Cost Analysis of Bypassing Agent Prophylaxis Treatment versus On-Demand Therapy in Hemophilia A with Inhibitor in Spain

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Introduction

- Hemophilia A (HA) is a genetic disease characterized by bleeding episodes caused by factor VIII (FVIII) deficiency[1].
- Severe HA and FVIII inhibitor patients are at increased risk for serious bleeding complications and progression to end-stage hemophilia[2]. Costs associated with treatment and complications are one of the largest economic burdens of Health Systems around the world[3].

Objective

To estimate the annual cost of prophylaxis with Activated Prothrombin Complex Concentrate (aPCC) versus annual cost of acute bleeds treatment with recombinant activated Factor VII (rFVIIa) in severe HA with inhibitor patients, from the Spanish Healthcare System perspective.

Methods

- A cost-analysis model was used to compare annual cost per patient of aPCC prophylaxis versus rFVIIa on-demand treatment.
- Total cost estimation included:
  - prophylaxis treatment (aPCC)
  - on-demand treatment for each bleeding event (aPCC and rFVIIa)
  - bleeding event resources (excluding factor)
  - annual surgeries
  - HA general management
- A baseline bleeding management cost (considering health resources consumed in joint bleeds [62.5%], muscle and soft tissue [28.6%], mucous membranes [3.6%] and other sites [5.4%][4]), surgery costs and HA management costs were estimated for a 61.8 kg weight patient[5] based on resource use provided by an expert panel for each kind of bleeding site.
- aPCC prophylaxis regimen was 75.72U/kg, three times per week. Total dosage for each hemorrhagic event treatment was 673.46µg/kg for rFVIIa (103.73µg/kg per infusion) and 233.13U/kg for aPCC (50U/kg per infusion) (expert panel).
- The number of annual bleeding events considered was 25 for on-demand therapy[6] and 8 for prophylaxis, assuming a 69% reduction in hemorrhages due to aPCC prophylaxis (expert panel).
- Drug (ex-factory price with mandatory 7.5% rebate[7]) and resources unitary costs (€, 2013) were obtained from local databases[8,9] (table 1).
- One-way sensitivity analysis were performed to test model robustness.

Table 1. Drug and administration costs

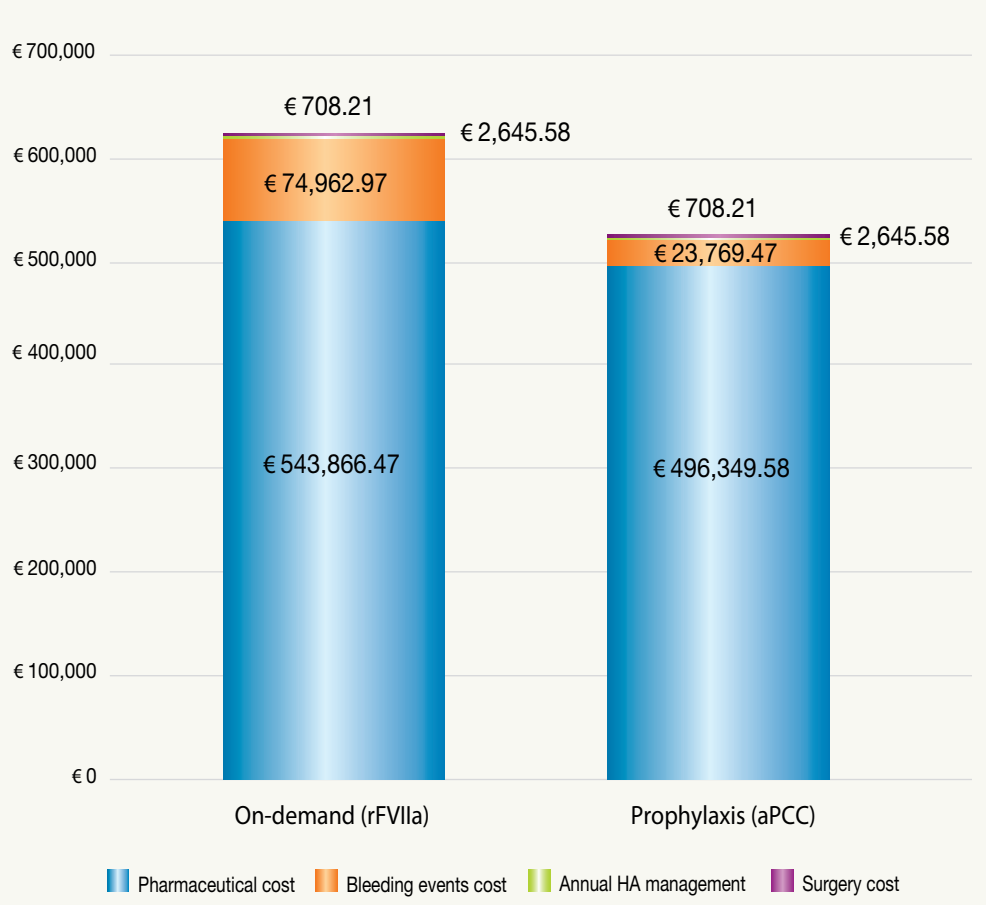
	Cost (€ 2013)
Resources cost[9]	
Bleeding management	2,971
Surgery	708
HA management	2,645
Drug cost[8]	
aPCC (per U) (Feiba®*)	0.63
rFVIIa (per µg) (NovoSeven®*)	0.52

* Average Price of all packs availables.

Results

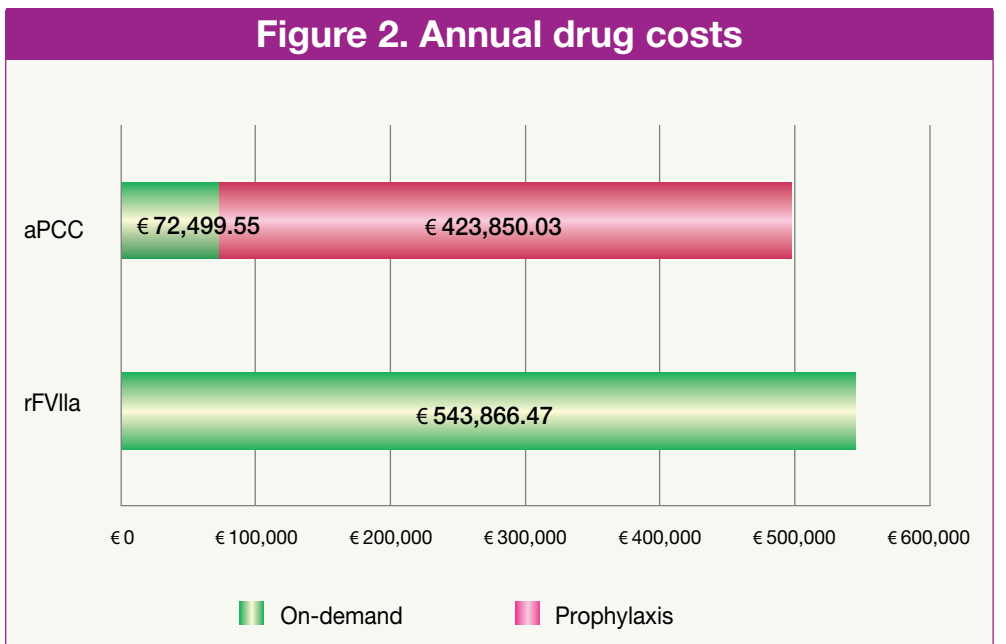
- Estimated annual cost per patient was €523,473 for prophylaxis with aPCC and €622,183 for on-demand treatment with rFVIIa, yielding a difference of €98,710 (figure 1).

Figure 1. Annual cost per patient



- Based on the total agent consumption (789,109U for aPCC and 1,050,067µg for rFVIIa), the drug cost accounted was €496,350 for aPCC (14.6% corresponding to on-demand therapy and 85.4% to prophylaxis) compared to €543,866 for rFVIIa (figure 2). Average bleeding cost was €9,062 (aPCC) and €21,556 (rFVIIa).

Figure 2. Annual drug costs



- Yearly bleedings cost (excluding factor) was €23,770 for prophylaxis versus €74,963 for on-demand resource consumption.
- Results for sensitivity analyses showed cost-savings ranging from €22,525 (considering 28% reduction in bleeding events with prophylaxis) to €996,384 (considering 65 bleeds/year).

Conclusions

- **Results suggested that 3 times weekly aPCC prophylaxis could reduce 16% the entire treatment cost of severe HA with inhibitor, saving up to €98,000 per patient/year by reducing the annual number of bleeding events with prophylaxis.**
- **Sensitivity analysis showed that the more severe is HA with inhibitor (large number of annual bleeds), the more savings produce prophylaxis with aPCC.**

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