SUMMARY AND CONCLUSIONS

Keloids and hypertrophic scars are fibrotic conditions that have been thought to be caused by a disorder in regulation of cellularity that occurs during wound healing. They appear as firm, mildly tender or pruritic, well-demarcated tumors. The exact etiology and pathophysiology of keloids and hypertrophic scars are still poorly understood. Disrupted balance between ECM protein deposition and degradation is the cornerstone of keloids and hypertrophic scars. The predisposing factors include location of keloids, infection, trauma, tension, hormonal factors, tissue hypoxia, immunological factors and apoptosis.

No single therapeutic modality is best for all keloids and hypertrophic scars. Lines of treatment include occlusive dressings, compression therapy, intralesional corticosteroid injections, cryosurgery, excision, radiation therapy, laser therapy, interferon therapy, 5-fluorouracil, topical doxorubicin, intralesional bleomycin, intralesional verapamil, intralesional retinoic acid, topical imiquimod 5% cream, topical tamoxifen, topical tacrolimus, phototherapy, transforming growth factor–beta3, tumor necrosis factor alpha inhibitors and recombinant human interleukin.

5-FU, a pyrimidine analogue with antimetabolite activity, inhibits fibroblastic proliferation in tissue culture and is believed to reduce postoperative scarring by decreasing fibroblast proliferation. Its efficacy and safety have been reported when used as a monotherapy or when used in combination with other drugs (e.g. TAC) for the treatment of fibrosing conditions .

Bleomycin is a secondary metabolite of a strain of streptomyces obtained from soil and has antitumor, antiviral and antibacterial activity. It acts by binding to DNA causing strand scissions. Bleomycin have been used for treatment of several malignancies including squamous cell carcinoma, testicular cancer and malignant lymphoma. In addition to these applications, the use of intralesional bleomycin has been documented for the treatment of keloids and hypertrophic scars with promising results.

The present study was a trial to evaluate the efficacy and safety of intralesional injection of 5-FU and bleomycin in treatment of keloids and hypertrophic scars.

This study was conducted on 60 patients attending the Dermatology and Andrology out patient clinic of Benha University Hospital, El-Mahalla Hospital and Samannoud Hospital. All included patients had normal liver and kidney functions and normal blood picture. These patients were divided into the following groups:

Group (IA): included patients who were injected intralesionally with 5-FU in a concentration of 50 mg/ml. Multiple injections were given at 1cm intervals on average, 0.2 to 0.4 ml/cm^2. The maximum dose was 2 ml per session with two weeks interval .

Group (IB): included patients who were injected intralesionally with a mixture of 0.1 ml of 40 mg/ml triamcinolone acetonide and 0.9 ml of 5-FU (50 mg/ml). Multiple injections were given at 1cm intervals on average, 0.2 to 0.4 ml/cm^2. The maximum dose was 2 ml per session with two weeks interval**.**

Group (II): included patients who were injected intralesionally with bleomycin in a concentration of 1.5 IU/ml. Multiple intralesional injections of bleomycin in a dose of 0.5-1 ml/cm^2 with maximum dose of 4 ml per session with two weeks interval. The maximal number of sessions for each patient was 6

The patients underwent follow up by photographing and Vancouver scar scale system where (0) reflected normal skin. Follow up for the patients were performed at 4,8,12,weeks during treatment period and after stopping treatment for 6 months.

Regarding improvement of Vancouver scar scale

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 with mean total improvement of 54%.

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 with mean total improvement of 55%.

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. with mean total improvement of 73%. The mean value of group II after treatment was statistically significant ($P<0.05$) compared to group I after treatment.

Regarding number of required sessions **In group IA,** ranged from 4 to 6 sessions. **In group IB,** ranged from 5 to 6 sessions. **In group II,** ranged from 2 to 6 sessions. The difference was statistically significant ($P<0.05$) compared to group **I** (**IA** and group **IB**).

Regarding the side effects, there was hyperpigmentation, pain and ulceration in all the studied groups. However, pain was significantly decreased in group IB compared to group IA, ulceration was significantly

decreased in group II than group I ,while pain after injection was increased in group II than group I.

Regarding relapse, there was relapse in 6 patients (40%) of group IA**,** in 7 patients (46.67%) of group IB and no relapse occurred in all patients of group II.

In conclusion, It was found that intralesional injection of bleomycin was more effective and better in remission than intralesional 5-FU injection in treatment of keloids and hypertrophic scars regardless patient's age, sex, disease duration or site of the lesion.