RESULTS

This study included 60 patients (30 males and 30 females) suffering from keloids and hypertrophic scars. They were selected from the outpatient clinics of dermatology department of Benha University Hospital , El-Mahalla Hospital and Samannoud Hospital from January to August 2010.

The ages of the patients ranged from 16 to 54 years with mean values of (29.87),(32.07) and (31.5) in group **(IA), (IB)** and **(II)** respectively **Table (3)**.

The duration of the lesions ranged from 4 months to 23 months. The sex distribution among studied groups was:

Group (IA): Fifteen patients, 8 males (53.33%) and 7 females (46.67%).

Group (IB): Fifteen patients, 10 males (66.67%) and 5 females (33.33%).

Group (II): Thirty patients, 12 males (40%) and 18 females (60%).

Table (3): Age distribution of patient groups .

Group	Age		T-test	
	Range	Mean ± SD	t	P-value
Group IA	16-53	29.87 ± 11.44		
Group IB	17-52	32.07 ±12.15	-0.51	0.614
Group II	16-54	31.5 ±10.48	-0.46	0.647

Table (4):The Site distribution of keloid and hypertrophic scars in patient groups

Site		Group IA		Group IB		Group II		Total	
		N	%	N	%	N	%	N	%
Face		0	0.00	0	0.00	3	10.00	3	5.00
Neck		2	13.33	0	0.00	3	10.00	5	8.33
Chest		3	20.0	3	20.00	3	10.00	10	16.67
Hand		2	13.33	1	6.67	2	6.67	4	6.67
Forearm		0	0.00	1	6.67	5	16.67	7	11.67
Shoulder		3	20.0	4	26.67	4	13.33	11	18.33
Abdomen		1	6.67	1	6.67	3	10.00	4	6.67
Back		2	13.33	3	20.00	3	10.00	8	13.33
Pubic area		1	6.67	0	0.00	0	0.00	1	1.67
Thigh		0	0.00	1	6.67	1	3.33	2	3.33
Foot		1	6.67	1	6.67	3	10.00	5	8.33
Total		15	100.0	15	100.0	30	100.00	60	100.00
Chi-square	**X^2**	-		3.592		3.639			
	P-value	-		0.610		0.147			

The most common affected sites were mainly chest, shoulder, back, forearm and neck.

Table (5): The duration of keloids & hypertrophic scars in patient groups.

Group	Duration of keloids & hypertrophic scars		T-test	
	Range	Mean ± SD	t	P-value
Group IA	5-23	12.07 ± 5.59		
Group IB	4-19	11.2 ± 4.33	0.47	0.639
Group II	6-21	14.27 ± 4.27	-1.34	0.193

This table indicates that the difference in duration of keloids and hypertrophic scars was statistically non significant between different groups (P >0.05).

Regarding the improvement of Vancouver scar scale, the results were as follows:

A) Vascularity:

Table (6): Vascularity of keloids & hypertrophic scars in patient groups

Vascularity		Group IA		Group IB		Group II		Total		Chi-Square		Chi-Square	
		N	%	N	%	N	%	N	%	X^2	P1 value	X^2	P2 value
Before treatment	0	0	0	0	0	0	0	0	0	0.97	0.82	0.53	0.84
	1	1	6.67	2	13.33	4	13.33	7	11.67				
	2	8	53.33	7	46.67	16	53.33	31	51.67				
	3	6	40.00	6	40.0	10	33.33	22	36.67				
First follow (at 4th week)	0	0	0	0	0	2	6.67	2	3.33	1.38	0.5	3.56	0.27
	1	2	13.33	4	26.67	10	33.33	16	26.67				
	2	9	60.00	6	40.0	12	40.0	27	45.0				
	3	4	26.67	5	33.33	6	20.0	15	25.0				
second follow (at 8th week)	0	0	0	2	13.33	11	36.67	13	21.67	2.59	0.46	10.39	0.015
	1	4	26.67	5	33.33	10	33.33	19	31.67				
	2	7	46.67	5	33.33	7	23.33	19	31.67				
	3	4	26.67	3	20.0	2	6.67	9	15.0				
third follow (at 12th week)	0	5	33.33	6	40.0	19	63.33	30	50.0	3.36	0.92	4.36	0.04
	1	8	53.33	7	46.67	10	33.33	25	41.67				
	2	2	13.33	2	13.33	1	3.33	5	8.33				
	3	0	0	0	0	0	0	0	0				

P1 comparison between group IA & group IB , P2 comparison between group I & group II

As regards to Vancouver scar scale, **0** = normal vascularity, **1** = pink colorations, **2** = red colorations, **3** =purple. There was improvement in the vascularity of the lesions in all **groups**

In group IA, 33.33% showed normal vascularity.

In group IB, 40% showed normal vascularity.

In group II, 63.33% showed normal vascularity.

The improvement was better in group IB than group IA but the difference was statistically non significant (P>0.05).

The improvement was significantly better in group II when compared to group I and the difference was statistically significant (P<0.05).

This indicates that bleomycin is more effective than 5FU alone or combined with TAC.

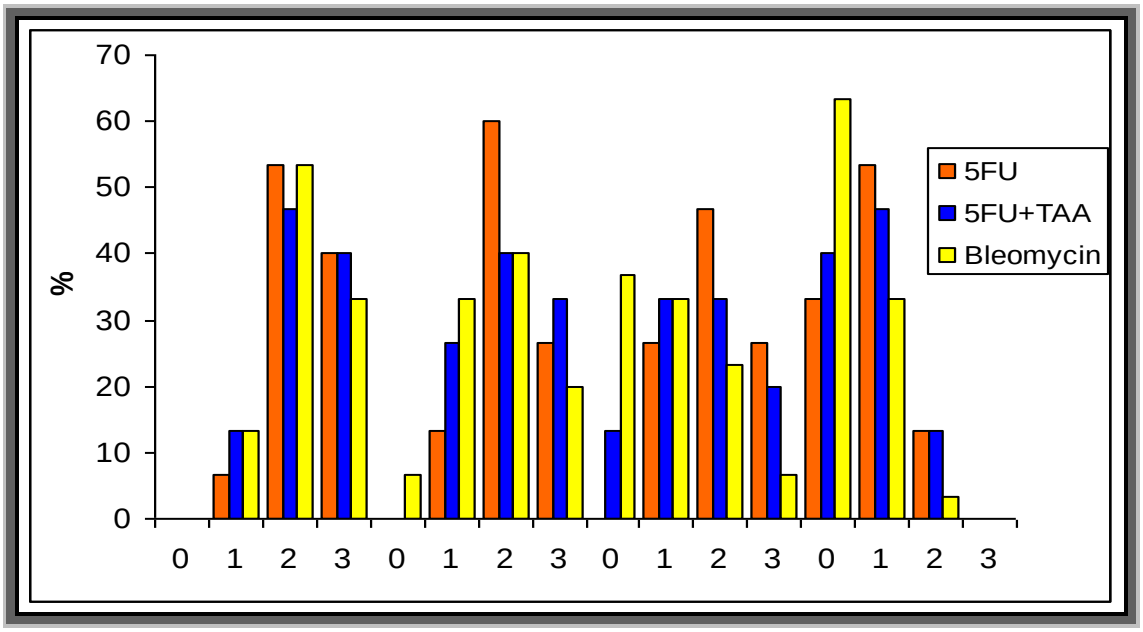

Fig. (13): Vascularity of keloids & hypertrophic scars in patient groups

B) Pigmentation:

Table (7): Pigmentation of keloids & hypertrophic scars in patient groups.

Pigmentation		Group IA		Group IB		Group II		Total		Chi-Square test			
		N	%	N	%	N	%	N	%	X^2	P1 value	X^2	P2 value
Before treatment	0	9	60.00	7	46.67	16	53.33	32	53.33	0.54	0.46	0.27	1.00
	1	0	0	0	0	0	0	0	0				
	2	0	0	0	0	0	0	0	0				
	3	6	40.00	8	53.33	14	46.67	28	46.67				
First follow (at 4th week)	0	7	46.67	6	40.00	15	50.0	28	46.67	0.4	0.71	0.04	0.6
	1	0	0	0	0	0	0	0	0				
	2	0	0	0	0	0	0	0	0				
	3	8	53.33	9	60.00	15	50.0	32	53.33				
second follow (at 8th week)	0	7	46.67	6	40.00	11	36.67	24	40.00	5.21	0.71	0.42	0.598
	1	0	0	0	0	0	0	0	0				
	2	0	0	0	0	0	0	0	0				
	3	8	53.33	9	60.00	19	63.33	36	60.00				
third follow (at 12th week)	0	5	33.33	5	33.33	11	36.67	21	35.00	0.0	1.00	0.05	0.79
	1	0	0	0	0	0	0	0	0				
	2	0	0	0	0	0	0	0	0				
	3	10	66.67	10	66.67	19	63.33	39	65.00				

P1 comparison between group IA & group IB , P2 comparison between group I & group II

As regards to Vancouver scar scale, **0** = normal Pigmentation, **1** = hypopigmentation, **2** = mixed, **3** = hyperpigmentation.

Hyperpigmentation in the score system was roughly assessed regardless the exaggerated pigmentation induced by drugs or the grading of hyper pigmented colour. There was worsening in the pigmentation of the lesions in all groups. There was no significant differences between different groups (P>0.05).

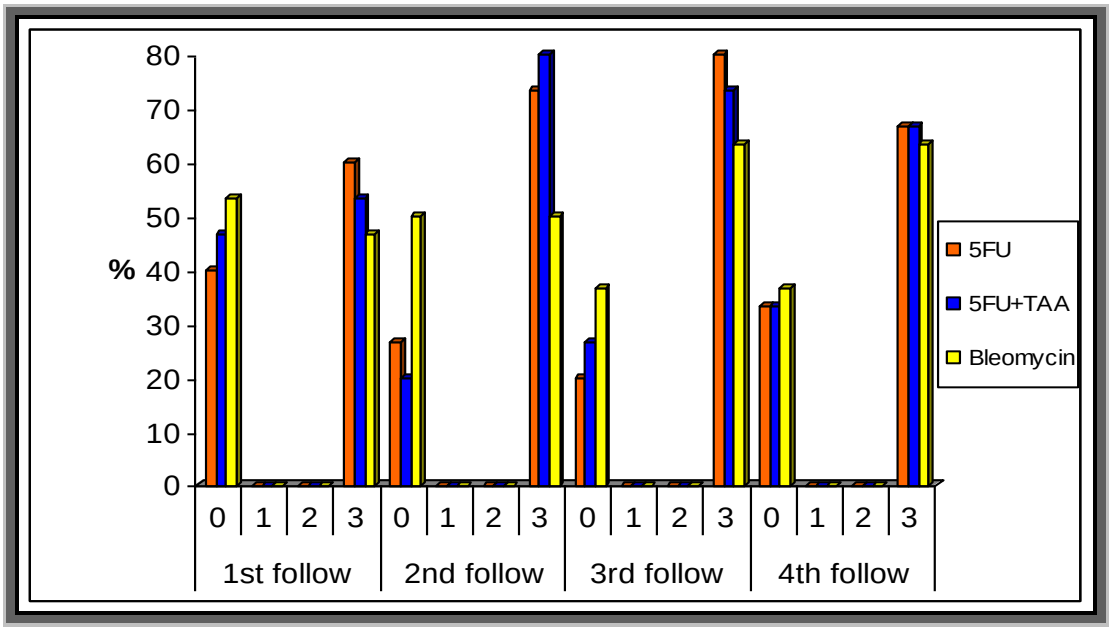

Fig. (14): Pigmentation of keloids & hypertrophic scars in patient groups.

(C) Pliability:

Table (8): Pliability of keloids & hypertrophic scars in patient groups.

Pliability		Group IA		Group IB		Group II		Total		Chi-Square test			
		N	%	N	%	N	%	N	%	X^2	P1 value	X^2	P2 value
Before treatment	**0**	0	0	0	0	0	0	0	0	0.14	0.71	0.72	0.398
	1	0	0	0	0	0	0	0	0				
	2	0	0	0	0	0	0	0	0				
	3	6	40.0	7	46.67	16	53.33	39	65.0				
	4	9	60.0	8	53.33	14	46.67	21	35.0				
	5	0	0	0	0	0	0	0	0				
First follow (at 4th week)	**0**	0	0	0	0	0	0	0	0	0.29		2.25	0.047
	1	0	0	0	0	0	0	0	0				
	2	2	13.33	3	20.00	4	13.33	9	15.0				
	3	7	46.67	6	40.00	14	46.67	27	45.0				
	4	6	40.00	6	40.00	12	40.00	24	40.0				
	5	0	0	0	0	0	0	0	0				
second follow (at 8^{th} week)	**0**	0	0	1	6.67	14	46.67	15	25.0	2.29		6.32	0.005
	1	2	13.33	3	20.00	10	33.33	15	25.0				
	2	5	33.33	6	40.00	5	16.67	16	26.67				
	3	6	40.00	3	20.00	1	3.33	10	16.67				
	4	2	13.33	2	13.33	0	0	4	6.67				
	5	0	0	0	0	0	0	0	0				
third follow (at12th week)	**0**	6	40.00	7	46.67	25	83.33	38	63.33	2.55		10.25	0.001
	1	5	33.33	5	33.33	5	16.67	15	25.0				
	2	4	26.67	3	20.00	0	0	7	11.67				
	3	0	0	0	0	0	0	0	0				
	4	0	0	0	0	0	0	0	0				
	5	0	0	0	0	0	0	0	0				

P1 comparison between group IA & group IB , P2 comparison between group I & group II

As regard to Vancouver scar scale, **0** = normal pliability, **1** =supple, **2** = yielding, **3** = firm**, 4** = ropes, **5** =contracture**. ,**

There was improvement in the pliability of the lesions in all groups.

In group IA, (40%) showed normal pliability.

In group IB, (46.67%) showed normal pliability.

In group II, (83.33%) showed normal pliability.

The improvement was better in group IB than group IA but the difference was statistically non significant (P>0.05).

The best improvement in pliability was reported in group II and the difference was statistically significant (P<0.05) compared to group I. This indicates that bleomycin is more effective than 5FU alone or combined with TAC.

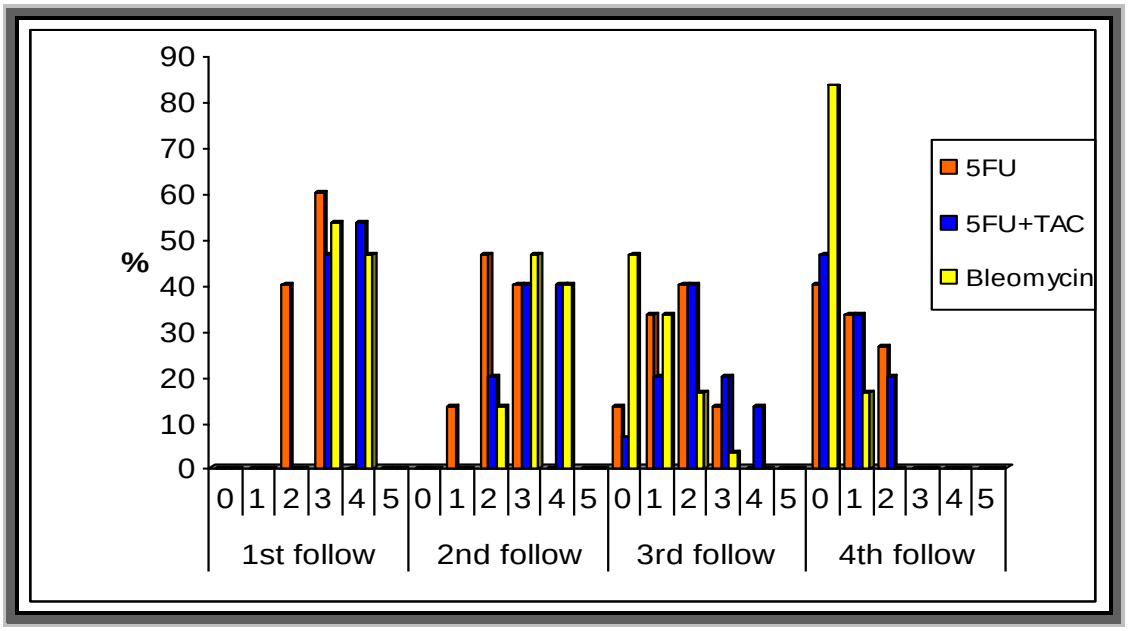

Fig. (15): Pliability of keloids & hypertrophic scars in patient groups.

D) Height:

Table (9): Height of keloids & hypertrophic scars in patient groups.

Height		Group IA		Group IB		Group II		Total		Chi-Square test			
		N	%	N	%	N	%	N	%	X^2	P1 value	X^2	P2 value
Before treatment	0	0	0	0	0	0	0	0	0	1.94	0.38	0.206	0.652
	1	0	0	1	6.67	4	13.33	5	8.33				
	2	7	46.67	9	60.00	14	46.67	30	50.00				
	3	8	53.33	5	33.33	12	40.00	25	41.67				
First Follow (at 4th week)	0	0	0	0	0	2	6.67	2	3.33	0.65	0.72	2.20	0.361
	1	2	13.33	2	13.33	9	30.00	13	21.67				
	2	7	46.67	9	60.00	12	40.00	28	46.67				
	3	6	40.00	4	26.67	7	23.33	17	28.33				
Second Follow (at 8th week)	0	0	0	1	6.67	15	50.00	16	26.67	3.63	0.59	6.369	0.001
	1	3	20.00	5	33.33	10	33.33	18	30.00				
	2	8	53.33	6	40.00	5	16.67	19	31.67				
	3	4	26.67	3	20.00	0	0	7	11.67				
Third follow (at12th week).	0	6	40.00	7	46.67	26	86.67	39	65.00	2.11	0.86	5.258	0.001
	1	7	46.67	5	33.33	4	13.33	16	26.67				
	2	1	6.67	2	13.33	0	0	3	5.00				
	3	1	6.67	1	6.67	0	0	2	3.33				

P1 comparison between group IA & group IB , P2 comparison between group I & group II

As regard to Vancouver scar scale, **0** flat, **1** =height less than 2 mm, **2** = height From 2-5 mm, **3**=height from 2-5 mm **.**

In group IA, (40%) flat.

In group IB, (46.67%) flat.

In group II, (86.67%) flat.

The improvement was better in group IB than group IA but the difference was statistically non significant (P>0.05). The best improvement in height was reported in group II and the difference was statistically significant (P<0.05) compared to group I. This indicates that bleomycin is more effective than 5FU alone or combined with TAC.

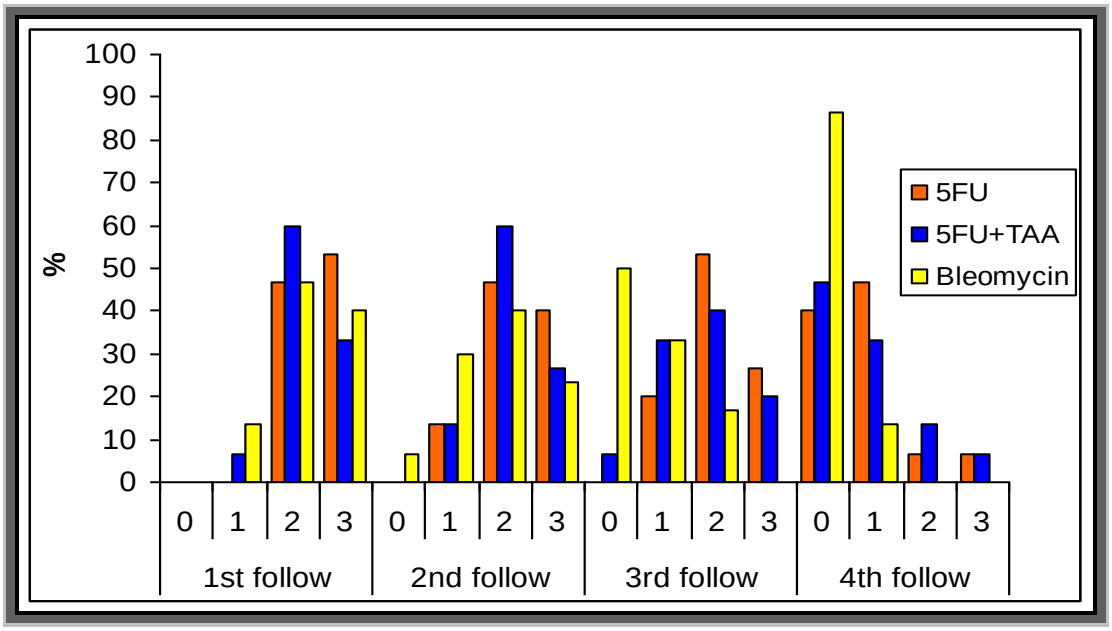

Fig.(16): Height of keloids & hypertrophic scars in patient groups.

Regarding the Vancouver scar scale:

Table (10): Vancouver scar scale in all studied groups.

		Group IA	Group IB	Group II	T-test	
		Mean ± SD	Mean ± SD	Mean ± SD	t	P-value
Before		9.67 ± 1.35	9.67 ± 1.63	9.32 ±1.46		
After		4.47 ±1.3	4.46±1.55	2.7±0.95	6.83	0.000
% of improvement		54	55	73		
Paired T-test	**T-value**	10.61	18.61	26.35		
	P-value	0.000	0.000	0.000		

There was statistically significant improvement between group II and group I after treatment (P<0.05).

In group IA: The mean Vancouver scar scale in all patients before treatment was 9.67 ± 1.35 and it was 4.47 ± 1.3 after treatment. The difference was statistically significant (P<0.05) ,with mean total improvement of 54%. **(Table 10 Figure 17)**.

In group IB: The mean Vancouver scar scale in all patients before treatment was 9.67 ± 1.63 and it was 4.46±1.55 after treatment. The difference was statistically significant (P<0.05), with mean total improvement of 55% This means that the combination of TAC and 5FU is more effective than 5FU alone **(Table 10 Figure 17)**.

In group II: The mean Vancouver scar scale in all patients before treatment was 9.32 ± 1.46 and it was 2.7 ± 0.95 after treatment. The difference was statistically significant (P<0.05),with mean total improvement of 73%. Also, the mean value of group II after treatment was statistically significant (P<0.05) compared to group I after treatment.

This means bleomycin is more effective than 5-FU alone or mixed with TAC **(Table 10 Figure 17)**.

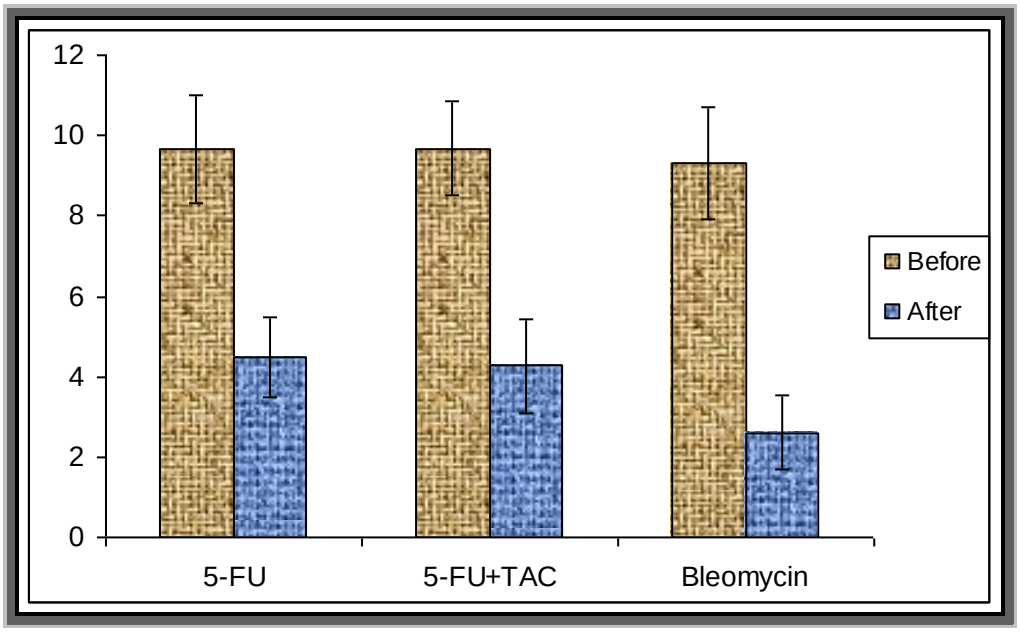

Fig. (17): Vancouver scar scale in all studied groups.

Regarding the number of sessions required:

In all groups, it varied from one patient to the others according to the response of the patients with maximum of 6 session for each patients in all studied groups.

Table (11): The number of sessions required for patient groups.

No. of sessions		Group IA		Group IB		Group II		Total	
		N	%	N	%	N	%	N	%
2		0	0.00	0	0.00	2	6.67	2	3.33
3		0	0.00	0	0.00	2	6.67	2	3.33
4		1	6.67	0	0.00	9	30.00	10	16.67
5		4	26.67	4	26.67	11	36.67	19	31.67
6		10	66.67	11	73.33	6	20.00	27	45.00
Total		15	100.00	15	100.00	30	100.00	60	100.00
Chi-square	**X^2**	-		2.331		10.362			
	P-value	-		0.592		0.001			

In group IA: The numbers of intralesional injections of 5-fluorouracil received ranged from 4 to 6 sessions.

In group IB: The numbers of intralesional injections of 5-fluorouracil combined with triamcinolone acetonide received ranged from 5 to 6 sessions.

In group II: The numbers of intralesional injections of bleomycin received ranged from 2 to 6 sessions. The difference was statistically significant ($P<0.05$) compared to group **I** (**IA** and group **IB**). This means that bleomycin is more effective than 5FU alone or mixed with TAC **.**

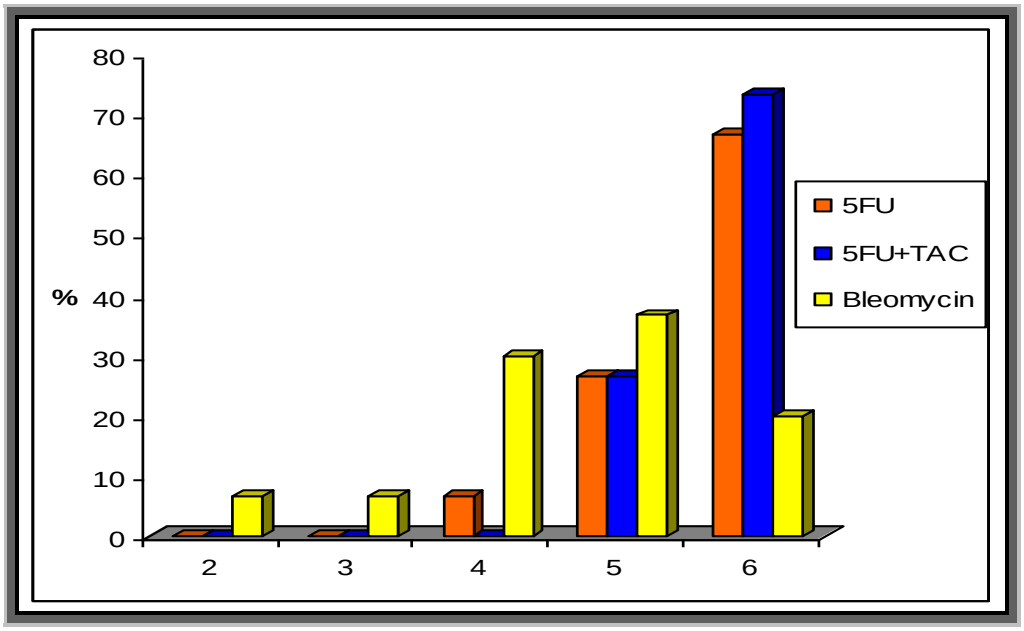

Fig (18): The number of sessions required for patient groups.

Regarding the side effects:

Table (12): Side effects in patients of different groups.

	Group IA		Group IB		Group II		Total	
	N	%	N	%	N	%	N	%
Hyperpigmentation	10	66.67	9	60.00	21	70.00	40	66.67
Ulceration	9	60.00	9	60.00	7	23.33	25	41.67
pain	11	73.33	5	33.33	30	100.0	46	76.67

The commonly encountered side effects were hyperpigmentation ulceration and pain. Hyperpigmentation was considered when there was any induced or exaggerated hyperpigmentation after injection . Also pain here refers to a complaint by patients after injection as we used local anesthesia during injection.

In group IA: Hyperpigmentation was present in 10 patients (66.67%), began from the 2nd to the 4th session and decreased gradually from 2weeks to 2months after ending treatment. Ulceration was present in 9 patients (60%) which healed in two weeks using topical antibiotic , Pain at the injection site was present in 11 patients (73.33%) that ended gradually in 2days. **In group IB:** Hyperpigmentation was present in 9

patients (60%) began from the 2nd to the 5th session and decreased gradually from 2 weeks to 2 months after ending treatment. Ulceration was present in 9 patients (60%) which healed in two weeks using topical antibiotic. Pain at the injection site was present in 5 patients (33.33%) that ended gradually in 2days. The side effects in group IB were nearly the same as group IA except for pain which was significantly decreased in group IB ($P<0.05$).

In group II: Hyperpigmentation was present in 21 patients (70%) began from the 3rd to the 4th session and decreased gradually from 4weeks to 3 months after ending treatment Only one case had residual hyperpigmentation after 6 months . Ulceration was present in 7 patients (21.33%) which healed in two weeks using topical antibiotic. Pain at the injection site was present in all patients (100%) that ended gradually in 2days. Ulceration was significantly decreased in group II ($P<0.05$) than group I while pain was significantly increased in group II than group I ($P<0.05$) **.**

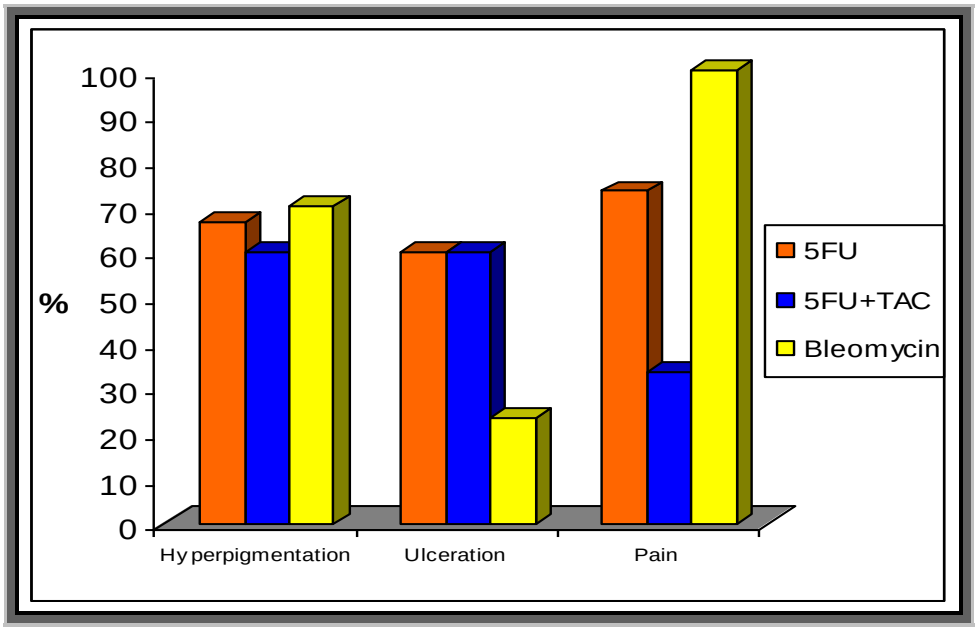

Fig. (19): Side effects in patients of different groups

Table (13): Correlation between the clinical response and age, sex and the disease duration in all studied groups:

Parameter	Pearson value	P-value
Age	-0.0002	0.999
Sex	0.215	0.1
Disease duration	-0.103	0.432

There was no significant statistical correlation between the clinical response and the age, sex and disease duration .This indicates that the clinical response wasn't affected by the age, sex or the disease duration in all groups.

Table (14): Mean values of liver function, renal function and blood count of all patients before and after treatment.

	Group IA			Group IB			Group II		
	Before	**After**	**P-value**	**Before**	**After**	**P-value**	**Before**	**After**	**P-value**
SGOT U/L	32.12	34.15	0.07	41.78	39.47	0.12	37.46	35.4	0.65
SGPT U/L	38.45	41.25	0.63	40.05	31.45	0.5	42.78	40.02	0.76
Serum total Bilirubin mg/dl	0.85	0.69	0.45	0.81	0.67	0.07	0.77	0.91	0.08
Serum albumin mg/dl	4.8	5.12	0.38	4.76	4.98	0.43	5.32	4.77	0.48
Serum creatinine mg/dl	0.69	0.78	0.66	0.85	0.7	0.15	0.85	0.1.1	0.09
Blood urea mg/dl	38.4	33.45	0.47	35.1	41.77	0.45	42.1	39.89	0.14
Hb%	85.2%	81.7%	0.76	78.6%	81.47%	0.71	75.1%	73.76%	0.82
RBCs count	5,221,455	5,140,212	0.09	5,241,501	5,018,611	0.09	4,998,212	4,568,651	0.43
WBCs count	7806.58	7617.2	0.14	6984.3	7126.22	0.24	7219.66	7536.21	0.34
Platelet count	385,455	356,422	0.52	405,244	398,677	0.26	367,471	374,966	0.22

The table shows that there was no significant changes in blood count, liver function tests and kidney function tests before and after treatment in all patient groups.

As regards to relapse of keloids and hypertrophic scars:

Table (15): Relapse of keloids & hypertrophic scars in all studied groups.

Time of relapse (Months)	Group IA		Group IB		Group II	
	N	**%**	**N**	**%**	N	%
1	1	6.67	2	13.33	0	0.00
2	0	0.00	2	13.33	0	0.00
3	3	20.00	1	6.67	0	0.00
4	1	6.67	0	0.00	0	0.00
5	0	0.00	0	0.00	0	0.00
6	1	6.67	2	13.33	0	0.00
Total	6	40.00	7	46.67	0	0.00

All patients were followed up for 6 months

In group IA: Relapse occurred in 6 patients (40%).

In group IB: Relapse occurred in 7 patients (46.67%).

In group II: No relapse occurred in all patients of this group**.**

This indicates that remission in bleomycin was better than 5 FU.

Table (16): Comparison between 5-FU cost and bleomycin cost in treatment of keloids and hypertrophic scars according to the number of sessions.

	5-FU	5-FU +TAC	Bleomycin
Dose per one cm^2 per session	0.2 to 0.4 mL/cm^2	0.2 to 0.4 mL/cm^2	0.5-1 ml/cm^2
Cost of dose per one cm^2 per session	0.4 to 0.8 Egyptian pounds	0.85 to 1.7 Egyptian pounds	4.2 to 8.4 Egyptian pounds
Maximum dose per session	2 ml	2 ml	4 ml
Cost of Maximum dose per session	1.6 Egyptian pounds	3.4 Egyptian pounds	33.6 Egyptian pounds

The table shows that the cost of 5-FU alone or in combination with TAC is much lower than bleomycin. However, the therapeutic efficacy of bleomycin is better than that of 5-FU alone or in combination with TAC.