received at least one FCM dose (safety population), 420 had baseline Hb measurements within 10 days of first FCM dose (BL; effectiveness population), and 364 also had at least one follow-up measurement to assess Hb increase (primary endpoint). Transfused patients were censored from analysis prior to the transfusion. Data are shown as median (Q1, Q3).
Results: 91.2% of the effectiveness population (54.8% female, 67 years [58, 73]) presented with solid tumours (61.0% metastatic). BL Hb was 10.0 g/dL (9.1, 10.6), 75.6% had a TSAT <20% but 62.5% had a ferritin >100 ng/mL. Median total iron dose per patient was 1000 mg (600, 1500). Hb increase was comparable (1.4−1.6 g/dL) and significant vs. baseline ($p \leqslant 0.0001$) for transfused and not transfused patients with or without ESA supplementation. Patients with BL ferritin levels <100 ng/mL rapidly achieved median Hb levels ⩾11 g/dL (in 3−4 weeks, Tab.). Patients with BL ferritin 100–500 ng/mL also achieved Hb ⩾11 g/dL but slower (from week 7 onwards). FCM was well tolerated, 2.3% reported possibly or probably drug-related adverse events (AEs). One fatal case occurred after a possibly related respiratory failure. Two serious AEs of tachycardia and dyspnoea were unlikely related.
Conclusions: FCM significantly increased and stabilised Hb levels at 11−12 g/dL after week 5. This observational study suggests a role for I.V. iron alone in the correction of anaemia in cancer patients with absolute or functional iron deficiency.

	Median Hb			
	BL	Wk 5	Wk 7	Wk 12 or end of study
All uncensored (420)	10.0	11.1	11.3	11.5
All* (328)	10.0	11.1	11.6	11.9
Hb*				
<10 g/dL (152)	9.2	11.0	11.0	11.6
10−11 g/dL (128)	10.4	11.4	11.8	11.1
Ferritin*				
⩽30 ng/mL (65)	10.0	11.6	12.0	11.0
30-<100 ng/mL (29)	10.4	12.1	11.8	12.2
100–500 ng/mL (92)	10.1	11.0	11.7	11.6
TSAT*				
<20% (131)	10.0	11.3	11.6	11.4
⩾20% (39)	9.8	10.4	10.7	11.4
FCM*				
FCM no ESA (277)	10.0	11.1	11.5	11.9
FCM + ESA (51)	9.6	11.2	11.9	11.1

*Censored for transfusions.

3001 POSTER DISCUSSION

Ultra-low-molecular-weight Heparin (ULMWH) Semuloparin for Prevention of Venous Thromboembolism (VTE) in Cancer Patients Receiving Chemotherapy: Consistent Beneficial Effect Across Cancer Stage and Location Subgroups

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Background: VTE is a serious complication for cancer patients receiving chemotherapy. Semuloparin is a novel ULMWH with high anti-factor Xa and residual anti-factor IIa activities. We recently completed a multinational, randomized, placebo-controlled trial (SAVE-ONCO, NCT00694382, sanofi-aventis) to assess the efficacy and safety of semuloparin for thromboprophylaxis in cancer patients receiving chemotherapy.
Materials and Methods: Patients were eligible for inclusion in this double-blind study if they had metastatic or locally advanced solid tumours and were initiating a new chemotherapy regimen. Patients with creatinine clearance <30mL/min and requirement for/contraindication to anticoagulation were excluded. Patients were randomized to subcutaneous once-daily semuloparin 20 mg or placebo until change of chemotherapy regimen. The primary efficacy outcome was the composite of any symptomatic deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE) and VTE-related death. Any clinically relevant bleeding and major bleeding were the main safety outcomes.
Results: Of the 3212 patients randomized, 68% had metastatic cancer; 37% had lung, 29% colon-rectum, 13% stomach, 12% ovary, 8% pancreas, and 2% bladder cancer. Median treatment duration was 3.5 months. In an intent-to-treat analysis, treatment with semuloparin resulted in a 64% risk reduction in the incidence of the primary efficacy outcome versus placebo: 1.2% vs 3.4%; hazard ratio (HR) 0.36 [95% confidence interval (CI) 0.21–0.60], $p < 0.0001$. Treatment effect was consistent across DVT and PE with a 59% reduction in PE incidence; HR 0.41 [0.20–0.86]. No heterogeneity of treatment effect was detected for cancer stage (interaction p-value=0.3236) or location (interaction p-value = 0.7994): lung HR 0.36 [0.17–0.77]; colon/rectum HR 0.54 [0.18–1.60]; stomach HR 0.25 [0.03–2.20]; ovary (HR not applicable, 0 VTE in placebo, 1 in semuloparin); pancreas HR 0.22 [0.06–0.76]; bladder HR 0.30 [0.03–2.95]. Incidence of any clinically relevant bleeding was 2.8% with semuloparin vs 2.0% with placebo; HR 1.40 [0.89–2.21] and the incidence of major bleeding was similar: 1.2 vs 1.1%; HR 1.05 [0.55–1.99].
Conclusions: In cancer patients receiving chemotherapy, semuloparin significantly reduced the risk of VTE without increasing the incidence of major bleeding. No heterogeneity of treatment effect was detected across cancer stage and location. Thromboprophylaxis should be considered in cancer patients receiving chemotherapy.

3002 POSTER DISCUSSION

Venous Thromboembolism (VTE) in Cancer Patients Receiving Chemotherapy: a Real-world Analysis of VTE Risk and the Impact of VTE on Healthcare Expenditure

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Background: VTE is an important complication in cancer patients receiving chemotherapy. The aim of this analysis was to determine VTE risk in cancer patients initiating chemotherapy and assess the economic impact of VTE occurrence.
Materials and Methods: The InVision™ Data Mart Multiplan database (US) was used to retrospectively identify patients with lung, pancreatic, stomach, colon/rectum, bladder or ovarian cancer initiating chemotherapy between 1/1/2005−12/31/2008; the first day of chemotherapy after cancer diagnosis was defined as the index date. Patients with ⩾12 months of continuous medical coverage prior to the index date and ⩾3.5 months during follow-up, and without prior VTE within 12 months, major bleeding within 3 months, or anticoagulant treatment within 2 weeks of the index date were included. The incidence of VTE was assessed at 3.5 and 12 months post-index. Healthcare costs (i.e. pharmacy, inpatient, emergency room, and outpatient costs) were assessed 1 year pre- and post-index.
Results: 30,552 eligible patients were identified. Patient baseline characteristics and VTE incidence by cancer location are summarized in the Table. Patients who developed VTE within 3.5 months post-index had comparable healthcare costs during 1 year pre-index ($37,542) to those without VTE ($35,342). However, during 1 year post-index, costs in patients with VTE were significantly higher ($110,362) than in those without VTE ($77,984), primarily driven by higher inpatient ($34,875 vs $16,834) and outpatient costs ($70,310 vs $57,397). These results were consistent when VTE was assessed 12 months post-index.

	3.5 months		12 months	
	Patients with VTE	Patients without VTE	Patients with VTE	Patients without VTE
Age, mean±SD, years	63.9±10.4	63.1±11.1	63.6±10.5	63.1±11.1
Female, n (%)	1100 (48.9)	13,524 (47.8)	2015 (48.6)	12,609 (47.8)
Charlson Comorbidity Index, mean±SD	6.98±3.22	6.25±3.26	6.30±3.20	6.30±3.27
n (%)				
Total	2248 (7.4)	28,304	4147 (13.6)	26,405
Bladder	130 (4.8)	2559	267 (9.9)	2422
Colon/rectum	683 (6.1)	10,462	1326 (11.9)	9819
Ovary	152 (6.2)	2299	279 (11.4)	2172
Lung	942 (8.5)	10,129	1642 (14.8)	9429
Stomach	97 (8.5)	1047	191 (16.7)	953
Pancreas	244 (11.9)	1808	442 (21.5)	1610

Conclusions: The risk of VTE in cancer patients 3.5 months after chemotherapy initiation ranges 4.8–11.9%; the highest risk is observed in patients with pancreatic, stomach, and lung cancer. The VTE risk continues to increase over a 1-year period. In addition, VTE is associated with a significant economic burden.