Cost Assessment of Implementation of ITI in Iran

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OBJECTIVES

This study was designed to compare costs attributed to implementation of immune tolerance induction (ITI) for management of Good risk Iranian hemophilia patients with high titer and high responding inhibitors, and on-demand (OD) use of bypassing agents for them from the perspective of the national health system.

The main objective was to find the ***breakeven point for ITI method in comparison with on-demand (OD) use*** of bypassing agents in Iranian hemophilia patients with high titer and high responding inhibitors.

METHODS

According to the consensus of three main study groups on ITI in the world. Patients with Peak historical titer less than 200 BU ; pre ITI titer less than 10 BU ;and an interval of less than 5 years between inhibitor diagnosis and the start of ITI considered as good risk patients.
After a systematic review of articles, we used the results for Pre-assumption for both arms of study:

Table 1- Pre assumption for ITI arm

Success rate of ITI FVIII dose	80% 100 IU/kg/day
Mean time to success	12 months
Dose of Novoseven® for controlling bleeding events in 1st year	Minor event 270 mcg/kg Intermediate 540 mcg/kg Major 5400 mcg/kg
No. of bleeding events in 1st year (during ITI) No. of events in 2nd and 3rd year (for on demand therapy with FVIII)	Minor events 1.5 Intermediate events 1 Major events 0.1 Minor events 27 Intermediate events 3 Major events 0.2
Dose of for controlling bleeding events with Factor VIII in 2nd and 3rd year	Minor event 40 IU/Kg/day Intermediate 80 IU/Kg/day Major 100 IU/Kg/day
FVIII price* Mean estimated patient`s weight of 6 years old child	2500 Rials /IU 20 kg (with annual 10% increase)

*Based on official exchange rate 1USD=1,2000 Rials

Table 2- Pre assumption for by passing agent group

Success rate of Novoseven®	95%
Novoseven® Dose for controlling bleeding events	Minor event 270 mcg/kg Intermediate 540 mcg/kg Major 5400 mcg/kg
No. of bleeding events/year in On Demand treatment	Minor events 27 Intermediate events 3 Major events 0.2
Novoseven®® price*	7750 Rials/mcg

*Based on official exchange rate 1USD=1,2000 Rials

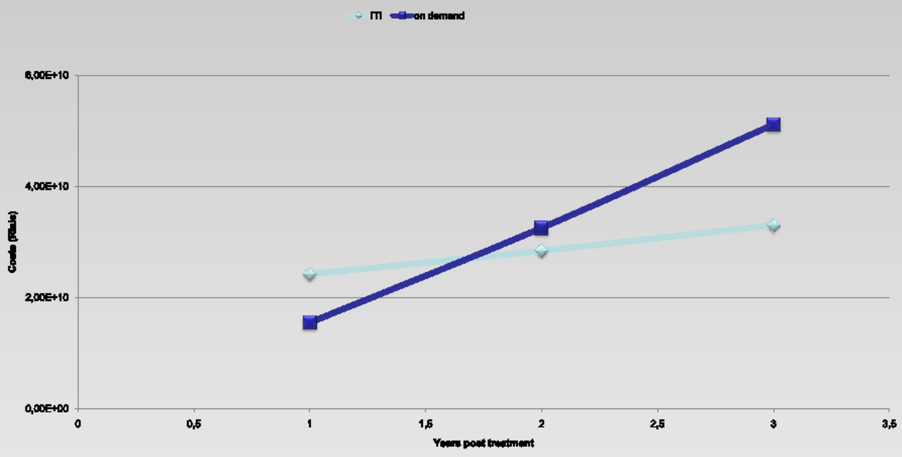
FVIII price(2011)	**2,000-4,000 Rials/IU**
Novoseven® price (2011)	**6,000-8,000 Rials/mcg**

	FVIII;IU/kg/day	Patient Wt. (kg)	time length (day)	total FVIII	price of FVIII	cost /patient	No. of Patients	Total Costs/year	
	100	20	365	730,000	3,000	2,190,000,000	10	21,900,000,000	
	rFVIIa: mcg/kg/event	Patient Wt. (kg)	No. of Events	Price of rFVII/mcg	Total rFVIIa	cost /patient		Total Costs	Total Costs (cumulative)
1st Year	270	20	1.5	7,750	8,100	62,775,000	10	627,750,000	
	540	20	1	7,750	10,800	83,700,000	10	837,000,000	
	5400	20	0.1	7,750	10,800	83,700,000	10	837,000,000	2,301,750,000
									24,201,750,000
2nd year	FVIII;IU/kg/day	Pateint Wt. (kg)	No. of Events	total FVIII	price of FVIII	cost /patient		Total Costs	Total Costs (cumulative)
	40	22	27	23,760	3,000	71,280,000	8	570,240,000	
	80	22	3	5,280	3,000	15,840,000	8	126,720,000	
	1000	22	0.2	4,400	3,000	13,200,000	8	105,600,000	802,560,000
	rFVIIa: mcg/kg/event			Price of rFVII/mcg	Total rFVIIa	cost /patient		Total Costs	
	270	22	27	7,750	160,380	1,242,945,000	2	2,485,890,000	
	540	22	3	7,750	35,640	276,210,000	2	552,420,000	
	5400	22	0.2	7,750	23,760	184,140,000	2	368,280,000	3,406,590,000
									4,209,150,000
									28,410,900,000
3rd year	FVIII;IU/kg/day	Patient Wt. (kg)	No. of Events	total FVIII	price of FVIII	cost /patient		Total Costs	Total Costs (cumulative)
	40	24	27	25,920	3,000	77,760,000	8	622,080,000	
	80	24	3	5,760	3,000	17,280,000	8	138,240,000	
	1000	24	0.2	4,800	3,000	14,400,000	8	115,200,000	875,520,000
	rFVIIa: mcg/kg/event			Price of rFVII/mcg	Total rFVIIa	cost /patient		Total Costs	
	270	24	27	7,750	174,960	1,355,940,000	2	2,711,880,000	
	540	24	3	7,750	38,880	301,320,000	2	602,640,000	
	5400	24	0.2	7,750	25,920	200,880,000	2	401,760,000	3,716,280,000
									4,591,800,000
									33,002,700,000

Table – Sample of costs calculation for ITI method versus on demand therapy with Novoseven®

RESULTS

According to this analysis, breakeven point of ITI and Novoseven® methods varies between 16-34 months (Mean: 21 Months)post treatment.



CONCLUSIONS

❖The most realistic scenario for price of FVIII and Novoseven® Iranian market show that breakeven point for these two methods will be at 21 months post treatment. Therefore Iran MOH will recover all costs attributed to ITI method in 21 months and will have substantial saving on management of these patients in coming years afterwards.

❖Both medicines used for management of these patients (FVIII and Novoseven®) are imported medicines and exchange rate play a major role in their final price. this might have effect on final result and conclusion of this study

❖this study clearly show that ITI method is a cost saving method for management of high responder inhibitor haemophilia patients when compared with on demand therapy with by passing agents

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DOI: 10.3252/pso.eu.WFH2012.2012