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Comorbid cardiovascular risk factors during danazol long-term prophylaxis in patients with HAE-C1-INH

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Rationale: Attenuated androgens have been used for long-term prophylaxis (LTP) in patients with hereditary angioedema (HAE) for decades and are still being used in different regions worldwide. A current review of the tolerability of attenuated androgens appears essential in view of the novel safe and effective medicines for LTP. This study aimed to investigate the presence of comorbid conditions which are associated with an increased cardiovascular risk, in HAE patients receiving the attenuated androgen danazol for LTP of HAE-attacks.

Methods: In this retrospective observational single center study, documented co-morbidities in records from 296 patients with HAE-C1-INH, 148 danazol ever-users and 148 matched never-users, were investigated regarding the presence of comorbid conditions that represent cardiovascular risk factors. This analysis was related to the period of danazol use in danazol patients and the respective age period of the individually matched control patient.

Results: The incidence rate for diabetes in danazol-users during exposure was 5.7 per 1000 patient years observed and 1.1 in never-users in the respective age period. For documented hypertension the incidence rate was 26.0 in danazol users during the treatment period and 15.7 in never-users during the respective age period. Documented use of lipid-lowering drugs as surrogate marker for dyslipidemia was observed more in danazol-users than in never-users: incidence rates per 1000 years observed were 9.2 in danazol-users during the treatment period and 3.5 in never-users.

Conclusion: For the conditions investigated here, diabetes and hypertension, a higher incidence rate was observed in danazol-ever users as compared to never-users. At the same time danazol-users had higher rates of documented medical treatment of dyslipidemia. The findings may indicate a potential for an increased atherogenic risk in association with the use of the attenuated androgen danazol.