Intelligence®. Continuous variables were expressed as mean and standard deviation. The Kaplan-Meier method was used to adjust the 1-year survival curve using the software STATA 13.1 (Stata Corp, College Station, TX, USA). This historical cohort resulted in no interventions, neither during the course of the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance to the ethical principles of the Declaration of Helsinki.

RESULTS:

Overall, seventeen patients with a mean age of 80.5 years (68-91) underwent TAVI; 59 percent were women. Peri-operative mortality rate was 23.5 percent ($n = 4$) and accumulated overall one-year mortality was 35.3 percent ($n = 6$). Mean length of hospital stay was 26.9 ± 16.6 days. Prolonged hospital stay (≥ 7 days) occurred in 14/17 cases (82.3 percent), with a maximum of 51 days.

CONCLUSIONS:

In similarity to our findings, other authors described a high early and late mortality rate in patients undergoing TAVI. The strategy to use TAVI as an alternative in patients at high risk for open surgery is still under debate and should be carefully discussed taking into consideration the local team expertise as well as local healthcare available recourses.

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PP092 Real World Data: Biologic Treatment For Naive Patients In Lazio Region

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INTRODUCTION:

The introduction of new biologic treatments has radically changed the management of Immune-mediated inflammatory diseases (IMID). Due to the high costs of the treatments a strong control and monitoring of claims databases could help decision makers to understand the consequences of their decisions.

The objective of the study was to identify the cohort of biologics treatment-naïve patients in the years 2011–2013 in the Lazio region (6 millions of inhabitants), in order to investigate the parameters influencing the biologic treatment expense at the regional level.

METHODS:

Patients were enrolled based on administrative databases of the Lazio region. Treatment-naïve patients were defined as subjects who did not have a prescription in the two years before the index prescription. Switcher patients were defined as those who had an Anatomical Therapeutic Chemical classification (ATC) prescription different than the one at enrolment, within one year of the index date. Treatment adherence was estimated as the number of doses actually prescribed as compared to the number indicated in the Summary of Product Characteristics (SPC).

RESULTS:

From a total number of 10,120 patients treated with biologic drugs between 2011–2013 in the Lazio region, 2,929 were estimated as treatment-naïve patients (42 percent male). The most frequently used drugs were etanercept (31 percent), adalimumab (30 percent) and infliximab (17 percent). Considering the disease

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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 Hematopoetic 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.

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