Introduction. European agencies evaluate the adverse events (AEs) of asthma drugs in studies. The impact of these evaluations on reimbursement decisions remains unclear.

Methods. Adult asthma evaluations were accessed from initial regulatory decision by the European Medicines Agency (EMA) through reimbursement evaluations. Omalizumab and reslizumab were chosen for the comparison of an older with a newer asthma drug. A timeline was then constructed to evaluate the effect of AEs on reimbursement recommendations. Evaluations from the United Kingdom (NICE) were not used because their documents are not as complete or in depth, including those from Sweden (TLV) and Germany (IQWIG).

Results. Omalizumab was first approved as add-on therapy to improve asthma control in October 2005. Of the 6 decisions made between 2006 and 2012, safety information was found in 4 of them, all from 2006 and evaluated by either Scotland (SMC) or France (HAS). These desicions all received either a 'Do not recommend' or a 'Recommend with restrictions' decision. Reslizumab was first approved as add-on therapy for patients with severe eosinophilic asthma in August 2016. Of the 9 decisions made in 2017, safety information was found in 5 decisions evaluated by IQWiG, Germany (G-BA), HAS, or SMC, which gave them a Do not recommend, Recommend with restrictions, or Recommend decision. Of the Do not recommend decisions, both the omalizumab and reslizumab safety evaluations mentioned common AEs (worsening asthma) and less common AEs (malignant tumors). Of the Recommend with restrictions decisions, the same AEs were seen. Only reslizumab had Recommended decisions. In the safety evaluation, there were no specific AEs named.

Conclusions. The impact of AEs on reimbursement decisions could not be detected when comparing omalizumab and reslizumab reviews, as other factors may contribute to the decisions. Further research should be conducted to explore this issue.

VP35 Effectiveness and Safety of Cyanoacrylate Ablation for Varicose Veins

Esther García-Carpintero (eegarcia@isciii.es), Montserrat Carmona, Juan Pablo, Chalco Orrego, Jesús González-Enríquez and Iñaki Imaz-Iglesia

Introduction. Treatment of varicose veins is currently performed by different interventionist alternatives that include surgical, endothermal and non-thermal ablation therapies. The main guidelines recommended endovenous thermal treatment as the first choice therapy; however present side effects related to thermal energy. Non-tumescent endovenous ablation techniques such as cyanoacrylate ablation (CA) started to develop to avoid these problems. The objective of this study is to assess the effectiveness and safety of CA for saphenous vein incompetence.

Methods. A systematic review with meta-analysis was carried out. The search of scientific literature was performed in Medline, Embase, Cochrane library, CDR, WoS and Scopus databases. GRADE methodology was used to assess the quality of the evidence and Cochrane risk of bias tool to assess methodological quality of randomized control trials (RCT). Pooled risk ratio was calculated using a random effects model.

Results. Two RCTs and one non-RCT comprising 1,077 participants were included. Additionally, 10 case series were included for safety assessment. Pooled analysis of closure rates by the two RCTs indicated there were not significant differences between CA and radiofrequency ablation (RFA) or endovenous laser ablation (EVLA). Improvements in venous clinical severity score were reported by all comparative studies without significant differences among groups. The most frequently reported adverse events were ecchymosis, phlebitis, paraesthesia, and thrombosis. The pooled analysis showed significant differences only in ecchymosis rates, with lower probability of ecchymosis in CA groups. CA treatment showed lower pain rates and shorter intervention times and recovery compared to endothermal therapies.

Conclusions. The effectiveness of CA devices in the treatment of varicose veins is comparable to EVLA and RFA, while the rates of adverse effects are lower. Despite the limitations of the evidence, CA may be a promising alternative to existing treatments, with the advantages of better patient comfort.

VP37 Patient Involvement In EUnetHTA Assessments (Non-Pharma Technologies)

Sabine Ettinger (sabine.ettinger@hta.lbg.ac.at), Judit Erdos and Cecilia De Villiers

Introduction. Patients can provide valuable experience on living with diseases, health-related quality of life, various therapies and relevant outcomes. Their input and perspectives can be helpful in complementing health technology assessment (HTA) processes. The European Network for HTA (EUnetHTA), funded by the European Commission, aims to further advance and standardise patient involvement processes in order to add to the quality and applicability of HTAs and to allow capability building.

Methods. Different methods for patient involvement in HTAs on non-pharmaceutical technologies were tested: Patient input templates (open questions sent to relevant patient organizations, or published on EUnetHTA website); scoping meeting with patients/patient representatives; one-on-one conversation and group conversation. Applied methods depended on the scope of the HTA and other factors like timelines of HTAs and burden of disease for patients.

Results. Patients were included in eight of sixteen HTAs on non-pharmaceutical technologies. Applied methods were: group conversation (n = 2), scoping meeting (n = 1), patient input templates (n = 4), one-on-one conversation (n = 2,) and other approach (i.e. written feedback on scope n= 2). In some HTAs more than one method was used. Main reasons for not including patients were inability to identify suitable patients or tight timelines. Patients´ feedback on health-related quality of life and outcome measures proved most useful in the scoping phase.

Conclusions. The different approaches were useful for complementing HTA processes. Those need to be further tested and evaluated in order to formulate deeper understanding about the impact of patient involvement on HTA. Additionally, feedback from patients that were actively involved in the HTAs should be collected to further improve the involvement methods that should serve as basis for future recommendations post 2020.

https://doi.org/10.1017/S0266462319003106 Published online by Cambridge University Press