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PROPHYLAXIS TREATMENT FOR PATIENTS WITH HEMOPHILIA A WITHOUT INHIBITORS: EXPERIENCE MONITORING SURVEY ON THE USE OF DAMOCTOCOG ALFA PEGOL

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BACKGROUND and AIMS

Hemophilia A is a genetic bleeding disorder characterized by a deficiency of clotting factor VIII (FVIII) requiring lifelong prophylactic treatment, typically with recombinant FVIII (rFVIII)[1].
Damoctocog alfa pegol (Jivi®) is a site-specifically PEGylated extended half-life rFVIII product approved in the European market for the treatment of bleeding in previously treated patients ≥12 years old with hemophilia A[2]. Damoctocog alfa pegol has been available on the Italian market since January 2020 with the indication for intravenous administration twice a week, every 5 days or every 7 days. The clinical efficacy and safety of damoctocog alfa pegol were demonstrated in the PROTECT VIII Phase 2/3 international, multicenter clinical development program[3,4]. To evaluate the physicians' experience with damoctocog alfa pegol, we carried out an experience monitoring survey among Italian hematologists with proven experience in hemophilia A management.

METHODS

A Computer Assisted Web Interviewing (CAWI) survey was performed to assess:

- The **value** and **degree of satisfaction** with damoctocog alfa pegol use in the clinical practice
- The **dynamics** and **rationale for switching** to damoctocog alfa pegol
- **Doubts** or **concerns** about damoctocog alfa pegol use

The survey, spread across **15 centers**, involved patients on prophylaxis with damoctocog alfa pegol for at least 3 months.

RESULTS

Participating centers reported 1947 patients with hemophilia A without inhibitors, **91** of whom **were treated with damoctocog alfa pegol (Figure 1)**. Fifty-two percent of these patients were between 12 and 40 years, and 42% were aged between 41 and 65 years. Seventy-five percent of these patients had severe hemophilia A.

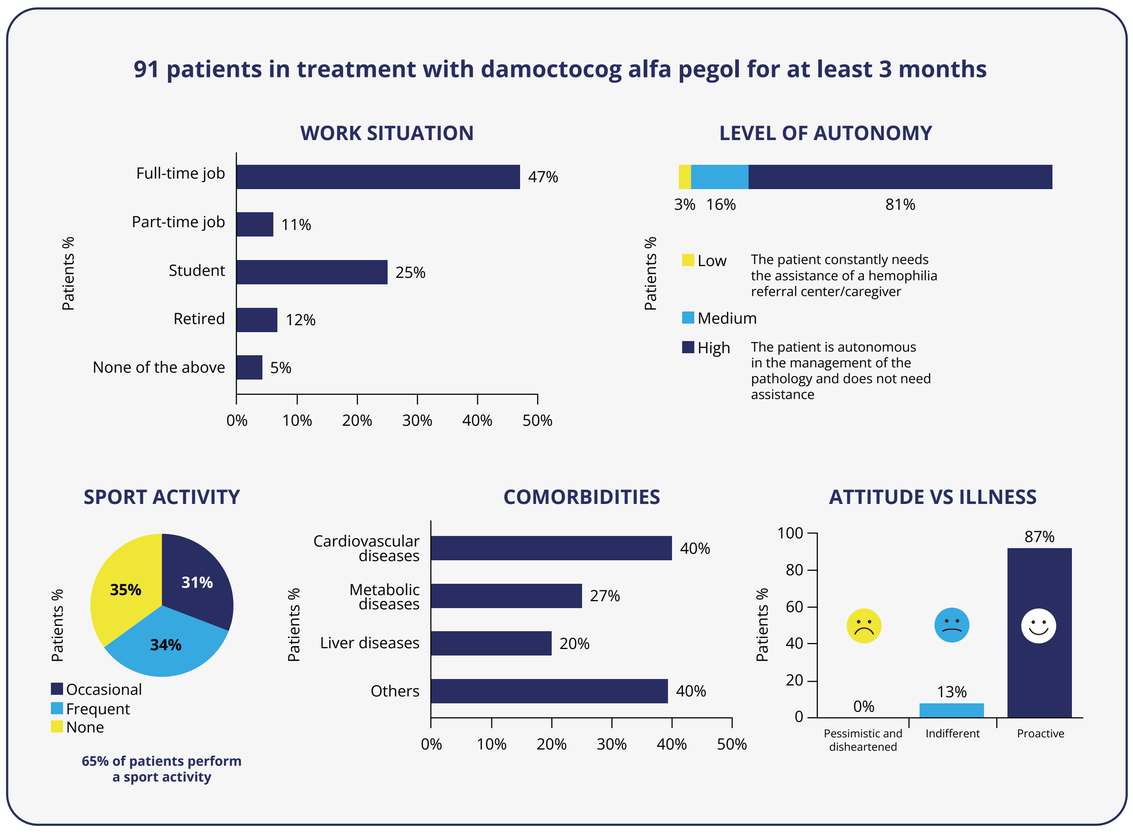

Figure 1. Baseline characteristics of 91 patients in treatment with damoctocog alfa pegol for at least 3 months

Most of the 91 patients were previously on prophylaxis treatment with a standard half-life rFVIII; the **physician** was the **primary decision-maker of the switch** (92% of cases). The main **reasons for switching** were the **reduction in the number of injections** and the perception of **better bleeding control**. **Most patients had an infusion every 5 days** (58%), and 8% of patients had an infusion every 7 days. Reduced weekly infusions were reported in 89% of patients **(Figure 2)**.

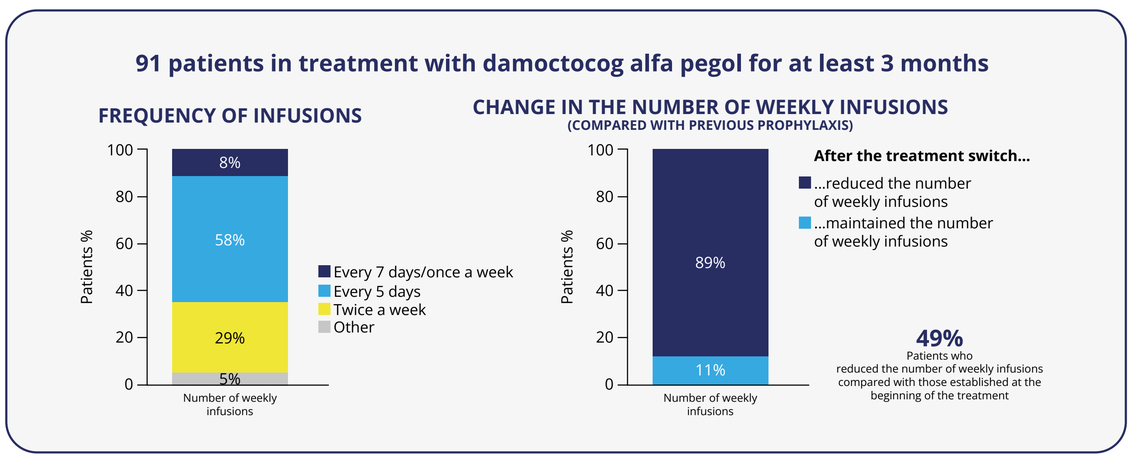

Figure 2. Frequency and change in the number of weekly infusions

Specifically, **80% and 86%** of patients reported **zero bleeds** and **zero joint bleeds**, a significant improvement compared with the previous treatment, where 46% patients reported zero bleeds and 55%, zero joint bleeds (*P*=0.05) **(Figure 3)**. According to 71% of respondents, the **joint function** of patients who switched to damoctocog alfa pegol **improved**.

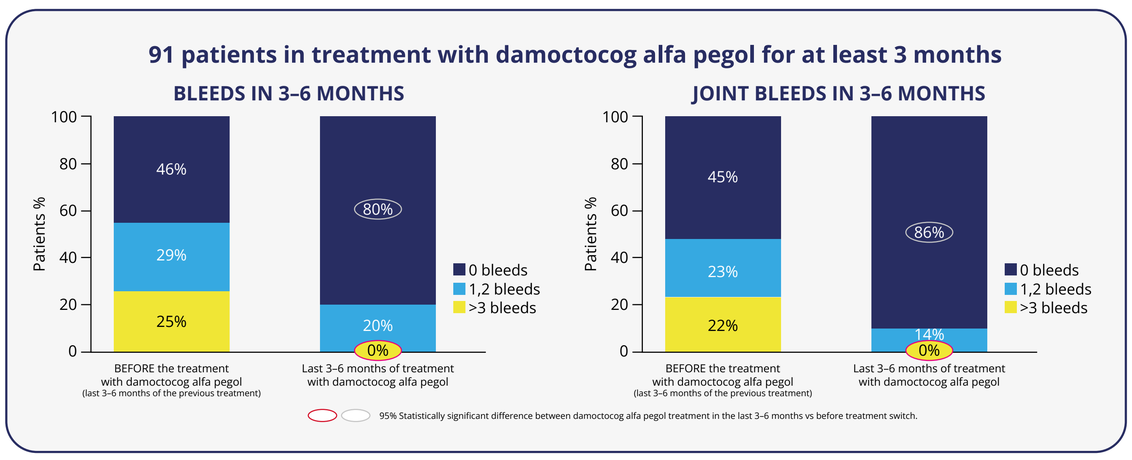

Figure 3. Total and joint bleeds in 3-6 months

All the clinicians were satisfied with the drug, and the reported **perception of patient satisfaction was good.** In the competitive scenario, damoctocog alfa pegol was considered the **drug with the highest value**, recognized primarily for the robust clinical data, functional improvement in the joints and pain reduction, along with possible therapy customization.
The physicians reported being interested in exploring further laboratory monitoring to achieve the every 7 days infusion.

CONCLUSIONS

Prophylactic use of damoctocog alfa pegol was able to:

- **Reduce the bleeding rate and joint bleeding rate** in most patients
- **Improve joint health** and patients' **quality of life**
- **Reduce** the number of **weekly infusions**.

This experience monitoring survey confirms the clinical study outcomes with damoctocog alfa pegol and suggests that the **annual drug utilization and overall prophylaxis costs** for damoctocog alfa pegol **could be reduced** in compliance with the dosages indicated in the product characteristics summary.

References

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