

الحمد لله رب العالمين

*Comparative study of two doses of filgrastim
(5 and 15 μ gr/kg) in children with cancer*

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Introduction

granulocyte colony-stimulating factors
maximize medical benefit
limit potential toxicity
cost effectiveness

Indication based on guidelines

American society of clinical oncology (ASCO)

European organization for research and
treatment of cancer (EORTC)

Setting of stem cell transplantation
Setting of chemotherapy

Setting of stem cell transplantation:

donor stimulation of peripheral blood stem cell Pheresis

HSCT recipients as part of most immediate post transplant regiments

Setting of chemotherapy:

Primary Prophylaxis

secondary Prophylaxis

Supportive treatment in high-risk FN

Standard dosage is 5ug/kg

Higher dosage :

in the setting of prophylaxis has not shown benefit

**in the setting of peripheral blood stem cell pheresis
advantage to the use of 10μgr/kg**

Evaluation this drug in different doses
in FN setting

Method:

60 patients were included.

Inclusion criteria : ANC <1500/mm + fever

And One of these criteria:

ANC<100/mm

Age <12month

Hypotention

Sepsis(Blood culture)

Pneumonia (clinical examination and CXR)

Fungal infection (culture)

Randomized controlled trial

group A:5μgr/kg

group B :15μgr/kg

checklist

Days of hospitalization

Period of fever

Days of antibiotic therapy

ANC increase at 5th day

Results

Table: frequency distribution by sex in two groups

	SEX					p-value	
		Male	female	Total			
GORUP	5µgr/kg	Number	20	10	30	0.184	
		percent	66.7%	33.3%	100.0%		
	15µgr/kg	Number	16	14	30		
		percent	53.3%	46.7%	100.0%		
	Total	Number	36	24	60		
		percent	60%	40%	100.0%		
	Chi-Square						

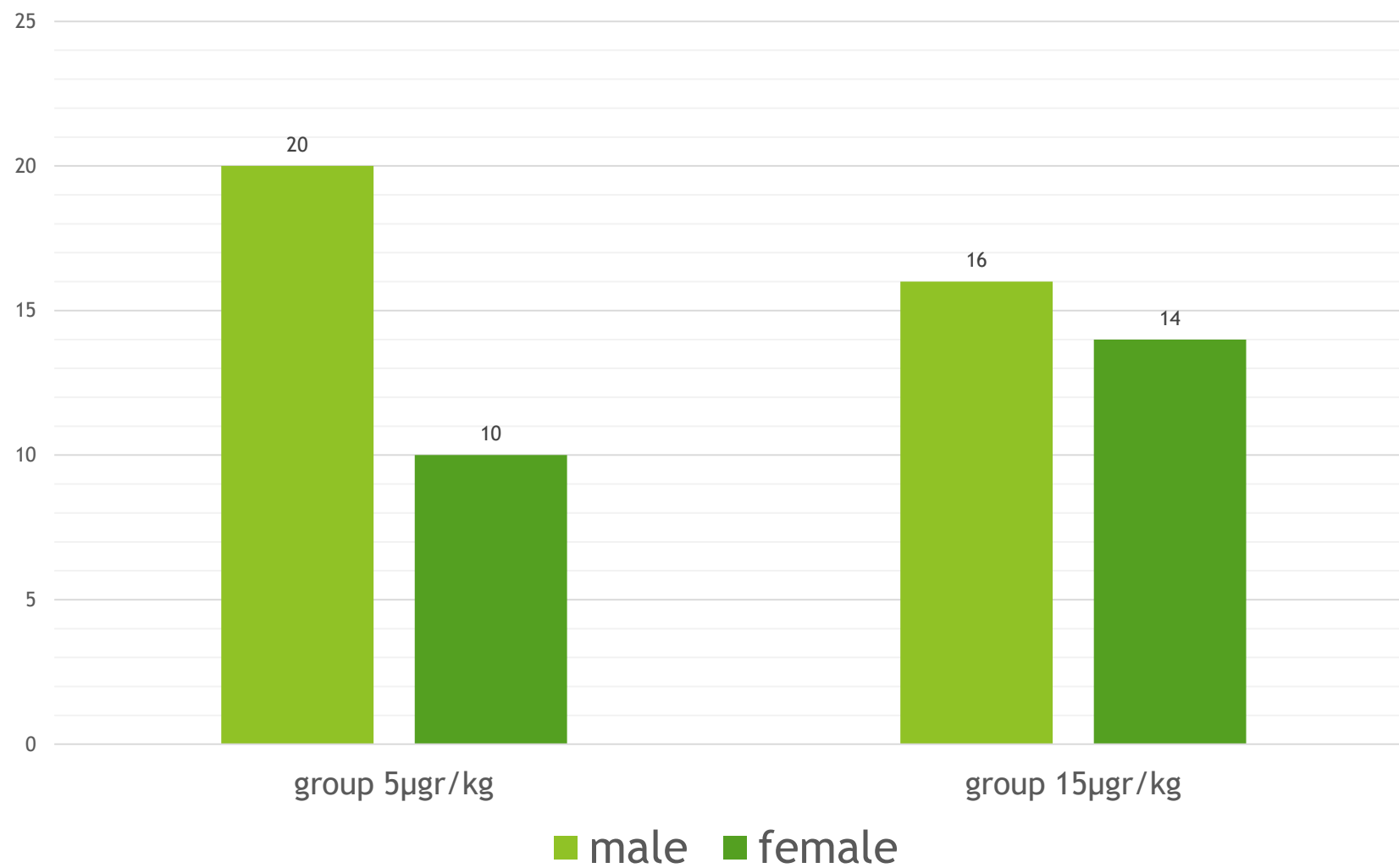


Chart: frequency distribution by sex in two groups ►

Table: frequency distribution of Malignancy in two groups

Dose			Type of malignancy											
			Osteo sarco ma	ALL	AML	Brain Tum or	Wilm s Tum or	Hodyk in diseas e	Neuro blasto ma	LYMPHOM A	Rabdomy o sarcom	Germ cell Tumor	Ewing sarco ma	p- value
	5μgr/kg	numbe r	2	15	3	2	1	3	2	1	0	0	1	0.010
		percen t	6.7%	50.0%	10%	6.7%	3.3%	10.0%	6.7%	3.3%	0.0%	0.0%	3.3%	
	15μgr/kg	numbe r	5	6	2	0	1	0	9	0	5	1	1	
		percen t	16.7%	20.0%	6.7%	0.0%	3.3%	0.0%	30.0%	0.0%	16.7%	3.3%	3.3%	
	Total	numbe r	7	21	5	2	2	3	11	1	5	1	2	
		percen t	11.7%	35.0%	8.3%	3.3%	3.3%	5.0%	18.3%	1.7%	8.3%	1.7%	3.3%	
	Fisher's Exact test													

Chart: frequency distribution of malignancy in two groups

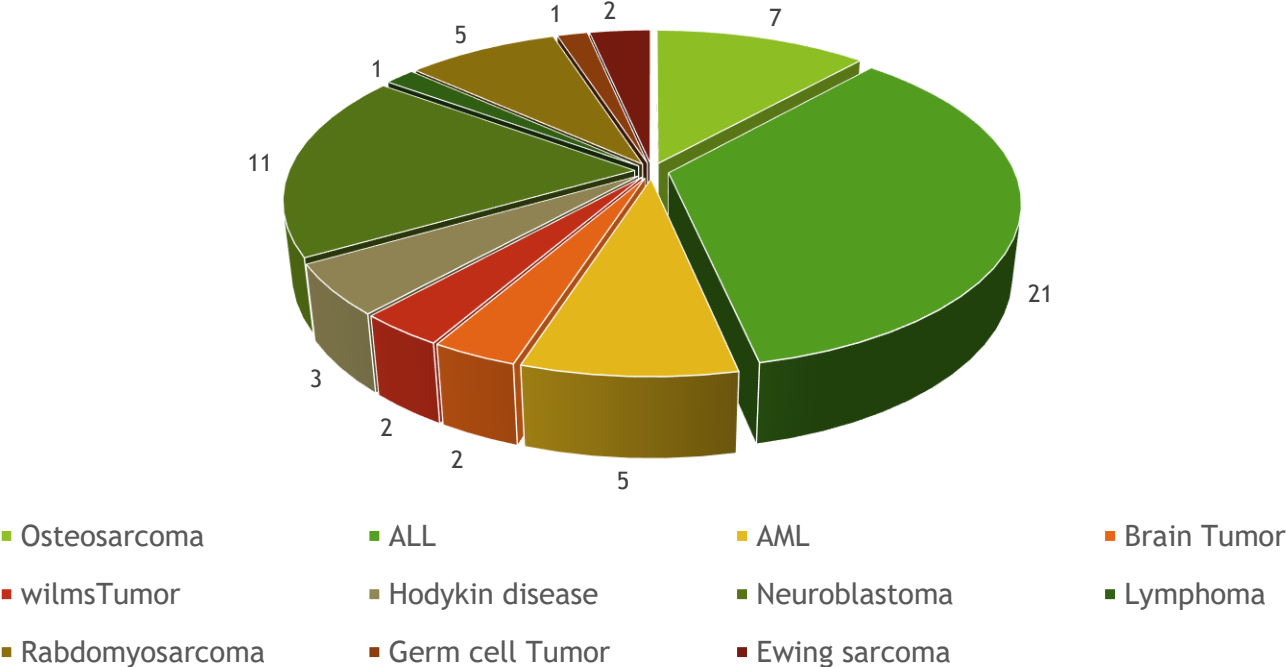


Table : Mean and standard deviation of ANC at start and 5th day of Neutropenia in 2 groups

ANC at start and 5th day	group	Mean	Standard deviation	p-value
ANC at start of Neutropenia	5µgr/kg	739.34	402.33	0.427
	15µgr/kg	644.34	451.00	
ANC at 5th day of Neutropenia	5µgr/kg	1320.00	941.53	0.023
	15µgr/kg	1851.72	797.59	

Mean and standard deviation of duration of hospitalization , fever , Neutropenia , and Antibiotic consumption in two groups

Duration (day)	group	Mean	Standard deviation	p-value	
Hospitalization	5µgr/kg	7.96	6.39	0.513	
	15µgr/kg	8.23	8.36		
fever	5µgr/kg	2.71	1.97	0.257	
	15µgr/kg	2.89	3.21		
Neutropenia	5µgr/kg	5.80	5.19	0.944	
	15µgr/kg	5.70	5.85		
Antibiotic consumption	5µgr/kg	7.70	6.08	0.237	
	15µgr/kg	8.27	8.06		
Mann-Whitney U					

Conclusion:

Better effect of high dose filgrastim on ANC

No difference in days of hospitalization

no difference on period of fever

No difference on the days of antibiotic therapy

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More studies are needed

Higher sample size

Specific malignancy

Specific cause of hospitalization



