Evaluation of the analgesic efficacy and short-term tolerance of a single 6 ml injection of hyaluronic acid (Suplasyn® 1-Shot) on osteoarthritis of the knee

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RESUMEN

La osteoartritis de rodilla es una enfermedad frecuente que limita la movilidad del paciente. El ácido hialurónico inyectable se encuentra dentro de las recomendaciones terapéuticas actuales. Hasta hace poco, esta sustancia tenía que ser administrada en tres inyecciones sucesivas con un intervalo de una semana. Actualmente, se puede reducir el tratamiento a una inyección única de 6 ml. En este estudio observacional de 95 pacientes, tanto la tolerancia como la disminución del dolor a corto plazo resultan similares.

Palabras clave: Ácido hialurónico. Osteoartritis de la rodilla.

ABSTRACT

Knee osteoarthritis is a frequently observed disease which limits patient’s mobility. Injection of hyaluronic acid belongs to the current therapeutic recommendations. Until recently, this substance had to be administered by three successive injections at a one week interval. Currently, therapy can be reduced to a single 6 ml injection. Short-term pain reduction and tolerance are similar in this observational study of 95 patients. (DOLOR. 2013;28:89-92)

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Key words: Hyaluronic acid. Osteoarthritis of the knee.
INTRODUCTION

Osteoarthritis is the most common osteoarticular disease, and the knee is one of the most commonly affected joints, leading to intense pain and significant restrictions to daily life or leisure activities. As there is currently no curative treatment, medical societies such as the Osteoarthritis International Research Society\(^1\), the European League Against Rheumatism\(^2\), and the American College of Rheumatology\(^3\) have published recommendations to optimize and harmonize the treatment of gonarthrosis. One of these recommendations involves the option of injecting hyaluronic acid (HA) into the affected joint\(^1\)-\(^3\). Until recently, this treatment required three to five successive injections at weekly intervals. Alternatives have recently been put forward to reduce the number of injections to one single injection. The aim of the present observational study was to evaluate the short-term analgesic efficacy and tolerance of a single 6 ml injection of HA in the knee of patients suffering from gonarthrosis.

METHOD AND PATIENTS

This was a prospective, observational study carried out by a group of 21 Swiss rheumatologists who collected clinical data during standard clinical practice. Patients were included successively between September and December 2010. Demographic data were recorded at study entry. Their reasons for accepting the Suplasyn\(^\circledR\) 1-Shot treatment were also recorded. In addition, information was collected in relation to whether the knee osteoarthritis was unilateral or bilateral and whether HA injections had already been given in the relevant knee. Analgesic efficacy was evaluated based on a semi-quantitative scale with four levels, ranging from unchanged to excellent improvement. Subjective and clinical tolerance was evaluated after two to three weeks and, optionally, after five to six weeks, depending on the routine practice of the treating physician (Fig. 1). Statistical analysis (descriptive and comparative) was carried out by M Köhler-Institute, GmbH, Freiburg, Germany.

RESULTS

Ninety-five patients (66 women, 29 men) with confirmed osteoarthritis of unspecified radiological stage were included in the study. The mean age (standard deviation) was 66 years (11.7), ranging from 35 to 92 years of age. Ten patients were less than 50, 40 were between 51 and 70, and 42 were between 71 and 92 years old. The age of one patient was not recorded. Forty-two patients suffered from bilateral symptomatic osteoarthritis, and 44 had previously been treated with HA. Thirty percent of patients were undergoing concomitant treatment (over half with chondroitin sulfate). Eleven patients underwent simultaneous or successive bilateral treatment. Patient reasons for accepting the Suplasyn\(^\circledR\) 1-Shot injection are shown in table I.

**Table 1. Reasons for choosing SUPLASYN 1-Shot\(^\circledR\)**

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of treatment and time savings</td>
<td>64</td>
<td>67%</td>
</tr>
<tr>
<td>Hope for effective treatment (intense pain, difficulty in moving, failure of previous treatment)</td>
<td>14</td>
<td>16%</td>
</tr>
<tr>
<td>One single visit</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>14</td>
<td>15%</td>
</tr>
</tbody>
</table>

Analgesic efficacy

Seventy-nine percent of patients showed improvement at the first follow-up control (Fig. 2), and 78% of patients attended a second control after an average of six weeks. Pain had decreased in 72% of these patients. No difference was noted between patients having had an HA injection for the first time and those who had already received previous HA injections. The different degree of improvement for the patient population is shown in figure 2.

![Figure 1. Data collection.](image-url)
Tolerance

Three adverse effects were observed. These included two instances of pain at the injection site that disappeared spontaneously, and one incident of localized swelling that required administration of NSAID for five days. No systemic effects were reported.

DISCUSSION

The concept of viscosupplementation, with the aim to improve the rheological homeostasis of joints, was first proposed at the end of the 1960s4,5. However, HA may also act by protecting cartilage from enzymatic degradation6 and by stimulating chondrocyte metabolism7. Although its efficacy is still being debated8-10, intra-articular HA injections are widely used in many countries and by numerous practitioners. Its use provides relief for a significant number of patients, particularly in the early stages of the disorder. Reducing the number of injections not only reduces the risk of local reaction or infection but also the cost of treatment. Furthermore, a single injection also saves time for the patient as well for the physician.

To this end, several methods have been explored, including increasing the HA concentration, adding free radical scavengers and HA chain stabilizers and, for the knee, increasing injected volumes. Suplasyn® 1-Shot is based on the latter. The assumption that the efficacy of a single injection would be similar to that found in traditional administration of the product was based on the residual effect of HA following the drug’s relatively short passage through the joint. In fact, evidence shows that the analgesic effect of HA treatment can often persist for between six and 12 months.

The results of this study confirm that, in the short term, the analgesic efficacy and tolerance of this treatment are the same as those found when HA is administered in three successive injections at weekly intervals. The results are also identical to those obtained by most studies published in the literature and carried out with other forms of HA9,11. Following our pilot study, a recently published study (ASKOT Study) with 411 patients confirmed the good results and tolerance of Suplasyn 1-Shot12.

CONCLUSIONS

In this unselected population with osteoarthritis of the knee, the Suplasyn® 1-Shot injection relieved approximately 75% of patients for between three to six weeks. The simplified administration of HA gave identical results to those achieved by repeated injections, while reducing the number of intra-articular procedures. Long-term evaluations should confirm these results.

ACKNOWLEDGEMENTS

The authors would like to thank the patients and rheumatologists who participated in this unpaid study.
PRACTICAL IMPLICATIONS

- Osteoarthritis of the knee is common and painful and limits patient mobility.
- One single 6 ml injection of hyaluronic acid provides a similar short-term analgesic effect and identical tolerance to that achieved by three 2 ml injections at weekly intervals.

REFERENCES