



# ***A DESCRIPTIVE STATISTICS ON ADVERSE DRUG REACTIONS OF ANTI-PSYCHOTIC DRUGS***

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## **ABSTRACT:**

The main purpose of anti-psychotic pharmaceuticals is to treat psychotic symptoms such as delusions, hallucinations, and disordered thought patterns. Bipolar disorder, schizophrenia, and severe depression with psychotic symptoms are among the disorders for which they are frequently prescribed. This study's objective is to compile the ADRs that have been reported from the chosen studies and assess the data regarding the prevalence of ADRs among the most often prescribed anti-psychotic medications. Additionally, we have examined the prevalence of ADRs in adults versus older adults and males versus females. The information on adverse drug reactions (ADRs) for anti-psychotic drugs comes from original research publications that are published in nation. The medications that caused the highest incidence of adverse drug reactions (ADRs) among the analysed trials were second-generation anti-psychotics, such as olanzapine and risperidone. Since women and people between the ages of 40 and 60 are more likely than men to experience adverse drug reactions (ADRs), healthcare professionals should consider all pertinent factors when providing anti-psychotics to these populations. We

included the data from all the studies in our analysis to support earlier findings that revealed older people and adult females experienced more ADRs than adult males.

**KEYWORDS:** Adverse Drug Reactions, Psychosis, Risperidone, Schizophrenia, Populations.

## 1. INTRODUCTION :

"The wisdom and conditioning relating to the discovery, assessment, understanding, assessment and forestalment of adverse goods or any other medicine related problems" is how the World Health Association defines pharmacovigilance. It is essential to ensuring that patients are given safe medications. Numerous colourful methods, such as robotic reporting, intense monitoring, and database studies, can expand our understanding of a medication's adverse effects.

In India's healthcare system, adverse drug reactions (ADRs) linked to anti-psychotic medications are a major concern. The most successful medications used in psychiatry for the maintenance treatment of schizophrenia, psychosis, and mania are anti-psychotics <sup>(2)</sup>. However, any medication meant to treat this incurable illness may occasionally have unanticipated and detrimental side effects on patients. These adverse drug reactions (ADRs) cover a broad spectrum of side effects, from minor discomfort to potentially fatal consequences. The difficulties presented by ADRs are particularly noteworthy in the Indian context because of things like the reduction of organic and functional psychotic symptoms <sup>(3)</sup>. differences in patient demographics and healthcare infrastructure.

"Any noxious and unintended response to a drug, occurring at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function," is how the World Health Organisation defines an adverse drug reaction (ADR) <sup>(4)</sup>. In medical facilities, adverse drug responses happen virtually every day. They can have a negative impact on a patient's quality of life and frequently result in significant morbidity and mortality. Globally, the occurrence of adverse drug reactions (ADRs) is influenced by a growing number of medications on the market, an ageing population, and an increasing trend in polypharmacy <sup>(5)</sup>. These days, there are two widely accepted classification schemes for adverse medication reactions. Type A or augmented (dose dependent and predictable) and type B or bizarre (dose-independent and unpredictable) were the initial categories<sup>(6)</sup>.

Adverse drug reactions (ADRs) are often linked to pharmacotherapy for mental health conditions. A patient may need to try several medications to manage their symptoms, which raises the possibility of an adverse drug reaction. Nearly every mental illness has a short-term cure and requires lifelong care <sup>(7)</sup>. Since the topic of drug safety has gained more attention in recent years, the advent of new medications (atypical anti-psychotics, SSRIs,

and SNRIs) has fundamentally altered psychopharmacological treatment. Because adverse drug reactions (ADRs) involving psychotropic medications are common but frequently go unreported, pharmacovigilance in psychiatric units is essential for ensuring therapeutic safety by identifying early warning signs to evaluate the risk/benefit pharmacological profile <sup>(8)</sup>. Anti-psychotic medications frequently cause side effects such weight loss, convulsions, and hypotension.

At least 6.5% of Indians suffer from some kind of severe mental illness, according to a National Commission on Macroeconomics and Health research <sup>(10)</sup>. According to epidemiological research conducted over the last 20 years, the prevalence of mental diseases varies between 18 and 207 per 1000 people, with a median of 65.4 per 1000 at any given period. In India, the rate of urban morbidity is 3.5% more than that of rural areas <sup>(10)</sup>. The National Institute of Mental Health and Neurosciences in Bangalore estimates that the prevalence of schizophrenia is 4/1000 in both sexes and all age groups<sup>(11)</sup>.

**Psychotic disorders:** are a group of mental health conditions characterized by a disconnection from reality. This disconnection can lead to significant distress and impairment in daily functioning.

## 1.1 ANTI-PSYCHOTIC DRUGS

Anti-psychotic drugs are a class of medications primarily used to manage symptoms of psychotic disorders. Anti-psychotics help to alleviate symptoms such as delusions, hallucinations, disorganized thinking, and agitation.

### Classification of anti-psychotics drugs

#### 1.First-generation anti-psychotics drugs:

First-generation anti-psychotics are dopamine receptor antagonists (DRA) and are known as typical anti-psychotics <sup>(12)</sup>.

##### A. Phenothiazines –

1. Aliphatic (low/medium-potency agents): Chlorpromazine and Triflupromazine
2. Piperidine (low/medium potency agents): Thioridazine
3. Piperazine (medium/high-potency agents): Fluphenazine, Trifluoperazine

##### B. Butyrophenones (high-potency agents): Droperidol, Haloperidol, Trifluoperidol

**C. Thioxanthenes** (low/medium-potency agents): Thiothixene and Flupenthixol

**Mechanism of action:** Typical or first-generation anti-psychotics act by blocking the dopamine D2 receptors in the CNS. There are five subtypes of dopamine receptors-D1 to D5. They are all G protein coupled receptors as proposed in DA hypothesis, dopaminergic overactivity mainly in the limbic area is thought to be responsible for schizophrenia, and typical anti-psychotics block dopamine D2 receptors in the CNS particularly in the mesolimbic area. Some drugs like phenothiazines also block D1, D3 and D4 receptors. However, anti-psychotics efficacy correlates with D2 blocking ability. Dopamine receptor blockade also is responsible for the classical side effects (Fig. 17.2) of these agents including extrapyramidal effects<sup>(14)</sup>.

**Second-generation anti-psychotics drugs**

Second-generation anti-psychotics are serotonin-dopamine antagonists and are also known as atypical anti-psychotics. The Food and Drug Administration (FDA) has approved 12 atypical anti-psychotics as of the year 2016<sup>(13)</sup>.

**Mechanism of action:** Second generation anti-psychotics work by blocking the excitatory activity of dopamine and serotonin, chemicals (neurotransmitters) released by nerve cells (neurons) to transmit nerve signals. Dopamine and serotonin regulate many functions including pleasure sensation, mood, behaviour, learning and memory, among others.

While most FGAs block only D2 dopamine receptors, SGAs block both D2 receptors and 5-HT<sub>2A</sub> serotonin receptors. Receptors are protein molecules on the surface of neurons that initiate action when stimulated by these neurotransmitters. D2 and 5-HT<sub>2A</sub> receptors are types of excitatory receptors, believed to be involved in psychosis.

Some SGAs work by also stimulating 5-HT<sub>1</sub> serotonin receptors, which are inhibitory receptors, in addition to blocking 5-HT<sub>2A</sub> receptors. SGAs also have effects on other neurotransmitters such as norepinephrine <sup>(15)</sup>.

Anti-psychotic is used to treat psychosis and different mental disorders. But they also have a capacity to cause a wide range of potential adverse drug reactions that can lead to non-compliance that can impair quality of life, may cause the extra-pyramidal symptoms which can lead to discontinuation of therapy and in

extreme cases it may be fatal<sup>(9)</sup>. Hence this study was conducted to collate, analyze and represent ADRs due to anti-psychotic drugs as per aim and objective of this study.

## 2. Methodology

### 2.1 Data sources and searches

Studies were identified through International and National electronic databases including PubMed, Scopus and Google scholar. Databases using the MESH terms: Anti-psychotics drugs ADRs, pharmacovigilance and free text words that included the search terms are ADRs, anti-psychotics drugs, pharmacovigilance and observational studies are the primary selections of the papers were done without restricting the fields.

### 2.2 Eligibility criteria

The criteria used for the search were limited to Cohort studies and cross-sectional studies conducted among inpatients and outpatients prescribed with anti-psychotics drugs. The articles were excluded if they were conference proceedings, study article, reviews, and meta-analysis, not conducted on humans. Studies involving less than 50 patients are not considered.

### 2.3 Study selection

Five graduate students independently screened the titles and abstracts of the initially identified studies to determine whether they would satisfy the predetermined selection criteria. The disagreements on the selection selected titles. Reference lists of the retrieved articles were searched for additional publications. All the graduate students who are involved in this study have assessed again the retrieved studies independently to ensure that they satisfied the inclusion criteria.

### 2.4 Study quality

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were used to assess the quality of the eligibility criterion, sources and methods of selection of participants, reported numbers of outcome events or summary measures, and mentioned limitations of the study. Studied fourteen articles, which met the eligibility criteria, were included for the preparation of review and studies that did not meet the quality scores were excluded.

## 2.5 Data extraction and quality assessment

The number of papers published in each year is listed and the design of the study involved in each article is noted down. The sample size in each study, the design, sampling period, explored medicines and geographical location were recorded. The number of ADRs in the whole sample, in males and females and in patients' age groups below 40 years, 40 to 60 years and above 65 years are extracted separately for individual drugs to analyze the influence of sex and age on the percentage incidence ADRs. Qualitative analysis of all the studies are done to report the type of ADRs recorded in the studies selected to compare whether there are any differences in the type of ADR occurrence among the drugs studied. We have also tabulated the reported ADRs in the articles selected for the individual anti-psychotics drugs analysed in the present studies.

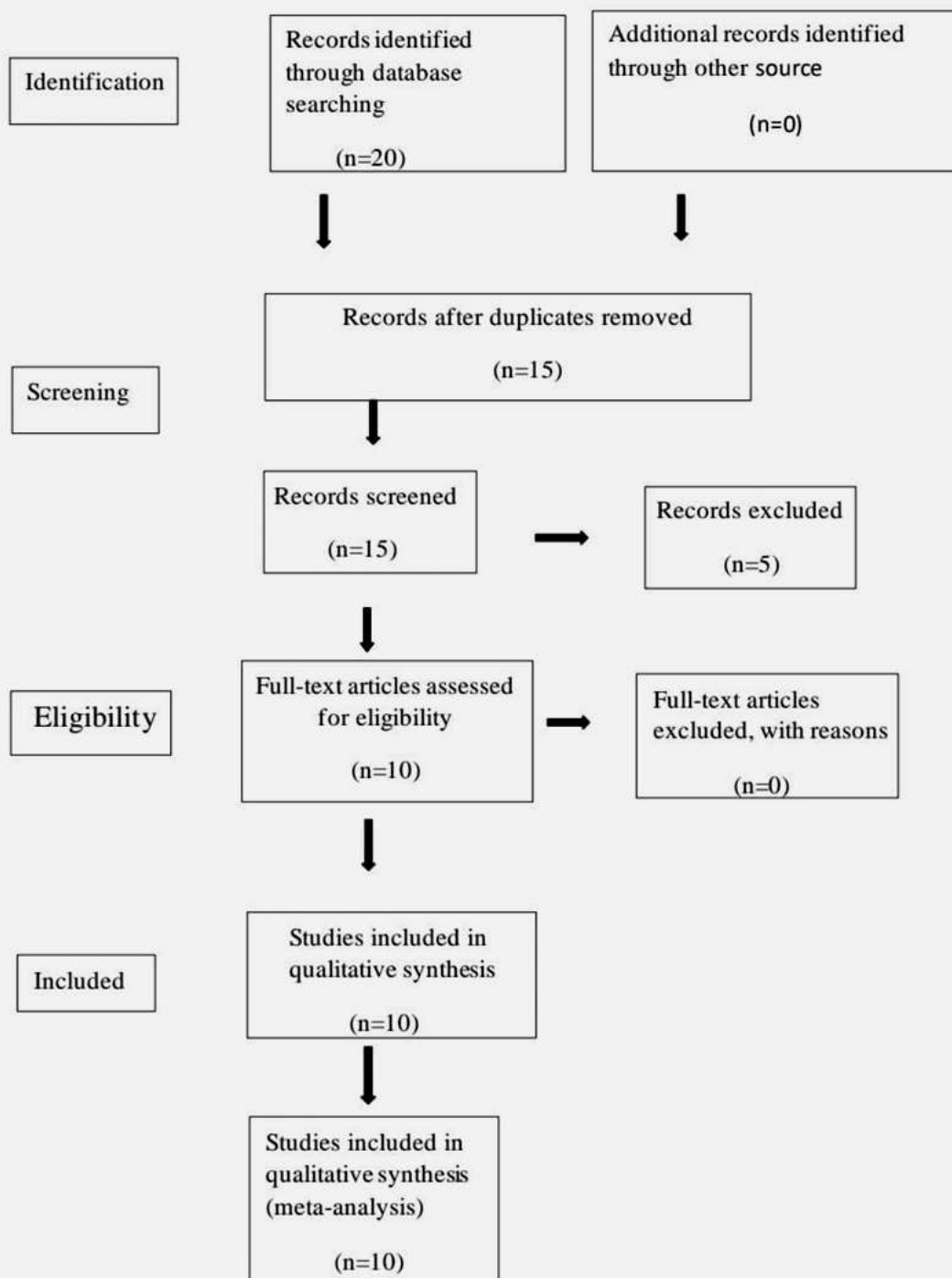
## 2.6 Inclusion criteria

- Observational studies conducted from the year 2019 to 2024.
- Original research papers which offer relevant information concerning the objectives of the study.
- Studies conducted on humans
- Articles which are having Anti-psychotics drugs

## 2.7 Exclusion criteria:

- Case studies.
- Abstracts only.
- Review papers.



**PRISMA 2009 Flow Diagram****3. Results****Table 1: Detailed characteristics of the included studies.**

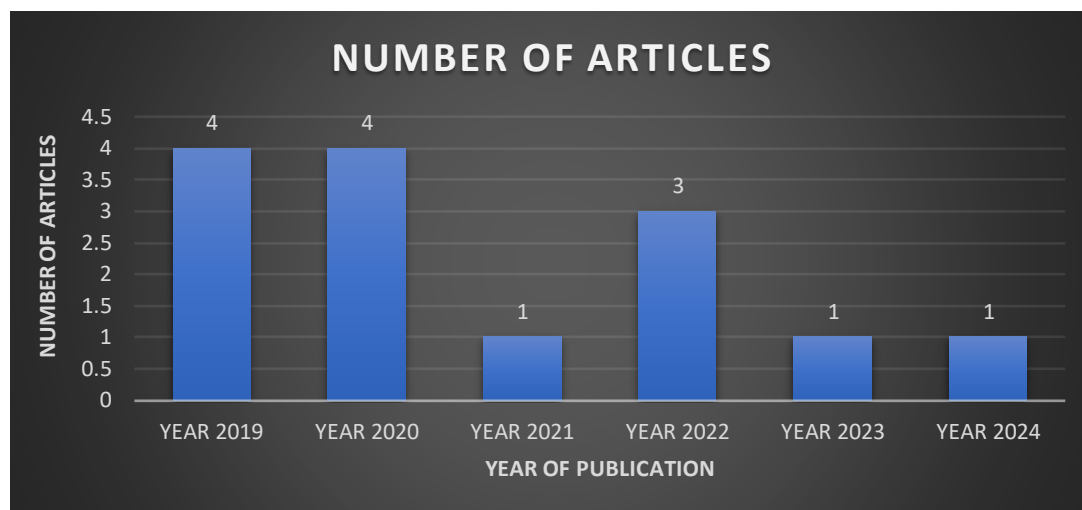
| Author, year | Country | Study design | Study duration | Drugs involved/ used in patient | References |
|--------------|---------|--------------|----------------|---------------------------------|------------|
|              |         |              |                |                                 |            |

|                       |                   |                                 |           |                                                                                          |    |
|-----------------------|-------------------|---------------------------------|-----------|------------------------------------------------------------------------------------------|----|
| Subeesh.V et al, 2019 | Banglore,India    | Prospective observational study | -         | Risperidone,<br>Olanzapine,<br>Quetiapine,<br>Aripiprazole,<br>Amisulpride               | 16 |
| Oommen S et al, 2019  | Pondicherry,India | Prospective observational study | 12 months | Clozapine,<br>Risperidone,<br>Olanzapine,<br>Quetiapine,<br>Aripiprazole,<br>Amisulpride | 17 |
| Chikowe et al, 2019   | Malawi, India     | Cross sectional study           | 4 weeks   | Chlorpromazine,<br>Haloperidol                                                           | 18 |
| Wubeshet YS et al,    | Ethiopia          | Cross sectional study           | 4 months  | Chlorpromazine<br>Thioridazine<br>Trifluoperazine<br>Fluphenazine<br>Haloperidol         | 19 |
| Mahakalkar S et al.,  | Maharastra, India | Prospective study               | 3 months  | Chlorpromazine<br>Levosulpride,<br>Clozapine                                             | 20 |

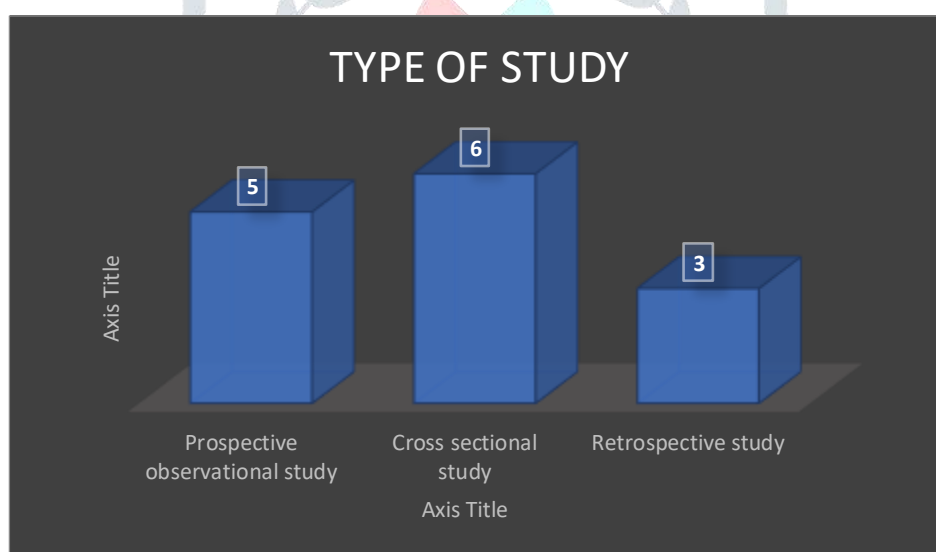
|                            |                  |                       |          |                                                                                                                        |    |
|----------------------------|------------------|-----------------------|----------|------------------------------------------------------------------------------------------------------------------------|----|
|                            |                  |                       |          | Risperidone<br>Olanzapine<br>Lurasidone                                                                                |    |
| Angadi NB et al.,          | Karnataka, India | Cross sectional study | 6 weeks  | Trifluoperazine<br>Haloperidol<br>Clozapine<br>Risperidone<br>Olanzapine<br>Aripiprazole<br>Ziprasidone<br>Amisulpride | 21 |
| Bahta M et al.,            | Saudi Arabia     | Cross sectional study | 45 days  | Chlorpromazine<br>Fluphenazine<br>Haloperidol                                                                          | 22 |
| Lakshmi Prasanna T et al., | Gaziabad ,India  | Retrospective study   | 2 years  | Chlorpromazine<br>Haloperidol<br>Clozapine<br>Risperidone<br>Olanzapine<br>Quetiapine                                  | 23 |
| Rallabandi SS et al.,      | Warangal , India | Prospective study     | 6 months | Chlorpromazine<br>Trifluoperazine<br>Haloperidol                                                                       | 24 |

|                   |                     |                       |           |                                                                                                                                               |    |
|-------------------|---------------------|-----------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------|----|
|                   |                     |                       |           | Clozapine<br>Risperidone<br>Olanzapine<br>Quetiapine<br>Aripiprazole<br>Ziprasidone<br>Amisulpride                                            |    |
| Minjon L et al.,  | Netherlands         | Retrospective study   | 1.6 years | Clozapine<br>Risperidone<br>Olanzapine<br>Quetiapine<br>Aripiprazole<br>Ziprasidone<br>Asenapine<br>Iloperidone<br>Lurasidone<br>Paliperidone | 25 |
| Lavanya G et al., | Telangana, India    | Prospective study     | 6 months  | Clozapine<br>Risperidone<br>Olanzapine<br>Quetiapine<br>Aripiprazole<br><b>Amisulpride</b>                                                    | 26 |
| Sidhu JK et al.,  | Uttarpradesh, India | Cross sectional study | 6 months  | Haloperidol<br>Risperidone                                                                                                                    | 27 |

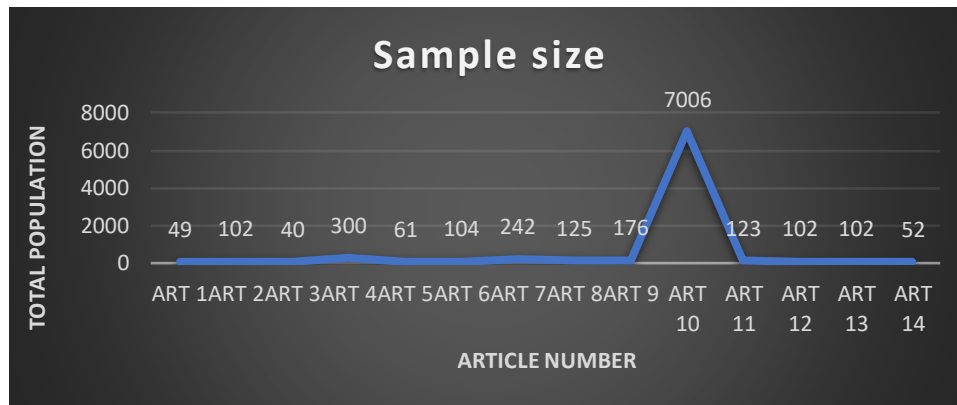
|                            |         |                        |          |                                                                                                     |    |
|----------------------------|---------|------------------------|----------|-----------------------------------------------------------------------------------------------------|----|
|                            |         |                        |          | Aripiprazole                                                                                        |    |
| Fekete S et al.,           | Germany | Retrospective study    | 2 years  | Thioridazine<br>Haloperidol<br>Clozapine<br>Risperidone<br>Olanzapine<br>Quetiapine<br>Aripiprazole | 28 |
| Rojas-Valladares E et al., | Mexico  | Cross sectional study, | 6 months | Clozapine<br>Risperidone<br>Olanzapine                                                              | 29 |

**Fig 3.1: The below graph represents year of publication of articles**

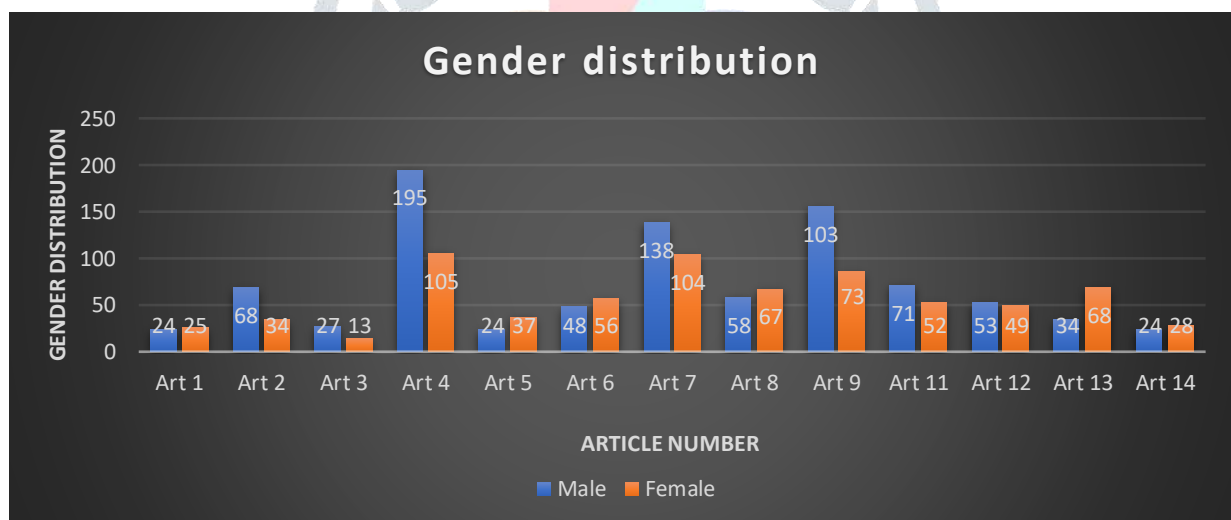
Based on the inclusion and exclusion criteria in this review work 14 articles were selected. The research articles were selected from the year 2019 to 2024 are 2019 (n=4), 2020(n=4),2021(n=1),2022(n=3),2022(n=3), 2023(n=1),2024(n=1), are showed in fig 5.1.

**Fig 3.2: The below graph represents the type of study conducted from selected articles.**

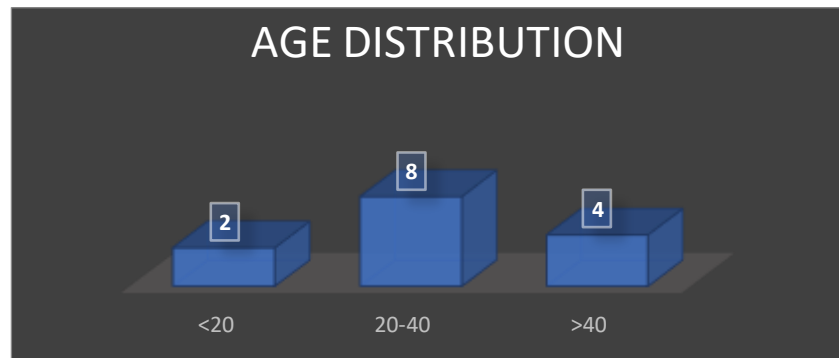
The above graph shows, Out of 14 articles ,5 studies were prospective observational studies (n=1,n=2,n=5,n=9,n=11), 7 studies were cross sectional study(n=3, n=4, n=6, n=7,n=9,n=12,n=14), and 3 studies were retrospective study (n=8, n=10, n=13 )

**Fig 3.3: The below graph represents the sample size of selected studies are depicted.**

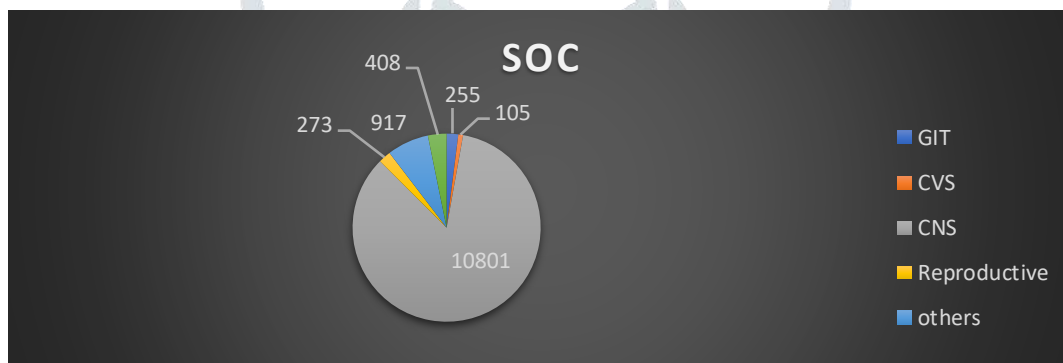
The above graph shows, in the selected articles, article 10 has the maximum number of individuals involved i.e., 7006 and article 3 has the least sample size of 40.

**Fig 3.4: The below graph represents number male and female participants in the study.**

The above graph shows, the number of articles reviewed, in that article 10 has the maximum number of male and female participants, i.e., males: 2676, females: 4330.

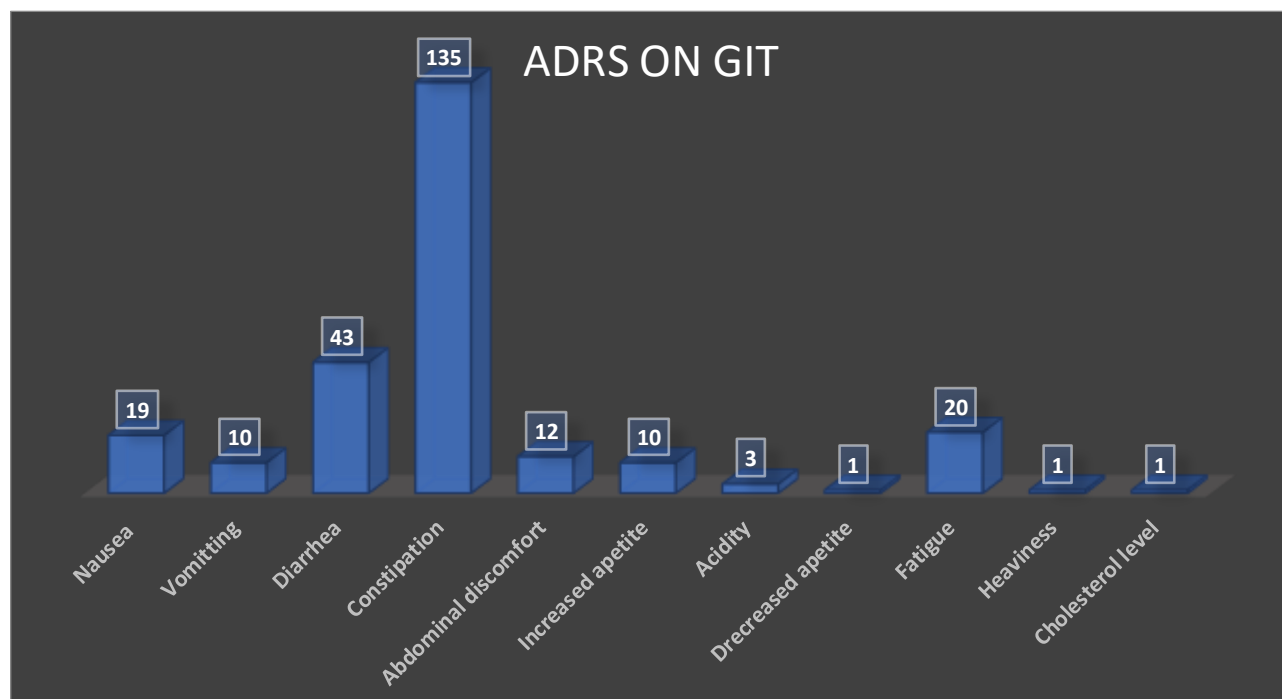
**Fig 3.5: The below graph represents the age distribution in the study.**

The above graph shows, the number of articles reviewed on age distribution and the highest number of ADRs reported in the age group between 20 to 40.

**Fig 3.6: The below graph represents ADR s according to SOC (System Organ Classification)**

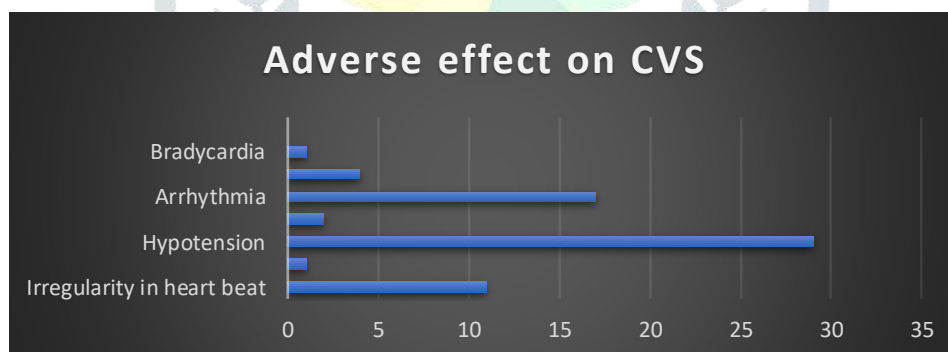
The above graph shows ADRs reported according to SOC, ADRs are classified as their effect on organ systems. From the obtained data, the central nervous system is affected by the maximum number of ADRs of 10,801 and the cardiovascular system has the least number of ADRs of 105, and the other kinds of ADRs observed were 917 and weight gain condition is observed in 408.

**Fig 3.7: The below graph represents the adverse effects of anti-psychotics on G**

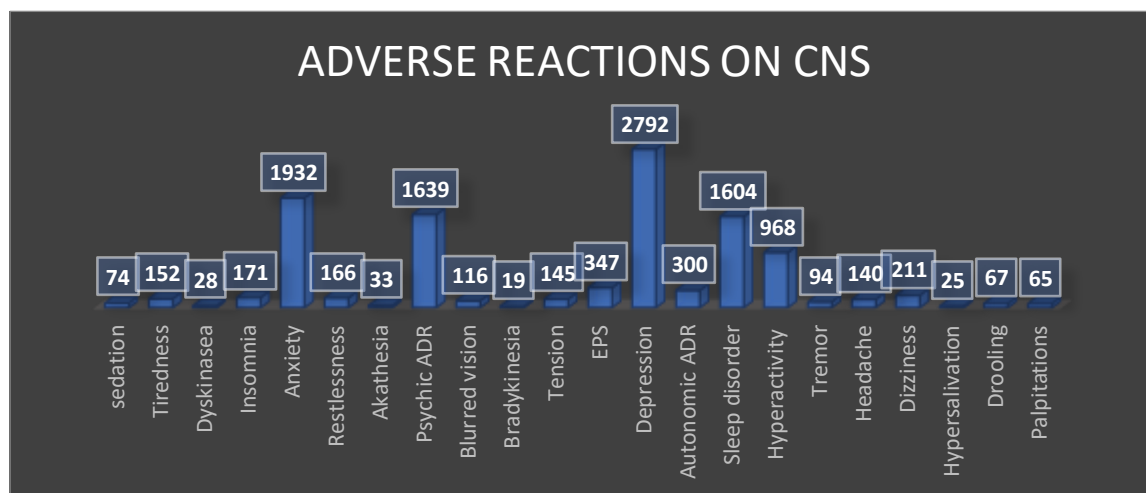


From the graph it is significant that, the major adverse effect accounted on GI is constipation (135). And the other numbers looked like this: Nausea (19), vomiting (10), diarrhoea (43), stomach discomfort (12), increased appetite (10), fatigue (20), heaviness (1), and cholesterol level (1). Data gathered from a combined review of articles

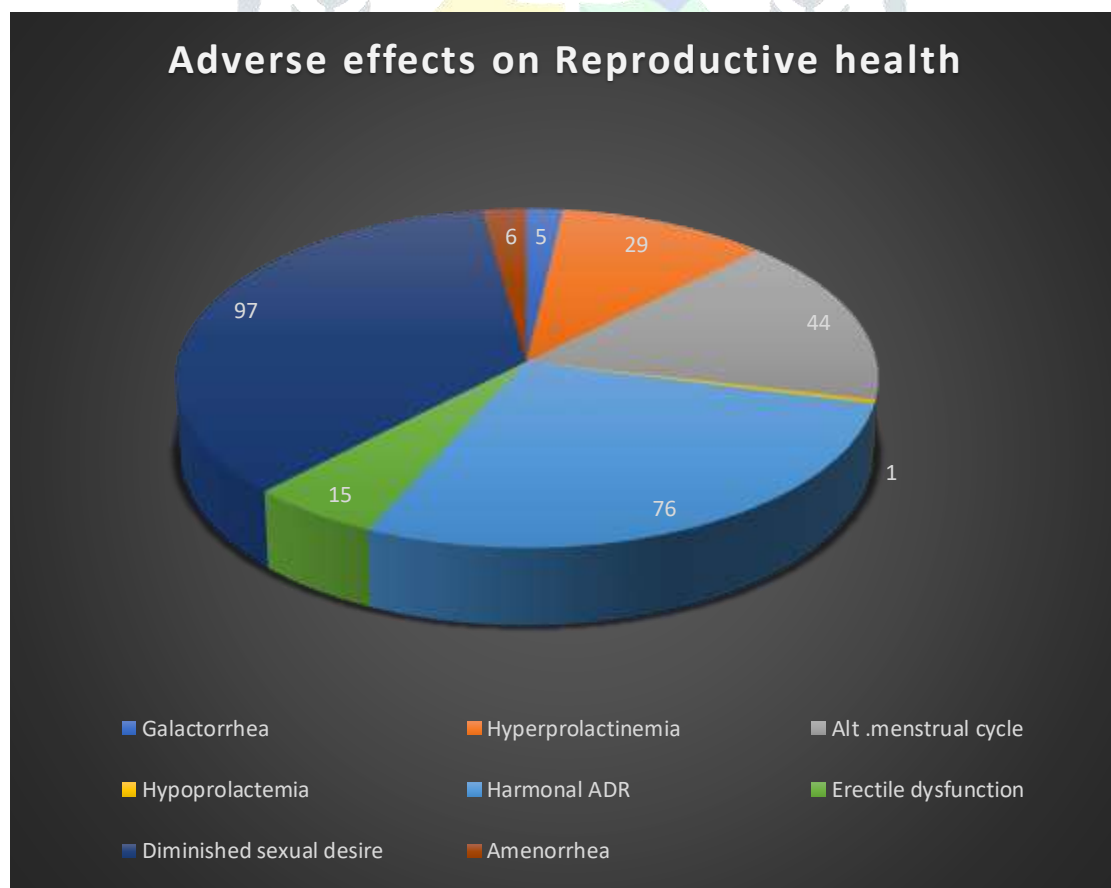
**Fig 3.8: The below graph represents the adverse effects of anti-psychotics on CVS.**



In our review, it was estimated that 105 ADRs were reported on CVS, with 29 being hypotension disorders and the rest being bradycardia-1, dyslipidemia-4, arrhythmia-17, hypertension-2, ECG deviation-1, and irregularity of heartbeat-11. Other CV-related ADRs were also recorded as 40 cases.

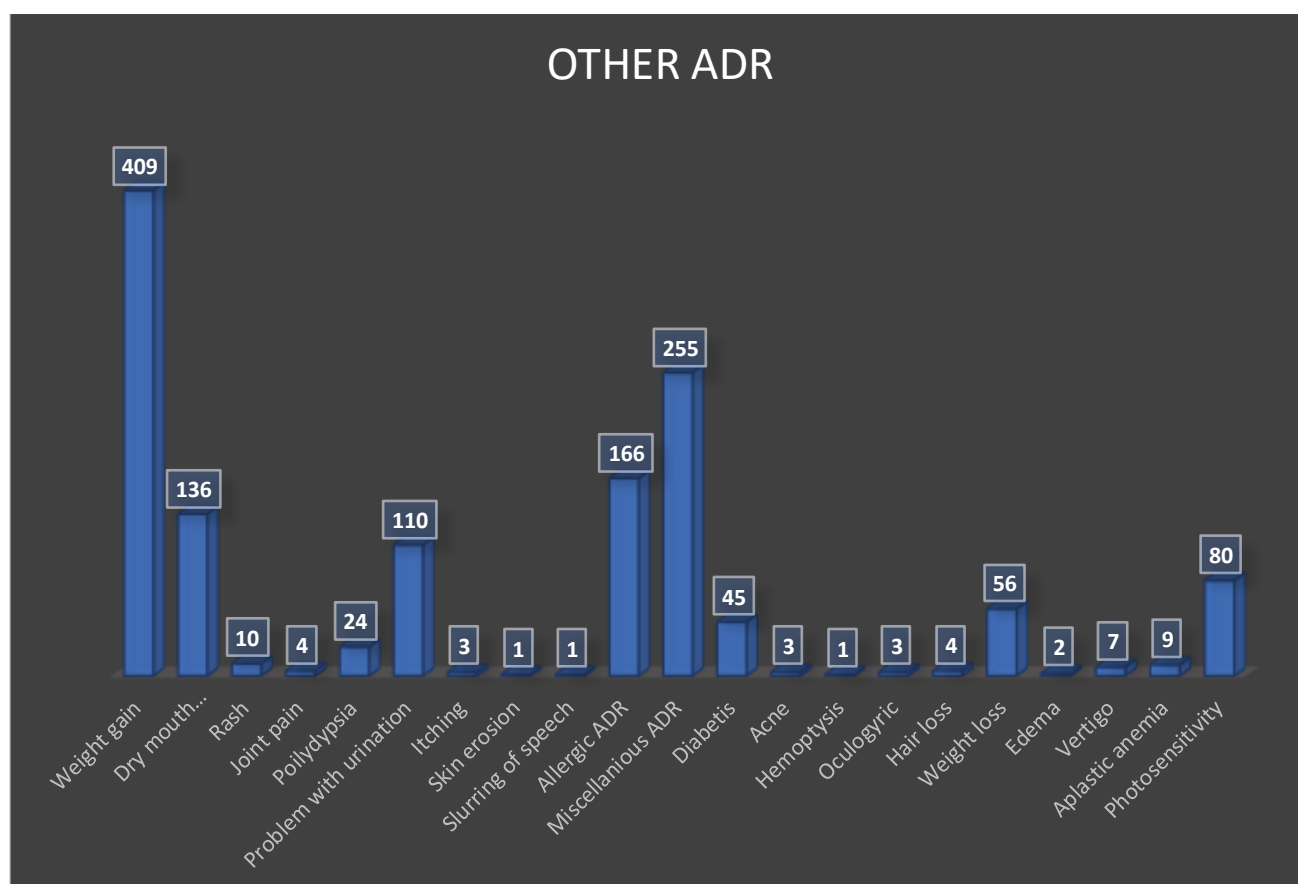
**Fig 3.9: The below graph represents the adverse effects of anti-psychotics on CNS.**

From the data obtained from the review, nervous system is the organ system that is being effected adversely by the use of anti-psychotics with 10,801 cases. Apart from the conditions mentioned graphically, somnolence(8), lethargy (1), dystonia(1), suicidal thoughts(1) , delirium(3), irritability(3), rigidity (5), personality disorder (1), seizures(6), parkinsons(1), stress- aggression(2), pin rolling movement (2), myoclonic jerks(1), perioral movements (1), daze (12), dystonia(3), dysphagia(1) are the adverse effect on CNS.

**Fig 3.10: The below graph represents the adverse effects of anti-psychotics on reproductive health.**

The graph above depicts the ADRs related to reproduction on drug exposure. These findings are based on the selected papers. The adverse effect on reproduction was shown to be 273, in that reduced sexual desire condition resulted in a greater number

**Fig 3.11: The below graph represents the other adverse effects of anti-psychotics.**



The above graph demonstrates the negative effects of anti-psychotics on several organ systems. In that weight gain condition, the number is 409

#### 4. DISCUSSION:

Adverse medication responses are often linked to pharmacotherapy for psychiatric illnesses. Psychotropic pharmaceuticals differ from other medications in that they frequently alter emotion and cognition. Therefore, it is crucial to monitor and evaluate ADRs linked with these medications. There is a large selection of psychotropic medications on the market to treat mental illnesses. Furthermore, polypharmacy the repeated use of several psychiatric medications in a single patient has become a standard procedure in clinical psychiatry, which increases the risk of adverse drug reactions. The most popular approach in pharmacovigilance is spontaneous reporting, which works well for generating alerts about novel and occasionally uncommon adverse drug reactions (ADRs) of well-known medications.

This review work involves the online database search for the original research articles published from 2019 to 2024. Articles for the analysis of data were selected based on STROBE guidelines and inclusion criteria. The number of papers published in each year is listed, the design of the study, duration of the study, place and data analysis method in each article is noted down. Information pertaining to incidence of ADRs in different genders, in adults and elderly populations and different classes of anti-psychotics drugs are analyzed. In this review we have recorded that the different comorbid conditions present in the patients and ADRs contributed by different class of anti-psychotics drugs are tabulated from different studies. Results were presented in the percentage of incidence of ADRs in male and female population, occurrence of ADRs in adults and elders were analyzed during ratio scale.

Statistics show that 1 in every 5 individuals suffers from some form of mental health illness symptoms. 50% of mental health conditions begin by age 14 and 75% of mental health conditions develop by age 24. 970 million people around the world struggle with some mental

## 5. CONCLUSION:

This study indicates that anti-psychotics medication users experience adverse drug reactions (ADRs) regularly, and these reactions are typically mild in nature. Therefore, identifying these side effects and managing them can guarantee the patient receives the best care possible. In psychiatry OPD settings, rigorous monitoring of ADRs on a regular basis may aid in the early detection of ADRs. It reduces the danger brought on by ADR, which may enhance patients' quality of life, lower treatment costs, and increase treatment compliance

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### Author contribution

**All the authors involved equally in carrying this research work**

### Funding

“none to declare”

## CONFLICT OF INTEREST:

“none to declare”

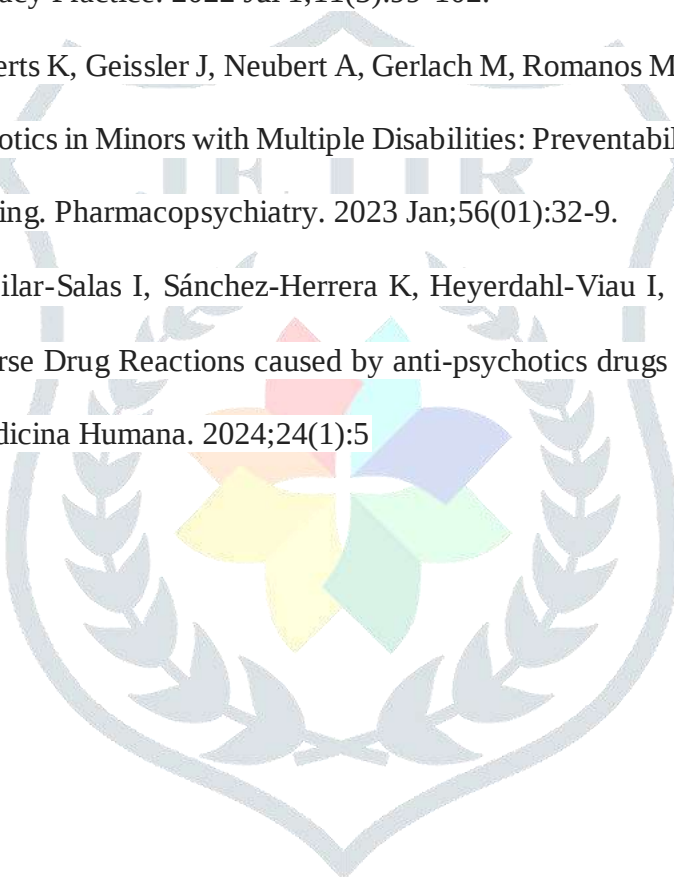
**Ethics approval**

“none to declare”.

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- A large, faint watermark of the JETIR logo is centered on the page. It features a shield-like shape with a laurel wreath border. Inside the shield is a stylized flower or star with multiple colored petals (yellow, green, blue, red, orange) and a white center.