Efficacy of treatment by iontophoresis of botulinum toxin type A free from complexing proteins for stump hyperhidrosis

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REASONS FOR THE PREMATURE ENDING OF THE TRIAL

No more participants were found to complete the study.

The partial results obtained are shown below.

STATISTICS

Continuous descriptive variables have been defined by means and standard deviation, categorical variables by relative frequencies (%). Confidence intervals have been calculated at 95%. The normality of all the variables has been checked using the Kolmogorov-Smirnov test. The pre- and post-intervention measures have been assessed using Student's T for related samples, after verifying their normal distribution. The correlation between scales and other continuous variables has been determined using the Pearson correlation coefficient. Statistical significance has been established at p-value < 0.05. The data has been analyzed with the statistical software SPSS version 15.

RESULTS

A total of 11 patients have been analyzed, of which 36.4% were women (4). The mean age was 47.7 years (SD 14.1) and the years since amputation had been a mean of 19.2 (SD 14.9). The rest of the descriptive variables (laterality, level of amputation, functionality K scale) are shown in Table 1.

The pain during the performance of the first intervention was, on average, according to the VAS scale valued from 0-10 of 0.55 (SD 1.03) and during the second one of 0 (SD 0).

There were no adverse reactions secondary to treatment, neither cutaneous nor related to botulinum toxin.

The evolution in sweating measured by the VAS scale shows a statistically significant progressive decrease from the real treatment intervention, in the measurement two weeks after it (3rd evaluation in the scheme) and in the following evaluation 1.5 months after treatment. (4th evaluation). We found no significant differences between the baseline value of VAS for sweating and the value analyzed after the placebo intervention (2nd evaluation). (Table 2).

The rest of the variables studied are also shown in Table 2, the only statistically significant difference apart from the previous ones is that of the VAS of sweat interference with the placement of the prosthesis between the second and the fourth evaluation, that is, from the real intervention up to 1.5 months later. The number of times per day that the prosthesis have to be removed due to sweat to dry it, the time that they could walk without losing the adhesion of the prosthesis, the pain in the amputation stump, the phantom limb pain, the quality scale of life SF-36 and the 6-minute walk test did not show significant differences in the different evaluations.

A strong correlation was found at baseline between sweat intensity and sweat interference with the placement of the prosthesis with r 0.81 (p 0.002) that is maintained in the different determinations in the time, showing in the second evaluation r 0.86 (p 0.001), in the third r 0.91 (p 0.000) and in the fourth r 0.915 (p 0.000).

There was also evidence of a correlation between the intensity of sweat and the number of prosthesis changes to dry the sweat during a day, although in this case the correlation lost intensity (strong to moderate) and statistical significance as time progressed. , with r 0.77 (p 0.006) in the first evaluation, in the second r 0.62 (p 0.04), in the third r 0.58 (p 0.06) and in the fourth r 0.47 (p 0.17).

In the correlation between the intensity of the sweat and the years of evolution of the amputation, we found an r -0.61 (p 0.048). Although the correlation of sweat with the age of the patients is slightly negative, r -0.498 (p 0.119), in this case no statistical significance was found, nor was a strong degree of connection, but moderate.

TABLES:

Table 1

Descriptive Variables		
Laterality	Right	54.55(6)
	Left	45.5%(5)
Amputation	Femoral	63,6%(7)
	Tibial	36.4%(4)
K Scale	K1	0%(0)
	K2	9,1% (1)
	K3	27.3%(3)
	K4	63.6%(7)

Table 2

	1st evaluation	2nd evaluation	3rd evaluation	4th evaluation	Difference 1st-2nd evaluation	Difference 2nd-3rd evaluation	Difference 2nd-4th evaluation
	Mean(SD)	*Mean(SD)*	*Mean(SD)*	*Mean(SD)*	*Difference(IC95%) p*	*Difference(IC95%) p*	*Difference(IC95%) p*
Sweat/day	6.83(2.17)	6.20(2.93)	4.57(2.87)	3.30(2.21)	0.63(-0.85 a 2.12)	1.63(0.14 a 3.12) *	2.52(0.45 a 4.59) *
prosthesis placement interference	5.77(3.16)	4.81(3.33)	3.91(3.04)	2.10(2.23)	0.96(-0.00 a 1.93)	0.89(-0.45 a 2.23)	2.18(0.44 a 3.93)*
walking without loss of prosthesis adherence	49.30(47.72)	96.04(89.94)	93.42(74.48)	115.50(88.27)	-46.73(-104.87 a a11.39)	2.62(-28.02 a 33.27)	-21.85(-82.91 a 39.19)
Prosthesis changes/day	2.02(1.45)	2.02(1.61)	1.39(1.07)	0.80(0.92)	0.00(-0.7 a 0.71)	0.62(-0.05 a 1.31)	1.08(0.07 a 2.09)
stump pain	2.75(3.13)	1.87(3.12)	1.68(2.73)	2.40(1.12)	0.87(-0.18 a 1.92)	0.19(-0.30 a 0.69)	-0.34(-1.71 a 1.03)
Phantom limb pain	1.81(2.70)	1.65(2.33)	1.39(0.71)	1.90(0.78)	0.16(-0.47 a 0.79)	0.25(-0.21 a 0.73)	-0.08(-0.58 a 0.411)
SF-36	64.12(17.72)	65.69(17.93)	69.54((17.29)	70.14(16.74)	-1.57(-10,90 a 7.76)	-3.95(-10.62 a 2.71)	-1.17(-10.78 a 8.44)
6 minutes walking test	352.82(156.60)	369.18(160.83)	370.60(148.34)	351.70(136.59)	-16.36(-38.0 a 5.28)	-1.8(-23.16 a 19.56)	-5.1(-20.79 a 10.59)

* $p<0.05$