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EVALUATION OF PATIENT AND PHYSICIAN REPORTED REASONS FOR SWITCHING FVIII REPLACEMENT THERAPIES AMONG PATIENTS WITH HEMOPHILIA A

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Abstract

OBJECTIVE: While a new generation of therapies for patients with Hemophilia A are available, it is unclear what patient characteristics, perceptions, and barriers are associated with the decision to switch FVIII replacement therapies. This study assessed patient characteristics, health history, and reasons for switching from a FVIII product with more frequent dosing (³3x infusions/week) to a product with less frequent dosing (≤2x infusions/week) from patient/caregiver and physician perspectives. METHODS: Data collection was a mix of qualitative and quantitative procedures. The qualitative portion consisted of two online discussion forums: patients (n=17) and caregivers of patients (n=11) receiving a FVIII product dosed ³3x/week, and patients (n=22) and caregivers of patients (n=5) who switched to a product dosed ≤2x/week. The quantitative portion was a retrospective medical chart review (n=207) which captured variables (e.g., bleed rate, treatment history) 6 months pre- and 6 months post-switching to a product with less frequent dosing. SUMMARY: Prominent drivers among patients for starting a FVIII product with less frequent dosing included: 1) experiencing diminished effectiveness while on a product dosed ³3x/week resulting in increased breakthrough bleeding, 2) experiencing vein access issues, and 3) beginning prophylaxis as opposed to on-demand infusions after a bleed. Key barriers to changing included: 1) fears regarding the process of switching being complicated, time consuming, and costly, 2) perceived risks associated with switching, and 3) possible lack of healthcare provider support. Physicians were most likely to report that patients switched products because they sought a newer product with twice weekly dosing or less per FDA-approved dosing recommendations (35.3%), followed by patient requested the switch (30.4%), and patient sought a reduction in infusion frequency to improve adherence (27.5%). Switching to a product with less frequent dosing was associated with improvements in patient-reported bleeding-related outcomes. Patients were more likely to self-administer the treatment post-switch (63.8%) compared with pre-switch (48.8%; $p<0.001$) and had fewer infusions per week post-switch (2.8 vs. 3.3; $p<0.001$). Patients' annualized bleed rate was lower (5.9) post-switch compared with pre-switch (7.7; $p<0.001$). Both the number of spontaneous joint bleeds and joint bleeds after trauma or injury were lower (3.2 and 2.7) post-switch (3.6 and 4.3; $p=0.044$ and $p<0.001$). The bleeding event was less likely to be classified as moderate or severe (34.5% and 5.9%) post-switch compared with pre-switch (55.0% and 10.0%; $p<0.001$ and $p=0.049$). Fewer infusions were required to resolve the bleeding event post-switch (2.6 vs. 3.2; $p<0.001$). CONCLUSION: A prominent reason why patients switch treatment is to improve bleeding-related outcomes. Indeed, we found that switching to a

FVIII product with less frequent dosing was associated with improved patient-reported bleeding-related outcomes. These findings are critical for improving patient outcomes and support the FDA mandate to incorporate patient perspectives in the regulatory process.