SB02

EFFECTIVENESS AND SAFETY OF LMWH TREATMENT IN CANCER PATIENTS DIAGNOSED WITH NON-HIGH RISK VENOUS THROMBOEMBOLISM (VTE) - RESULTS OF TURKISH OBSERVATIONAL STUDY (TREBECA)

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Introduction - Purpose: Venous thromboembolism (VTE) is one of the important causes of death in cancer patients, with VTE risk being 4-7 times higher among these patients compared to normal population. TREBECA is a prospective observational study on cancer outpatients with low risk of VTE treated with low molecular weight heparins (LMWH). It is aimed to compare the effectiveness and safety of LMWH selected by the center's own protocol in cancer patients who are at low risk for VTE.

Methods - Tools: Patients were treated by medical oncologists in Turkey at 15 sites, where they were enrolled and followed-up for a period of 12 months. Due to the study design, there was no specific LMWH treatment protocol. Primary endpoint was effectiveness, and the time to change in VTE status, by measuring thrombus regression.

Findings : Data for 250 patients who met the study inclusion criteria were examined and analyzed. Of the included patients: 239 patients (95.6%) completed their Day 15 visit, 176 (70.4%) completed their Month 3 visit, 130 (52.0%) completed their Month 6 visit, and 91 (36.4%) completed the entire study. The mean age of the patients was 60.2 ± 13.7, while 53.2% (n=133) were women. Colorectal (21.2%), lung (16.8%) and breast (14.8%) cancers were the most common forms of cancer. One hundred thirty-three patients were treated with enoxaparin, 112 patients were treated with bemiparin and 5 patients were treated with tinzaparin. Anticoagulant therapy provoked thrombus resolution in 15 (6.5%) patients on Day 15, and specifically in 1.2% of patients using enoxaparin, and 12.7% of patients using bemiparin (p=0.004). Thrombus ressolution was observed in 81 more patients (46% of patients who came for a 3rd visit) at Month 3 visit. This ratio was 35 out of 87 (40.2%) patients recieving enoxaparin, and 46 out of 85 (54.1%) patients in the bemiparin group at the 3rd visit (p=0.038). In 21 (16.2%) additonal patients, thrombus resolution was observed during the Month 6 visit. This ratio was 5 out of 65 (7.7%) among patients taking enoxaparin, and 15 out of 64 (23.4%) among patients receiving bemiparin at the 4th visit (p=0.022) (figure 1). LMWH was discontinued in only 2 patients due to gastrointestinal bleeding; apart from this, there were no other serious drug related adverse events requiring discontinuation of therapy (table 1). There were no patients with grade 3 or 4 thrombocytopenia or other adverse events. Thrombus recurrence was observed in 10 patients during the follow-up period after LMWH treatment was discontinued. Five of these patients were on bemiparin treatment, and the other 5 were on enoxaparin. The total rate for the thrombus dissolution during the 6-month and 12-month period was 47.2% and 49,2%,

respectively.

Discussion : This is the first published study comparing the effectiveness and tolerability of LMWHs which shows that bemiparin is more effective than enoxaparin in thrombosis resolution with a similar tolerability profile.

	Enoxaparin	Bemiparin
Major bleeding	1 (0.89 %)	1 (0.75 %)
Minor bleeding	0 (0.0 %)	1 (0.75 %)

Keywords: Low moleculer weight heparin, bemiparin, enoxaparin, venous thromboembolism, cancer

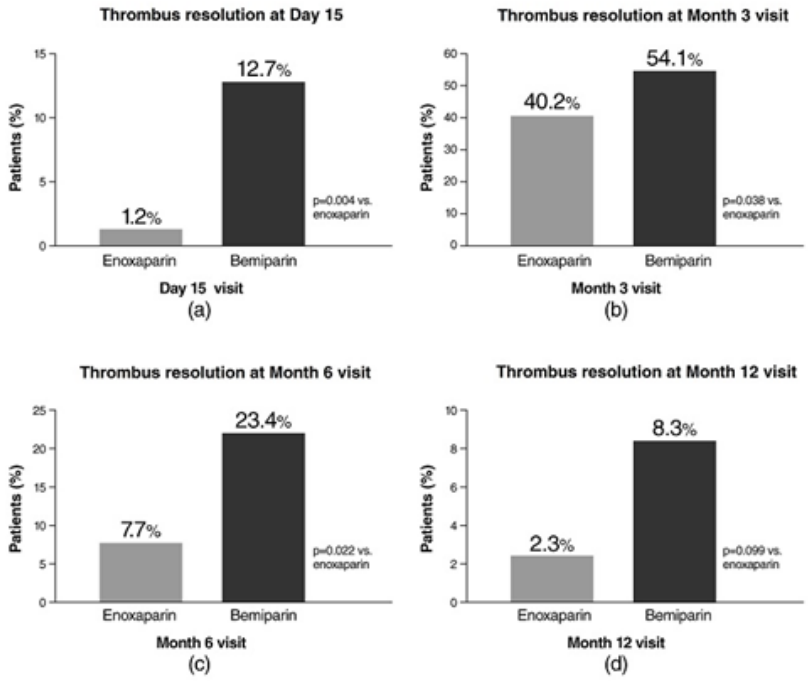

Fig. 1. (a), Impact of anticoagulant therapy in the thrombus resolution in the early stages of treatment; (b), impact of anticoagulant therapy in the thrombus resolution at Month 3 visit; (c), impact of anticoagulant therapy in thrombus resolution at Month 6 visit; and (d), impact of anticoagulant therapy in thrombus resolution at month 12 visit.