

Prevalence of risk factors associated with development of capsular contracture after placement of breast implants

Prevalencia de factores de riesgo asociados al desarrollo de contractura capsular posterior a la colocación de implantes de mama

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Abstract

Objective: To determinate the prevalence of the main risk factors associated with development of capsular contracture after placement of breast implants in a referral center. **Method:** Retrospect study on 210 patients where sociodemographic variables, Baker's clinical scale and histopathological results were recorded. **Results:** Statistical analysis of 210 patients was performed; 98.1% were women. The average age was 47 years (± 11), body mass index 25 (± 10) and onset of symptoms 13 years (± 8.5). Sociodemographic factors: domestic work 63.3%. Alcoholism 70% and smoking 65.7%. The main reason for consultation was pain plus deformity in 81.6%. The risk factors with statistical significance were the history of trauma, with 83.3% ($p = 0.004$), and the subglandular plane, with 73.8% ($p = 0.0115$). Histopathology: fibrous capsule 81.4%. **Conclusions:** The prevalence of the risk factors described are similar to those reported in the literature. Only for the history of trauma and the subglandular plane there was statistical significance.

Keywords: Capsular contracture. Epidemiology. Risk factors. Backer's classification.

Resumen

Objetivo: Determinar la prevalencia de los principales factores de riesgo asociados a contractura capsular posterior a mamoplastia de aumento en un centro de referencia. **Método:** Estudio retrospectivo de 210 pacientes en el que se registraron variables sociodemográficas, escala clínica de Baker y resultados histopatológicos. **Resultados:** Se realizó el análisis estadístico de 210 pacientes; el 98.1% fueron mujeres. La edad promedio fue de 47 años (± 11), el índice de masa corporal 25 kg/m² (± 10) y el inicio de los síntomas 13 años (± 8.5). Factores sociodemográficos: labores domésticas 63.3%. Alcoholismo 70% y tabaquismo 65.7%. El principal motivo de consulta fue dolor más deformidad, en el 81.6%. Los factores de riesgo con significancia estadística fueron el antecedente de traumatismo, con un 83.3% ($p = 0.004$), y el plano subglandular, con un 73.8% ($p = 0.0115$). Histopatología: cápsula fibrosa 81.4%. **Conclusiones:** La prevalencia de los factores de riesgo descritos es similar a lo reportado en la literatura. Solo para el antecedente de traumatismo y el plano subglandular hubo significancia estadística.

Palabras clave: Contractura capsular. Epidemiología. Factores de riesgo. Clasificación de Baker.

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Introduction

Since their appearance in 1962, the use of breast implants for breast augmentation and reconstruction has increased dramatically¹. According to the latest report from the International Society of Aesthetic Plastic Surgery, breast augmentation was the most common operation performed 2018, with nearly 2 million procedures performed². In Mexico alone, nearly 45 570 surgeries are performed, making it the 2nd most widely performed procedure in our country after liposuction³. Capsular contracture is a hyperreactive response to a foreign body that can result in pain and distortion of the breast^{4,5}.

Capsular contracture is the most widely reported complication, and holds the highest rates of morbidity and reintervention^{3,4}. Its prevalence ranges from 3% up to 18.9% between 5 and 10 years after breast augmentation, and up to 30% at 3 years after reconstruction¹. This prevalence depends on multiple factors, such as bacterial contamination, absence of antibiotic prophylaxis during surgery, silicone implants, rupture of silicone breast implants, history of radiation therapy, and postoperative hematomas⁶⁻⁸. Regardless of the exact triggering factor, chronic inflammation and dysregulation of the immune system seem to play a central role in its pathogenesis^{7,9}. In 1978, Baker introduced a clinical classification of capsular contracture for the very first time, which to this date is still the most widely used one and generally accepted^{10,11} (Table 1).

Capsular contracture is one of the most unpredictable and problematic complications that occur after breast augmentation. Despite extensive study, the exact etiology for its development and associated risk factors remains elusive¹². There are still no encouraging results with the different interventions described, and prevention of recurrences remains uncertain¹³.

The aim of this study was to determine the prevalence of the most common risk factors associated with capsular contracture in patients undergoing breast implantation and determine which are statistically significant.

Method

In March 2021, after approval by the center research committee, the healths records of patients diagnosed with capsular contracture (older than 18 years old) from 2016 through 2020 were retrospectively reviewed. Patients with a history of uncontrolled collagen disease were excluded since they exhibit a clinical

Table 1. Baker scale

Grade I	Breast with normal appearance and touch
Grade II	Hardened touch without visible deformity
Grade III	Firm breast with visible deformation without causing pain
Grade IV	Hard breast with visible deformation causing pain

picture of generalized inflammation that complicates differential diagnosis with capsular contracture. Both the clinical and sociodemographic data were extracted from the health records of patients who met the inclusion criteria. The variables included were age, body mass index (BMI), occupation, chronic degenerative diseases, substance abuse, time from implantation to symptom onset, reason for consultation, history of trauma, surgical approach, and histopathology. Descriptive and inferential statistical analysis of a database of 210 observations was performed, using R and Excel software, and for qualitative variables, the chi-square test was used, comparing the 4 Baker grades with risk factors. Prevalence was estimated for each risk factor detected in the sample. p values ≤ 0.05 were considered statistical significant.

Results

Regarding the results obtained, the health records of 210 patients were included; 98.1% were women and 1.9% were men. The mean age was 47 years (± 11), the BMI was 20 kg/m² (± 10), and the mean time elapsed since breast implantation until symptom onset was 13 years (± 8.5). The risk factors associated with capsular contracture with the highest prevalence are listed in table 2. The most common occupation of patients with Baker III and IV capsular contracture was housework (20.5% and 21.9%), totaling 63.3%. The main chronic degenerative diseases associated with grades III and IV were arterial hypertension and type 2 diabetes mellitus (31.4% and 37.1%), totaling 96.7%. Substance abuse associated with patients with Baker IV grade was alcoholism in 29% and smoking in 25.7%, while in those with Baker III grade, rates were 21% and 20.5%, respectively; overall, the rates of alcoholism and smoking were 70% and 65.7%, but they were statistically nonsignificant. Regarding implant-related aspects, the main reason for implantation was aesthetic (90%), followed by reconstructive (10%). The surgical approach site was periareolar in 73.3% and

Table 2. Prevalence of the main risk factors identified

Risk factors	Baker scale				Total according to variable
	Grade I	Grade II	Grade III	Grade IV	
Domestic chores	8.1%	12.9%	20.5%	21.9%	63.3%
Arterial hypertension and type 2 diabetes mellitus	11.0%	17.1%	31.4%	37.1%	96.7%
Alcoholism	6.7%	13.3%	21.0%	29.0%	70.0%
Smoking	7.6%	11.9%	20.5%	25.7%	65.7%
History of trauma	7.6%	16.2%	28.6%	31.0%	83.3%
Periareolar	10.0%	16.2%	21.0%	26.2%	73.3%
Submammary	4.5%	20%	19%	27.2%	70.7%
Submuscular	6.06%	18.1%	33.3%	39.3%	96.76%
Subglandular	8.6%	11.9%	25.2%	28.1%	73.8%
Fibrous capsule	10.0%	15.2%	26.2%	30.0%	81.4%

submammary in 70.7%, without statistical significance ($p = 0.98$) vs the implantation plane, which was submuscular in 73.8% and subglandular in 96.76%, with statistical significance ($p = 0.0115$). The type of implant was smooth in 90% of cases, while it was textured in the remaining 10% of the cases.

History of trauma occurred in 28.6% for grade III and 31% for grade IV, totaling 83.3%, with statistical significance ($p = 0.004$). The degree of involvement according to the Baker classification was grade I, 11.43%; grade II, 18.1%; grade III, 32.38%; and grade IV, 38.10%. Regarding histopathological results, the fibrous capsule was reported as grade III in 26.2% and grade IV in 30%, totaling 81.4% (Fig. 1).

No statistically significant differences were found across the different levels of the Baker classification regarding age, occupation, diabetes mellitus, arterial hypertension, BMI, and time of clinical presentation. The only statistically significant data were the history of trauma ($p = 0.004$) and the subglandular plane ($p = 0.0115$) (Table 3).

Baker grades correlate with statistically significant data in our study supporting that, with a higher degree of capsular contracture, the rates of previous traumas and subglandular approach were higher in grades III and IV (Fig. 2).

Discussion

Capsular contracture is a serious complication following breast implantation. Various risk factors have

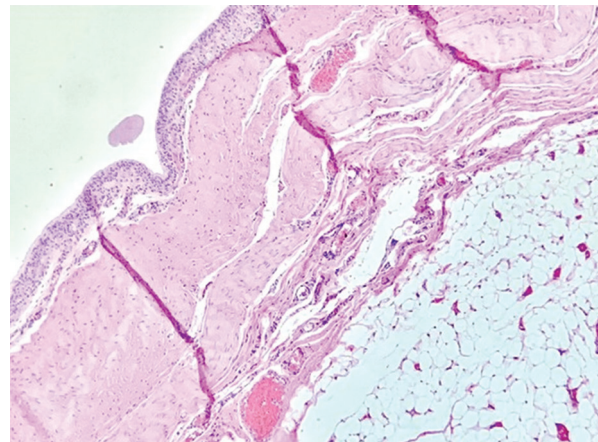


Figure 1. Capsular tissue composed of granulomatous tissue with hypocellular fibrous stroma and residual adipose tissue.

been described in the literature, such as age, textured implants, presentation time, implant volume, hematomas, and postoperative injuries; however, only radiation therapy has been documented¹⁴. In our study, the risk factors associated with capsular contracture were occupation (housework) in 63.3%, BMI of 20 kg/m² (± 10), smoking in 65.7%, alcoholism in 70%, and arterial hypertension and type 2 diabetes mellitus in 96.7%. The only statistically significant factors were a history of trauma, 83.3% ($p = 0.004$), and the subglandular plane, 73.8% ($p = 0.0115$).

Regarding the results obtained, the age range was 47 years (± 11), which is consistent with the literature, and there is evidence that age is a particularly

Table 3. Risk factors and statistical significance

Risk factors	Results	P
Mean age	47 years ($\pm$ 11)	0.6257
Body mass index	20 ($\pm$ 10)	0.2744
Time to clinical presentation	13 years ($\pm$ 8.5)	
Domestic chores	63.3%	0.6204
Arterial hypertension and type 2 diabetes mellitus	96.7%	0.6435
Substance abuse		
Alcoholism	70.0%	0.5097
Smoking	65.7%	0.687
History of trauma	83.3%	0.004
Periareolar	73.3%	0.98
Submammary	70.7%	0.98
Submuscular	96.76%	0.1136
Subglandular	73.8%	0.0115

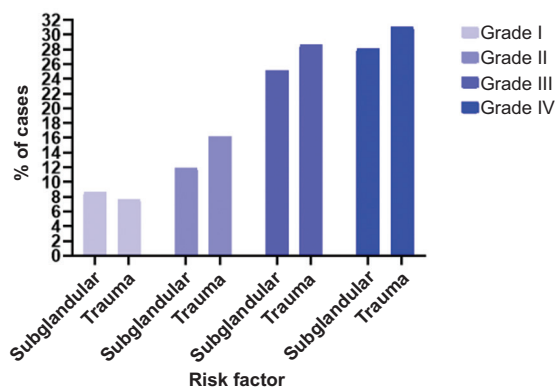


Figure 2. Baker grades correlate with statistically significant data; higher grades of capsular contracture show a higher percentage of previous traumas and subglandular approach in grades III and IV.

significant factor when the patient is older than 54 years ($p < 0.001$). Therefore, the age of the patients has an impact on the formation of capsular contracture associated with more than 10 years after implantation¹⁵. The most common occupation in patients with Baker III and IV capsular contracture was housework (20.5% and 21.9%), totaling 63.3%; however, there are no current studies in the literature supporting this data.

We identified that the main conditions related to capsular contracture in Baker grades III and IV were arterial hypertension and type 2 diabetes mellitus (31.4% and 37.1%), totaling 96.7%. In patients with uncontrolled diseases, an interaction among inflammatory cells, the extracellular matrix, and fibroblasts

has been reported, leading to an abnormal fibroblast response within the capsules surrounding the implants statically, creating more capacity to contract⁸. Substance abuse associated with patients with Baker IV grade was alcoholism in 29% and smoking in 25.7%, while in patients with Baker III grade, these rates were 21% and 20.5%, respectively; overall, the rates of alcoholism and smoking were 70% and 65.7%, respectively, but not statistically significant. Smoking causes a chronic inflammatory process that triggers the progressive formation of fibrotic tissue in the peri-prosthetic space, and elevated serum fibrosis indices (e.g., hyaluronate, N-terminal propeptide of type III procollagen, matrix metalloproteinases, and tissue inhibitors of metalloproteinases), causing progressive thickening and contraction, and eventually leading to asymmetry and symptoms from local hypersensitivity to severe pain⁷⁻⁹. In the study reported by Dancey¹⁶, no association was ever found between alcohol and capsular contracture ($p = 0.413$). Although the BMI of 20 kg/m² ($\pm$ 10) reported in our study is consistent with the one reported by Dancey¹⁶, it disagrees with the one reported by Largent et al.¹⁷, who found an adjusted relative risk of 1.02 (95% confidence interval [CI95%], 0.98-1.07), while Dancey¹⁶ found no significant differences ($p = 0.83$) in patients with BMI < 30 kg/m² vs those with BMI > 30 kg/m². The main reasons for implantation were aesthetic (90%) and reconstructive (10%). The cause of capsular contracture is different for reconstruction patients, in whom radiation therapy plays a key role by inducing capsule and pectoral muscle fibrosis (in retropectoral reconstructions), resulting in contracture and cephalic displacement of the implant^{16,18}.

The surgical approach site with the highest rate of reported capsular contracture in our study was periareolar, 73.3%, followed by submammary, 70.7%, with no statistical significance. Wiener¹⁸ relates the periareolar incision approach to capsular contracture due to the potential for implant contamination by bacteria colonizing mammary ducts. In contrast, the implantation plane showed statistical significance, with 96.76% for the submuscular plane and 73.8% for the subglandular one ($p = 0.0115$). A randomized controlled clinical trial found fewer capsular contracture symptoms with the use of textured implants in the submuscular plane³. However, when smooth implants were placed in the subfascial plane, their capsular contracture rate was significantly higher than that of textured implants¹⁸.

The most widely reported type of implant in our study was textured in 90% of the cases; in the

remaining 10%, the type of implant was the smooth one. The literature available reports that textured implants result in thicker and in the formation of more inflammatory capsule than smooth surface implants. Microtextured implants have been reported to reduce the rates of capsular contracture due to diversion force vectors around the implant^{19,20}. In their study, Filiciani et al.²⁰ reported that smooth implants had a higher rate of capsular contracture rate 1 year after surgery vs textured implants, although with borderline statistical significance ($p = 0.06$). Smooth-surfaced breast implants in the subfascial plane had a 4-fold higher risk of capsular contracture vs textured-surfaced implants in the same plane (OR, 4.4; 95%CI, 1.6-12.4). However, when implanted in the submuscular plane, both textures had a similar risk of contracture. The rate of contracture was similar 2 years after implantation ($p = 0.21$).

Regarding clinical presentation and the degree of capsular contracture, our study is consistent with what has been reported in the scientific medical literature currently available²¹. The history of trauma was presented by 83.3%, which was statistically significant ($p = 0.004$). This data is crucial, as the current literature reports it as a potentiator of the inflammatory process related to biofilm, bleeding, and silicone gel irrigation following the rupture of the implant¹¹.

The capsule is initially thin and soft, with little or no effect on breast appearance; however, over time, it undergoes progressive thickening, contraction, and compression, causing asymmetry and producing symptoms that can go from local hypersensitivity to acute pain^{7,9}. The diagnosis was clinical according to the Baker classification, being the highest percentages grades III (32.38%) and IV (38.10%). However, there is still no evidence that this scale is the most reliable for the diagnosis of capsular contracture. One study found that the inter-observer reliability of Baker's classification was poor (95%CI, 0.37-0.72) for the clinical parameters of firmness (0.64; 95%CI, 0.49-0.79), displacement (0.49; 95%CI, 0.26-0.73), and symmetry (0.61; 95%CI, 0.34-0.88). The inter-observer agreement reliability using Baker's classification for capsular contracture performed poorly²². There is a lack of consensus on how to appropriately assess and grade the symptoms and signs presented by patients as early signs of capsular contracture to avoid subjective values may underdiagnose this condition.

Regarding the limitations of our study, the implant volume > 355 mL is a factor reported in the literature as a risk factor for developing capsular contracture.

However, in our study, the precise data could not be collected as most patients did not have this information accurately recorded, or the implant warranties to corroborate it.

Within the histopathological results obtained, the fibrous capsule was reported as grade III in 26.2% and grade IV in 30%, totaling 81.4%; findings that are consistent with what is reported in the literature. By fluorescence microscopy, populations of fibroblasts associated with severe contractures were oriented perpendicular to the long axis, suggesting a spiral orientation in the compaction of these cable-like structures. These findings were absent in less severe contractures²³. In the study conducted by Schreml et al.²³ they obtained samples from 45 patients with unilateral capsular fibrosis after breast augmentation with silicone implants and found no colonization for Baker grades I or II contractures vs a 67.7% colonization for grades III or IV contractures.

Another interesting aspect that should be investigated in future studies is the biofilm, as it is one of the theories described for the development of capsular contracture. There are few studies in the literature available on these histopathological findings in breast implant capsules, the biological mechanisms involved in the reorganization of collagen fiber bundles leading to capsular contracture, which are critical steps in developing therapeutic strategies to control the pathophysiology of this disease.

Conclusions

The prevalence of the most common risk factors associated with capsular contracture in patients undergoing breast implantation was determined. Only for the history of trauma and the subglandular plane, there was statistical significance, so these 2 factors can be safely studied when diagnosing capsular contracture.

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Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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