Results of a combination of bleomycin and triamcinolone acetonide in the treatment of keloids and hypertrophic scars

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Abstract While treatment of keloids and hypertrophic scars normally shows modest results, we found that treatment with bleomycin was more promising. The present study was divided into two parts. In the first part the aim was to show the results using a combination of bleomycin and triamcinolone acetonide per cm² (BTA). In the second part the objective was to determine the response to both drugs in large keloids that were divided into 1 cm² squares, treating each square with the dose previously used. In the first part of the study, the clinical response of 37 keloids ranging from 0.3 to 1.8 cm² treated with BTA were followed up over a period of 1-2 years. 0.375 IU bleomycin and 4 mg triamcinolone acetonide were injected every 3 months. In the second part of the study we reviewed the clinical response in six patients with large keloids. The monthly dose administered never exceeded 3 IU of bleomycin. The first study showed 36 keloids (97.29%) softening after the first dose. In the second study, 5 showed different responses (the response was complete in the four smaller keloids). The largest keloid needed 9 doses to achieve an improvement of 70%. In conclusion, combined treatment with 0.375 IU of bleomycin and 4 mg of triamcinolone acetonide to 1 cm² was considered to be an acceptable procedure for the treatment of keloids. The best results were obtained in keloids over 1 cm² or when divided into 1 cm² square areas. Larger series need to be performed in order to confirm these results.

Keywords: Bleomycin; Keloid; Triamcinolone acetonide

Resumo Enquanto normalmente o tratamento de queloides e cicatrizes hipertróficas mostra resultados moderados, o tratamento com bleomicina revelou resultados mais promissores. Este estudo foi dividido em duas partes. Na primeira parte, o objetivo foi mostrar os resultados da utilização de uma combinação de bleomicina e acetonido de triancinolona por cm² (BAT). Na segunda parte, o objetivo foi determinar a resposta aos dois medicamentos em queloides grandes, quais foram divididos em quadrados de 1 cm², tratando cada quadrado com a dose utilizada anteriormente. Na primeira parte do estudo, a resposta clínica de 37 queloides de 0,3 a 1,8 cm² tratados com BAT foi monitorada por um período de 1 a 2 anos. Injeções de 0,375 UI de bleomicina e 4 mg de acetonido de triancinolona foram aplicadas a cada 3 meses. Na segunda parte do estudo, revisamos a resposta clínica em 6 pacientes com queloides grandes. A dose mensal administrada nunca excedeu 3 UI de bleomicina. O primeiro estudo mostrou que 36 queloides (97,29%) amoleciam após a primeira dose. No segundo estudo, 5 mostraram diferentes respostas (a resposta foi completa nos quatro queloides menores). O queloide maior necessitou de 9 doses para apresentar melhora de 70%. Concluindo, o tratamento combinado com 0,375 UI de bleomicina e 4 mg de acetonido de triancinolona por cm² foi considerado um procedimento aceitável para o tratamento de queloides. Os melhores resultados foram obtidos em queloides com mais de 1 cm² ou divididos em áreas de 1 cm². Estudos mais amplos deveriam ser realizados, para confirmar esses resultados.

Palavras-chave: Bleomicina; Queloide; Triancinolona acetonida

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INTRODUCTION

Keloids are benign hyperproliferative growths of dermal collagen usually resulting from excessive tissue response to skin injury; they are characterized by a tendency to recur. However, spontaneous keloids can occur without previous skin trauma. Keloids invade clinically normal adjacent skin and are often painful or/and pruritic.

Although their etiology is not fully understood, it is well-known that the combination of high proline activity (up to four-fold compared to normal skin) and the increase of type I procollagen and type I collagen concentration in the tissue (especially the latter) are involved. There is hereditary or racial predisposition. The condition affects the presternal area, ear lobes, shoulders, ankles and/or face.

Keloids may cause pain, movement limitation, and other physical and psychological problems. The search for an effective treatment is therefore essential. Different options such as intralesional injections of bleomycin or corticosteroids either alone or combined with cryotherapy, compression therapy, silicone sheeting, radiation therapy, laser therapy, 5-fluorouracil, interferon, retinoids, imiquimod 5% cream, tacrolimus, verapamil and botulin toxin have been used, most of them with the aim of achieving the best functional and cosmetic solution possible. Different reports present bleomycin as an effective treatment in keloid therapy and hypertrophic scars using different application methods such as dermojet, multiple needle punctures or syringe injection.

However, the dose required per cm² of surface and the possibility of avoiding side-effects with subsequent injections of triamcinolone acetonide has not been investigated to date in large series.

The objective of the first study was to find the ideal dose of bleomycin and triamcinolone acetonide for each 1 cm² of keloid. In the second study the aim was to demonstrate the response of larger keloids divided into 1 cm² squares in order to inject into each area the dose that had been previously demonstrated as being more effective.

MATERIAL AND METHODS

Between May 2004 and May 2006 we treated 10 white patients, 4 males and 6 females, aged 19 – 39 years, with Fitzpatrick skin phototypes II, III and IV. Two patients (nos. 8 and 9) presented one keloid; the others had between 3 and 9. 38 keloids and 2 hypertrophic scars (patient no. 7) were included in our study (Table 1). Three keloids bigger than 2 cm² (patients nos. 1, 4, and 6) were considered in the second study. In the first study 35 keloids of under 2 cm² and two hypertrophic scars were treated.

The keloids were located on the back, shoulders, presternal and scapular regions (Figures 1 - 6). The hypertrophic scars were located in the right abdominal wall and right thigh. The keloids were second-

| Patient | Sex | Age | Skin Type | Etiology | Location | Lesion (size cm²) | Previous Treatment |
|---------|-----|-----|-----------|----------|----------|-------------------|--------------------|
| 1       | M   | 19  | III       | NODULOCYSTIC ACNE | PRESTERNAL | 6 (0.5-1.5) | SURGERY |
|         |     |     |           |          | BACK      | 3 (1-1.8)      | LASER THERAPY      |
| 2       | F   | 23  | III       | SURGERY   | PRESTERNAL | 2 (1.1/1.5) | TRIAMCINOLONE ACETONIDE |
|         |     |     |           |          | SHOULDER L | 2 (1.2/1.5) | SILICONE |
| 3       | F   | 27  | II        | SPONTANEOUS | PRESTERNAL | 1(1.8)   | NO |
|         |     |     |           |          | SCAPULAR R/L | 2 (1.0/1.5) | |
| 4       | M   | 39  | III       | NODULOCYSTIC ACNE | PRESTERNAL | 2 (1.0/1.3) | TRIAMCINOLONE ACETONIDE |
| 5       | M   | 19  | IV        | NODULOCYSTIC ACNE | PRESTERNAL | 4 (0.3-1.8) | SILICONE |
| 6       | M   | 27  | III       | NODULOCYSTIC ACNE | PRESTERNAL | 4 (1.2-1.8) | NO |
| 7       | F   | 20  | II        | TRAUMATIC SCAR | CHEST     | 2 (1.0/1.3) | NO |
|         |     |     |           |          | ABDOMINAL WALL | 1 (1.4)   | (Hypertrophic scar-HS) |
|         |     |     |           |          | SHOULDER L | 1 (1.5)      | |
|         |     |     |           |          | RIGHT THIGH | 1 (1.4)     | (Hypertrophic scar-HS) |
| 8       | F   | 28  | III       | SPONTANEOUS | PRESTERNAL | 1 (1.2)     | SILICONE |
| 9       | F   | 26  | III       | SURGERY   | PRESTERNAL | 1 (1.5)     | TRIAMCINOLONE ACETONIDE |
| 10      | F   | 29  | III       | TRAUMATIC SCAR | SHOULDER L | 1 (1.6)     | SILICONE |
|         |     |     |           |          | SCAPULAR R | 3 (0.6-1.3) | |

L= Left  R= Right
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**Figure 1:** Three keloids of 1.0 cm², 1.2 cm² and 1.8 cm² right-to-left on back, before (a) and after two sessions of treatment (b).

**Figure 2:** Two keloids of 1.2 cm² and 1.5 cm² on the left shoulder in a woman before (a) and after two sessions of treatment (b). Atrophy, most evident in the outer

**Figure 3:** Presternal keloid of 1.8 cm² before (a) and after two sessions of treatment (b), showing complete flattening.

**Figure 4:** Keloid of 1.0 cm² in right scapular region before (a) and after two sessions of treatment (b), showing significant flattening.
We used the same method in all our patients. In previous studies we had injected different doses from 0.25 to 0.50 ml (= 0.375 – 0.750 IU) for keloids of 1 cm², demonstrating that 0.25 ml was sufficient enough to obtain good results. In this present study we injected 0.25 ml (= 0.375 IU by cm²) into an area of 1 cm²-1.2 cm² and increased the dose by 0.05 ml for each additional 0.2 cm².14,15

In the second study we divided keloids into 1 cm² squared areas (patient nos. 1, 4 and 6) and accepted three new patients with large keloids (nos. 11, 12 and 13) (Figures 7 and 8). The three latter were men aged 19-35 years, all with phototypes III, and with large keloids in the center of the chest as a result of nodulocystic acne. The size of these six keloids was 20.46 cm² (6.2 x 3.3 cm) in patient no. 1; 3.96 cm² (2.2 x

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Figure 5: Four presternal keloids between 0.3 to 1.8 cm² before (a) and after two sessions of treatment (b). Excellent softening but different flattening from significant to complete in relation to size

Figure 6: Large keloids of 3.96 cm² located on left shoulder, before (a) and after three sessions of treatment (b). Complete flattening

Figure 7: Keloid on left shoulder of 1.5 cm² before (a) and after three sessions of treatment (b). Excellent softening, high significant flattening and slight atrophy

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FIGURE 8: Double presternal keloid (a) divided into 24 and 8 squares up-and-down respectively (b). Reduction of numbers of 1 cm² squared areas can be observed as result of treatment. After three sessions (nine subsessions of 4 (b), 3 (c), and 2 (d) in which maximum of 3.0 IU bleomycin was injected in each, the result showed excellent softening and highly significant flattening (e,f).

A concentration of 1.5 IU/ml of bleomycin dilution was prepared from 15 IU in 10 ml of physiologic serum. The injection of bleomycin was slow – a rate of 0.05 ml per second. We never injected more than 3 IU of bleomycin per session. For this reason the large keloids received 3 IU for each 8 cm² with follow-up subsessions every 6 weeks for patient nos. 6 and 12, and monthly sessions for patients no.1 and 13. The latter patient received his total dose in four, three and two subsessions over a total period of thirteen and a half months as the size of keloid gradually reduced. (Figure 8). In three cases only we injected 0.2 ml/cm² (0.3 IU/cm²) in the first treatment, but this variant was not taken into account in the study overall. Subsequently, we infiltrated 4-5 mg/cm² of a 40 mg/ml triamcinolone acetonide solution to obtain whitening (0.10-0.125 ml in a syringe of 0.5 ml). We never injected more than 5 mg/cm² of triamcinolone acetonide, nor a total dose of 30 mg per keloid. The final step was to apply a silicone patch which had to be kept in place for two days. The sessions were repeated at 3 monthly intervals, with the exception of the above-mentioned larger keloids. Treatment response was evaluated in terms of flattening and softening of the lesions.

Patients were followed up every three months during 1-2 years to observe recurrences and any side effects. The same physician assessed all the patients during their follow up (FMC), together with an external assessor.

Flattening was evaluated by comparing photos of the keloid before and after treatment and by measuring scar height (reduction percentage from baseline), classified on a 5-point scale – “1” was minimal flattening (< 50%); “2” moderate flattening (50-75%); “3” significant flattening (75-90%); and “4” highly significant flattening (> 90%) and “5” complete flattening (100%). Softening was evaluated according to a personal pliability scale by means of the “pinching technique”: level 1 signified impossible to pinch (bad response); level 2 represented easy to pinch but with permanent erythema (partial response); and level 3 was assessed by a pinch producing an effect similar to normal skin (excellent response). We consider this personal method easier to perform than the 4-point scale commonly used in burn scars.16

| Patient | Sex | Age | Skin Type | Etiology          | Location   | Lesion (size cm²) | Previous Treatment |
|---------|-----|-----|-----------|-------------------|------------|-------------------|-------------------|
| 1       | M   | 19  | III       | Nodulocystic acne | Presternal | 1 (6.2x3.3)      | Surgery           |
| 4       | M   | 39  | III       | Nodulocystic acne | Shoulder L | 1 (2.2x1.8)      | Triamcinolone acetonide |
| 6       | M   | 27  | III       | Nodulocystic acne | Presternal | 1 (4.0x2.1)      | No                |
| 11      | M   | 35  | III       | Nodulocystic acne | Presternal | 1 (3.2x2.2)      | Triamcinolone acetonide |
| 12      | M   | 28  | III       | Nodulocystic acne | Presternal | 1 (4.1x2.3)      | No                |
| 13      | M   | 31  | III       | Nodulocystic acne | Presternal | 1 (8.2x3.3 + 4.1x2.0) | No                |

L= Left  R= Right
RESULTS

The response of each keloid in both studies (1 and 2) is indicated in Table 3, numbered from 1 to 43.

From an aesthetic point of view all the patients in the first study were satisfied with the final results, although in our view the results obtained in the two presternal keloids of patient No. 4 (keloid nos. 18 and 19) were not entirely satisfactory.

In 36 cases (97.29%), partial or complete softening (level 2-3) was obtained after the first session. Complete flattening was achieved in 24 keloids (64.86%) in the second session. Only in four keloids (10.81%) were patients satisfied after the first session (patient no. 1 – keloids nos. 5, 6, 7 (1-1.5 cm²) and patient no. 9 – keloid no. 36 (size 1.5 cm²) all located in the presternal area), and two keloids (5.40%) (no. 34, 39) achieved highly significant flattening, although no. 40 called for four sessions; and six (16.21%) (keloid nos. 15, 18, 19, 23, 24 and 37) showed significant flattening (Figures 3, 5 and 6).

In the second study the six larger keloids, divided into 1 cm² square areas (nos. 1, 20, 29, 41, 42 and 43), responded excellently after three sessions in 50% of the cases (nos. 20, 41 and 42), and partial softening after 4, 3 and 3 sessions in case nos. 1, 29 and 43, although case 1 needed 12 subsessions, and case 43 a total of 9 subsessions, the last one completed after about 14 months of treatment (Figure 8 and Table 3).

Three lesions (nos.11, 12 and 15) recurred within 3-12 months, and the treatment was repeated at a follow-up session three months later. After 18-24 months of follow-up, keloids of the first study and numbers 41 and 42 of the second study maintained their softening and flattening, as well as normal skin color, with the exception of no. 1 which maintained erythema and telangiectasias.

Eight keloids in the first study (nos. 13, 14, 31, 32, 33, 34, 37, 39) presented atrophy. This was especially evident in no. 13. All needed a twice-a-day applica-

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### Table 3: First Study Patients’ characteristics

| PATIENT Nº | SESSIONS | RESULTS | SE | R |
|------------|----------|---------|----|---|
| KELOIDS    | S F      | U-A     | ●  | Δ ** |
| 1          | 4 (3) [12]| 2 2     | ●  | Δ ** |
| 2          | 2 2      | 3 5     |
| 3          | 2 2      | 3 5     |
| 4          | 2 2      | 3 5     |
| 5          | 1 2      | 3 5     |
| 6          | 1 2      | 3 5     |
| 7          | 1 2      | 3 5     |
| 8          | 2 2      | 3 5     |
| 9          | 2 2      | 3 5     |
| 10         | 2 2      | 3 5     |
| 11         | 2 2      | 3 4     |
| 12         | 2 2      | 3 4     |
| 13         | 2 2      | 3 4     |
| 14         | 2 2      | 3 5     |
| 15         | 2 2      | 3 5     |
| 16         | 2 2      | 3 3     |
| 17         | 2 2      | 3 3     |
| 18         | 2 2      | 3 3     |
| 19         | 4 2      | 2 3     |
| 20         | 3 2      | 3 5     |
| 21         | 2 2      | 3 5     |
| 22         | 2 2      | 3 4     |
| 23         | 2 2      | 3 3     |
| 24         | 2 2      | 3 3     |
| 25         | 2 2      | 3 5     |
| 26         | 2 2      | 3 5     |
| 27         | 2 2      | 3 5     |
| 28         | 2 2      | 3 4     |
| 29         | 3 (2) [6]| 2 5     |
| 30         | 2 2      | 3 5     |
| 31         | 2 2      | 3 5     |
| 32         | 2 2      | 3 5     |
| 33         | 2 2      | 3 5     |
| 34         | 4 2      | 3 5     |
| 35         | 2 2      | 3 5     |
| 36         | 1 2      | 3 5     |
| 37         | 3 2      | 3 3     |
| 38         | 3 2      | 3 5     |
| 39         | 4 2      | 3 5     |
| 40         | 4 2      | 3 4     |
| 41         | 3 2      | 3 5     |
| 42         | 3 (2) [6]| 3 5     |
| 43         | 3 (4-3-2) [9] + 2 4 | ● |

$S = $ softening, $F = $ flattening, $SE = $ side effects, $+ = $ atrophy, $● = $ ulceration, $R = $ recurrence (Δ), $Fig = $ Figure, ** = loss of follow-up.

(n): sub-session/doses each session, [n]: Total sub-sessions.

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effect of corticosteroids, the effect of TA is to induce a
from the fungus Streptomyces verticillus. It is used as a
ystemic chemotherapeutical agent since its mode of
ction appears to inhibit DNA synthesis and DNA
destruction. RNA and protein synthesis is also inhib-
ited to a lesser extent.7,13 The active effect of bleomycin
used in the treatment of keloids and hypertrophic scars
may possibly be explained by the inhibition of collagen
synthesis by human dermal fibroblasts or
stimulated by the presence of TGF-β.1, a cytokine
detected in scar tissues at high levels.17 Other action
mechanisms of bleomycin on keloids might be the
increase of fibroblast apoptosis or the reduction of the
lysyl oxidase levels, an enzyme found in high concen-
trations in keloids and hypertrophic scars.18,19

Previous studies have demonstrated that
tralesional injections of bleomycin in keloids and
hypertrophic scars is a well-tolerated treatment, with
few local and systemic side-effects, which suggests
that this treatment can be used as first line therapy for
keloids.12

In our experience, intralesional bleomycin is
painful, especially when dermojet injected, and partic-
ularly when treating planar warts, where the pain is
extreme and unavoidable, occasionally requiring
anesthetics.20

On the other hand, the treatment of keloids
with triamcinolone acetonide (TA) is a well-known,
long-term standard therapy that has been employed
as a single therapeutical procedure immediately after
surgery, with a reduction from 50% to 91.90% of the
possibility of a recurrence of keloids and of 50% to
95.24% in the case of hypertrophic scars, within 5
weeks after surgery.21-25 Unlike the anti-inflammatory
effect of corticosteroids, the effect of TA is to induce a
specific protein involved in the System A amino acid
transport in human keloid fibroblasts that reduces the
production of collagen and inhibits alpha.2-
macroglobulin, which in turn inhibits collagenase.24,25
The injection must always be performed in the papil-
lar dermis, where collagenase is produced, and not
in the subcutaneous tissue, given that it may produce
underlying fat atrophy.25 As for the pain caused by
injecting triamcinolone acetonide, when we injected
triamcinolone acetonide as the single therapeutic
agent, this was certainly painful for the patient, as it
was with bleomycin. For treating keloids, a number
of authors have proposed injecting a dose of 10 mg/ml
of TA at 3-6 ml/hour intervals, using an electric
syringe and pumping 40 times, 22 times with lido-
caine and 18 times without it.26 Hoigne’s effect was
reported after intra-keloid injection of triamcinolone
acetonide and lidocaine.27 Other authors used EMLA
or L-M-Y- (previously known as EMLA-Max) two
hours before the procedure.22 Finally, the combined
use of TA with cryotherapy seems to be better than
other combinations such as 5-fluorouracil or 585 nm
flash lamp-pumped pulsed-dye laser, or at least com-
parable.3,28,29 We did not employ radiation therapy as
proposed by other authors.25,30 Regarding the suitable
dose to be injected per cm², we found only one report
proposing 1-10 mg of TA, depending on the size of the
lesion, to be applied at four-week intervals.31 Other
side effects of TA frequently include hypopigmenta-
tion, which remains for between six and twelve
months.25

When we injected triamcinolone acetonide
immediately after bleomycin, pain was reduced in
minutes or even seconds, suggesting that this combi-
nation could well beneficial, at least hypothetically.

In the course of our study the greatest difficul-
ty was to correctly determine the exact quantity of
bleomycin and triamcinolone to be injected, as well as
deciding on the most suitable size of surface for such
doses. Our previous experiences with triamcinolone
acetonide after cryotherapy taught us which dose was
best able to reduce the pain caused by inflammation
after cryotherapy, although it had previously caused
minimal side effects.3

With respect to the bleomycin dose, although
Tanigaki and Endo applied 0.4 ml/cm² (=0.60 IU/cm²)
following a local anesthetic (2% prilocaine hydrochlo-
ride) - probably needed because they had used the
dermojet (not our current practice), we prefer to apply
0.375 IU using insulin syringes to inject the bleomycin
while slowly withdrawing the 1-cm-long needle.10
While is no significant difference between the quanti-
ity injected by the above authors (0.60 IU) and our rec-
ommendation (0.375 IU), we believe that it is simpler
iject 0.25 ml with insulin syringes of 0.5 ml or 1 ml.
The maximum volume per session was 2 ml (3 IU), sufficient to treat 8 keloids of 1 cm² or 8 quadrants in large keloids.

In conclusion, we consider that 0.375 IU of bleomycin for each 1 cm² is an effective and safe treatment regardless of the technique employed. When used in combination with 4mg triamcinolone acetonide for each 1 cm², side effects such as necrosis and especially pain do not appear to be substantial, although this combination may increase the risk of dermal atrophy. We believe that our results were the best obtained so far, and this is the reason why we started using the technique routinely in our department for all patients presenting for treatment of keloids. However, we do believe that it is important to undertake other comparative studies in order to confirm the significance of the results we obtained.

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