



Original article

# Comparative study between intralesional injection of bleomycin and 5-fluorouracil in the treatment of keloids and hypertrophic scars

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## Abstract

The aim of this work was to evaluate the efficacy and safety of intralesional injection of 5-fluorouracil and bleomycin in the treatment of keloids and hypertrophic scars. One hundred and twenty patients were divided into the following groups: group IA was injected intralesionally with 5-fluorouracil; group IB was injected intralesionally with a combination of triamcinolone acetonide and 5-fluorouracil; group II was injected intralesionally with bleomycin. Patients underwent follow up by photographing and Vancouver scar scale system. There was a significant improvement in the Vancouver scar scale in group II compared to group I after treatment. There was hyperpigmentation, pain and ulceration in all the studied groups. Pain was significantly decreased in group IB compared to that in group IA, ulceration was significantly decreased in group II than in group I while pain after injection was increased in group II than in group I. Relapse occurred in 12 patients of group IA, 14 patients of group IB and no relapse occurred in group II. So, intralesional injection of bleomycin was more effective and better in remission than intralesional 5-fluorouracil injection in the treatment of keloids and hypertrophic scars regardless of patient's age, sex, disease duration or site of the lesion.

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**Keywords:** Bleomycin; Fluorouracil; Keloids; Hypertrophic scars

## 1. Introduction

Keloids and hypertrophic scars are characterized by excessive deposition of dermal collagen with resultant scar

tissue. A keloid scar is benign, non-contagious and sometimes accompanied by severe itching, sharp pains and changes in texture. In severe cases, it can affect movement of skin and may ulcerate. The probability of recurrence of keloids after surgical removal is high, usually greater than 50% (Hunasgi et al., 2013; Maghrabi and Kabel, 2014).

Five-Fluorouracil (5-FU) is a pyrimidine analog, which is used in the treatment of cancer. It is also used in ophthalmic surgery, specifically to augment trabeculectomy in patients deemed to be at high risk for failure. 5-FU acts as an anti-scarring agent in this regard, since excessive scarring at the trabeculectomy site is the main cause for failure of the surgery (Rothman et al., 2000). Recent trials have

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used 5-FU topically for treating hypertrophic scars and some types of basal cell carcinomas of the skin. Some studies had used 5-FU intralesionally in the treatment of keloids and hypertrophic scars alone or mixed with triamcinolone acetonide (TAC). The latter is thought to decrease pain and inflammation (Davison et al., 2009).

Bleomycin is a glycopeptide antibiotic that is widely used as an anti-cancer agent. The drug is used in the treatment of Hodgkin lymphoma, squamous cell carcinomas and testicular cancer, as well as in the treatment of plantar warts (Lewis and Nydorf, 2006). Also, bleomycin has been tried intralesionally to treat keloids and hypertrophic scars. The commonest complication of bleomycin injection was hyperpigmentation, which was seen in 75% of patients (Saray and Güleç, 2005). This work was a trial to evaluate the efficacy and safety of intralesional injection of 5-fluorouracil and bleomycin in the treatment of keloids and hypertrophic scars.

## 2. Methods

### 2.1. Location

This study was conducted at dermatology, venereology and andrology department, faculty of medicine, Benha University, Egypt. This study was approved by the Research Ethics Board at Benha University. This work complied with the principles laid down in the Declaration of Helsinki.

### 2.2. Study design

#### 2.2.1. Equipments

- A 1 ml insulin syringe with a fixed 30 gauge needle.
- Mepivacaine HCl 3% (Mepacaine ampoule, Alexandria Pharmaceutical Co., Egypt).
- Five-fluorouracil (Fluorouracil 250 mg ampoule, Biosynthesis Pharmaceutical Co., Egypt).
- Bleomycin (Bleocip 15 mg vial, Cipla Co. Ltd, Verna industrial state, Goa, India).
- Triamcinolone acetonide (Kenacort vial, Bristol-Myers Squibb).

This study was conducted on one hundred and twenty patients with keloids and hypertrophic scars of varying sizes and durations selected from the Dermatology and Andrology outpatient clinic of faculty of medicine, Benha University, Egypt.

#### 2.2.2. Inclusion criteria

A minimum age of 15 years, acceptable pretreatment laboratory studies (complete blood cell count, serum chemistries, urine analysis, and pregnancy test) and a written consent was taken from each patient before the study.

#### 2.2.3. Exclusion criteria

Pregnancy, lactation, chronic renal failure and any abnormalities of liver function tests or complete blood count.

#### 2.2.4. Groups

The patients were divided into the following groups:

Group (IA): included thirty patients who were injected intralesionally with 5-FU at a concentration of 50 mg/ml. Initially, local anesthetic Mepivacaine HCl 3% was administered at the lesion site. Then, the patients were injected intralesionally with 5-fluorouracil at a concentration of 50 mg/ml, multiple injections were given at 1 cm intervals on average, 0.2–0.4 ml/cm<sup>2</sup>. The maximum dose was 2 ml per session with a two week interval (Kontochristopoulos et al., 2005).

Group (IB): included thirty patients who were injected intralesionally with a mixture of 0.1 ml of 40 mg/ml TAC and 0.9 ml of 5-FU (50 mg/ml). Initially, local anesthetic (Mepivacaine HCl 3%) was administered at the lesion site. Then, the patients 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 1 cm intervals on average, 0.2–0.4 ml/cm<sup>2</sup>. The maximum dose was 2 ml per session with a two week interval (Asilian et al., 2006).

Group (II): included sixty patients who were injected intralesionally with bleomycin at a concentration of 1.5 IU/ml. Initially, local anesthetic (Mepivacaine HCl 3%) was administered at the lesion site. Then, multiple intralesional injections of bleomycin at a dose of 0.5–1 ml/cm<sup>2</sup> with a maximum dose of 4 ml per session using insulin syringe were administered with a two week interval (España et al., 2001).

All patients were subjected to complete history taking and dermatological examination included site, size, shape, color and consistency of the lesion. Investigations into blood count, liver and kidney functions were done before treatment and then at a monthly interval during therapy. The patients were informed about the nature of each procedure, expected number of treatments and also expected side effects of the procedure. Follow up of the patients was performed by the Vancouver scar scale system after stopping the treatment for 12 months.

### 2.3. Assessment of the clinical response

Assessment of keloids was done at the beginning of the treatment, at 4, 8, and 12 weeks, and during the follow up period. The assessment included clinical changes in the keloids by photographs and by reporting any side effects that the patients experienced. Clinical assessment was carried out using Vancouver scar scale that includes vascularity, pigmentation, pliability and height. The results were recorded from (0) to (14) where (0) reflected normal skin (Baryza and Baryza, 1995). The clinical improvement was

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