Natural-biomembrane dressing and hypersensitivity *

Curativo de biomembrana vegetal e hipersensibilidade

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Abstract: BACKGROUND: The natural biomembrane of latex extracted from *Hevea brasiliensis* has been used as a dressing for skin ulcers.
OBJECTIVES: To evaluate how safe the natural biomembrane is in relation to hypersensitivity to latex when used as a dressing.
METHODS: We selected patients with skin ulcers, forming the following groups: control - low occupational exposure to latex (n = 17); latex-exposed control - high occupational exposure (n = 14); ulcerated, using the natural biomembrane (n = 13); ulcerated control, not using the natural biomembrane (n = 14); and new cases (n = 9), assessed before and after 3 months of using the natural biomembrane. All patients underwent clinical and epidemiological evaluation for latex hypersensitivity and specific IgE (UniCap®), and the control and latex-exposed control groups underwent the patch test.
RESULTS: Hypersensitivity was positive in 64.7% of the patients in the control group, 71.4% of the patients in the latex-exposed control group, 61.5% of the ulcerated using the natural biomembrane, 35.7% of the ulcerated control, and only 22 , 2% of the new cases. In the patch test of the control and latex-exposed control groups, only one individual in the control group (low contact) showed erythema in the first reading, which became negative in the second. The mean contact with latex in the latex-exposed control group was 3.42 hours / day. In the fluoroimmunoenzymatic assay, most of the sera was classified as zero (range 0-6). No serum was rated above 2, which is not considered significant for hypersensitivity (classification > 4).
CONCLUSION: The natural biomembrane proved to be safe as a dressing, for it did not induce hypersensitivity reactions among the volunteers who underwent the patch test or among users of the natural biomembrane, as it was clinically and immunologically demonstrated by IgE levels.
Keywords: Biological dressings; Latex hypersensitivity; Leg ulcer; Wound healing

Resumo: FUNDAMENTOS: A biomembrana vegetal do látex da seringueira *Hevea brasiliensis* tem sido usada como curativo para úlceras cutâneas.
OBJETIVOS: Avaliar a segurança da biomembrana vegetal como curativo em relação à hipersensibilidade ao látex.
MÉTODOS: Foram selecionados pacientes com úlceras cutâneas constituindo-se os grupos: controle - baixa exposição profissional ao látex (n=17); alta exposição profissional (n=14); ulcerados em uso da biomembrana vegetal (n=13); ulcerados-controle sem uso da biomembrana vegetal (n=14) e casos novos (n=9), submetidos à avaliação pré e após 3 meses de uso da biomembrana vegetal. Todos foram submetidos à avaliação clínico-epidemiológica quanto à hipersensibilidade ao látex e IgE específica (UniCap®), e os grupos controle e controle exposto ao látex ao "*patch test*".
RESULTADOS: A história de hipersensibilidade foi positiva em 64,7% dos pacientes do grupo-controle, 71,4% do controle exposto ao látex, 61,5% dos ulcerados em uso da biomembrana vegetal, 35,7% dos ulcerados-controle, e apenas 22,2% no grupo casos novos. Ao teste de contato dos grupos controle e controle exposto ao látex, apenas um indivíduo do grupo C (baixo contato) apresentou eritema na primeira leitura, negativando-se na segunda. A média de contato com látex no grupo-controle exposto ao látex foi de 3,42 horas/dia. No ensaio fluoroimunoenzimático, a grande maioria dos soros foi classificada como zero (variação 0 a 6). Nenhum soro recebeu classificação acima de 2, não sendo considerada classificação significante para hipersensibilidade (classificação > 4).
CONCLUSÃO: A biomembrana vegetal mostrou-se segura como curativo, pois não induziu reações de hipersensibilidade entre os voluntários submetidos ao "*patch test*", nem entre os usuários da biomembrana vegetal, como demonstrado clinica e imunologicamente pela dosagem de IgE.
Palavras-chave: Cicatrização; Curativos biológicos; Hipersensibilidade ao látex; Úlcera da perna

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INTRODUCTION

Prevalence of leg ulcers varies from 0.18% to 1.3% in the adult population. [1] The condition most commonly affects the elderly population, and its prevalence has increased with the increase in life expectancy worldwide, becoming common in the medical routine. [2,3]

Several types of dressings are currently used for treatment of skin ulcers, with different indications, advantages and disadvantages. [4] The choice of dressing to be used should be essentially based on efficacy, safety and cost, so that the patient can keep it and thus obtain a satisfactory result, since evolution and healing of the lesions take long time in most cases.

Among the many treatment options for leg ulcers, there is the natural biomembrane of latex extracted from *Hevea brasiliensis,* which consists of biocompatible material originally developed by Faculdade de Medicina de Ribeirao Preto - Universidade de Sao Paulo (Medicine School of Ribeirao Preto - University of Sao Paulo), Brazil. Experiments in dogs have shown that this biomaterial works as an important inducer in the healing of esophageal walls, with a significant increase in vascularization (neoangiogenesis), epithelialization (pseudostratified epithelium), submucosal glandular neoformation and formation of muscle fibers. [5] Clear signs of stimulus to granulation were clinically and histopathologically observed in phlebopathic ulcers starting on the 15th day of treatment with the natural latex biomembrane, when there was significant reduction of symptoms, including total pain relief. [6]

Nowadays, there are reports according to which the natural-biomembrane dressing acts in various stages of the healing process of leg ulcers, as in the removal of necrotic tissue (debridement), granulation tissue proliferation (angiogenesis) and re-epithelialization, especially in chronic ulcers in diabetic patients presenting with complications such as diabetic microangiopathy, hypertension and surgical difficulties. [6-8] However, little is known about its real mechanism of action and there are no reports on induction of hypersensitivity related to its clinical use. [7]

Prevalence of complications arising from the use of latex products such as gloves, condoms, diving equipment, diaphragms, probes, etc has increased in recent decades. In this context, we emphasize delayed hypersensitivity reactions or type IV hypersensitivity reactions, which clinically manifest as contact dermatitis, especially triggered by latex-adjuvant substances used during the industrialization process of rubber products. Recently, there are numerous reports of type I or immediate hypersensitivity among professionals who deal with latex, directly related to the latex protein makeup. [9]

Epidemiologically, some groups are reported to be at high-risk of developing hypersensitivity, such as individuals with spina bifida, health-care workers, workers at latex factories, and patients with history of allergy to fruit like avocado, banana, kiwi, chestnut and papaya. In addition to these groups, there are also atopic patients and/or patients with a family history of atopy and those with a history of multiple surgical procedures. [9,10]

Since the natural latex extracted from *Hevea brasiliensis* is the main constituent of the natural biomembrane - which has been consolidated as an important adjuvant in the healing of various tissues, it becomes important to investigate hypersensitivity reactions among individuals with leg ulcers treated with the natural latex biomembrane in comparison with untreated ulcerated individuals and healthy professionals that belong to the group at risk of developing latex hypersensitivity.

PATIENTS AND METHODS

Patients

After signing the informed consent form, volunteers and patients from the Ambulatório de Úlceras Neurovasculares (Outpatient Clinic of Neurovascular ulcers), Hospital das Clinicas de Ribeirao Preto (Clinics Hospital of Ribeirao Preto), FMRP – USP, were randomly selected according to the following groups:

1. **Control (C): employees in the administrative sector, representing individuals with minimal contact with natural latex (No. = 17);**

2. **Latex-exposed control ($_{LX}$C): operating room staff, representing individuals with chronic history of latex contact (No. = 12);**

3. **Patients with ulcers treated with natural biomembrane (U_{NBM}):** patients from the Ambulatório de Úlceras Neurovasculares (ADUN) that had already been using the natural biomembrane for over three months (No. = 13);

4. **Patients with ulcers without contact with the natural biomembrane ($_{C}$U):** ADUN patients who had never used the natural biomembrane to treat their ulcers (No. = 17);

5. **New case:** patients selected for treatment of ulcers with the natural biomembrane (No. = 9);

a) New case 1 (N1) patients evaluated for latex hypersensitivity prior to treatment with the natural biomembrane;

b) New case 2 (N2) patients evaluated for latex hypersensitivity after 3 months of treatment with the natural biomembrane.

Selection and participation of the patients are in agreement with the rules established by the Research Ethics Committee (CEP) of HCFMRP-USP, according to process number 11722/2003.

METHODS

It was a cross-sectional, randomized study regarding the selection of patients and volunteers in their respective groups.

Clinical and epidemiological evaluation of latex hypersensitivity

All individuals in the C, $_{LX}$C, U_{NBM}, $_{C}$U, N1 and N2 were asked to answer a questionnaire containing identification data, time of exposure to latex, past medical history and family history of atopy and/or hypersensitivity.

Patch-test evaluation of hypersensitivity

The patch test was performed among the volunteers in the C and $_{LX}$C groups. It consisted in applying a tape on the medial side of the right arm with the following antigens: surgical glove, natural latex biomembrane and carbamix, in addition to 0.9% saline solution and filter paper as negative controls. The readings were carried out after 48 and 96 hours using a logarithmic scale (number of crosses).

Immunoenzymatic evaluation of latex hypersensitivity

The individuals in the C, $_{LX}$C, U_{NBM}, $_{C}$U, N1 and N2 groups had 15 mL of venous serum collected by puncture of the cubital vein using the Vacuntainer system. The blood sample was centrifuged, and the serum was frozen at -70° C. The serum samples collected were submitted to ELISA for determination of specific IgE by the automated fluoroenzymatic assay technique, using the UniCAP® system, Pharmacia, which presents its results in six classes according to KU/L range and the respective result: 0 (<0.35/undetectable); 1 (0.35-0.7/weak); 2 (0.7-3.5/moderate); 3 (3.5-17.5/strong); 4 (17.5-50.0/very strong); 5 (50.0-100.0/very strong); 6 (> 100.0/very strong). [9,10]

Dressing procedure

All patients in the U_{NBM}, $_{C}$U, N1 and N2 groups were instructed about the dressing procedures performed on alternate days at home. The ulcers were cleaned only with 0.9% saline solution and dried with gauze. After that, the natural latex biomembrane was applied to the ulcer bed, not exceeding the limits of normal skin and covered with gauze and bandages.

Statistical analysis

We performed a descriptive statistical analysis of the variables, distributed according to their respective group regarding patients' demographic characteristics, history of hypersensitivity and hypersensitivity test results. The differences between the individuals in the C and $_{LX}$C groups were analyzed using the Fisher's exact test for sex and color. As for age, we used the Mann-Whitney test, with the level of statistical significance being estabished as $p<0.05$.

RESULTS

The demographic characteristics of each group, that is, volunteers (C and $_{LX}$C), patients using the natural latex biomembrane (U_{NBM}), control users ($_{C}$U) and new cases (N), respectively, are described in Table 1. It is important to note that the medical history for hypersensitivity was positive in 64.7% of the patients in the C group, 71.4% of the patients in the $_{LX}$C group, 61.5% of the patients in the U_{NBM} group, 35.7% of the patients in the $_{C}$U group, and only in 22.2% of the patients in the group of new cases (N).

The personal history of hypersensitivity of the individuals in the groups are described in Table 2. The results obtained from patch test readings among the volunteers in groups C and $_{LX}$C are described in Table 3. The mean time of contact with latex for the patients in the $_{LX}$C group was 3.42 hours per day. Only one individual in the control group (low latex contact) showed erythema in the first reading, showing a negative result in the second reading.

In the fluoroimmunoenzymatic test, the sera of the individuals were classified according to concentration of specific IgE to the natural latex extracted from *Hevea brasiliensis,* with the great majority being classified as zero. No serum was rated above 2 as shown in Table 4.

DISCUSSION

In view of the natural origin of the latex biomembrane and the relationship of latex with sensitization, we proposed to study hypersensitivity to ensure safety in its clinical use. In this study, we did not observe statistically significant differences between the volunteers in groups C and $_{LX}$C with respect to sex and color according to the Fisher's exact test ($p>0.05$) or in relation to age according to the Mann-Whitney test ($p>0.05$).

Group C consisted of professionals with low exposure to latex, while the $_{LX}$C group presented mean exposure to latex of 3.42 hours per day. However, although two patients in group C presented positive clinical history of allergies to condoms, they were not positive to the natural latex biomembrane. Only one volunteer in group C presented erythema due to the natural latex biomembrane. This patient had a history of positive hypersensitivity to atopy, insect bites and surgical tape, but obtained a zero score in the serological test. No volunteers in the $_{LX}$C group presented a positive patch test.

Regarding food allergy, only one patient in group C showed reaction to shrimp, not related to cross-reactivity to latex, while two patients in the $_{LX}$C group presented reaction to citrus, which cross-react to latex.

However, in a serological analysis using anti-

latex IgE ELISA, no patient in the C group showed positive reaction, while in the $_{LX}$C group one patient presented reaction CLASS 2 (moderate), but without positive history of allergy.

Health care workers, especially those that are atopic and that use rubber gloves regularly, present increased risk of latex sensitization. [11] Research based on questionnaires and skin tests or determination of latex-specific serum IgE showed that 5% to 17% of those workers have been documented as sensitive. [12,13] Although volunteers from both groups (C and $_{LX}$C) have not shown clinical history of allergy to latex or specific IgE prior to the patch test, only one individual in the $_{LX}$C group became positive regarding IgE (CLASS 2), which corroborates the findings of Liss et al. (1997).

Regarding the patients in the group of users, who had been using the natural latex biomembrane for more than three months, most were male, which differs from the other sample groups that had mainly women. Only one patient had clinical history of allergy to tomatoes; however, no patient showed signs of dermatitis while using the natural biomembrane. Moreover, serologically, all of the individuals were classified as zero.

Regarding the group of new cases (N), it is important to emphasize the low incidence of personal history of allergy and that only one patient was classified as Class 1 for serum IgE in the analyses before and after use of the natural latex biomembrane. Only one patient was positive in the serological analysis after using the natural biomembrane, being classified as Class 2, but without clinical signs or complaints of dermatitis and/or type I reaction to the natural biomembrane.

Surprisingly, the control group of ulcerated

Table 1: Demographic characteristics of individuals selected for the study of hypersensitivity distributed into their respective groups

Demographical data		C No. = 17		$_{LX}$C No. = 14		U_{NBM} No. = 13		$_{C}$U No. = 14		N No. = 9	
		No.	%	No.	%	No.	%	No.	%	No.	%
Sexo	Male	3	17.6	1	7.1	7	53.8	2	14.3	4	44.4
	Female	14	82.4	11	78. 6	6	46.2	12	85.7	5	55.6
Age	20 to 30	4	23.5	2	14.3	3	23.1	2	14.3	0	0.0
	31 to 40	2	11.8	4	28.6	0	0.0	4	28.6	1	11.1
	41 to 50	7	41.2	5	35.7	5	38.5	1	7.1	2	22.2
	51 to 60	4	23.5	1	7.1	3	23.1	2	14.3	3	33.3
	61 or over	0	0.0	0	0.0	2	15.4	5	35.7	3	33.3
Color	White	14	82.4	6	42.9	9	69.2	10	71.4	6	66.7
	Non-white	3	17.6	6	42.9	4	30.8	4	28.6	3	33.3
Marital Status	Single	6	35.3	2	14.3	4	30.8	4	28.6	0	0.0
	Married	10	58.8	9	64.3	7	53.8	7	50.0	4	44.4
	Divorced	0	0.0	1	7.1	1	7.7	0	0.0	0	0.0
	Widower	1	5.9	0	0.0	1	7.7	2	14.3	5	55.6
Place of Origin	Ribeirao Preto	15	88.2	12	85.7	3	23.1	1	7.1	1	11.1
	Cities in the region	2	11.8	0	0.0	8	61.5	9	64.3	7	77.8
	Other States	0	0.0	0	0.0	2	15.4	4	28.6	1	11.1
Occupation	Clerk	8	47.1	-	-	-	-	-	-	-	-
	Administrative worker	9	52.9	-	-	-	-	-	-	-	-
	Surgical technologist	-	-	2	14.3	-	-	-	-	-	-
	Nursing Technician	-	-	8	57.1	-	-	-	-	-	-
	Nurse	-	-	2	14.3	-	-	-	-	-	-
	Housewife	-	-	-	-	5	38.5	5	35.7	3	33.3
	Retired	-	-	-	-	3	23.1	5	35.7	3	33.3
	Other	-	-	-	-	5	38.5	4	28.6	3	33.3

No. = number of patients; C = control group with low exposure to latex; $_{LX}$C = control group with high exposure to latex; U_{NBM} = natural-biomembrane-user group ; $_{C}$U = ulcerated control group; N = new case group

Table 2: Personal history of hypersensitivity of the volunteers and patients evaluated, distributed into their respective groups

Antecedentes pessoais para alergia	C n=17		C_{LX} n=14		U_{BMV} n=13		U_C n=14		N n=9	
	n	%	n	%	n	%	n	%	n	%
Negative	6	35.3	4	28.6	5	38.5	9	64.3	7	77.8
Contact Dermatitis	3	17.6	2	14.3	2	15.4	2	14.3	1	11.1
Metals	2	11.8	0	0.0	0	0.0	0	0.0	0	0.0
Perfume	1	5.9	0	0.0	0	0.0	0	0.0	0	0.0
Latex Condoms	2	11.8	0	0.0	0	0.0	0	0.0	0	0.0
Topical Neomycin	0	0.0	0	0.0	0	0.0	2	14.3		0.0
Asthma	2	11.8	1	7.1	0	0.0	0	0.0	0	0.0
Rhinitis	5	29.4	7	50.0	0	0.0	0	0.0	0	0.0
Hives 0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	
Conjunctivitis	0	0.0	3	21.4	0	0.0	0	0.0	0	0.0
Food										
Shrimp	1	5.9	1	7.1	0	0.0	0	0.0	0	0.0
Citrus	0	0.0	2	14.3	0	0.0	0	0.0	0	0.0
Tomatoes	0	0.0	0	0.0	1	7.7	0	0.0	0	0.0
Seasoning	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0
Food coloring	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0
Chocolate	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0
Pork	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0
Avocado / Papaya / Kiwi / Chestnut / Banana /Nuts	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Medications	2	11.8	0	0.0	3	23.1	3	21.4	1	11.1
Insects	1	5.9	0	0.0	1	7.7	0	0.0	0	0.0
Adhesive tape (surgical tape)	1	5.9	0	0.0	1	7.7	0	0.0	0	0.0

No. = number of patients; C = control group with low exposure to latex; LXC = control group with high exposure to latex; UNBM = natural-biomembrane-user group; CU = ulcerated control group; N = new case group

patients ($_C$U), who represent an important control group due to the many treatment options already used to treat their chronic ulcers, showed the largest number of anti-latex IgE serum positive individuals, with three being classified as Class 1 and two as CLASS 2.

These findings corroborate reports from the literature according to which prevalence of latex allergy in the general population is less than 2%. [14] This prevalence increases when associated with a predisposing factor such as atopy, history of chronic occupational contact with latex or repetitive surgeries as in spina bifida. [9]

Of the several antigens identified (Hev b1 to 13), Hev b2, Hev b4, Hev b5 and Hev b6 are especially important in health care workers. [14,15] Combined research of Hev b 2, 5 and 6 is able to identify latex

Table 3: Distribution of the results obtained with the patch test among individuals of the volunteer groups C (CONTROL) and LXC (LATEX-EXPOSED CONTROL) after 48 and 96 hours

Reading	C (No. = 17) 1st (48h)				2nd (96h)				LXC (No. = 12) 1st (48h)				2nd (96h)			
Results	+		-		+		-		+		-		+		-	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Glove	0	0	17	100	0	0	17	100	0	0	12	100	0	0	12	100
NBM	1	5.9	16	94.1	0	0	17	100	0	0	12	100	0	0	12	100
Carbamix	0	0	17	100	0	0	17	100	0	0	12	100	0	0	12	100
Negative Control 1	0	0	17	100	0	0	17	100	0	0	12	100	0	0	12	100
Negative control 2	0	0	17	100	0	0	17	100	0	0	12	100	0	0	12	100

Controles negativos: 1 = micropore + papel filtro; 2 = micropore + papel filtro + soro fisiológico 0,9%

Table 4: Classification of the serum samples of the individuals regarding specific IgE to natural latex from the rubber tree in their respective groups

Classes	C (No.=17)		$_{LX}$C (No.=14)		U_{NBM} (No.=13)		$_{C}$U (No.=14)		N1 (No.=09)		N2 (No.=09)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Class 0	17	100	11	92	13	100	9	64	8	89	7	78
Class 1	-	-	-	-	-	-	3	21	1	11	1	11
Class 2	-	-	1	8	-	-	2	15	-	-	1	11

n = número de pacientes; C = grupo-controle de baixa exposição ao látex; C_{LX} = grupo-controle de alta exposição ao látex; U_{BMV} = grupo usuário BMV; U_C = grupo ulcerado-controle; N = grupo caso novo

allergy in 90% of the health care workers. [16] The method used for determination of serum IgE levels was ImmunoCAP, Pharmacia, since it is internationally accepted and approved by the FDA and presents high sensitivity and specificity (79.5% and 90.2% respectively). [17] It is also suggested that there may be a direct quantitative relationship between the ImmunoCAP class and the severity of symptoms such as hives, asthma and rhinoconjunctivitis. [17] In the clinical practice of allergology, results are considered significant and worrying when greater than or equal to Class 4, which was not found among all of the subjects studied. The ImmunoCAP test has satisfactory levels of detection of the following antigens: Hev b1, Hev b2, Hev b3, Hev b5, Hev b6, Hev b 6.01, Hev b 6.02 Hev b7.01, Hev b 7.02, Hev b8, Hev b10 and Hev b11 . [9]

The various published studies show differences in terms of prevalence of latex allergy in health care workers using the same diagnostic method. [11, 18-21] It is known that the use of gloves without powder and of vinyl reduces the prevalence of latex hypersensitivity among health care workers. [21] It is important to notice that, for the manufacture of the natural biomembrane, only natural latex vulcanized at a temperature of 60ºC is used, not at 140 ºC as in the manufacture of gloves, which promotes protein breakdown and formation of peptides that are related to allergenicity. In addition, extra chemical substances, which are normally used in the manufacture of gloves to give greater durability and better appearance, are not used in the production of the natural biomembrane. These factors may explain the low rates of sensitized individuals among the users of the natural biomembrane, which confers security to its clinical use.

CONCLUSION

Although limited by a small sample, the results of this study showed that the natural latex biomembrane proved that its use as a dressing for skin ulcers is safe, for it did not induce hypersensitivity reactions among low and high-risk volunteers subjected to the patch test or among ulcerated patients using the natural biomembrane, as it was clinically and immunologically demonstrated by serum IgE levels. ❑

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