

Intralesional Cryotherapy Versus Excision with Corticosteroids or Brachytherapy for Keloid Treatment: Preliminary Results of a Randomized Controlled Trial

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INTRODUCTION: Keloids are a burden for patients due to physical, aesthetic and social complaints. Treatment remains a challenge because of therapy resistance and high recurrence rates. Decision making in keloid treatment is difficult due to heterogeneity of the condition and the lack of comparative studies with informative outcomes. The main goal of treatment is to improve the patients' quality of life (QoL); this implies that, apart from surgical outcomes, patient-reported outcome measures (PROMs) need to be taken into account.

MATERIAL AND METHODS: This is a multicenter randomized controlled open trial that compares intralesional cryotherapy versus excision with corticosteroids or brachytherapy. The primary outcome is the patient and observer scar assessment scale (POSAS) consisting of 12-items. Secondary outcomes are recurrence rates, volume reduction, Skindex-29 scores, SF-36 scores and complication rates.¹ During the study we added an outcome measure 'patient satisfaction' defined as; patients not seeking further medical treatment for their keloid.

RESULTS: There were 179 keloid patients with surgical indication seen during the inclusion period. Seventy-four of them were eligible by our inclusion criteria, unfortunately only 26 patients gave informed consent for randomization. Due to the small study group statistical analysis of our planned outcome measures will not be possible.¹ We saw comparable patient satisfaction between cryotherapy and excision with corticosteroids, but lower patient satisfaction with cryotherapy than with excision and additional brachytherapy treatment ($p < .05$). Most patients (9 out of 14) that underwent cryotherapy asked for excision with additional brachytherapy due to inadequate volume reduction, hypopigmentation or ongoing pain complaints (Figure 1 and 2).

DISCUSSION: Intralesional cryotherapy did not give as good results previously reported, at least not for the keloid patients in this study.^{2,3} The previous studies (cohort studies) might have selected patients with keloids well suitable for intralesional cryotherapy. Besides, in this randomized trial patients were eligible and informed about another treatment option, which might have influenced their search for further treatment. For future research on keloid treatment we advise to look for study designs other than randomized controlled trials in order to improve inclusion and generalizability of the results.

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FIGURE LEGEND:

Figure 1: Keloid around the left scapula after trauma.

Figure 2: Keloid around the left scapula 54 weeks after first and 38 weeks after second cryotherapy treatment.