"Factor VIII continuous infusion in El Salvador, seven years' experience"

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OBJECTIVES

Demonstrate the safety and effectiveness of CI as replacement therapy in paediatric patients with Haemophilia A.

BACKGROUND

Continuous infusion (CI) was widely introduced in the beginnings of the 1990 decade, shortly after Martinowitz et al presented a convenient protocol of "adjusted dosage". In the last two decades there has been numerous reports confirming the effectiveness of Factor VIII continuous infusion as replacement therapy. In contrast to bolus Factor VIII therapy, CI also has demonstrated a reduction in factor consumption to reach adequate plasmatic levels and efficacious bleeding control during surgical events.

METHODS

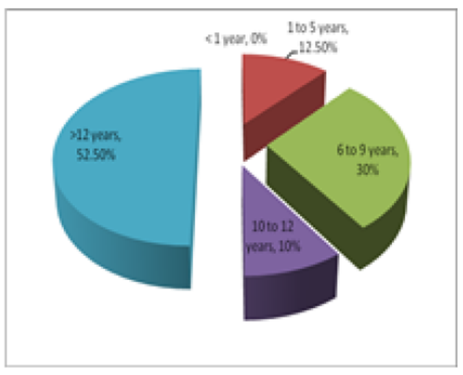
It was a retrospective and descriptive study, reviewing clinical database files from 2005 to 2012 of 84 patients from 0 to 18 years with moderate and severe Haemophilia A diagnosis. Dilutions of recombinant or plasma derived Factor VIII (FVIII) was prepared in normal saline solution to be administered in 24 hours, at velocity rates of 10.4 to 20.8 ml/hr, without heparin administration. No FVIII: C adjusted dose were performed during the CI days. For moderate bleedings the protocol included an initial bolus (IB) administration of FVIII at 30U/kg followed by CI between 2 and 2.5 U/kg/Hour. For major surgeries, severe bleeding and Central Nervous System (CNS) haemorrhage the protocol performed included an initial 50U/Kg IB followed by CI at 3U/Kg/Hour. In order to measure the safety and efficacy of CI we evaluated the bleeding complications, FVIII increase usage, use of blood components for excessive haemorrhage and increase of FVIII inhibitors and infections.

RESULTS

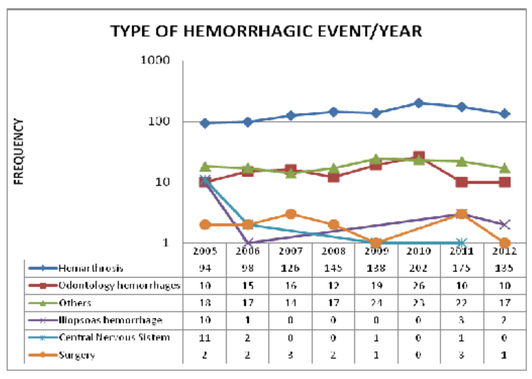
In a population of 84 patients, 55 were categorized as severe and 29 moderate Haemophilia A. The total number of bleeding episodes was 1428, with total of 8131 CI administrations.

GRAPHICS & CHARTS

Graphic 1: Distribution by age group



Graphic 3: Haemorrhage type events per year, expressed in logarithmic equation



Graphic 4: Number of CI administrations/year

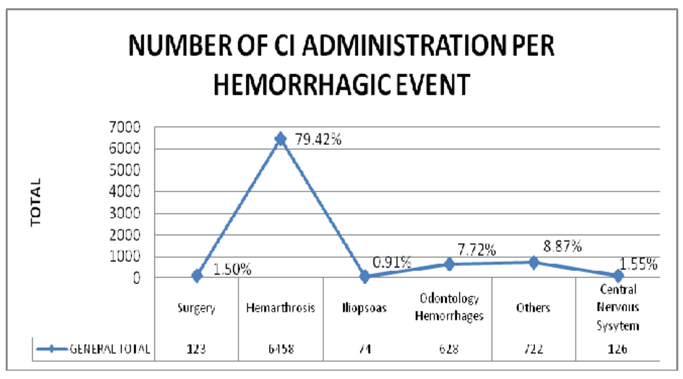
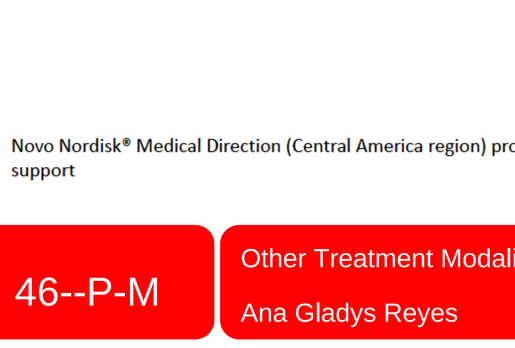


Chart 1: Adverse events related to CI

ADVERSE EVENT	FREQUENCY		%
Thrombus phlebitis	15		17.8%
Catheter Related Infections	3		3.6%
Blood Components Transfusion	0		0%
Inhibitor Development	5	HR* 3 LR** 2	5.9%

*HT: High titer inhibitor
**LT: Low titer inhibitor

Graphic 2: Total Haemorrhagic events/year



Graphic 4: Number of CI administrations/year

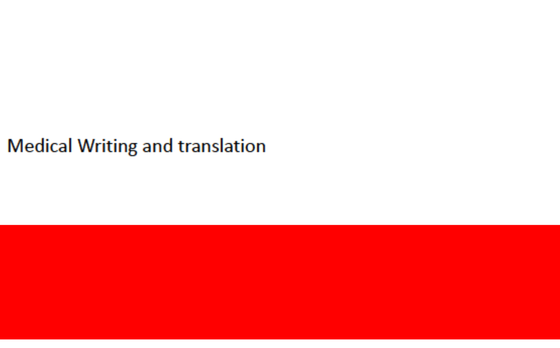


Chart 2: General data on inhibitor development in Heamophilia A patients, Comparison between 1990 decade vs 2000 decade

YEAR	NUMBER OF PATIENTS WITH HAEMOPHILIA A***	HT INHIBITOR*	%	LT** INHIBITOR	%	TOTAL PER YEAR
1993-2004	55	1	1.81 %	4	7.27%	9.09%
2005-2012	84	3	3.57 %	2	2.38%	5.95%

***In both groups the identification of inhibitors was clinically performed to patients with torpid evolution of bleeding episodes in spite of adequate FVIII treatment

CONCLUSIONS

FVIII CI demonstrated to be a safe and effective treatment option for bleeding and surgery management in the paediatric setting.

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