

# Duty of information on injectable aesthetic fillers with hyaluronic acid

## Dever de informação em preenchimentos estéticos injetáveis com ácido hialurônico

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### ABSTRACT

**Introduction:** All risky treatments must be preceded by the patient's informed consent.

**Objective:** To analyze the duty to provide information about facial fillers with injectable hyaluronic acid.

**Methods:** Cross-sectional study with an online self-administered questionnaire.

**Result:** Sample comprised 257 participants, women (91.4%), who underwent procedures with physicians (77.4%) and non-physicians (22.6%) through information (77.8%), signed consent (69.3%), photographic documentation (89.1%), prior evaluation (76.3%), pre- and post-treatment recommendations (75.1%). There was greater satisfaction with the results among those who underwent the procedure based on recommendations from friends and family ( $p = 0.001$ ) and the professional's academic background ( $p = 0.005$ ) than those who chose based on price and before-and-after images.

**Conclusion:** In most cases, the procedure was performed by a physician and was carried out after verbal explanation and signed consent.

**KEYWORDS:** Dermal fillers. Hyaluronic acid. Aesthetics. Adverse events.

### Central Message

Currently, injectable hyaluronic acid ranks 2nd in non-surgical facial aesthetic procedures in the world, behind only botulinum toxin. It is a biocompatible and biodegradable product used to attenuate the natural aging process, shape the appearance, express self-care, self-acceptance or self-esteem, personal or professional fulfillment. This study sought to analyze the duty of information about facial fillers with injectable hyaluronic acid.

### Perspective

Patients should be informed about the risks and benefits of facial fillers with injectable hyaluronic acid, through improved communication, provision of written information, and detailed documentation of the procedure. These practices, when used, improve the quality of care and patient safety, but can also minimize any litigation arising from complications or dissatisfaction with the results.

### RESUMO

**Introdução:** Todo e qualquer tratamento de risco deve ser precedido do consentimento informado do paciente.

**Objetivo:** Analisar o dever de informação sobre os preenchimentos faciais com ácido hialurônico injetável.

**Método:** Estudo transversal com questionário autoaplicado online.

**Resultados:** Amostra composta por 257 participantes, mulheres (91,4%), que realizaram procedimentos com médicos (77,4%) e não médicos (22,6%) mediante informação (77,8%), consentimento assinado (69,3%), documentação fotográfica (89,1%), avaliação prévia (76,3%), recomendações pré e pós-tratamento (75,1%). Houve maior satisfação com os resultados entre aqueles que realizaram o procedimento com base em indicações de amigos e família ( $p = 0,001$ ) e na formação acadêmica do profissional ( $p = 0,005$ ) do que aqueles que escolheram pelo preço e imagens de antes e depois.

**Conclusão:** Na maioria dos casos o procedimento foi realizado por médico e ocorreu mediante esclarecimento verbal e consentimento assinado.

**PALAVRAS-CHAVE:** Preenchedores dérmicos. Ácido hialurônico. Estética. Eventos adversos.

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## INTRODUCTION

Currently, injectable hyaluronic acid ranks 2nd in non-surgical facial aesthetic procedures in the world, in women and men, behind only botulinum toxin. It is a biocompatible and biodegradable product used to attenuate the natural aging process, shape the appearance, express self-care, self-acceptance or self-esteem,<sup>1-3</sup> personal or professional fulfillment.<sup>4</sup>

In Brazil, injectable hyaluronic acid is registered as a drug with maximum risk IV. Invasive aesthetic procedures should be administered only by an authorized professional due to its potential for complications.<sup>1,2,5,6</sup> There are risks inherent to the anesthetic used in the procedure and to the potential adverse events of injectable hyaluronic acid, which can be classified as immediate, early or late<sup>5</sup> (Table 1).

**TABLE 1** — Adverse events related to the use of injectable hyaluronic acid in non-surgical facial aesthetics

Immediate start (within 24 hours)	Early start (24 hours to 30 days)	Late start (after 30 days)
<ul style="list-style-type: none"> <li>Vascular alterations: embolization, arterial occlusion, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Vascular changes: ischemia, necrosis, telangiectasia</li> </ul>	<ul style="list-style-type: none"> <li>Vascular changes: telangiectasia</li> </ul>
<ul style="list-style-type: none"> <li>Allergic reaction</li> </ul>	<ul style="list-style-type: none"> <li>Color changes: persistent erythema, ecchymosis, Tyndall effect, post-inflammatory hyperpigmentation</li> </ul>	<ul style="list-style-type: none"> <li>Color changes: post-inflammatory hyperpigmentation, persistent erythema</li> </ul>
<ul style="list-style-type: none"> <li>Hematoma</li> </ul>	<ul style="list-style-type: none"> <li>Systemic changes: infection, inflammation</li> </ul>	<ul style="list-style-type: none"> <li>Scar: atrophic, keloid</li> </ul>
<ul style="list-style-type: none"> <li>Overcorrection</li> </ul>	<ul style="list-style-type: none"> <li>Paresthesia</li> </ul>	<ul style="list-style-type: none"> <li>Irregularities: ETIP, nodulation, delayed edema</li> </ul>
<ul style="list-style-type: none"> <li>Ecchymosis</li> </ul>	<ul style="list-style-type: none"> <li>Scars: hypertrophic, atrophic</li> </ul>	
<ul style="list-style-type: none"> <li>Paresthesia</li> </ul>	<ul style="list-style-type: none"> <li>Irregularities: overcorrection, infiltration (cellulite), nodulation</li> </ul>	

Source: Almeida, Sampaio and Queiroz<sup>2</sup>

ETIP=persistent intermittent late oedema

The patient should be submitted to a prior evaluation, informed about risks, benefits, limitations, consequences and contraindications,<sup>3,6-8</sup> proposed technique, products and pre- and post-procedure care. Severe conditions, although rare, require timely and adequate medical support<sup>9,10</sup> as they can be deforming, irreversible and even fatal.

Complications of aesthetic procedures, depending on the case, affect the patient and the performing professional due to the psychological, emotional, occupational and financial implications.<sup>3,6,11,12</sup> Clear, complete and adequate information on the use of products, goods and services, as well as their risks to health and safety is fundamental for freedom of choice and public protection.

In view of this, this study aimed to analyze whether the duty of information occurred in facial aesthetic fillers with injectable hyaluronic acid.

## METHOD

This is a cross-sectional descriptive study carried out through an online questionnaire, structured in Google Forms and made available in specific groups related to aesthetic procedures on WhatsApp, Instagram and Facebook from 07/01/2022 to

09/10/2023. The project was approved by the Research Ethics Committee of Positivo University (CAAE 59219422.0.0000.0093). A previous pilot study verified the clarity of the questions and the time needed to answer the questionnaire.

The sample consisted of 271 participants (90% CI). Adults of any gender/race/color/ethnicity who underwent facial injectable fillers with hyaluronic acid in the last 2 years, performed by a physician or non-physician, and who voluntarily agreed to participate in the research with informed consent, were included. Those with fillings of other types were excluded.

The collection instrument consisted of 24 objective questions to obtain sociodemographic data of the participants, facial procedures performed and complications. For the purposes of this study, immediate, early, or late adverse events related to aesthetic filling with injectable hyaluronic acid were considered complications.<sup>5</sup> The clarification to the patient and the obtaining of his written consent in each session was interpreted as an indicator of the fulfillment of the duty to inform.

## Statistical analysis

It was carried out with the aid of the SPSS 17.0 program. Categorical variables were expressed as percentages and compared with Fisher's exact test or chi-square test,  $p < 0.05$ .

## RESULT

A total of 257 participants were included, women (91.4%) in the age group of 19 to 80 years ( $41 \pm 14$ ), users of Instagram (95.3%) and Facebook (52.1%), with a monthly income above 10 minimum wages, who knew what facial filler is (68.1%), defining it as a substance that volumizes, supports or defines the characteristics of the face.

General information about the procedures was sought through social networks (48.6%) and from family, friends or acquaintances (43.6%) and the reason for filling out the questionnaire was the desire to reduce expression lines (68.5%). The main factors that influenced the choice of professional were the indication of friends, family or acquaintances (59.1%) and academic background (56%).

Regarding the frequency of observation on social media of posts with negative results of aesthetic procedures, 44.4% said they observed very little or occasionally and 20.6% quite frequently. About 46.3% answered that they had undergone facial filling only once.

Regarding the precautions that should be taken before the session, most received verbal explanation about the risks and benefits (77.8%), signed written authorization for each session (69.3%), had the application site sanitized before the procedure (96.9%), underwent photographic documentation before and after (89.1%) and obtained the planning in writing or in the form of control labels. the material, the name of the product and the quantity used in the procedure (58.4%, Table 2).

**TABLE 2** – Characteristics of facial fillers injectable with hyaluronic acid (n = 257)

Features of the facial filler procedure		n	%
Know how to define what a facial filler is	Correct answer	175	68,5
	Incorrect answer	82	31,9
Search source for information about the facial filler	Social media	62	24,1
	Before/After Image	25	9,7
	Indications	112	43,6
	Independent research	58	22,6
Influence of the media in the dissemination of procedures	No	48	18,7
	Very little	84	32,7
	Much	125	48,6
Purpose of the procedure performed	Attenuation expression	176	68,5
	Facial reshaping	46	17,9
	Lip filler	19	7,4
	Skin blemishes/dark circles	16	6,2
Criteria for choosing the executing professional *	Indications	152	59,5
	Education	144	56
	Safety	75	29,2
	Results publications	57	22,2
	Price	38	14,8
Duration of effect of hyaluronic acid perceived in your face	Number of followers	1	0,4
	More than 6 months	77	30
	6 to 12 months	120	46,7
	12 to 18 months	45	17,5
Satisfaction with the outcome of the procedure	More than 18 months	15	5,8
	No	11	4,3
	Very little	23	9
	Very much	223	86,8

\*=Questions that were accepted more than one answer.

Facial filling performed by a physician (77.4%) predominated, with prior evaluation (76.3%), provision of pre- and post-treatment recommendations (75.1%), occurring without complications (57.2%) and with satisfactory results (86.8%).

The most frequently filled areas were the lips in women ( $p = 0.041$ ) and frontal region in men ( $p = 0.037$ ). Those who received written clarifications about the product applied perceived a longer duration of its effects than those who did not receive this information ( $p = 0.031$ ).

Among the cases with adverse events (44.3%), the occurrences were hematoma (56.1%), severe pain (35%), nodules (14.9%) and asymmetry (10.5%). The affected areas were the lips (45.6%), nasolabial fold (23.7%), zygomatic and malar region (17.5%) and eyelid (16.7%). Correction occurred in 48.8% of the cases in a maximum of 1 week (Table 3).

Complications (44.3%) were paresthesia (5.2%), allergic reaction (4.4%), visual alteration (4.4%), scarring (0.9%) and necrosis (0.9%). They affected men (50%) and women (43.82%) in the age group between 31 and 60 years (65.4%). In 90% of the cases, the affected regions were the zygomatic ( $p < 0.0001$ ) and the chin ( $p < 0.006$ ), in 80.7% the lips ( $p < 0.0001$ ), in 76.9% the mandible contour and in 66.6% the nasolabial fold ( $p = 0.023$ ). In the frontal region, the percentage of complications was higher in men (28.5%) than in women (9.4%). There was a difference in complications between those who received pre- and post-treatment recommendations (40.4%) and those who did not (56.3%) ( $p = 0.031$ ).

**TABLE 3** – Characteristics of complications of facial fillers injectable with hyaluronic acid (n=257)

Characteristics of complications of facial procedures with injectable hyaluronic acid (n = 257)		n	%
Frequency of social media observation of results negative in facial aesthetic procedures	Never	90	35
	Very little	114	44,4
	Frequently	53	20
Number of facial filler sessions in the last two years	Once	119	46,3
	Twice	75	29,2
	Three	33	12,8
	Four times	12	4,7
	Five times	18	7
He received verbal explanations about the risks and the benefits of this procedure	Yes	200	77,8
	No	57	22,2
Signed any ICF/written authorization to each procedure session	Yes	178	69,3
	No	79	30,7
There has been photographic documentation of his face before and then	Yes	229	89,1
	No	28	10,9
You have received information, in writing or in the form of a control label, over planning, material, the name of the product and the quantity used in the procedure	Yes	150	58,4
	No	107	41,6
Performed medical evaluation of the face before the procedure	Yes	196	76,3
	No	61	23,7
Received written pre- and post-treatment recommendations	Yes	193	75,1
	No	64	24,9
There was some kind of complication with filling with hyaluronic acid	Hematoma	64	56,1
	Pain	40	35,1
	Nodules	17	14,9
	Asymmetry	12	10,5
	Visual alteration	5	4,4
Injectable facial filler was performed by a doctor	Other complications	34	29,8
	Yes	199	77,4
	No	58	22,6
If there was a complication of the procedure, inform the area of the face where the complication occurred	Lip	52	45,6
	Nasolabial fold	27	23,7
	Zygomatic or malar region	20	17,5
	Eyelid region	19	16,7
	Front region	16	14
	Tear leak	16	14
	Jaw contouring	13	11,4
	Chin	10	8,8
	Nose	8	7
If there was a complication of the procedure, inform in how long it has been corrected	Immediate (soon after)	19	15,4
	Up to 1 week	60	48,8
	Up to 1 month	18	14,6
	6 to 12 months	6	4,9
	>12 months	6	4,9
	Not fixed	14	11,4

## DISCUSSION

This study addressed the duty of information on the risks of adverse events associated with hyaluronic acid filler injection for non-surgical facial aesthetics.<sup>3,6,13</sup> As they are considered “minimally invasive” procedures, they cause the false feeling of low risk, low complexity, and absence of adverse effects. Although the potential for invasion of fillers is minimal and their recovery time is short, dispensing with general anesthesia and hospitalization, this procedure reaches deep planes and should not be trivialized.<sup>6</sup>

The predominance of women in the sample is compatible with the literature and was attributed to greater sociocultural pressure on women to internalize the contemporary standard of beauty.

Aesthetic procedures in men are also on the rise<sup>14</sup> and require the professional to master the facial

attractions of each gender to obtain harmonious and balanced results.<sup>4,15</sup> Medical examination, product selection, administration techniques, and injection depths for each anatomical area and specific indication make it possible to individualize the treatment. In the present sample, the age variation demonstrates the versatility of filling for facial rejuvenation.

The performance of these procedures requires legal qualification, adequate structure, good quality products, respect for hygiene and safety standards,<sup>9</sup> full information and patient consent to favor the safety and efficacy of the treatment.<sup>3,7</sup> However, the detection of injectable facial aesthetic fillers performed by non-physicians (22.6%) and the failure to provide information (30.7%) raise concerns due to the increase in the occurrence of diseases.<sup>6,9</sup>

Patient preferences and the feasibility of products, services, and brands can be influenced by digital media and marketing strategies.<sup>4,16,17</sup> In the present study, it was found that the social networks Instagram and Facebook played an important role in obtaining information about aesthetic procedures and searching for professionals.

In addition to the duties of care and confidentiality, adequate communication is the basis of a good doctor-patient relationship and the development of the relationship of trust that should permeate professional practice.<sup>11</sup> A clear and specific explanation of the service that will be provided denotes ethics, and informed consent documents the patient's autonomy.<sup>11,15</sup> Good communication skills allow for better post-procedure recovery. In the present study, most participants were informed and underwent the procedure with written authorization, photographic documentation and a record of the intervention process, expressing satisfaction with the results.

Those who underwent the procedure based on recommendations from friends and family 90% ( $p = 0.001$ ) and the professional's academic background 88.9% ( $p = 0.005$ ) were more satisfied than those who chose it based on price, before-and-after results, and number of followers. Untrained professionals are an additional risk for the application of injectable hyaluronic acid for aesthetic purposes.<sup>13</sup>

The competency matrix and the qualifications of physicians, especially dermatologists and plastic surgeons<sup>3,9</sup> prevent and reduce the chance of deleterious effects and serious consequences. However, this study did not aim to analyze the specificities of the range of professionals performing these aesthetic interventions.

The predominant adverse events in the lip region are probably explained by the greater female participation in the present sample and the search for sensuality and youthfulness through lip volumization.<sup>15,18</sup> The greater frontal involvement in men can be attributed to differences in demands and aesthetic interests.<sup>4,15</sup> However, further studies could analyze the anatomical areas filled in and the adverse events between genders; the qualifications, record, and experience of the performing professionals; the products used; and the long-term reactions and support offered.

The higher occurrence of complications detected among those who did not receive pre- and post-treatment recommendations (56.2% vs. 40.4%,  $p = 0.031$ ) demonstrate the relevance of aligning the patient's expectations, preparing them for the intervention and adherence to the pertinent care, promoting joint and conscious decision-making.<sup>13</sup>

In agreement with the literature, most adverse events were transient and had few repercussions. Informed consent, patient education, and professional training are crucial for safe and successful outcomes.

It should be noted that free and informed consent is not merely a bureaucratic act. Much more than a right, duty or agreement, it is a continuous process of dialogue, respect, understanding, transparency and bilateral trust. In addition, it enables the patient to play an active and responsible role in their health and beautification journey.

The limitations of this study include the design, small sample size, possible selection and/or recall bias. Methodological and sociodemographic differences make it difficult to compare with other studies. However, the findings reinforce the importance of patient information and consent.

## CONCLUSIONS

Although most patients have been verbally informed about the risks and benefits of facial fillers with injectable hyaluronic acid, there is still room for improvement in communication, especially in providing written information and detailed documentation of the procedure. These practices not only improve the quality of care and patient safety but can minimize any litigation arising from complications or dissatisfaction with the results.

### Authors' contributions

Conceptualization: Kátia Sheylla Malta Purim  
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Writing (original draft): All authors  
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