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Adverse drug reactions in cancer patients: Analysis of spontaneously reported cases

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Background: Although the number of domestic adverse drug reactions (ADRs) reported is rapidly increasing in Korea, there have been few analysis for ADRs in cancer patients. We aimed to investigate the clinical features of ADRs in cancer patients reported from a single university hospital. **Methods:** ADRs were collected from a spontaneous reporting system at our university hospital between July 2010 and May 2015. The cases assessed as 'unlikely' and 'unclassifiable'based on World Health Organization-Uppsala Monitoring Center(WHO-UMC) criteria were excluded. Additional medical information was retrospectively collected from chart review and clinical features of ADRs were analyzed. **Results:** A total of 1578 cases were reported, of which 822 ADRs (52.1%) were observed in cancer patients. The mean age was 61 years (range 17- 90 yr), 46.1% were male. The most prevalent clinical features were gastrointestinal abnormalities (31.6%) such as nausea and vomiting, followed by skin (27.5%) and neurologic manifestations (25.1%). Forty nine (6%) and 297 cases (36.1%) were classified as severe and moderate reactions, respectively. The most common offending drugs were nutritional supplements (40.5%). Antibiotics (17.9%), tramadol (12.8%), and radiocontrast media (RCM, 11.1%) also frequently reported. Antineoplastic agents were 2.8%, however it was one of the common drugs for severe reactions with antibiotics, nutritional supplements, and RCM. **Conclusions:** Although it is well known that antibiotics, RCM, and non-steroidal anti-inflammatory drugs induce ADRs, nutritional supplements and antineoplastic agents should be considered as common causative drugs of ADRs in cancer patients. Further investigation and mornitoring to evaluate causality associated with these drugs is needed.

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Clinical outcomes of omaliumab treatment on cholinergic urticaria

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Background: Cholinergic urticaria is one of the inducible urticaria and it's symptoms are provocated by a rise in body temperature. There are some conflicting case reports of omalizumab effect on cholinergic urticaria. **Objective:** The aim of this study was to evaluate the clinical effect of omalizumab on refractory cholinergic urticaria. **Methods:** We performed a single center, retrospective study. Since January 2014 to July 2015, 13 patients were treated with omalizumab after failure of antihistamine. Telephone survey including visual analog scale (VAS) and urticaria control test (UCT, 0-16, high score means better control) is performed and response is defined as complete (post treatment VAS≤2 & UCT≥12), partial and no response (post treatment VAS≤2 & UCT≥12). **Results:** 12 men and 1 women, with a mean age and disease duration of 28 years and 53 months, were included. All patients had at least 5 aggravating factors and 4 patients had chronic spontaneous urticaria and 6 patients had house dust mite sensitization on MAST. After omalizumab, VAS decreased from 8.23±0.93 to 3.69±2.56 ($p<0.0001$) and UCT increased from 3.77±1.42 to 9.77±3.66 ($p><0.0001$) and 5 patients had complete response, while 5 and 3 patients had partial and no response. In responders, the number of injection, injection interval and serum eosinophil count were statistically significant higher than no responders. **Conclusions:** Our result shows that omalizumab might be useful in refractory cholinergic urticaria. Clinician should consider omalizumab in patients with antihistamine failure.

Table 1. Baseline characteristics

Pt. Number	Age	Sex	Response	Previous VAS	Post VAS	Previous UCT	Post UCT	Disease duration (mo.)	Other allergic disease*	Aggrevating factors (n.)	Antihistamine effect	N.of injection	Dose (mg/4wks)	Serum total IgE(kU/L)	Serum eosinophil count(10^3/uL)
1	21	M	complete	7	2	6	12	48		8	no effect	2	300	37.7	170
2	22	M	complete	9	1	3	13	36	AR	6	Partially effect	7	150	155	240
3	29	M	complete	9	1	2	14	36		5	Partially effect	14	150	269	210
4	35	M	complete	9	2	3	12	60	AR	7	Partially effect	8	150	59.7	490
5	20	M	complete	7	1	5	14	24	CSU	7	Partially effect	18	150	94.7	210
6	48	M	partial	8	3	5	11	72		6	Partially effect	2	300	1042	
7	19	M	partial	8	4	3	10	36	CSU	6	no effect	15	200		870
8	19	M	partial	8	5	4	9	24	AR	5	no effect	8	300	192	160
9	30	M	partial	10	3	1	10	96		7	no effect	18	150		
10	27	M	partial	9	3	5	10	84	CSU	6	no effect	10	300		
11	18	M	none	7	7	4	4	18		5	no effect	2	300	84.1	150
12	30	M	none	8	8	5	5	120		6	no effect	1	300		
13	40	F	none	8	8	3	3	30	CSU	5	Partially effect	2	300		70

*AR=allergic rhinitis, CSU=Chronic spontaneous urticaria