

PREVALENCE AND QUALITY OF INFORMED CONSENT FOR PATIENTS UNDERGOING COSMETIC PROCEDURES: A CROSS SECTIONAL STUDY

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Abstract: Background: Failure of the physician to disclose potential risks and benefits associated with cosmetic procedures is one of the main causes of legal disputes over informed consent. The objective was to assess the prevalence and quality of the informed consent given by patients who undergone cosmetic procedures and its association with post-procedure adverse events. Methods: It was a cross-sectional, online, questionnaire-based study conducted during September and October 2020. Eligible adult male and female patients who were attending a governmental dermatology clinic at Al-Kharj city (Saudi Arabia) were invited to join the study. Results: A total of 246 patients were included in the study. Out of 246, 111 (45.1%) patients performed at least one cosmetic procedure before, and 89 (80.2%) of them signed an informed consent. 62 (69.7%) of them signed a consent before the procedure, 17 (19.1%) reported post-procedure adverse events, 16 (18.0%) reported dissatisfactions, and 27 (30.3%) reported either. None of the consent characteristics were significantly associated with higher prevalence of post-procedure adverse events or non-satisfactions. Conclusions: The prevalence and the quality of informed consent before cosmetic procedures are inadequate. Urgent corrections are required to protect the patient's rights and to legally protect the treating physician.

Keywords: consent, cosmetics, adverse events, ethical, Saudi Arabia

Prevalencia y calidad del consentimiento informado de los pacientes sometidos a procedimientos estéticos: un estudio transversal

Resumen: Antecedentes: Que el médico no revele los posibles riesgos y beneficios asociados a los procedimientos estéticos es una de las principales causas de las disputas legales sobre el consentimiento informado. El objetivo fue evaluar la prevalencia y la calidad del consentimiento informado dado por los pacientes sometidos a procedimientos estéticos y su asociación con los eventos adversos posteriores al procedimiento. Métodos: Fue un estudio transversal, online, basado en un cuestionario, realizado durante septiembre y octubre de 2020. Se invitó a participar en el estudio a pacientes adultos de ambos sexos que acudían a una clínica dermatológica gubernamental en la ciudad de Al-Kharj (Arabia Saudí). Resultados: Un total de 246 pacientes fueron incluidos en el estudio. De los 246, 111 (45,1%) pacientes se habían sometido al menos a un procedimiento cosmético antes, y 89 (80,2%) de ellos firmaron un consentimiento informado. 62 (69,7%) de ellos firmaron un consentimiento antes del procedimiento, 17 (19,1%) informaron de acontecimientos adversos posteriores al procedimiento, 16 (18,0%) informaron de insatisfacciones y 27 (30,3%) informaron de cualquiera de los dos. Ninguna de las características del consentimiento se asoció significativamente con una mayor prevalencia de acontecimientos adversos posteriores al procedimiento o insatisfacciones. Conclusiones: La prevalencia y la calidad del consentimiento informado antes de los procedimientos cosméticos son inadecuadas. Se requieren correcciones urgentes para proteger los derechos del paciente y proteger legalmente al médico tratante.

Palabras clave: consentimiento, cosméticos, acontecimientos adversos, ética, Arabia Saudí

Prevalência e Qualidade de Consentimento Informado para Pacientes Submetendo-se a Procedimentos Cosméticos: Um Estudo Transversal

Resumo: Contexto: A falha do médico em comunicar os potenciais riscos e benefícios associados a procedimentos cosméticos é uma das principais causas de disputas legais sobre consentimento informado. O objetivo foi avaliar a prevalência e qualidade do consentimento informado dado a pacientes que sofreram procedimentos cosméticos e sua associação com eventos adversos pós-procedimento. Métodos: Estudo transversal, online, baseado em questionário, realizado durante setembro e outubro de 2020. Pacientes homens e mulheres, adultos elegíveis, de uma clínica dermatológica governamental da cidade de Al-Kharj (Arábia Saudita) foram convidados a participar do estudo. Resultados: Um total de 246 pacientes foram incluídos no estudo. Dos 246, 111 (45,1%) pacientes realizaram pelo menos um procedimento cosmético anterior e 89 (80,2%) deles assinaram um consentimento informado. 62 (69,7%) deles assinaram um consentimento antes do procedimento, 17 (19,1%) relataram eventos adversos pós-procedimento, 16 (18,0%) relataram insatisfações e 27 (30,3%) relataram ambos. Nenhuma das características do consentimento foram significativamente associadas com mais alta prevalência de eventos adversos pós-procedimento ou não satisfação. Conclusões: A prevalência e a qualidade do consentimento informado antes de procedimentos cosméticos são inadequados. Correções urgentes são requeridas para proteger os direitos dos pacientes e para legalmente proteger o médico responsável.

Palavras chave: consentimento, cosméticos, eventos adversos, ética, Arábia Saudita

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Introduction

There has been global increase in the number of cosmetic procedures performed over the last two decades, mainly due to more availability of minimally invasive procedures(1,2). Several personality, social, and psychological characteristics influence the increasing interest in cosmetic procedures(3). Cosmetic procedures are considered different from traditional surgical procedures as they are done on apparently healthy individuals(4). Nevertheless, medical ethics and regulations are still required to ensure safety and satisfaction of the patient as well as protection of the physician(5,6).

Informed consent is a tool for mutual communication between the physician and patient in which the patient authorizes, permits, or allows the physician to act in a specific way(4). For consent to be informative, the physician must provide the patient with comprehensive information about the nature of the medical condition, the proposed procedure, alternative treatments, risks of adverse events and complications, and the probable degree of improvement(7,8). The informed consent should be written in an understandable language and voluntarily signed by individuals with mental and legal competency to take informed decision(7,9).

In reality, obtaining informed consent for cosmetic procedures is getting challenging due to demanding patient expectations and influences as well as changing legal regulations(10,11). Additionally, cosmetic procedures and plastic surgeries are not without complications(12-14). These complications are currently reflected as increasing number of lawsuits against physicians(15,16). Failure of the physician to disclose potential risks and benefits is the main source of legal disputes over informed consent(16,17). In Saudi Arabia, the consent has been studied in relation to surgical procedures and the quality was poor(18). There is lack of data focusing on consent in cosmetic procedures and post-procedure adverse events. The objective of the current study was to assess the prevalence and quality of informed consent and its association with post-procedure adverse events among patients attending cosmetic clinic. Further this paper could initiate further discus-

sion regarding the possible need for modifying the informed consent or being more diligent with the process of informed consent for cosmetic procedures.

Methods

Setting: The current study was conducted at the dermatology clinic at the University hospital of the Prince Sattam bin Abdulaziz University (PSAU) at Al-Kharj city, Saudi Arabia. The newly established PSAU University hospital is a governmental hospital that provides largely free-health-care services to patients in the central region of Saudi Arabia, through 36 general and specialized clinics.

Population: The target population included adult male and female patients above 18 years who were attending the dermatology clinic at the PSAU University hospital during September and October 2020.

Design: It was a cross-sectional, online, questionnaire-based study. The study design obtained the required ethical approvals of the ethical committee at the PSAU.

Data collection tool: Internet-based study questionnaire was created in Arabic and English language. It included questions about the demographic characteristics of the patients as well as their experience with last cosmetic procedure, other cosmetic consultations, details of pre-procedure informed consent administration, and details of post-procedure adverse events or non-satisfactions. Two bilingual (Arabic and English) speakers, translated the questionnaire forth and back and adjusted accordingly. The study questionnaire was reviewed and approved by two experts in dermatology and cosmetic procedures. A pilot study of 15 participants, used to get the feedback of participants before having the final version of the questionnaire.

Recruitment: Patients who were attending the dermatology clinic during September and October 2020 were invited to participate in the study by receiving the link of the study questionnaire. Patients who declined the online informed consent were not allowed to complete the question-

naire (1.6%, 4 out of 250 patients). Those who never had experience with cosmetic procedures were asked to prematurely exit the questionnaire (54.9%, 135 out of 246 patients).

Statistical analysis: The questionnaire data were exported in MS Excel file and then read by SPSS software. All categorical variables were presented as frequencies and percentage while continuous variables were presented as means and standard deviations (SD). Demographic characteristics, experience with previous cosmetic procedures, and informed consent characteristics were compared between those who developed and those who did not develop post-procedure adverse events or non-satisfactions (Tables 1 through 4). Chi-square or Fisher's exact test, as appropriate, were used to examine differences in categorical variables while student t-test was used to examine differences in continuous variables. All P-values were two-tailed. P-value <0.05 was considered as significant. SPSS software (release 25.0, Armonk, NY: IBM Corp) was used for all statistical analyses.

Results

Out of 246 patients included in the study, 111 (45.1%) patients performed at least one cosmetic procedure before (Figure 1). Out of 89 patients who performed a cosmetic procedure and completed the informed consent section, 62 (69.7%) signed a consent before doing the procedure, 17 (19.1%) reported post-procedure adverse events, 16 (18.0%) reported dissatisfactions, and 27 (30.3%) reported either (Figure 1). As shown in Table 1, these dissatisfactions largely included unsatisfactory cosmetic improvement 16 (59.3%), bruises 7 (25.9%), and pigmentations 6 (22.2%). The majority (77.8%) of the patients filed a complaint to the administration of the hospital/center with only few (19.0%) who were granted free treatment of the complications. Post-complication follow-up was equally done with same and other physicians.

As shown in Table 2, the average age of the respondents was 30.3 ± 8.4 years and the vast majority of the respondents were females (93.3%). Married (49.4%) and single (47.2%) status were similarly represented. The majority of the patients

had college (74.2%) or postgraduate (11.2%) education. Approximately 55.1% of patients were working, mainly as governmental or private employees. The monthly income was split into approximately three equal groups; one third <3,000 Saudi Riyals (SAR), one third 3,000-9,999 SAR, and one third $\geq 10,000$ SAR. There were no significant associations between demographic characteristics and prevalence of post-procedure adverse events or non-satisfactions.

As shown in Table 3, the most frequently performed procedures were laser procedures (49.4%), filler injection (36.0%), Botox injection (30.3%), and surgical procedures under general anesthesia (16.9%). Approximately two-thirds (65.2%) of the procedures were done over the last year. Dermatology (52.8%) and plastic surgery (27.0%) were the most frequent specialty of physician who performed the procedure. The information that were frequently provided to the patients before procedure included the type and purpose of the procedure (61.8%), current medical and aesthetic conditions (43.8%), and advantages and disadvantages of the procedures (42.7%). On the other hand, other treatment options including no treatment (12.4%) was the least frequently provided information. More than half (57.3%) of the patients believed that the risk of complications was underestimated and more than quarter (27.0%) believed that the doctor was promoting the procedure. There were no significant associations between the patient's experience with the last cosmetic procedure and the prevalence of post-procedure adverse events or non-satisfactions. However, the belief that the doctor was promoting the procedure tended to be associated with higher prevalence of post-procedure adverse events or non-satisfactions (45.8% versus 24.6%, $p=0.053$).

As shown in Table 4, approximately 37.9% of the patients previously consulted with other physicians on the same cosmetic issue, and the majority (59.4%) of these patients were not convinced with physicians because they underestimated the risk of adverse events. The patients who had previous consultation (18.2% versus 38.9%, $p=0.043$) and who were not convinced (5.3% versus 38.5%, $p=0.029$) were significantly less likely to develop post-procedure adverse events

or non-satisfactions. The majority (83.3%) of the patients who had filler injection around the eye, nose, or forehead were not told that filling in these areas can rarely cause blindness.

Table 5 shows that the majority of the patients have either fully (62.3%) or at least partially (21.3%) read the consent before signing. The risk of adverse events in the consent was understandable (63.9%) to the participants and the used language was Arabic with or without English translation in the majority of the cases (82.9%). Approximately half (49.2%) of the patients were provided with a written post-procedure instruction sheet. None of the consent and instruction characteristics were significantly associated with higher prevalence of post-procedure adverse events or non-satisfactions.

Discussion

Approximately 30% of the cosmetic procedures were done among patients in the current study were performed without taking informed consent. This is considered a clear deviation from the standard medical practice(5). In addition to breaching patient's rights, it may be used as the basis of suing the physician in case the outcomes are lower than expected(5). Actually, problems with informed consent represent approximately 30% of legal cases of medical malpractices(15,19). Plastic surgeons performing plastic surgeries or cosmetic procedures are the highest physician group associated with problems with informed consent, including lack of consent(16). Similarly, cosmetic procedures represent 16% of all legal disputes over informed consent in different medical specialties(17). The lack of informed consent may be related to the elective nature of the treatment(4) and the physician's believe that discussing negative consequences of the procedure with patients may have negative unwanted impact on their decision(20).

The quality of informed consent among the patients in the current study was generally poor, both in content and administration. In the literature, the standard ethical requirements of the informed including the risk of adverse events and complications were met in 12% to 62% of the cases(7-9). Additionally, several issues are

still required to improve the administration of informed consent. These include giving enough time to read and understand the content. Additionally, all consent should be in Arabic language with or without English translation according to the patient's background. Finally, the patient should be given a copy of the signed consent before leaving the clinic. Similarly, previous studies showed that the quality of informed consent in Saudi Arabia was still poor and required several modifications(18). Essentially, most physicians still adopt a paternalistic attitude while taking informed consent from their patients(18,20).

The current study found that cosmetic procedures ended up with post-procedure adverse events in 19%, and non-satisfactions in 18% of patients. We could not compare such finding with local data, as there is almost lack of data about adverse events associated with cosmetic procedures in Saudi Arabia(21). Internationally, the rate of adverse events ranged between <1% in minimally invasive cosmetic procedures(13) (as in the majority of procedures studied in the current study) and 84% in traditional plastic surgeries(14).

The findings of the current study did not detect any significant associations between the prevalence, content and administration of the informed consent and post-procedure adverse events or non-satisfactions. It seems that the issues related to lack or poor consent are getting focus only when the procedure ends up with adverse events or non-satisfactions, but without actual association. For example, insufficient or unclear explanation of the risk of post-procedure complications represents 70% of all allegations made in legal cases related to informed consent, which highly exceed the mere lack or insufficient informed consents(16,17).

Approximately 45% of the patients in the current study performed at least one cosmetic procedure before. The current prevalence is generally similar to previous studies done in Saudi Arabia(22-24). For example, 42% to 55% of Saudi women of different ages interviewed at public places such as shopping malls and Universities had at least one cosmetic procedure(22,23). The most frequently performed procedures in the current study were laser procedures, filler injection, and Botox in-

jection. This was again very similar to the distribution of procedures reported in different local studies, where laser procedures, filler injection, Botox injection, and chemical peeling were the top procedures performed(22,23,25). The demographic profile of patients undergoing cosmetic procedures in the current study was similar to previous local studies(22-25). They were typically females who were around 30 years old, who are either married or single, and who have a college degree. This profile of patients are likely to be influenced by models of beauty propagated in the social media and TV programs(26,27) and who has a strong wish to improve self-esteem and to pick, attract or keep her partner(23).

The current study is considered the first local study to focus on the prevalence, content and administration of the informed consent for cosmetic procedures and its association with post-procedure adverse events or non-satisfactions. Nevertheless, few limitations are acknowledged. We relied only the participants' views without reviewing the actual consents, however, the study shows the findings of the informed consent process from the patient perspective, which could add to the existing evidence in the literature. Further, one-third of the current patients had their last cosmetic procedure more than a year ago, therefore, recall bias cannot be excluded. Also, being a single center study, results should be generalized with caution outside governmental dermatology clinics. Fur-

ther, most of those interested in completing the questionnaire were females, therefore, the results may not be applicable to males or the population in general. However, this study is considered a unique addition to the field of patient consent and the impact of the limitations on the findings is minimal.

In conclusion, approximately 30% of the cosmetic procedures done among patients attending the dermatology clinic are performed without taking informed consent and ended up with adverse events (19%) or non-satisfactions (18%). The quality of informed consent was generally poor in content and administration. There were no significant associations between the prevalence, content and administration of the informed consent and post-procedure adverse events or non-satisfactions. Multiple changes in the content and administration of informed consent are urgently required to protect the patient's rights and the treating physician

Acknowledgment

This publication was supported by the Deanship of Scientific Research at Prince Sattam bin Abdulaziz University, Alkharj, Saudi Arabia.

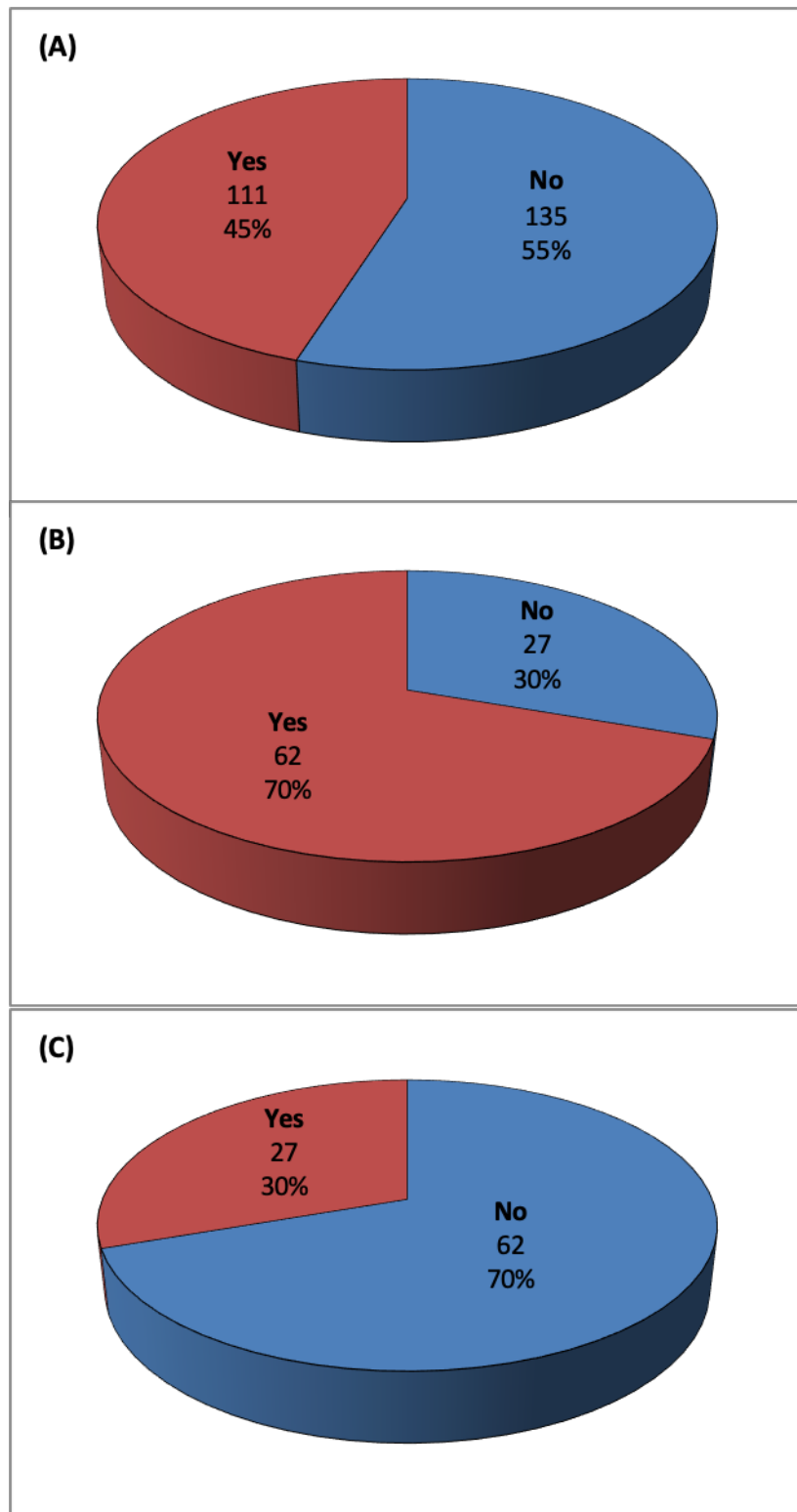


Figure 1: Ever done a cosmetic procedure (A), signing a consent before doing the procedure (B), and the development of post-procedure adverse events or non-satisfaction (C)

Table 1: Details of post-procedure adverse events or non-satisfactions

Items	Frequency
Type of adverse events or non-satisfactions	27 (100.0%)
Unsatisfactory cosmetic improvement	16 (59.3%)
Adverse events	17 (62.9%)
Bruises	7 (25.9%)
Pigmentations	6 (22.2%)
Slow or no healing	5 (18.5%)
Lumps	5 (18.5%)
Infections/inflamations	4 (14.8%)
Scars	3 (11.1%)
More than expected pain	3 (11.1%)
Burns	2 (7.4%)
Deformity	1 (3.7%)
Vascular blockage	0 (0.0%)
Awareness about the above risks before procedure	
No	14 (51.9%)
Yes	13 (48.1%)
Reaction after having adverse events or non-satisfactions	
Filed a complaint to the administration of the hospital/center	21 (77.8%)
Filed a legal complaint	1 (3.7%)
None	6 (22.2%)
Results of complaint	
No response	17 (81.0%)
Free treatment of complications	4 (19.0%)
Post-complication follow up	
With same physician only	12 (44.4%)
With other physician only	12 (44.4%)
With same and other physicians	2 (7.4%)
None	1 (3.7%)

Table 2: Demographic characteristics by the status of post-procedure adverse events or non-satisfactions

	Total (N=89)	Adverse events		P-value
		Yes (N=27)	Yes (N=27)	
Age (years)				
Mean \pm SD	30.3 \pm 8.4	28.7 \pm 8.3	31.0 \pm 8.5	0.248
<25	23 (25.8%)	9 (39.1%)	14 (60.9%)	0.547
25-35	46 (51.7%)	13 (28.3%)	33 (71.7%)	
>35	20 (22.5%)	5 (25.0%)	15 (75.0%)	
Gender				
Male	6 (6.7%)	4 (66.7%)	2 (33.3%)	0.066
Female	83 (93.3%)	23 (27.7%)	60 (72.3%)	
Marital status				
Married	44 (49.4%)	16 (36.4%)	28 (63.6%)	0.408
Single	42 (47.2%)	11 (26.2%)	31 (73.8%)	
Divorced	3 (3.4%)	0 (0.0%)	3 (100.0%)	
Educational level				
Less than college	13 (14.6%)	1 (7.7%)	12 (92.3%)	0.093
College	66 (74.2%)	24 (36.4%)	42 (63.6%)	
Post graduate	10 (11.2%)	2 (20.0%)	8 (80.0%)	
Working status				
No	40 (44.9%)	12 (30.0%)	28 (70.0%)	0.950
Yes	49 (55.1%)	15 (30.6%)	34 (69.4%)	
Occupation				
Employee (governmental or private)	43 (48.3%)	13 (30.2%)	30 (69.8%)	0.757
Self-employed	6 (6.7%)	2 (33.3%)	4 (66.7%)	
Student	22 (24.7%)	7 (31.8%)	15 (68.2%)	
Retired	2 (2.2%)	0 (0.0%)	2 (100.0%)	
Unemployed	4 (4.5%)	0 (0.0%)	4 (100.0%)	
Housewife	12 (13.5%)	5 (41.7%)	7 (58.3%)	
Monthly income (Saudi Riyals)				
<3,000	31 (34.8%)	7 (22.6%)	24 (77.4%)	0.498
3,000-9,999	28 (31.5%)	10 (35.7%)	18 (64.3%)	
\geq 10,000	30 (33.7%)	10 (33.3%)	20 (66.7%)	

* Mean \pm standard deviation, otherwise number and percentage

Table 3: Experience with last cosmetic procedure by the status of post-procedure adverse events or non-satisfactions

	Total (N=89)	Adverse events		P-value
		Yes (N=27)	Yes (N=27)	
Type of last procedure				
Laser procedures	44 (49.4%)	11 (25.0%)	33 (75.0%)	0.279
Filler injection	32 (36.0%)	13 (40.6%)	19 (59.4%)	0.114
Botox injection	27 (30.3%)	5 (18.5%)	22 (81.5%)	0.109
Surgical, under general anesthesia	15 (16.9%)	7 (46.7%)	8 (53.3%)	0.216
Chemical peeling	8 (9.0%)	3 (37.5%)	5 (62.5%)	0.694
Surgical, under local anesthesia	7 (7.9%)	3 (42.9%)	4 (57.1%)	0.429
Plasma therapy	6 (6.7%)	3 (50.0%)	3 (50.0%)	0.362
Thread lifting	6 (6.7%)	3 (50.0%)	3 (50.0%)	0.362
Body sculpting	4 (4.5%)	1 (25.0%)	3 (75.0%)	>0.99
Others	2 (2.2%)	0 (0.0%)	2 (100.0%)	>0.99
Time since last procedure				
<3 months	26 (29.2%)	4 (15.4%)	22 (84.6%)	0.134
3-12 months	32 (36.0%)	11 (34.4%)	21 (65.6%)	
> one year	31 (34.8%)	12 (38.7%)	19 (61.3%)	
Specialty of the physician				
Dermatology	47 (52.8%)	11 (23.4%)	36 (76.6%)	0.273
Plastic surgery	24 (27.0%)	11 (45.8%)	13 (54.2%)	
Others	6 (6.7%)	2 (33.3%)	4 (66.7%)	
Do not know	12 (13.5%)	3 (25.0%)	9 (75.0%)	
Information provided before last procedure				
Medical and aesthetic conditions	39 (43.8%)	12 (30.8%)	27 (69.2%)	0.938
Type and objective of procedure	55 (61.8%)	15 (27.3%)	40 (72.7%)	0.424
Risk of adverse events or complications	32 (36.0%)	10 (31.3%)	22 (68.8%)	0.888
Advantages and disadvantages	38 (42.7%)	8 (21.1%)	30 (78.9%)	0.100
Other options including no treatment	11 (12.4%)	4 (36.4%)	7 (63.6%)	0.729
Who is doing the procedure	27 (30.3%)	9 (33.3%)	18 (66.7%)	0.685
Experience with last procedure				
The risk of adverse events/ complications were underestimated	51 (57.3%)	18 (35.3%)	33 (64.7%)	0.239
The improvement described was bigger than noticed later	41 (46.1%)	14 (34.1%)	27 (65.9%)	0.470
The doctor was promoting the procedure	24 (27.0%)	11 (45.8%)	13 (54.2%)	0.053
The doctor told me about products and machines used in the procedure and other options	46 (51.7%)	14 (30.4%)	32 (69.6%)	0.983

Table 4: Experience with other consultations by the status of post-procedure adverse events or non-satisfactions

	Total (N=89)	Adverse events		P-value
		Yes (N=27)	Yes (N=27)	
Did you previously consult with other physicians on the same cosmetic issue?				
No	54 (62.1%)	21 (38.9%)	33 (61.1%)	0.043
Yes	33 (37.9%)	6 (18.2%)	27 (81.8%)	
Did you notice differences between physicians in explaining the risk of adverse events?				
No	15 (46.9%)	1 (6.7%)	14 (93.3%)	0.178
Yes	17 (53.1%)	5 (29.4%)	12 (70.6%)	
Do you think detailed explanation of the risk of adverse events can change your willingness to do the procedure?				
No	13 (40.6%)	2 (15.4%)	11 (84.6%)	>0.99
Yes	19 (59.4%)	4 (21.1%)	15 (78.9%)	
Were you more convinced with the physician who underestimated the risk of adverse events?				
No	19 (59.4%)	1 (5.3%)	18 (94.7%)	0.029
Yes	13 (40.6%)	5 (38.5%)	8 (61.5%)	
Did you have filler injection around the eye, nose, or forehead				
No	65 (73.0%)	19 (29.2%)	46 (70.8%)	0.709
Yes	24 (27.0%)	8 (33.3%)	16 (66.7%)	
Were you aware that filling in these areas can rarely cause blindness				
No	20 (83.3%)	7 (35.0%)	13 (65.0%)	>0.99
Yes	4 (16.7%)	1 (25.0%)	3 (75.0%)	

Table 5: Informed consent by the status of post-procedure adverse events or non-satisfactions

	Total (N=89)	Adverse events		P-value
		Yes (N=27)	No (N=62)	
Did you sign a procedure consent form before doing procedure?				
No	27 (30.3%)	9 (33.3%)	18 (66.7%)	0.685
Yes	62 (69.7%)	18 (29.0%)	44 (71.0%)	
Did you read the details of the procedure consent form before signing?				
Fully read	38 (62.3%)	13 (34.2%)	25 (65.8%)	0.619
Partially read	13 (21.3%)	3 (23.1%)	10 (76.9%)	
Only signed	10 (16.4%)	2 (20.0%)	8 (80.0%)	
Did you leave unfilled spaces in the procedure consent form?				
No	26 (42.6%)	6 (23.1%)	20 (76.9%)	0.344
Yes	8 (13.1%)	4 (50.0%)	4 (50.0%)	
Do not know	27 (44.3%)	8 (29.6%)	19 (70.4%)	
Did you feel the doctor or nurse want you to quickly sign the procedure consent form?				
No	40 (65.6%)	9 (22.5%)	31 (77.5%)	0.261
Yes	12 (19.7%)	5 (41.7%)	7 (58.3%)	
Do not know	9 (14.8%)	4 (44.4%)	5 (55.6%)	
Was the language of risk of adverse events in the procedure consent form understandable?				
No	8 (13.1%)	4 (50.0%)	4 (50.0%)	0.120
Yes	39 (63.9%)	8 (20.5%)	31 (79.5%)	
Do not know	14 (23.0%)	6 (42.9%)	8 (57.1%)	
What was the language of the procedure consent form?				
Arabic only	27 (44.3%)	8 (29.6%)	19 (70.4%)	0.487
English only	8 (13.1%)	1 (12.5%)	7 (87.5%)	
Both Arabic and English	26 (42.6%)	9 (34.6%)	17 (65.4%)	
Did you get a copy of the procedure consent form after signing?				
No	49 (80.3%)	15 (30.6%)	34 (69.4%)	>0.99
Yes	12 (19.7%)	3 (25.0%)	9 (75.0%)	
Did you get a written instruction sheet for what is allowed and non-allowed after procedure?				
No	31 (50.8%)	8 (25.8%)	23 (74.2%)	0.519
Yes	30 (49.2%)	10 (33.3%)	20 (66.7%)	

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Received: December 1, 2020

Accepted: December 18, 2020