ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4

Journal of Coastal Life Medicine

# A Pharmacovigilance Study of Adverse Drugreactions Report Forms in Dic Of Svcp, Tirupati

**Received:** 10 February 2023, **Revised:** 14 March 2023, **Accepted:** 16 April 2023

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## Keywords:

Pharmacovigilance, Post-marketing, Adverse drug effects, Effectiveness, Physiological function.

## Abstract

Pharmacovigilance is an important and necessary component of clinical research. Both clinical trial safety and post-marketing surveillance pharmacovigilance are critical throughout the product lifecycle.Pharmacovigilance is defined as "the pharmacological science relating to the detection, assessment, comprehension, and prevention of adverse effects of medicines." In India, pharmacovigilance is still in its infancy, Pharmacovigilance monitors any adverse drug effects.Improve public health and safety in the use of medications.Contribute to the assessment of medicine's benefit, harm, effectiveness, and risk, encouraging safe, rational, and effective use.ADR (Adverse drug reaction) is a noxious and unintended response to a drug that occurs at doses normally used in man for disease prevention, diagnosis, or therapy, or for the modification of physiological function.

## 1. Introduction

Pharmacovigilance is an important and necessary component of clinical research. Both clinical trial safety and post-marketing surveillance pharmacovigilance are critical throughout the product lifecycle.Pharmacovigilance is defined as "the pharmacological science relating to the detection, assessment, comprehension, and prevention of adverse effects of medicines." In India, pharmacovigilance is still in its infancy, Pharmacovigilance monitors any adverse drug effects.Improve public health and safety in the use of medications.Contribute to the assessment of medicine's benefit, harm, effectiveness, and risk, encouraging safe, rational, and effective use.ADR (Adverse drug reaction) is a noxious and unintended response to a drug that occurs at doses normally used in man for disease prevention, diagnosis, or therapy, or for the modification of physiological function. There are several types of ADR reporting systemsbut spontaneous reporting systems is widely used in pharmacovigilance. In this system health care professionals voluntarily reports Adverse effects in reporting forms to the national pharmacovigilance centres, this is very effective and inexpensive system.

## 2. Materials and Methods:

The current retrospective study was carried out by analysing the Spontaneous Adverse drug reactions reporting forms submitted by thehealth-care professionals, collected from the DIC of SVCP associated with Sri Venkateswara Institute of Medical Sciences (SVIMS) Hospital ofTirupati, Andhra Pradesh, India, during the period of 1 year from December 2021 to November 2022.

The ADRs were recorded by healthcare professionals using IPC Suspected ADR Reporting (SADRR) Forms version 1.4and contains various details like patient demographic's details: age, gender, weight, and patient initials,ADR related information: Suspected

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ISSN: 2309-6152 (Online)
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adverse reaction (description of the event, date of onset, and recovery),other relevant medical histories, seriousness, outcomes, Suspected drugs (dose, frequency and route of administration, and durationetc.)and seriousness of the reaction, outcome of the reaction, use of concomitant medications, and additional information.

All the data from Suspected ADR Reporting forms were extracted,

The data collected is categorised based on the various characteristics like Age, Gender, Suspected drugs & their pharmacological classes, type of ADRs,and Causality assessment is done by using Naranjo causality assessment scale (ADR Probability Scale), is a method by which to assess whether there is a causal relationship between an identified untoward clinical event (ADR) and a suspected drug using a simple questionnaire to assign probability scores, based on the scores this method classifies ADRs into four types i.e., definite (9≥), probable (4-8), possible (1-4) and doubt full (0≤).

Modified Hartwig and Siegel severity assessment scale is used to determine severity of ADRs which categorize ADR Severity into 3 categories Mild, moderate, &severe by determining the ADRs level of seriousnessthere are sevenlevels based on clinical consequence, including resultant harm and intensity of medical intervention required.Level 1 and 2 fall under mild category, Level 3 and 4 fall under moderate category, Level 5, 6 and 7 fall under severe category.

The data collected from Suspected ADR Reporting forms was statistically analysed in Microsoft Excel (Microsoft Office Professional 2021), and the results were presented as charts, tables, numbers and percentages.

## 3. Results:

Total 83 ADR report forms is collected for period of 1 year (Dec 2021 to Nov 2022).

ADR occurrence rate is high in adults i.e.,70% in that 34.93% in males and 34.93% in females out of 83 cases 58 cases are adults in that 29 are males and 29 arefemales followed by elders ADR occurrence is 16% in that 6.02% in males and 8.43% in females out of 83 cases 13 cases are elders in that 5 are males and 7 are females, then in teenagers ADR occurrence is 14% in that 12.04% in males and 3.61% in females i.e., out of 83 cases only 12 cases are teenagers in that 10 are males and 3 are females (Table 1 & Fig 1), The ADR occurrence is high in males i.e., 53% out of 83 cases 44 cases are males and in females ADR occurrence is 47% out of 83 cases 39 cases are females.

AGE GENDER

| | **Males (44)** | **Females (39)** |
|---|---|---|
| **Elders (above 60)** | 5 | 7 |
| **Adults (20-59)** | 29 | 29 |
| **Teenage (13-19)** | 10 | 3 |

**Table1:** Distribution of cases based on age and gender

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ISSN: 2309-6152 (Online)
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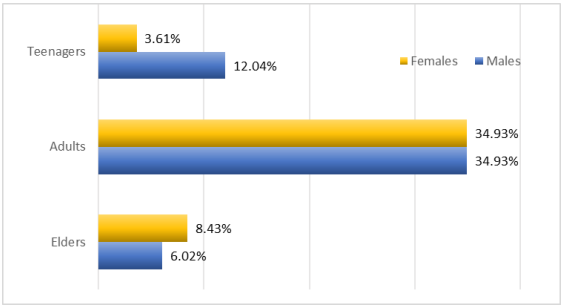


**Figure 1:** ADR occurrence based on age and gender

The vaccines are having highest ADR occurrence i.e., 61.44% out of 83 ADR case reports 51 are Vaccines, followed by the second highest is Antibiotics i.e., 9.63% then Anti-Cancer agents 8.43%, analgesic agents 7.22%, Anti-Diabetic agents, Anti-Convulsant agents, Anti-Fungal agents, Anti-Psychotic agents, Anti-Thyroid agents and Steroids all are having 2.40% ADR occurrence, then Anti-Emetic agents, Anti-Histamine agents, Anti-Viral agents, WBC growth stimulator and PPI are having 1.20% ADR occurrence (Table 2).

| Drug Category | No Of Cases | ADR Occurrence |
|---|---|---|
| Analgesic agents | 6 | 7.22% |
| Anti-Emetic agents | 1 | 1.20% |
| Anti-Biotic agents | 8 | 9.63% |
| Anti-Cancer agents | 7 | 8.43% |
| Anti-Diabetic agents | 2 | 2.40% |
| Anti-Convulsant agents | 2 | 2.40% |
| Anti-Fungal agents | 2 | 2.40% |
| Anti-Histamine agents | 1 | 1.20% |
| Anti-Psychotic agents | 2 | 2.40% |
| Anti-Thyroid agents | 2 | 2.40% |
| Anti-Viral agents | 1 | 1.20% |
| WBC Growth Stimulator | 1 | 1.20% |
| Steroids | 2 | 2.40% |
| PPI | 1 | 1.20% |
| Vaccines | 51 | 61.44% |

**Table 2:** Distribution of cases based on suspected drugs category

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In vaccinations Covishield - 2 dose vaccine have the highest ADR occurrence i.e., 33.33%, Covishield - 1 dose vaccine have the second highest ADR occurrence i.e., 27.45%, Covaxin- 2 dose vaccine have 21.56% ADR occurrence and Covaxin – 1 dose vaccine have 17.64%

| VACCINES | NO OF CASES | ADR OCCURRENCE |
|---|---|---|
| **Covishield- 1** | 14 | 27.45% |
| **Covishield- 2** | 17 | 33.33% |
| **Covaxin- 1** | 9 | 17.64% |
| **Covaxin- 2** | 11 | 21.56% |

**Table 3:** ADR occurrence based on suspected vaccines

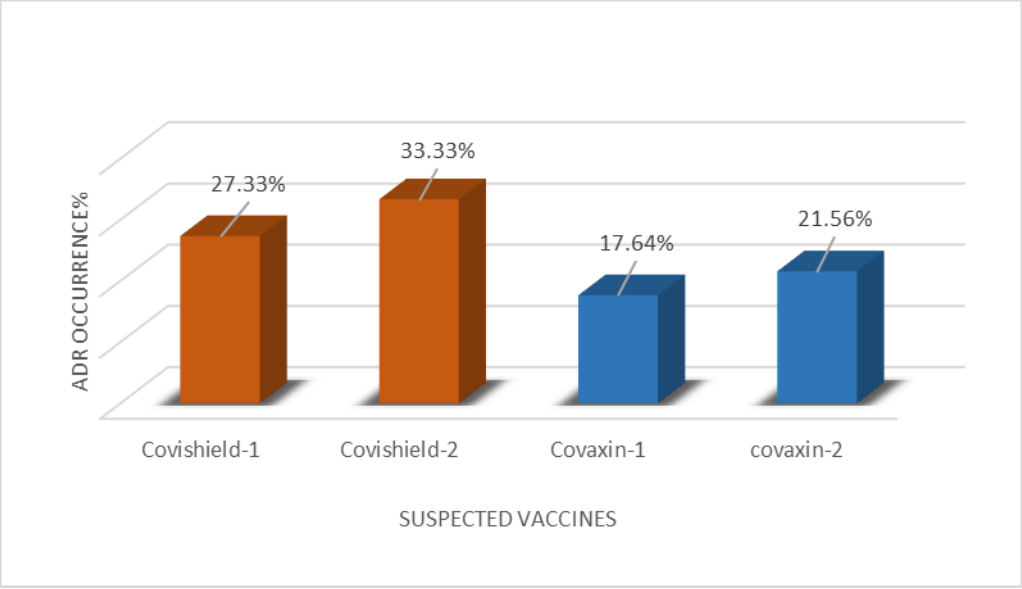


**Figure 3:** Suspected vaccines Vs ADR occurrence

In the suspected drugsCisplatin have the highest ADR occurrence i.e., 8.88%, Kolq and Amoxicillin have the second highest ADR occurrence i.e., 6.66%, Paclitaxel, carboplatin, sulbactam, Cefoperazone, Etorioxib, Gabapin-NT have 4.44% ADR occurrence and Carbimazole, Dacarbazine, Dexamethasone, Doxycycline, Dewax eardrops, Esomeprazole, Itraconazole, Filgrastim, Gliclazide, Hydrocortisone, Clobetasol, Haloperidol, Insulin, Lithium, Olanzapine, Podophyllum, Tinidazole, Ultracet, Prednisolone, Fluoxetine, Pyridostigmine, Pantoprazole, Tramadol, Ondansetron and Multi vitamin tablets are having the 2.22% of ADR occurrence (Table 4).

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| SUSPECTED DRUGS | NO OF CASES | ADR OCCURRENCE |
|---|---|---|
| **Amoxicillin** | 3 | 6.66% |
| **Kolq** | 3 | 6.66% |
| **Carbimazole** | 1 | 2.22% |
| **Cetirizine** | 1 | 2.22% |
| **Cisplatin** | 4 | 8.88% |
| **Cefoperazone** | 2 | 4.44% |
| **Sulbactam** | 2 | 4.44% |
| **Carboplatin** | 2 | 4.44% |
| **Paclitaxel** | 2 | 4.44% |
| **Dewax ear drops** | 1 | 2.22% |
| **Esomeprazole** | 1 | 2.22% |
| **Itraconazole** | 1 | 2.22% |
| **Filgrastim** | 1 | 2.22% |
| **Gabapin-NT** | 2 | 4.44% |
| **Etoricoxib** | 2 | 4.44% |
| **Gliclazide** | 1 | 2.22% |
| **Hydrocortisone** | 1 | 2.22% |
| **Clobetasol** | 1 | 2.22% |
| **Haloperidol** | 1 | 2.22% |
| **Insulin** | 1 | 2.22% |
| **Lithium** | 1 | 2.22% |
| **Olanzapine** | 1 | 2.22% |
| **Podophyllum** | 1 | 2.22% |
| **Tinidazole** | 1 | 2.22% |
| **Ultracet** | 1 | 2.22% |

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|---|---|---|
| **Prednisolone** | 1 | 2.22% |
| **Fluoxetine** | 1 | 2.22% |
| **Pyridostigmine** | 1 | 2.22% |
| **Pantoprazole** | 1 | 2.22% |
| **Tramadol** | 1 | 2.22% |
| **Ondansetron** | 1 | 2.22% |
| **Multi-vitamin tablets** | 1 | 2.22% |

**Table 4:** Distribution of cases based on the suspected drugs

The most common Adverse Drug Reactions are Injection site reactions i.e., 18.34% followed by fever, fever with myalgia is the second highest ADRs caused by the drugs, i.e.,14.40% then Myalgia is the third highest ADRs caused by the drugs i.e., 12.04% followed by vomiting 6.02%, Headache and Constipation 3.60%, Dry mouth, Diarrhoea, Blisters and Rashes 2.40%. then De novo type 2 Diabetes, Fits, Cushing's Syndrome, Ecchymosis, Skin Hardening, Hyper-thyroidism, Sticky eyes & discharge, Desquamation, Neuropathic pain, Numbness, paraesthesia, Psoriasis, Shortness of breath, decreased Na+ levels and stomach pain are 1.20% (Table 5).

| ADR'S | No of cases | PERCENTAGE |
|---|---|---|
| **Denovo type-2 diabetes** | 1 | 1.20% |
| **Constipation** | 3 | 3.60% |
| **Fits** | 1 | 1.20% |
| **Cushing's syndrome** | 1 | 1.20% |
| **Injection site reactions** | 15 | 18.34% |
| **Dry mouth** | 2 | 2.40% |
| **Ecchymosis** | 1 | 1.20% |
| **Fever** | 12 | 14.40% |
| **Fever with myalgia** | 12 | 14.40% |
| **Headache** | 3 | 3.60% |

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| | | |
|---|---|---|
| **Skin hardening** | 1 | 1.20% |
| **Hyper - thyroidism** | 1 | 1.20% |
| **Desquamation** | 1 | 1.20% |
| **Diarrhoea** | 2 | 2.40% |
| **Sticky eyes and discharge** | 1 | 1.20% |
| **Blisters** | 2 | 2.40% |
| **Myalgia** | 10 | 12.04% |
| **Neuropathic pain** | 1 | 1.20% |
| **Numbness** | 1 | 1.20% |
| **Paraesthesia** | 1 | 1.20% |
| **Rashes** | 2 | 2.40% |
| **Psoriasis** | 1 | 1.20% |
| **Shortness of breath** | 1 | 1.20% |
| **Decreased sodium** | 1 | 1.20% |
| **Vomiting** | 5 | 6.02% |
| **Stomach pain** | 1 | 1.20% |

**Table 5:** Distribution of cases based on type of ADRs

According to Modified Hartwig and Siegel Severity assessment scale the Severity of ADRs in our study is mostly Mild i.e., 51.82% of the ADRs followed by 44.57% of ADRs are Moderate and only 3.61% of the ADRs are Severe

(Table6& Fig 6).

| *Severity* | *No of cases* | *Percentage* |
|---|---|---|
| ***Mild*** | **43** | **51.80%** |
| ***Moderate*** | **37** | **44.57%** |
| ***Severe*** | **3** | **3.61%** |

**Table 6:** Severity assessment

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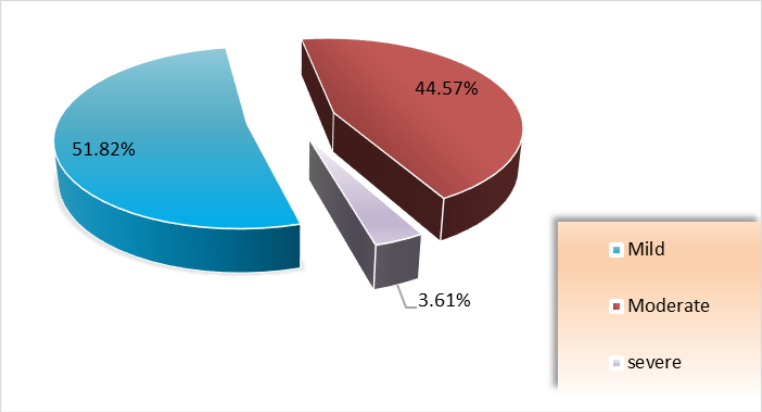


**Fig 6:** Distribution of ADRs based on severity

According to the Naranjo causality assessment scale 55.43% ADRs were Probable 44.57% ADRs were possible (Table 7& Fig 7).

**Table 7:** Causality assessment

| *Causality analysis* | *No of ADRs* | *ADR Occurrence* |
|---|---|---|
| *Probable* | 46 | 55.43% |
| *Possible* | 37 | 44.57% |

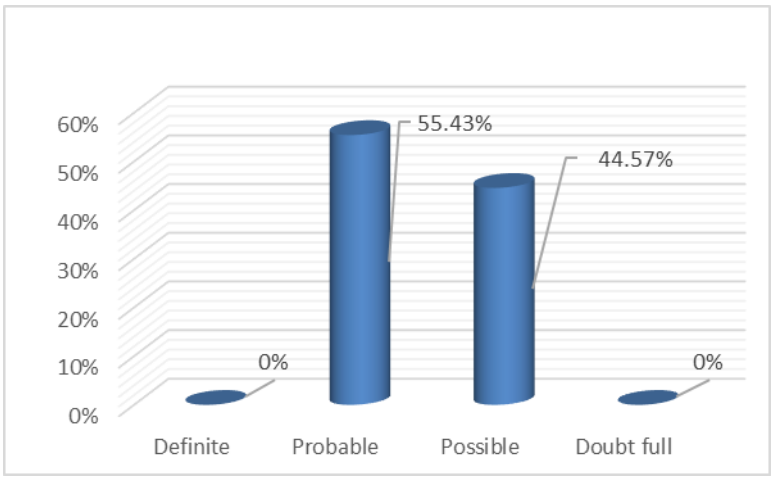


**Fig 7:** Causality of ADRs by using Naranjo causality assessment scale

## 4. Discussion:

In the present retrospective study of total 83 Suspected ADR reporting forms collected from DIC of SVCP associated with SVIMS Tertiary Care Hospital, Tirupati, during the period of 1 year we determined that the ADR occurrence is high in adults 70% out of 83 cases 58 cases are adults followed by elders 16% out of 83 cases 13 cases are elders and in teenage 14%. i.e., out of 83 cases only 12 cases are teenagers.

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When the ADR occurrence rate analysed based on the gender, we found out that the ADR occurrence is high in males i.e., 53% out of 83 cases 44 cases are males and in females ADR occurrence is 47% out of 83 cases 39 cases are females. Similar to this a study by **Sanket S. Gaidhane et al.,**[2]stated that the occurrence of ADR was found slightly higher in males i.e., 53.62% as compared to females i.e., 46.38%. In contrast to our study **Durga Prasad Thammisetty et al.,**[1]stated thatfemales (63.81%) had a higher ADR Occurrence than males (36.12%). This can explain possibly that there may be gender-specific difference in body weight, lipid composition, pharmaceutical susceptibility, or other factors could be the reason of this gender disparity in ADR occurrence. Even though the same has not been demonstrated beyond a reasonable doubt, hormonal implications or hereditary factors variances on the presence of different enzymes may exist.

Our study reveals that out of 83 case reports for adverse drug reactions, 51 of them involve vaccines, with vaccines having the highest ADR occurrence 61.44%, followed by anti-biotics at 9.63%, then analgesics at 8.84%, anti-cancer medications at 7.22%, anti-convulsant medications, anti-fungal medications, anti-psychotic medications, anti-thyroid medications, and steroids at 2.40%, and then anti-emetic, antihistamine, anti-viral, and WBC growth medications with 1.20% ADR occurrence. Almost similar to our findings the study by **Adil Ali Shakur et al.,**[6] stated that the Antibiotics are the most common class of drugs causing ADRs and also study by **Jerin James et al.,**[7] stated that Antibiotics were contributed to the maximum no. of ADRs which accounted for 52.5%. also study by **Ramadan M Elkalmi et al.,**[8]and**Liala Cardina Abu Esba et al.,**[9]stated antimicrobials are accountable for most of the ADRs then followed by analgesics.

According to our findings, the most prevalent Adverse Drug Reactions (ADRs) are injection site reactions (18.34%), fever (14.40%), and fever with myalgia (14.40%). Myalgia is the third most common ADR caused by drugs, accounting for 12.04%, Similar to our findings the study by **Sree Sudha TY et al.,**[5] stated that the most common organ system involved was skin.

Our observational study reveals that Covishield - 2 dose vaccine have the highest ADR occurrence(17.38%), Covishield - 1 dose vaccine (14.28%), followed by Covaxin - 2 dose vaccine (11.22%) and Covaxin - 1 dose vaccine (9.18%) ADR occurrence followed by Cisplatin (4.08%), Amoxicillin and Kolq (3.06%), cefoperazone, Sulbactam, Carboplatin, Paclitaxel, Gabapin-NT and Etoricoxib are having 2.04%, Carbimazole, Dacarbazine,Dexamethasone, Doxycycline, Dewax eardrops, Esomeprazole, Itraconazole, Filgrastim, Gliclazide, Hydrocortisone, Clobetasol, Haloperidol, Insulin, Lithium, Olanzapine, Podophyllum, Tinidazole, Ultracet, Prednisolone, Fluoxetine, Pyridostigmine, Pantoprazole, Tramadol, Ondansetron and Multi vitamin tablets are having the 1.02% of ADR occurrence.

Based on our findings by using Naranjo causality assessment scale 55.43% ADRs were Probable i.e., 46 cases out of 83 is probable, 44.57% ADRs were possible i.e., 37 cases out of 83 is possible and none of the cases in our study is neither definite nor doubt full. This is similar to the study conducted by **Hari Babu et al.,**[4]stated that 88.2% of the ADRs cases were probable while 11.7% were possibleand contrary to study conducted by **Debasish Misra et al.,**[3] stated that in his study 37.7% were probable and 62.3% were possible reactions in both of their studiesneither definite nor doubt full reactions is present just like in our study.

Severity assessment is carried out by using modified Hartwig and Siegel scale the severity of ADRs in our study is mostly mild, with 51.82% of ADRs being mild, 44.57% being moderate, and only 3.61% being severe. This is almost similar to the study by **Sanket S. Gaidhane et al.,**[2]72.73% ADRs belonged to the mild category and 27.27% ADRs belonged to the moderate category. and also, the study by **Hari Babu et al.,**[4]stated that mild (84.3%) and while moderate is (15.68%).

## 5. Conclusion:

In our conclusion Vaccines, Anti-biotics,and Analgesics are having the high ADR occurrence, the possible explanation for the Vaccines ADR occurrence can be due to the pandemic period vaccines brought into the usage in very short period of time than usual,so the proper attention is needed for the vaccines in order to prevent the ADRs. In case of Antibiotics and analgesics the irrational prescription might be the

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reason, hence the rational use of Antibiotics and analgesics may prevent the ADRs.We conclude that our data may be help full to the health care professionals in order to minimize ADRs and increase the patient quality of life.

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