Commentary

Towards standardised and effective keloid therapy: Lessons from a randomised controlled trial

Dear Editor,

Keloid, a commonly encountered entity, carries a significant cosmetic and functional burden. Management is challenging due to the complex pathophysiology and lack of a universally effective treatment strategy. Multiple treatment modalities, either alone or in combination, are available with varying levels of evidence. This is primarily because of poor study designs, subjectivity in the evaluation of treatment response, and limited follow-up for recurrences, hindering a direct comparison of their findings. The goal of an effective treatment for keloids should be twofold; improving the appearance and reducing recurrence.

Intralesional triamcinolone acetonide (TAC) remains the first-line treatment for keloids with good evidence, used as monotherapy or in combination with 5-fluorouracil. In this issue, Menon *et al* have compared the efficacy and safety of intralesional triple combination (triamcinolone acetonide, 5-flurouracil, and hyaluronidase) therapy with intralesional TAC monotherapy through a randomised controlled trial involving 72 patients, a first-of-its-kind study.[1] The triple combination is a relatively recent therapeutic approach that may offer favourable and sustained benefits in keloids due to the synergistic action of its constituents.[2] Patients receiving combination therapy showed significantly higher improvement on objective evaluation based on the Vancouver Scar Scale (VSS), as compared to monotherapy, at all-time points (3 weeks, 6 weeks, and 9 weeks during treatment and follow-up at 4, 8, and 12 weeks post-treatment). Pliability was found to be the first feature to respond to therapy in the combination group, with improvement seen as early as 3 weeks. Both treatments were reported as being safe with no evidence of atrophy, hypopigmentation, ulceration, or infection, though procedural pain was reported in both the groups.

The strengths of the study include the use of VSS, a widely recognised and validated tool to assess scar characteristics, including vascularity, pigmentation, pliability, and height. However, its efficacy and reliability can be insufficient, especially in large and irregular scars. The study also does not take into consideration the patient-reported outcomes and psychological impact. The VSS and the POSAS (patient and observer scar assessment scale), commonly used in trials, were originally designed for burn scars, not for keloids, which are biologically distinct from hypertrophic scars. A recently developed, validated tool that incorporates important scale domains is the Detroit Keloid scale.[3] It can be used for standardising and comparing results using keloid-specific outcome measures. With around eleven keloid assessment measures prevalent in literature, there is a need for a standardised keloid-specific scale that can be used to compare treatment outcomes with uniformity.[4]

Another limitation of the study is the short follow-up period, which is insufficient to capture recurrences. An extended follow-up is highly recommended to ensure the detection of potential recurrences. High recurrence rates in keloids are associated with several factors, including anatomical location, family history, previous treatments, secondary infection, and histological characteristics. There is a need to develop a predictive scoring system for keloid recurrence, incorporating these clinical and demographic factors.

Though intralesional TAC is the first line of treatment for keloids, the number and frequency of injections and duration of treatment are not defined by guidelines. Owing to prolonged therapy involving substantial doses of steroids, the potential effect on adrenal axis suppression needs to be considered.[5] In this scenario, combination therapy offers a potentially safer alternative by reducing the dose as well as duration of therapy with TAC in addition to the reduced adverse effects of individual agents.

With this publication, we foresee the emergence of an effective therapeutic modality for extensive and recalcitrant keloids. However, to generate more robust evidence, larger randomised trials (RCTs) are required that compare the combination against established treatment modalities and include an extended post-treatment follow-up period. Choosing a uniform and standardised keloid-specific scale

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across all studies is also important to compare treatment outcomes.[4] Comprehensive patient registries can provide data for analysis of risk factors contributing to recurrence and guide in selecting the appropriate treatment modality.

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