Belfast Adult's experience of using a pharmacokinetic personalised treatment tool to maximise factor replacement.

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Sub Topic: Self Infusion and Home Treatment

Introduction and objectives

It is of the utmost importance to show that treatment of people with haemophilia, which is expensive, is justified (Boehlen et al, 2014).

Outcome measures are a useful tool to evaluate treatment, allocate resources, justify treatment strategies and allow good follow up of care.

myPKFiT®, a website based, CE marked medical device, based on bayesian analysis, developed by Baxalta® to predict PK parameters of FVIII in patients with haemophilia receiving Advate prophylaxis, was used to calculate personalised treatment regimes using pharmacokinetic (PK) data.

It was planned to audit current prophylaxis treatment dosing against myPKFiT® PK data and in consideration with other available outcome measures, including most recent annual bleed rate (ABR), Haemophilia Activities List (HAL) and Haemophilia Joint Health Score (HJHS), reassess personalised dosing requirements.

Methods

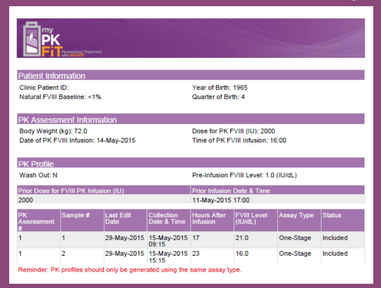
As the audit was commenced February 2015, using v1.0 of myPKFiT®, sampling for each patient's PK data required 2 blood samples, at least 6 hours apart and 4 to 48 hours post infusion of FVIII prophylaxis dose.
These samples were tested using the same coagulation assay.
Data was analysed using the myPKFiT® software program to calculate the individuals FVIII half-life and predict a personalised dosage calculation in selected dosing intervals.
Patients dosage calculations were based on a target trough of 2% above baseline.

Patient	Age	Prescribed dose of Advate (IU)	T ½ (Hours)	myPKFiT® dosing (IU) 48 hour interval	myPKFiT® dosing (IU) 72 hour interval	ABR	HJHS	HAL	Dose Adjustment
1	50	2000 Every 2 to 3 Days	14.4	923	2930	0	26	70.9	Unchanged
2	47	2000 Alternate Days	11.4	2244	*	1	32	58.6	Unchanged
3	44	1500 Alternate Days	13.6	1115	3789	0	32	31.7	Dose Reduced 1000iu
4	30	1500 Alternate Days	11.4	1800	*	1	31	80.0	Unchanged
5	34	2000 Alternate Days	14.4	1722	*	0	15	53.8	Unchanged
6	46	2000 Alternate Days	13.9	1434	4750	0	34	92.9	Dose Reduced 1500iu
7	24	2000 Alternate Days	15.3	673	1996	1	5	100	Dose Reduced 1500iu
8	41	2000 Alternate Days	14.6	1121	3509	2	42	38.5	Unchanged
9	77	1500 Twice per Week	17.2	*	1629	0	53	50.3	Unchanged
10	20	1500 Alternate Days	11.8	1280	5222	1	21	87.1	Unchanged
11	49	1500 Alternate Days	15.2	782	2342	0	36	42.93	Unchanged at present
12	29	2000 Alternate Days	12.0	1986	7967	0	16	87.0	Unchanged

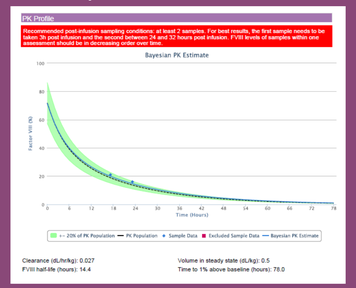
myPKFiT® Example: Patient 1

Images taken from myPKFiT® V1.1

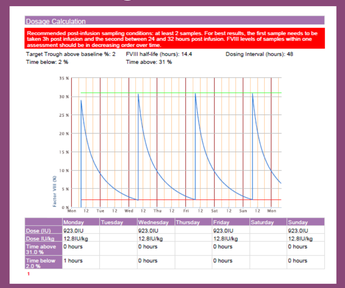
Patient Information Summary



Bayesian PK Estimate



Dosage Calculation



Results

12 patients with severe haemophilia A were audited regarding their prophylaxis dosing regimes.
The dose administered and its frequency were compared with the dose predicted by the myPKFiT® calculation.
3 patients on reviewing dosing and frequency, with a background of stable ABR and HJHS, were able to be dose reduced accordingly.
9 patients required no change in their current prescribed prophylaxis.
No patients in the audit cohort were seen to be infusing an inadequate dosage of prophylaxis and therefore did not require a dose elevation.

Conclusions

In consideration of various outcome measures: ABR, HJHS, Haemophilia Activities List (HAL), dose alterations to prescribed Advate prophylaxis could be evaluated, justified and helped to provide good follow up of care.
Implications for bleeding frequency in haemophilia, patients' confidence in clinical decisions and economic cost are of interest, and in using the MyPKFiT® tool to audit patient's PK data: these can be kept under constant review.

References

Boehlen F, Graf L, Berntorp E. Outcome measures in haemophilia: a systematic review. *European Journal of Haematology* 2014;93 (Suppl. 76):2-15.
myPKFiT user manual V1.0: Baxter Healthcare Corporation; 2015.