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A Promising Treatment of Keloids with Intralesional Bleomycin and Lidocaine

K. Youss[2*], H. Sobhi[2], O. Baladi[2], H. El Yazidi[2], K. El Yacoubi[2], B. Razem[2], O. Ilhami[1,2], A. Oukerroum[1,2], F. Slimani[1,2]

[1]Department of Stomatology and Maxillofacial Surgery, Hospital 20 Août 1953, University Hospital Ibn Rochd, Casablanca, Morocco
[2]Faculty of Medicine and Pharmacy, Hassan II University of Casablanca, B. P. 5696, Casablanca, Morocco

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***Corresponding author:** K. Youss
Department of Stomatology and Maxillofacial Surgery, Hospital 20 Août 1953, University Hospital Ibn Rochd, Casablanca, Morocco

Abstract **Original Research Article**

***Background*:** A keloid is an aberration of the scar formation process characterised by its indefinite overgrowth beyond the initial wound limits. Treatment of keloids has been a dilemma due to its poor response rates, and hight recurrence. Bleomycin has been introduced to the treatment panel of keloids in the nineties and it has been gaining interest and trust over the years. ***Aim*:** To present our experience of treating 27 keloids using a mixture of Bleomycin and Lidocaine. ***Methods*:** 24 patients with 27 keloids received a mixture of Bleomycin dissolved in Lidocaine 2% (1.5mg/ml) using the mid dermal injection technic. Parameters regarding the scar and the patient were recorded at baseline, monthly during the treatment and every semester after complete disappearance of the scar. ***Results*:** Three to twelve sessions were needed to obtain complete flattening in 81.5% of the keloids and highly significant flattening in the remaining 18.5%. Local side effects included hyperpigmentation (73%), blisters (41%), ulceration (26%), pain (21%) and necrosis (7%). No recurrence was reported. ***Conclusion*:** these clinical findings compared to those of various studies suggest that using a mixture of Bleomycin and Lidocaine leads to better success rate with fewer pain. Further investigations are needed to have a solid scientific support of this theory.

Keywords: keloids, Bleomycin, Lidocaine, intralesional.

INTRODUCTION

A keloid is the result of an abnormal scaring process. It is distinguished by its overgrowth beyond the initial wound edges and by its progression to form thick scars that rarely heals spontaneously [1]. Keloids are strictly human and their prevalence varies from 0.09% to 16% [2]. They may be due to various injuries (surgery, piercing, burns, vaccination, acne, inflammation, insect bite) [3–5], although they may also arise spontaneously [6]. First reports of keloids date back to 1700 B.C. and yet there is no consensus regarding its appropriate management. Treatment options include corticosteroids, surgical excision, silicone-based products, pressure therapy, radiotherapy, cryotherapy, laser therapy, application of Imiquimod, 5-Fluorouracil and some emerging treatments such as stem cell therapy, Mitomycin, Verapamil, Botulinum toxin type A, ACE inhibitors, Interferon, Tamoxifen, genetic and epigenetic therapies, Bleomycin and many others [1,4,6].

Bleomycin is an antineoplastic antibiotic and antiviral drug derived from Streptomyces verticillus[7]. It was first used by Bodokh and Brun in 1996 to treat keloid and hypertrophic scars [8] and ever since many authors have been reporting their study results using different technics in treating keloids with Bleomycin. Bleomycin's mechanism of action is DNA strand scissoring which results in apoptosis of keratinocytes, endothelium sclerosis and alteration of collagen synthesis [4,9,10]. It has also been demonstrated that local anesthetics selectively potentiate Bleomycin cytotoxicity [11], therefore we have opted for a knew technic diluting Bleomycin in Lidocaine 2% instead of Saline. The aim of our study is to present our experience of treating 24 patients with 27 keloids using a mixture of Bleomycin and Lidocaine.

MATERIALS AND METHODS

We selected a population of 24 patients with a total of 27 Keloid scars in the face and neck area. The inclusion criteria for patients included the following: aged above 15 years, keloids measuring more than 1 cm. pregnant and breast-feeding women were excluded along with patients with known systemic diseases or allergies. The nature of the treatment and its possible side effects were clearly explained to all patients; female patients

were warned not to get pregnant during and a few months after the end of treatment and informed consent was obtained. A preparation of injectable bleomycin was obtained by diluting 15 mg of bleomycin in 10 ml of lidocaine 2%. The solution was injected once a month into the mid-lesion in depth with a maximum of 5 ml per injection. Parameters regarding the scar (dimensions, pigmentation, blisters, ulceration, and pus) and the patient (pain and pruritus) were recorded at baseline and then monthly during the treatment and 6 months, 12 months and 18 months after complete disappearance of the scar. Systemic side-effects of bleomycin were not evaluated. Photographs were taken at baseline and at every visit. The treatment was followed until complete flattening (100%) or highly significant flattening (> 90%) of the keloid

RESULTS

Out of our 24 selected patients, 18 were females and 6 were males aged between 15 and 67 years. Out of 27 scars 17 were located on the ears (9 lobules and 8 helix), 7 cervical scars, 2 were retro auricular and 1 pre auricular. 11 keloids were due to piercings, 6 were spontaneous, 5 were of post-operative etiology and 2 were secondary to trauma. Seven patients had previous treatment (4 had surgery and 3 had steroids). The original volume of the scars was between 400 and 61200 mm^3 (mean volume: 8265 mm^3), with maximal length between 15 and 68 mm. the delivered dose of Bleomycin was volume depending with a maximum of 7.5 UI/session. Three to twelve sessions were needed to obtain complete flattening in 81.5% of the keloids (22/27 scars) and highly significant flattening in the remaining 18.5%

Figure 1: 18,5% Local side effects that were found included hyperpigmentation (73%), blisters (41%), ulceration (26%), pain (21%) and necrosis (7%). All the patients that had experienced pain affirmed that it didn't last mor than 48 hours and only two patients (out of five) needed medication (paracetamol). Hyperpigmentation was treated with daily application of Niacinamide 5%. No recurrence was reported after a minimum of 6 months follow up (6 to 32 months).

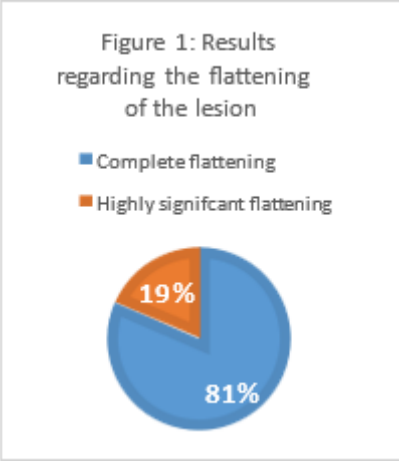
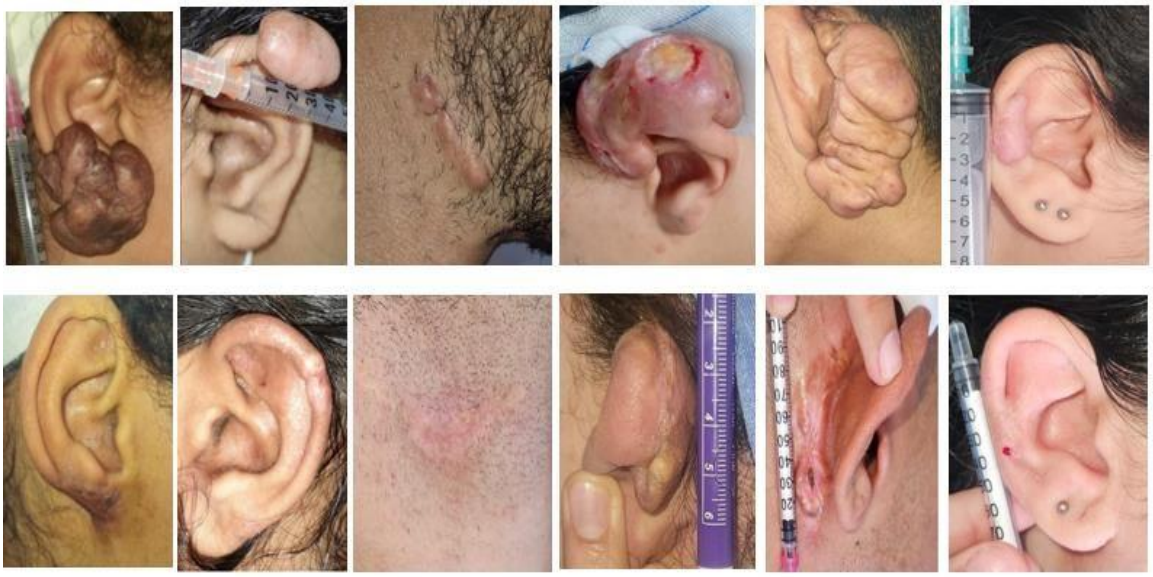


Table 1: studies of keloids treated with intralesional Bleomycin

Study Year	Technique	Complete Flattening	Significant Flattening	Hyperpigmentation	Pain	Ulceration	Blisters	Recurrence Rate
Bodokh (8), 1996	Mid dermal injection	47%	30%	ND	ND	ND	ND	ND
Espana (18), 2001	Tattooing	53.8%	38.5%	ND	ND	ND	ND	15.7%
Saray (5), 2005	Multiple injections	73%	6.7%	28.5%	50%	100%	ND	0%
Naeini (17), 2006	Tattooing	47%	30%	75%	ND	ND	ND	ND
Aggarwal (20), 2008	Tattooing	44%	22%	14%	ND	16%	ND	14%
Payapvipapong (16), 2015	Mid dermal injection	ND	ND	71.4%	21.4%	ND	7.1%	ND
Kabel (22), 2016	Multiple injections	ND	ND	70%	100%	21.3%	ND	0%
Khan (19), 2019	ND	ND	ND	70%	100%	27%	ND	ND
Huu (25), 2019	Mid dermal injection	70.8%	8.3%	56.7%	100%	5.8%	78.3%	14%
Mishra (15), 2021	Mid dermal injection	ND	ND	12%	28%	8%	ND	0%
Our study, 2024	**Mid dermal injection**	**81.5%**	**18.5%**	**73%**	**21%**	**26%**	**41%**	**0%**

ND: not determined



Keloids in different sites treated with intralesional Bleomycin.
Top row: Before
Bottom row: After

DISCUSSION

Keloid formation is an aberration in the process of wound healing. It is taught to be the result of over-proliferation and reduced apoptosis of dermal fibroblasts which results in an increased synthesis of collagen and extra cellular matrix and decreased degradation of these products, which is theorised to be related to the overstimulation of fibroblasts due to the overexpression of inflammatory mediators such as TGF-β1, EGF, VEGF, PDGF and many others [4,6,12,13]. The prevalence of keloids varies from 0.09% to 16% up to 20% in some reposts [2,6,14]. Some authors affirm that it has equal sex distribution [6], but most publications report a female predominance [15–20] with only two reports of male predominance [5,21]. In our study, the female predominance vas obvious (18F/6M). Keloids may occur at any age, with the highest incidence between 10 and 30 years [19,20]. They may develop several months to years after mild injuries and even spontaneously, they persist for a long time and they never regress spontaneously [4,6,20]. The main reported causes of keloids are surgery, trauma, acne, vaccination, burn, foreign body and elective cosmesis [4,15,16,18].

Most of our cases were due to piercing, surgery or of a spontaneous pattern. They are usually located on the thorax, back, shoulders, neck, lobules and other locations [15,20,22]. The scar tissue extends beyond the wound limits and causes both functional and aesthetic consequences such as body disfigurement, pain, pruritus, hyperesthesia and movement limitation [4,6]. Multiple studies on keloids have led to an abundance of therapeutic strategies whether to prevent or to treat keloids, some of which are considered classical such as pressure therapy, silicone-based products, flavonoids, corticosteroids, surgical excision, radiotherapy, cryotherapy, laser therapy [2,4,6], and others are still emerging: Imiquimod 5%, 5-Fluorouracil, stem cell therapy, Mitomycin C, Verapamil, Botulinum toxin A, ACE inhibitors, Interferon, genetic end epigenetic therapies and Bleomycin [2,4].

Bleomycin is an antitumor, antibiotic and antiviral isolated from Streptomyces verticillus, its main mechanism of action is DNA-strand scissoring which ends in cell cycle arrest. Its administration to the skin results in keratinocytes apoptosis, endothelial sclerosis and inhibition of collagen synthesis [6,9,23]. It was first used in the treatment of keloids by Bodokh and Brun in 1996 [8]. Scar improvement is significantly increased with intralesional Bleomycin compared to intralesional injection of Triamcicolone acetonide alone, or combined with 5-FU or to cryotherapy and compared to intralesional 5-FU [24]. It has also lower recurrence rate [21,22,24]. Many technics have been described to introduce bleomycin into the scar including tattooing [17,18,20], mid dermal single injection [8,15,16,25] and multiple injection using a standard insulin syringe or a jet injector [5,21,22]. In every published study, Bleomycin was diluted in a sterile 9% saline, however we chose to dissolve it in Lidocaine 2% since it has been proven that local anaesthetics selectively potentiate the cell killing of Bleomycin [11] and that adding anaesthetics to the Bleomycin solution led to higher complete cure rates in common warts than with Bleomycin alone [9]. The therapy led to complete flattening of 81.5% of the keloids and highly significant flattening of the remaining 18.5% with a complete success rate of 100% which is higher than the reported rates **(table 1)**. Side effects of intralesional Bleomycin are strictly local: hyperpigmentation, pain, pruritus, erythema, blisters, ulceration, necrosis [9,23,26]. No report of systemic side effects related to intralesional Bleomycin in keloids has been published up to this date.

These side effects are associated with higher doses of Bleomycin used in systemic chemotherapy [5,23,26]. The main side effect was hyperpigmentation (73%), followed by blisters (41%), ulceration (26%), pain (21%) and necrosis (7%). The pain rate was lower than most publications **(table 1)**. The recurrence rate is reported to be between 0-15% (5,15,18,20,22,25), no recurrence was noted in our study. The difference in the success and pain rates between our study and the rest may be accounted for by the combination of mid dermal injection technique and the use of Lidocaine 2% instead of Saline solution to dissolve Bleomycin. We recognize the limitations of this study since we did not use a control group. Therefore, we cannot certainly know which mechanism led to the better success rate and the fewer painful cases. However, we believe that, by using the intralesional mid-dermal injection technique, the amount of drug penetrating the lesion is greater than with the tattooing technique and by adding Lidocaine to the preparation we potentiated the apoptotic effect of Bleomycin.

Conclusion

Bleomycin has a proven role in the treatment of Keloids, and it is safe to suggest that it can be used as the first line treatment thanks to its high effectiveness, good tolerance, low recurrence rate and acceptable cost. However, there is still no consensus as to the technic of administration and the dose/volume needed. Considering the significantly better results of our study in terms of effectiveness and pain, we suggest that Bleomycin should be diluted in Lidocaine and delivered middermally to the keloid. Nevertheless, the small sample size and the absence of a control group are limiting this study. More specialised studies are needed in this area.

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