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**Long-term dual antiplatelet therapy and nuisance bleeding: retrospective analysis in an outpatient population.**

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**Background:** Long term dual antiplatelet therapy (LTDAPT), with ticagrelor 60 mg and low-dose aspirin, is indicated after acute coronary syndrome (ACS) for the secondary prevention of atherothrombotic events in high-risk patients with a history of ACS of at least 1 year. LTDAPT had a good tolerability and safety profile, but the risk of TIMI major bleeding was increased. However, even non-significant bleeding may be important because it has an effect on the quality of life and therefore may lead to treatment discontinuation. **Aim:** We, therefore, evaluated patients' experiences with LTDAPT and the impact of nuisance bleeding on quality of life and treatment adherence. **Methods:** We retrospectively reviewed 225 patients in follow-up after ACS with at least one high-risk condition, treated with ticagrelor 60 mg twice daily (after 90 mg twice daily for 12 months). The outpatient follow-up program after hospitalization provides a visit on day 30 after discharge, then after 3 months, continuing with six-monthly checks. We assessed the presence and intensity of bleeding, as well as health-related quality of life (HRQoL), at each visit. The TIMI score was used to determine the severity of the bleeding. Any overt bleeding event that did not meet the major and minor criteria was labeled "minimal" and could be framed as "nuisance bleeding." The HRQoL was assessed by the EuroQol-5 and Dimension (EQ-5D) visual analog scale (VAS) score. **Statistical analysis:** Normally distributed variables are presented as mean  $\pm$  standard deviation (SD) and were compared by Student's t-test for unpaired data. Categorical variables are summarized in terms of number and percentages and were compared by using Chi-square test. A p-value  $\leq 0.05$  was considered statistically significant. **Results:** The duration of follow up was  $51.5 \pm 12.9$  months. The high-risk groups were represented as follows: multivessel disease 191 pts (84%), diabetes 72 patients (32%), GFR < 60 mL/min 30 patients (14%), history of prior MI 44 patients (19%), >65 year aged 103 patients (45%). Intracranial hemorrhage was present in 1 patient. 4 pts had Minor Bleeding Minimal bleedings were present in 49 patients (21%) (A group), (Total minimal bleeding 56) and were represented as follows: Subcutaneous/dermal in 38 pts (77.5%), Epistaxis in 3 pts (6.1%), Urinary in 4 pts (8.1%) (after urinary tract infection), Rectal in 6 pts (12.2%) (caused by constipation), Gingival in 2 pts (4%), Conjunctival in 3 pts (6.1%). But only in one case (by decision of the patient) there was a cause for discontinuation of therapy. Treatment was withdrawn in 9 patients (0.4%): 4 cases showed atrial fibrillation and were placed on oral anticoagulant drugs, one case developed intracranial bleeding. Three patients had a temporary withdrawal due to surgery (2 cases of colon polyposis and 1 case of bladder papilloma). In one patient, the discontinuation was definitive (1 case of bladder papilloma). Excluding cases with atrial fibrillation and those with bleeding, 167 patients had no bleeding and continued LTDAPT (B group). However, in EQ-5D we have observed the significant differences for the first two levels in 5 dimensions of health status (absence or moderate problems). Only about anxiety/depression dimension, difference is significant even in the highest level (extreme problems) This demonstrates that motility, self-care and usual activities are not severely altered, although the perception of the state of health can be significantly altered (as shown by the EQ-VAS). In A group of 49 patients with nuisance bleeding, 39 (79%) subjects had asked opinion on stop

the therapy at the telephone consultation, but with focused counseling on actual risks and future benefits of LTDAPT, only in one case (by decision of patient) there was a cause for discontinuation. Therefore, the need to educate the patient, in order to improve adherence, should be emphasized. Factors influencing LTDAPT knowledge included access to medication counselling, engaging with information communicated during medication counselling, and access to timely, relevant and expert information and advice after discharge from the hospital. All adverse events, judged to be "not serious" in trials, may have an effect on the quality of life and therefore may lead to treatment discontinuation. The authors underline the importance of careful outpatient follow-up and ongoing counselling, to check out compliance and possible adverse effect of LTDAPT. **Conclusion:** We found that: i) participants adhered to treatment when they believed LTDAPT important to health outcomes; ii) those who experienced nuisance bleeding reported symptoms mild and manageable; iii) participants' and their family's understanding of LTDAPT risks and benefits, and their ability to manage symptoms, influenced medication adherence. Factors influencing LTDAPT knowledge included access to medication counselling, engaging with information communicated during medication counselling, and access to timely, relevant and expert information and advice after discharge from hospital.





