

## Effect of Sinovial High-Low<sup>®</sup> injections in trapeziometacarpal osteoarthritis

Sirs,

Trapeziometacarpal joint (TMJ) osteoarthritis (OA) is one of the most prevalent conditions in post-menopausal women, usually associated with pain, disability and articular function loss (1-4). Both non-pharmacological measures, including local heat application, physiotherapy and thumb base splints, and pharmacological treatments have been recommended for this disabling condition (5, 6). Among these, the efficacy of intra-articular hyaluronic acid (HA) injections is still a matter of debate. Although there is no definitive evidence of higher efficacy of HA in comparison to placebo or corticosteroid injections, prospective studies demonstrated that intra-articular HA lead to longer pain relief and better articular function improvement in comparison to corticosteroids or placebo (7, 8). However, the high heterogeneity of the few available studies, the variable dosing regimens and the different HA formulations employed hamper result comparison (8). Indeed, higher molecular weight (MW) HA formulations may have better and more persistent local effect than intermediate or low MW ones, even though low MW HA is preferred due to its viscosity and fewer local adverse events (9, 10). However, in TMJ OA no data are available on the effect of HA according to the different MWs.

Recently, a hybrid HA formulation, the Sinovial High-Low (HL)<sup>®</sup>, has been approved for OA treatment. It is a hybrid of high and low MW fractions and can reach 4-times higher intra-articular concentrations than other HA subtypes with a prolonged intra-articular persistence due to its resistance to hyaluronidase effects. In a recent retrospective study involving patients with TMJ OA, two injections of Sinovial HL<sup>®</sup> were more effective than corticosteroid injections in reducing pain and improving joint function at 30 days after treatment and persistence of efficacy at 6 months (11). However, no other studies evaluated the effect of hybrid HA formulations in patients with TMJ OA.

Thus, we aimed to prospectively assess the effect of Sinovial<sup>®</sup> HL injections in terms of pain relief and articular function in TMJ OA. Consecutive patients with symptomatic TMJ OA defined as local pain  $\geq 40$  on a 0–100 visual analogue scale (VAS) and diagnosed according to radiographic Kellgren method (12) were enrolled. Exclusion criteria were history of any inflammatory joint disease, major trauma, non-steroidal anti-inflammatory drug or HA treatment and corticosteroid intra-articular injections within the previous month. Outcomes were reduction of pain assessed by a change in

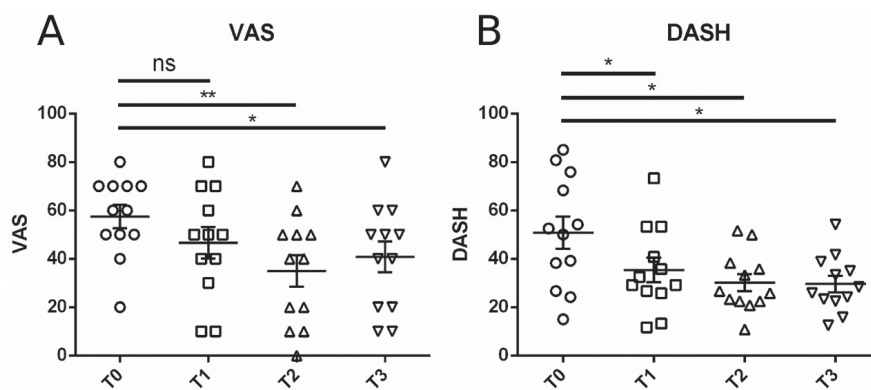


Fig. 1. \* $p < 0.05$ , \*\* $p < 0.01$ .

VAS score from baseline to follow-up and functional joint improvement evaluated through the Disability of the Arm, Shoulder and Hand (DASH) questionnaire. Study was approved by the local Ethics Committee. All patients provided written informed consent. Each patient received one cycle of two ultrasound-guided injections (baseline and 15 days apart) of 1 ml of Sinovial<sup>®</sup> HL. Pain on VAS scale and DASH questionnaire were recorded at baseline (T0) and at 1 (T1), 3 (T2) and 6 (T3) months. The Wilcoxon rank-sum test was used for statistical analysis. Data were expressed as mean  $\pm$  standard error (SE).

Twelve patients (83% women) with age of  $63 \pm 2.5$  years (mean  $\pm$  SE) were included. At baseline VAS and DASH scores were  $57 \pm 5$  and  $51 \pm 7$ , respectively. A statistically significant reduction of VAS score was observed at T2 and T3 ( $35 \pm 7$  and  $41 \pm 6$ , respectively), but not at T1 ( $47 \pm 6$ ) in comparison to baseline (Fig. 1A). DASH score significantly improved at T1, T2 and T3 ( $35 \pm 5$ ,  $30 \pm 3$  and  $29 \pm 3$ , respectively) in comparison to baseline (Fig. 1B). No side effects were reported.

In this prospective pilot study, local administration of a hybrid formulation of HA was effective in reducing pain and improving hand function in patients with symptomatic thumb OA. An interesting finding was the rapid efficacy on articular function, evident as early as the first month and persistent at 6 months of follow-up. Randomised controlled studies in larger patient populations would be desirable in order to confirm these data.

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E. BARTOLONI, MD  
F. LUCCIOLI, MD  
G.M.C. LA PAGLIA, MD  
G. CAFARO, MD  
E. MARCUCCI, MD  
R. GERLI, MD

Rheumatology Unit, Department of Medicine, University of Perugia, Italy.

Please address correspondence to:

Elena Bartoloni, MD,  
Divisione di Reumatologia,  
Dipartimento di Medicina,  
Università di Perugia,  
P.le Menghini 1,  
06128, Perugia, Italy.  
E-mail: elena.bartolonibocci@unipg.it

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