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Adriamycin PFS (Doxorubicin hydrochloride)

??? ??????: 30 ??????/?????? 2017

Dose limiting toxicities of therapy are myelosuppression and cardiotoxicity. Other reactions reported are:

)**WARNINGS.** - (See ***Cardiotoxicity***

- Reversible complete alopecia occurs in most cases. Hyperpigmentation of nailbeds and dermal creases, primarily in pediatric patients, and onycholysis ***Cutaneous*** have been reported in a few cases. Radiation recall reaction has occurred with doxorubicin administration. Rash, itching, or photosensitivity may occur.

-Acute nausea and vomiting occurs frequently and may be severe. This may be alleviated by antiemetic therapy. Mucositis (stomatitis and ***Gastrointestinal*** esophagitis) may occur within 5 to 10 of beginning therapy, and most patients recover from this adverse event within another 5 to 10 days. The effect may be severe leading to ulceration and represents a site of origin for severe infections. The dosage regimen consisting of administration of doxorubicin on three successive days results in greater incidence and severity of mucositis. Ulceration and necrosis of the colon, especially the cecum, may occur leading to bleeding or severe infections which can be fatal. This reaction has been reported in patients with acute non-lymphocytic leukemia treated with a 3-day course of doxorubicin combined with cytarabine. Anorexia, abdominal pain, dehydration, diarrhea, and hyperpigmentation of the oral mucosa have been occasionally reported.

)**WARNINGS.** - (See ***Hematologic***

- Fever, chills and urticaria have been reported occasionally. Anaphylaxis may occur. A case of apparent cross sensitivity to lincomycin has been ***Hypersensitivity*** reported.

- Peripheral neurotoxicity in the form of local-regional sensory and/or motor disturbances have been reported in patients treated intra-arterially with ***Neurological*** doxorubicin, mostly in combination with cisplatin. Animal studies have demonstrated seizures and coma in rodents and dogs treated with intra-carotid doxorubicin. Seizures and coma have been reported in patients treated with doxorubicin in combination with cisplatin or vincristine.

- Conjunctivitis, keratitis, and lacrimation occur rarely. ***Ocular***

- Malaise/asthenia have been reported.***Other***

Safety data were collected from approximately***Adverse Reactions in Patients with Early Breast Cancer Receiving Doxorubicin-Containing Adjuvant Therapy:*** 2300 women who participated in a randomized, open-label trial (NSABP B-15) evaluating the use of AC versus CMF in the treatment of early breast cancer involving axillary lymph nodes. In the safety analysis, the follow-up data from all patients receiving AC were combined (N=1492 evaluable patients) and compared with data from patients receiving conventional CMF (i.e., oral cyclophosphamide; N=739 evaluable patients). The most relevant adverse events reported in this study are provided in Table 2.

Table 2. Relevant Adverse Events in Patients with Early Breast Cancer Involving Axillary Lymph Nodes

Conventional CMF N=739	AC* N=1492	
		Treatment administration
5.5	3.8	Mean number of cycles
4068	5676	Total cycles
		Adverse events, % of patients
		Leukopenia
9.4	3.4	Grade 3 (1,000-1,999 $)^3$/mm
0.3	0.3	$)^3$ Grade 4 (<1000 /mm
		Thrombocytopenia
0.3	0	Grade 3 (25,000-49,999 $)^3$/mm
0	0.1	$)^3$ Grade 4 (<25,000 /mm
0.9	1.5	Shock, sepsis
1.2	2.4	Systemic infection
		Nausea and vomiting

42.8	15.5	Nausea only
25.2	34.4	Vomiting ? 12 hours
12.0	36.8	Vomiting >12 hours
1.6	4.7	Intractable
71.4	92.4	Alopecia
56.3	22.9	Partial
15.1	69.5	Complete
		Weight loss
5.7	6.2	5-10%
2.8	2.4	>10%
		Weight gain
27.9	10.6	5-10%
14.3	3.8	>10%
		Cardiac function
0.1	0.2	Asymptomatic
0	0.1	Transient
0	0.1	Symptomatic
0	0	Treatment-related death
* Includes pooled data from patients who received either AC alone for 4 cycles, or who were treated with AC for 4 cycles followed by 3 cycles of CMF		