on Mechanical error and DRPs in internal medicine setting but published on Radio and Nuclear pharmacy is scarce. DRPs may be a consequence of error. But it is not always true. A DRP as such not always consequences of error. In present piece of study, prescription errors were also observed during the study. Frequency of prescription error was 23 and their respective percentage was seen (35.38%). Another issue found was on the Imaging timing. It was observed in total of 18 of cases which accounts for 27.69%. There was also another issue of vein identification. In 8 (12.31%) patient this problem in vein identification issue was observed. Whereas in 57 (87.69%) patients it was not observed. Reason may be skill of healthcare provider or patient related factors or physicochemical properties of drug. There were 33 patients following instruction. Another issue identified was patients having no sticker. Out of 65 patients, 18 (27.69%) patients had no sticker. The Fluctuation of movement of hand was seen in 8 (12.30%) patients, the repetition of report was seen in total of 23 (35.38%) in 65 patients.

Meyboom *et al.*¹¹ noticed that a uniform classification of DRPs. Suitable for daily practice is not easily available. In literature, a variety of coding system and classification on DRPs are available. They should be suitable not only for studies but also for practice. A suitable system like PCNE classification most /may be easy to use in daily routine and facilities. But most of DRPs problem occurs in on piece of study did not find and fit in PCNE classification. That's why we modified a presentation and kept it in other class of PCNE classification. This approach found suitable for routine practice and data presentation in line of/with and complimentary to the standard practice of radio and nuclear medicine department of at Gujarat Cancer and Research Institute, Ahmedabad. To be able to make relevant comparison, evaluation and practice, there has been methodological similarly. At the present time, we used PCNE classification of DRPs. We feel that classification is incompetent and variation with respect to radio and nuclear pharmacy. Made confusing and therefore our result lie under other class of a PCNE classification.

Distribution of DRPs according to PCNE classification

Frequency of patients with DRPs according to PCNE classification - Nine patients were found with problem in dose selection. Sixteen patients had logistic problem. Higher number of DRPs found in other category which

is patient related problems followed by repetition of report, imagine timing problem, technical problem and administration problem.

Distribution of DRPs according to Hepler and Strand classification

Healthcare professionals perception of pharmacist services was requested result and view point is discussed separately in next section. As per Hepler and Strand classification problems found in present study comes under the other category. In our study dose selection, logistic problem, Imaging timing problem, patient related problem, administration problem, technical problem, repetition of report problem obtained which comes under other category.

Role of Pharmacist

Historically, physician has been wholly responsible for the patient's management. They still make the final decision but now a day's pharmacists are becoming increasingly involved in the management of the patients' drug regimen by providing comprehensive related study and services viz reviews, educational efforts, health promotional and screening activity, participation through multidisciplinary team.

This appears to be time consuming but since the question are often the same in other clinical/similar cares. Therefore, experience of clinical pharmacist in Radio and Nuclear pharmacy find essential.

For Instance, health care provider and technical staff welcome role, responsibilities and working of clinical pharmacist in the area of radio and nuclear pharmacy. Healthcare provider appreciated input and workout done by pharmacist in the area. Medicine management and pharmaceutical care where the prime concern of most of healthcare provider concern a lot. Collaboration among the various healthcare professionals with their respective expertise can lead to significant improvement in patient care. Historically, the physician diagnoses and prescribes while the pharmacist compounds and dispenses medicines. Clinical pharmacists are a primary source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medications.³⁰ Increasingly, however, the pharmacist has gained recognition as an important professional in the multidisciplinary provision of health care. The paradigm shift for pharmacy practice took place in 1990, when Hepler and Strand introduced the concept of 'pharmaceutical care'. The philosophy of pharmaceutical care is now accepted worldwide as a primary mission of pharmacy. The concept of pharmaceutical care can only

be achieved if pharmacists and doctors agree on each other's role, as different perceptions by pharmacists and doctors regarding the pharmacist's role could reduce the level of their cooperation. Several published studies have reported the existence of a communication gap between pharmacists and doctors, including the factors responsible. Already, the level of interaction between physicians and pharmacists in the developed world is high, resulting in safer, more effective, and less costly drug therapy. Pharmacists in the Indian practice in various settings, including community pharmacy, hospital pharmacy, drug information service, pharmaceutical industry, marketing, sales, regulatory agencies, academia, and drug distribution. There are only a few clinical pharmacists working in the public sector in India and virtually none in the private sector. Thus, clinical pharmacy – as special services like radio and nuclear pharmacy is still in its infancy stage in the India and, therefore, requires greater attention to achieve the objective of pharmaceutical care.

Acceptance of pharmacists providing these services is dependent on physicians' perception of pharmacists' competency. Successful implementation of pharmaceutical care requires cooperation between doctors and pharmacists. Therefore, one of the objectives of this study was to find out and evaluate views and acceptance of integrating clinical pharmacists into the radio and nuclear medicine- as a radio and nuclear pharmacist. This was carried out by assessing the perception of health care and providers and staff working at study place regarding the clinical pharmacists' roles and responsibilities in providing better pharmaceutical care to patients in area. Pharmacy practice in developing countries varies significantly from one country to another. In the case of India, the clinical pharmacy professional service is at an early stage of its development in terms of pharmaceutical care. Radio and Nuclear pharmacy and likewise patient services is a need of present time and such is already developed over the globe.

Physicians had low comfort and expectations of patient oriented pharmacist roles but were not threatened to learn more about these capabilities or explore enhanced collaboration in patient care.³¹

CONCLUSION

General use and trends of radio and nuclear pharmaceutical medicine were studied for DRPs in radio and nuclear pharmaceutical. Number of DRPs found more in female (80) than the male (60). Higher number of DRPs (41) found in patients with breast cancer. ^{99m}Tc MDP was most commonly used and prescribed drugs and more number of DRPs (96) as they compared to other three

drugs. Based on this study, it is concluded that apart from general medicines, DRPs also presented in nuclear and radio pharmaceutical product. There is a need to develop specific classification system to identify the DRPs associated with radio and nuclear pharmacy.

LIMITATION

- Several Limitations of the study need to be addressed even though study was carried out with at most care and precaution. Study data and its aspects refer to a highly selected sample who visited department of nuclear medicine as on Radio and Nuclear pharmaceutical.
- Benefit of clinical pharmacist intervention at full of glance was not reported because of unawareness about of role of pharmacist in present setting of India. Clinical pharmacy and Radio and Nuclear pharmacy is in infancy.
- Due to time constraint, it was impossible to follow patient and recruit more number of patients from multiple setting/site. Although the guideline are extensive in practice, due to lack of time and resources. It was not possible to disseminate them and assess their effectiveness in minimizing DRPs. However, this may be possible in future time.
- It is well known that the vast majority of DRPs are variable as we also found in our study. Root cause of the DRPs in this patient group were not specifically analyzed the data prescribed were clearly indicate that the patient were (being) cared for in a specialty unit.

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CONFLICT OF INTEREST

Authors declare no conflict of interest.

ABBREVIATIONS

DRPs: Drug related problems; **ADRs:** Adverse Drug Reactions; **PCNE:** Pharmaceutical Care Network Europe; **BRIT:** Board of Radiation & Isotope Technology; **BARC:** Bhabha Atomic Research Centre; **MDP:** methyl diphosphonate.

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