Real world evidence of a new bee venom extract

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Background

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Hymenoptera venom immunotherapy it's the only curative treatment for those sensitized patients that experienced systemic reactions to hymenoptera stings. The aim of this study is to explore the real practice in Spain among the hospitals that use this novel bee venom immunotherapy without human serum albumin.

Methods

This is an observational retrospective study developed in 7 hospitals in Spain, including patients older than 18 years old that had received this immunotherapy. Each center gathered information about their patients allergic to bee venom that had initiated treatment with a bee venom extract without human serum albumin. This information was the protocol used to initiate the immunotherapy, adverse reactions, field re-stings, and the patient clinical data.

Results

108 patients recruited

	Schedule			Patient per protocol
		Dose, ml	Dose, µg	
Protocol 1	Week 1	0.1ml	10µg	22 patients
	Week 2	0.2 + 0.3ml	20µg+30µg	
	Week 3	0.5 + 0.5ml	50µg+50µg	
	Week 4	1ml	100 µg	
Protocol 2	Week 1	0.1 + 0.1 ml	10µg +20µg	48 patients
	Week 2	0.2 + 0.3 ml	20µg+30µg	
	Week 3	0.5 + 0.5 ml	50µg+50µg	
Protocol 3	Week 1	0.1+0.2+0.2ml	10µg+10µg+20µg	18 patients
	Week 2	0.5 + 0.5 ml	50µg+50µg	
Protocol 4	Week 1	0.1 + 0.1ml	10µg +10µg	19 patients
	Week 2	0.2 + 0.3ml	20µg+30µg	
	Week 3	0.5 + 0.5ml	50µg+50µg	
	Week 4	0.75 + 0.75ml	75µg + 75µg	
	Week 5	1 + 1ml	100µg + 100µg	

Demographic data

		General	*No AR*	*Systemic AR*	*Systemic AR Grade 1*	*Systemic AR Grade 2*
Age (years)		52.12	52.3	57.7	54.75	63.5
Gender	Male	71%(76)	82.9%(63)	9.2%(7)	5.3%(4)	4%(3)
	Female	29%(31)	83.9%(26)	3.2%(1)	3.2%(1)	0%
Profession	Beekeeper	52%(55)	56%(49)	3.6%(2)	1.8%(1)	1.8%(1)
	Non Bk	48%(50)	44%(39)	8%(4)	6%(3)	2%(1)
Severity of sting reaction (Müller)	Grade 1	21.5%(23)	20.2%(18)	4.3%(1)	4.3%(1)	0%
	Grade 2	39.3%(42)	39.3%(35)	4.7%(2)	4.7%(2)	0%
	Grade 3	23.4%(25)	27%(24)	4%(1)	4%(1)	0%
	Grade 4	15.9%(17)	13.5%(12)	11.7%(2)	0%	11.7%(2)*

Adverse reactions (AR)

AR	*Protocol 1*	*Protocol 2*	*Protocol 3*	*Protocol 4*	*Total*
	N(%)	N(%)	N(%)	N(%)	N(%)
Local AR	7 (6.5%)	0	4 (3.7%)	2 (1.9%)	13 (12.1%)
Systemic AR	2 (1.9%)	5 (4.7%)	0	1 (0.9%)	8 (7.5%)
Incidence SAR each 100 injections	1.5	1.7	0	0.58	

IgE

Mean/ R atio*

	General	*No AR*	*Systemic AR*	*Grade 1*	*Grade 2*
IgE total (kU/L)	203.32/ NA	226/ NA	102.4/ NA	81.52/ NA	144.3/ NA
IgE Apis mellifera (kU/L)	21.4/ 10.5	23.1/ 10.2	26.5/ 11.7	31.78/ 39	15.98/ 11
IgE Api m 1 (kU/L)	9.95/ 4.9	10.8/ 4.8	0.83/ 0.8	0.83/ 1.01	-
IgE Api m 2 (kU/L)	3.36/ 1.65	3.8/ 1.7	0.22/ 0.2	0.22/ 0.27	-
IgE Api m 3 (kU/L)	0.97/ 0.48	1.1/ 0.48	0.18/ 0.18	0.18/ 0.22	-
IgE Api m 5 (kU/L)	4.05/ 2	4.46/ 2	1.89/ 1.8	1.89/ 2.3	-
IgE Api m10 (kU/L)	7.12/ 3.5	7.86/ 3.5	0.94/ 0.9	0.94/ 1.15	-
CCD's (kU/L)	0.48/ NA	0.48/ NA	0/ NA	0/ NA	- / NA
Triptasa (g/L)	5.41/ NA	5.33/ NA	7.49/ NA	8.82/ NA	2.2/ NA

32% of the sample have suffered spontaneous re-stings, after starting the immunotherapy without presenting systemic reactions

Conclusions

In conclusion, HBVIT is the only curative treatment for patients allergic to honeybee venom and it is essential to have a complete extract to treat all those patients regardless of their sensitization. The safety and indicating efficacy data support that this new honeybee venom extract has a balanced safety and efficacy profile indicated to treat bee venom allergic patients with different sensitization profiles. More studies will be needed to prove the disease-modifying potential of the product.