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Efficacy of "Safe Sea Lotion" in preventing *Chiropsalmus* jellyfish stings in normal volunteers

Purpose:

The purpose of this study was to test the protection levels of a jellyfish (coelenterate) sting inhibitor ("repellent"), called Safe Sea lotion, against the *Chiropsalmus* Box jellyfish.

Envenomation by cnidarians is a worldwide problem. Cnidarians are equipped with stinging cells, each of which contains a stinging apparatus capable of delivering toxins into the victim when activated. The product tested inhibits the stinging mechanism based on patented technology.

The lotion has been successfully tested on a dangerous species (Rhopilema nomdica) in the eastern Mediterranean and Chrysaora (sea nettle) in the United States, but so far no trials have taken place to evaluate the lotion against the lethal Box jellyfish. Chiropsalmus species were used for testing purposes in this experiment because of their prevalence in the waters of the United States, primarily in the Gulf of Mexico area and along the coastline of Florida, and because they generally produce severe pain, redness and swelling at the site of the reaction. This jellyfish is considered to be dangerous to humans and may be of special danger to small children.

Protocol:

Twelve subjects were enrolled in the study as normal volunteers. Each signed an informed consent, met inclusion and exclusion criteria and underwent a physical exam before enrollment in the study. Subjects were randomized in a double-blind fashion to receive application of either Safe Sea lotion or placebo (Coppertone) sunscreen to the left forearm with the other lotion to be applied on the right. An area of 18 x 6 cm was marked on each forearm and Safe Sea lotion and placebo sunscreen were applied to the forearms according to the randomization protocol. After the lotion was allowed to dry for 10 minutes, two marks were made in the center of the application area at a distance of 3 cm.

Tentacles were then removed with tweezers and held vertically in the air to allow excess water to drip off. The tentacles were placed on the skin with the lower end of the tentacles applies to the distal mark and 3 cm of tentacle placed in a straight line on the forearm until it reached the proximal mark. The tentacle was left in contact with the forearm for 10 seconds at which time it was removed with tweezers. The same protocol was repeated on the right arm. If the subject experienced no discomfort during the 10 seconds of application, fresh tentacles were applied to each arm for a total of 20 additional seconds. If the subject noted no discomfort, fresh tentacles were placed in contact with the forearms for an additional 30 seconds.

Subjects were asked to note any discomfort and medical evaluation took place at 0, 15, 30, 60, 90, and 120 minutes after completion of tentacle application. Pain was scored on a 0 (no pain): 1 (pain) scale. Additionally, the degree of inflammation was evaluated by a dermatologist according to the following criteria: 0 (no change), 1 (skin color change only), 2 (edema), 3 (blister or ulcer formation). These measurements were taken at the same time points. Additionally, digital and 35 mm photographs were taken of each arm at 0 and 15 minutes.

Results:

Pain:

All twelve enrolled subjects completed the protocol. The mean application time of tentacles was 15 seconds with a minimum time of 10 seconds and a maximum of 30 seconds (see Table 1). Of the twelve enrolled subjects, only three noted any discomfort in the arm treated with Safe Sea lotion. The mean and median times before maximum pain was felt were 2.5 minutes and 0 minutes respectively. The mean and median measures of discomfort were 0.3 and 0 respectively.

In contrast, ten subjects noted discomfort in the arm treated with placebo. The majority of subjects noted maximum discomfort at the time of application, with a mean time of 20 minutes and a median of 15 minutes. The mean and median measures of discomfort were 0.83 and 1 respectively in this. The p-values were <0.05 for comparison of discomfort in Safe Sea treated and placebo treated arms.

Skin Reaction:

On medical examination performed by a blinded physician and scored as above, there was only one evidence of reaction in arms treated with Safe Sea lotion. The arms treated with placebo did demonstrate visible and/or palpable evidence of sting in nine case with mean and median scores of 1 and 1.0 respectively. The time required to reach maximum skin changes was noted to be longer than the maximum time required to reach maximum discomfort with mean and median times of 47.5 minutes and 30 minutes respectively. Again p-values were <0.01 demonstrating a statistically significant difference between the two groups.

Table 1:

		Safe Sea				**Placebo**			
Subj #	**Max Tx**	**Max Pain**		**Max Rct**		**Max Pain**		**Max Rct**	
	Time (sec)	**Amount**	**Time (min)**	**Amount**	**Time (min)**	**Amount**	**Time (min)**	**Amount**	**Time (min)**
1	10	0	0	0	0	1	0	1	30
2	10	0	0	0	0	1	15	1	90
3	20	0	0	0	0	1	15	2	120
4	10	0	0	0	0	1	15	1	120
5	10	0	0	0	0	1	60	1	60
6	20	1	15	0	0	1	30	2	30
7	10	0	0	0	0	1	0	0	0
8	10	1	0	0	0	0	0	0	0
9	20	0	0	0	0	1	30	1	30
10	20	1[1]	15	1	90	0	0	0	0
11	30	0	0	0	0	1	60	2	60
12	10	0	0	0	0	1	15	1	30
median	10	0	0	0	0	1	15	1	30
mean	15	0.3	2.5	0.1	7.5	0.83	20	1	47.5
p value									

[1] The lack of any reaction or discomfort in subject 10 placebo arm in contrast with the results of the Safe Sea lotion arm may indicate on an error in application/identification switch between the treated arms.

Conclusion:
Safe Sea lotion inhibited the sting of Chiropsalmus jellyfish in nine of twelve subjects. Visible signs of sting was notable only on one arm treated with Safe Sea lotion, but were present in nine of the arms treated with placebo. Safe Sea lotion significantly inhibits the development of pain and skin reaction resulting from contact with Box jellyfish Chiropsalmus tentacles.