PS-066

INFUSION REACTIONS DOCUMENTED WITH DIFFERENT GENERIC PACLITAXEL FORMULATIONS BY MEANS OF AN ADVERSE DRUG REACTIONS REPORTING PROGRAMME

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BACKGROUND

Paclitaxel are commonly associated to infusion reactions (IR) with no clear influence by different Paclitaxel formulations.

PURPOSE

Analysis of Nº and severity of IR related with the administration of different generic formulations of paclitaxel registered by means of an adverse drug reactions reporting program (ADRRP)

MATERIAL AND METHODS

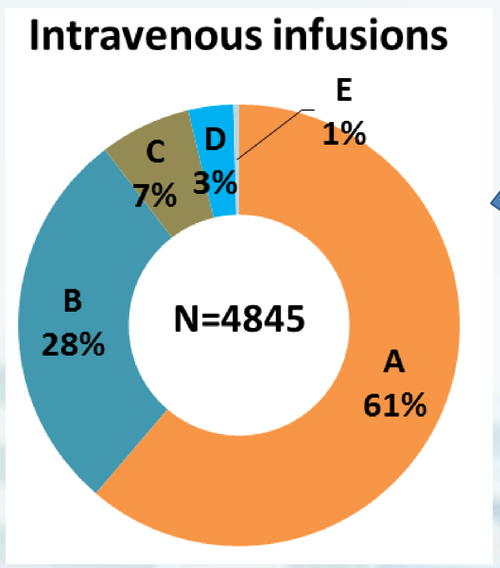
Retrospective study: January 2010-March 2015. Identification of IR by Day Hospital`s nursing staff based on voluntary reporting of adverse drug reactions (ADRs). Variables collected:

1. Sex, age, cycle
2. Generic brand name
3. IR severity (CTCAE v4.03)
4. ADRs management & re-administration tolerance.

Five generic formulations (A-E) → no significant differences in excipients. All patients received premedication as recommended by summary of product characteristics. Relative frequencies and severity were calculated, Chi-2 and Fisher exact were used for statistical comparison (SPSS®v19)

RESULTS

Population (n=648 patients)	
Woman	401 (61,9%)
Median age	59.5 y
Range	23-86 y



received

IR recorded (by paclitaxel formulation)	
A	36 (1.21%)
B	14 (1.02%)
C	6 (1.86%)
D	1 (0.62%)
E	4 (23.53%)
Total	61 (100%)

- ✓ 41% of IR occurred during the first administration.
- ✓ Only statistically significant differences (SSD) in IR number and severity with E paclitaxel ($p<0.001$)

IR severity (CTCAE v4.03) n=61	
Grade 2	46
Grade 3	14
Grade 4	1

- ✓ Managed by temporarily stopping infusion and symptomatic treatment as per protocol with corticosteroid +antihistamine ±acetaminophen.
- ✓ 18/61 did not tolerate the re-administration.

CONCLUSIONS

SSD only were observed with E paclitaxel without finding out the cause. Sample imbalance among formulations was due to regional Health Department centralized purchasing system through public tenders and several shortage supplies over the study period.

The **ADRRP** based on the active voluntary collaboration of nurses **is effective in detecting drug-related problems and implementing interventions** (notification to National surveillance program, laboratory involved and change the available presentation at hospital) accordingly to enhance drug safety.

21th Congress of the European Association of Hospital Pharmacists (EAPH). 16-18 March 2016 Vienna (Austria)