

National Pharmacovigilance Program

Gauhati Medical College & Hospital

Peripheral Centre = 114

Co-ordinator - Dr. Babul Kr. Bezbaruah

Asstt. Prof. of Pharmacology

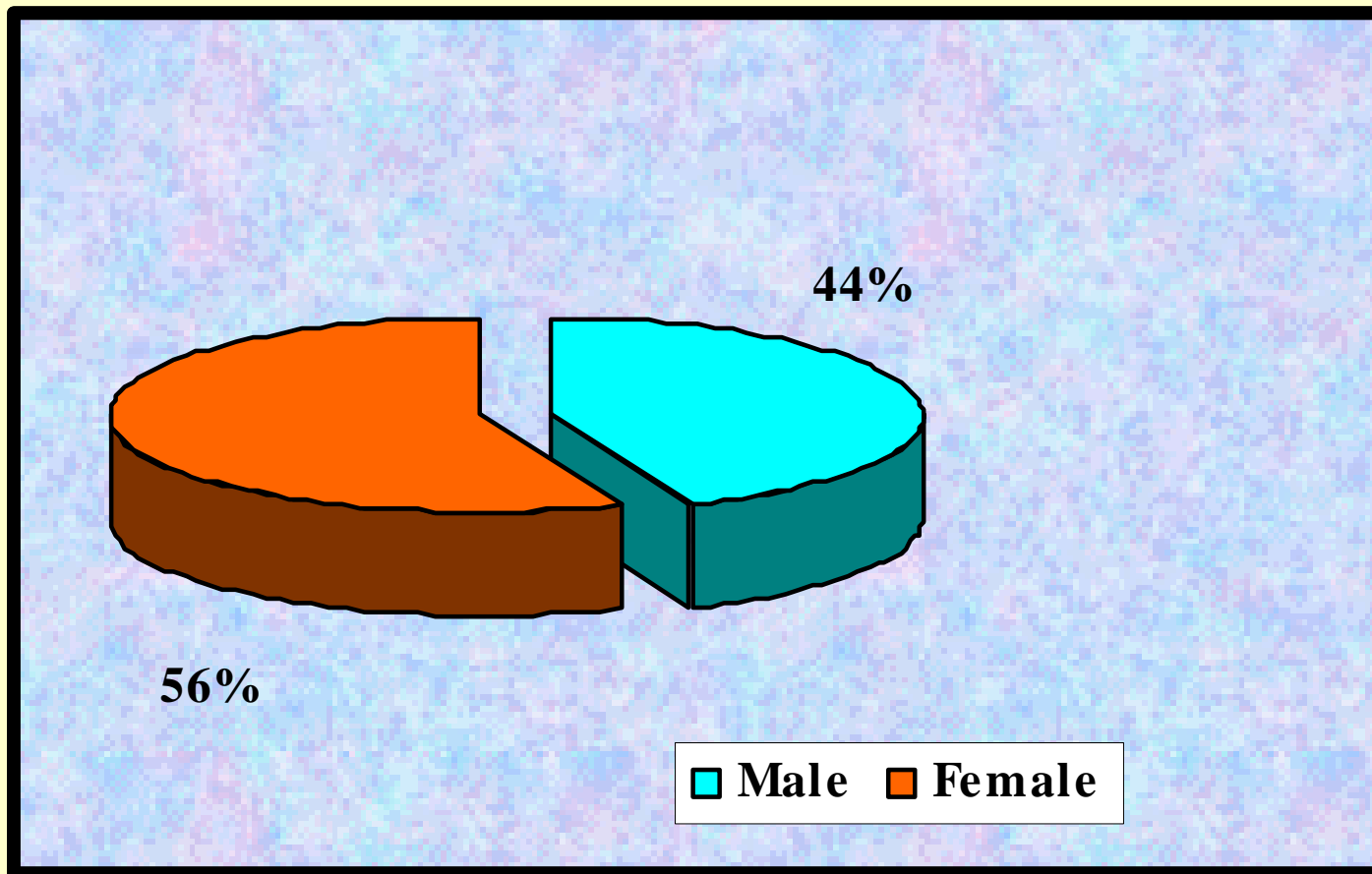
Introduction

- **Gauhati Medical College & Hospital is one of the premier medical institutes of N.E. region, situated in the heart of Guwahati, having a bed capacity of 1500.**
- **Ever since selection of Gauhati Medical College as peripheral centre for National Pharmacovigilance Program, clinicians of the institute are giving extensive support in collecting data.**
- **Other clinicians of the city are also supporting, knowing about the objectives and importance of the program.**
- **With such support from my colleagues, as coordinator of the centre, I have been able to collect total 350 cases since October, 2005.**

Materials and Methods

- **Vigilance is done on patients admitted to the hospital with drug reaction and those who have reaction during treatment in the hospital. Outdoor cases are usually not included in this search as data is not satisfactory.**
- **Frequent enquiry is made for admission of drug reaction cases in different departments and data is collected till complete treatment and discharge of the patients.**
- **ADR forms supplied are filled up and are being sent to the Regional Centre, first week of every month, keeping photocopies as back up.**

Sex distribution of the 350 cases studied



Age distribution of cases

Age in years	No of cases
0 – 10	13
11- 20	41
21 – 30	108
31 – 40	100
41 – 50	45
51 – 60	25
61 – 70	13
71 – 80	3
81 – 90	1
91 – 100	1

Different groups of drugs causing ADRs

Drug category	No of cases	Drug category	No of cases
Antibiotic	150	Antifungal	3
H ₂ -blocker	42	Anthelmintic	3
Analgesics	32	Hormone	3
Combination	29	Antipsychotic	2
Antiepileptic	18	Antihypertensive	2
Antitubercular	14	Antidiabetic	2
Vitamins	8	Antiplatelet	2
Antimalarial	6	I/V anaesthetic	1
Antispasmodic	6	Vasodilator	1
Antiamoebic	6	Vaccines	1
Corticosteroid	5	Diuretics	1
Topical	4	Methotrexate	1
PPIs	4	Allopurinol	1
Bronchodilator	3		

Observations

- Program was started from Oct, '05 and till Nov, '06 total 350 cases data has been collected.
- Out of 350 cases, 154 (44%) were male and the majority of patients were between 21 – 40 years age, i.e. young adults.
- Drugs categories causing maximum ADRs are Antibiotics (42.9%) → H₂-blockers (12%) → Analgesics (9.14%) → Combination therapy (8.28%).
- Maximum ADRs are related to intravenous route (45.71%) → oral (41.43%) → IM (10.3%).
- Combination therapy and IV route of drug administration are associated with considerable risk of ADRs.

Observations

- **No of death cases suspected to be drug related were 3:**
 - One due to Propofol, an IV anaesthetic (anaphylactic reaction)
 - One due to Cefoperazone + Sulbactam IV Gynae Dept.
 - One due to Ranitidine I/V (pulmonary oedema → respiratory distress)
- **Most of the patients were already hospitalized with life-threatening reaction or less severe drug reactions, leading to more prolonged hospital stay than could be expected from the primary illness.**

Difficulties faced

The centre is getting support from the Regional Centre whenever asked for and materials are being provided in due time. The center is thus able to work without any materialistic deficiencies. However, certain difficulties faced are:

- **Some data cannot be traced completely.**
- **Batch no., Exp. Date and Mfg. Date cannot be obtained in most of the reactions as patients do not carry medicines with them during admission.**
- **The central authority of National Pharmacovigilance Program has remained silent.**
- **The central authority should request State Govt. to avoid transferring those doctors who are engaged in this project to other institutions of the state while the Program is ongoing. Otherwise the project is hampered.**

Thank You

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