

treatment distribution, 28.6 percent of patients were treated for rheumatoid arthritis, 25.5 percent for psoriatic arthritis, 16.4 percent for psoriasis and the remaining patients for other diseases. Some patients switched biologic therapy (367), of which 22.6 percent were within the first 120 days. Total mean adherence was estimated in 87.7 percent: 21.5 percent of patients showed a low adherence (SPC < 60 percent) while 18.1 percent were estimated as dose increase patients (SPC > 110 percent), 11.4 percent for rheumatic diseases, 32.3 percent for dermatological diseases and 26.9 percent for inflammatory bowel disease.

CONCLUSIONS:

The study provides a map of the current treatment settinga with biologics in the Lazio region considering the disease, adherence and prescribed treatments. A considerable number of treatment-naïve patients were identified (2,929), 12.5 percent of whom switched ATC within 1 year. Total mean adherence was estimated in 87.7 percent, low adherence occurred in 21.5 percent of patients, while dose-increase was in 18.1 percent.

PP094 Autologous Stem Cell Transplantation For Multiple Sclerosis

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INTRODUCTION:

Multiple Sclerosis (MS) is an inflammatory neurological disease. The standard treatment is disease modifying drugs which may alleviate symptoms and slow the progress of disability, but not lead to remission. Autologous Hematopoietic Stem Cell Transplantation (AHSCT) is a new technology for treatment of MS in Norway. Disease remission in some patients treated with AHSCT has been postulated, in particular in patients in the early course of disease with high disease activity classified as having Relapsing-remitting

multiple sclerosis (RRMS), but severe complications have also been reported.

METHODS:

We conducted a systematic literature search. No restrictions were set in terms of study design, although case series should include at least ten patients with a majority having RRMS. We performed a cost analysis from a healthcare perspective with a time frame of one year.

RESULTS:

One randomized controlled trial (RCT) (n = 21, RRMS = 7), one registry study (n = 345), and seven case series (n = 442, RRMS = 277) without control groups were included. Estimated transplant-related mortality was 2 percent or lower. Serious adverse events, such as infections, were common during follow-up. Stabilization or improvement in neurological status was reported in 63 percent to 89 percent of the patients after three years, and the number of Gd+ and T2 lesion volume assessed by Magnetic Resonance Imaging was reduced. The quality of evidence assessed using the "Grading of Recommendation Assessment, Development, and Evaluation" tool was low for transplant-related mortality and very low for the other outcomes. HSCT costs were approximately between 480,000 and 605,000 Norwegian kroner per patient in the intervention year. A heterogeneous disease progression, significant risks associated with the method, lack of effective treatment options, and uncertainty about the benefit versus risk, implies that any decision to offer HSCT in the treatment of MS is ethically challenging.

CONCLUSIONS:

The main limitation in this HTA is the absence of controlled studies, which introduces a high risk of bias. Studies without control groups, including mainly patients with RRMS, reported that disease activity could be delayed or stopped for a period of up to three years in several patients, whereas adverse events were common. Ethical considerations are associated with significant uncertainty of benefit versus harm. The low level of evidence implies the need for controlled trials.