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Research

Is Office-Based Surgery Safe? Comparing Outcomes of 183,914 Aesthetic Surgical Procedures Across Different Types of Accredited Facilities

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Abstract

Background: There has been a dramatic rise in office-based surgery. However, due to wide variations in regulatory standards, the safety of office-based aesthetic surgery has been questioned.

Objectives: This study compares complication rates of cosmetic surgery performed at office-based surgical suites (OBSS) to ambulatory surgery centers (ASCs) and hospitals.

Methods: A prospective cohort of patients undergoing cosmetic surgery between 2008 and 2013 were identified from the CosmetAssure database (Birmingham, AL). Patients were grouped by type of accredited facility where the surgery was performed: OBSS, ASC, or hospital. The primary outcome was the incidence of major complication(s) requiring emergency room visit, hospital admission, or reoperation within 30 days postoperatively. Potential risk factors including age, gender, body mass index (BMI), smoking, diabetes, type of procedure, and combined procedures were reviewed.

Results: Of the 129,007 patients (183,914 procedures) in the dataset, the majority underwent the procedure at ASCs (57.4%), followed by hospitals (26.7%) and OBSS (15.9%). Patients operated in OBSS were less likely to undergo combined procedures (30.3%) compared to ASCs (31.8%) and hospitals (35.3%, $P < .01$). Complication rates in OBSS, ASCs, and hospitals were 1.3%, 1.9%, and 2.4%, respectively. On multivariate analysis, there was a lower risk of developing a complication in an OBSS compared to an ASC (RR 0.67, 95% CI 0.59-0.77, $P < .01$) or a hospital (RR 0.59, 95% CI 0.52-0.68, $P < .01$).

Conclusions: Accredited OBSS appear to be a safe alternative to ASCs and hospitals for cosmetic procedures. Plastic surgeons should continue to triage their patients carefully based on other significant comorbidities that were not measured in this present study.

Level of Evidence: 3

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Over the past decade there has been a dramatic rise in office-based surgery across several surgical subspecialties, particularly cosmetic surgery. Since the 1980s, there has been a steady decline in surgeries performed in hospitals, from 90% to 45%.[1] Concurrently, from 1995 to 2005, office-based procedures (surgical and non-surgical) have doubled to approximately 10 million cases per year.[2] According to the American Society for Aesthetic Plastic Surgery (ASAPS), there was over a 5% increase in office-based cosmetic procedures from 56.3% to 61.9% from 2014 to 2015.[3,4] Despite this significant increase in their utilization, office-based surgical suites (OBSS) are less regulated in comparison to ambulatory surgery centers (ASCs) and hospitals. Guidelines and regulations for office-based surgical practices exist in only 31 states, and regulations may vary from state to state.[5,6] As a part of the regulatory process, some states require accreditation from one of the three accreditation agencies which include The Joint Commission,[7] the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF),[8] and the Accreditation Association for Ambulatory Healthcare.[9] Moreover, the accreditation standards themselves differ among these agencies. The lack of standardization has raised the question of safety of office-based surgery.[10,11]

To date, there are no studies that compare outcomes of office-based surgery to other types of surgical facilities where cosmetic surgery is performed. The current published literature is limited to surveys, single practice/surgeon retrospective reviews, non-cosmetic literature, or studies with methodological limitations.[12-14] The aim of this study is to assess the safety of cosmetic surgery in accredited office-based surgical suites. Using CosmetAssure (Birmingham, AL), a large prospective, multicenter database, we compared cosmetic surgical procedures performed across three types of accredited facilities: OBSS, ASCs, and hospitals. CosmetAssure is a private insurance program that covers the costs associated with unexpected major complications following elective aesthetic surgery, which may not be reimbursed by patients' primary health insurance. The primary objective was to determine and compare the incidence of overall major complications among patients operated in these three types of facilities. Other objectives were to compare the patient profile and type of procedures at different facilities; to compare incidence of different major complications such as hematoma, infection, venous thromboembolism (VTE) at different facilities; and to evaluate the trend in utilization of these facilities during the study period (2008 to 2013).

METHODS

The Vanderbilt University Institutional Review Board (IRB) approved this prospective cohort study (IRB # 140082).

Study Population

The study cohort comprised of 129,007 patients who prospectively enrolled into the CosmetAssure (Birmingham, AL) insurance program and underwent cosmetic surgical procedures between May 2008 and May 2013. The database was accessed in February 2014 following IRB approval.

Database

CosmetAssure is an insurance program introduced in 2003 that offers financial coverage of unexpected major complications related to cosmetic surgical procedures. The program is offered in all 50 states in the United States. It is available exclusively to American Board of Plastic Surgery (ABPS) - certified plastic surgeons and to the American Society of Plastic Surgeons (ASPS) Candidates for Membership who have passed the ABPS Written Examination. Furthermore, the CosmetAssure program mandates that all surgical procedures by approved surgeons be performed in accredited facilities. Patients who undergo one or more of the covered procedures by a participating plastic surgeon at an accredited facility must enroll in the program prior to any procedure, making it a prospective cohort. Surgeon-reported major complications, filed as a claim, are recorded in the database. A major complication is defined as that occurring within 30 days of the operation that requires hospital admission, an emergency room visit, or a reoperation.[15] This excludes complications that can be managed in the surgeon's office, such as seromas, minor wound infections, minor wound dehiscence or sloughing, as they are not applicable for an insurance claim. The covered major complications include hematoma, infection, pulmonary dysfunction, cardiac complication, suspected or confirmed VTE, wound related problems, myocardial infarction, and fluid overload. Other major complications (nerve injury, urinary retention etc.) have been reported to CosmetAssure but may not qualify for expense reimbursement. The database lists all procedures performed on the patient, making it possible to study specific individual procedures as well as procedure combinations (ie, patients undergoing multiple procedures under the same anesthetic). The database also records demographic and comorbidity data including age, gender, body mass index (BMI), smoking, diabetes mellitus (DM), and type of surgical facility (OBSS, ASC, hospital). Personnel employed by CosmetAssure enter data provided by the surgeon at the time of patient enrollment, as well as any claims filed by the surgeon. CosmetAssure, being a private insurance company, has a vested interest in maintaining an accurate database for actuarial and audit purposes.

Exposure

In this cohort, exposure was defined as the type of accredited facility where a cosmetic surgical procedure(s) is

performed: OBSS, ASC, or hospital. OBSS is defined as an operating room within a surgeon or group of surgeon's single practice, while ASC is considered a freestanding, usually multispecialty surgical facility.

Outcomes

The primary outcome was the occurrence of major complication(s) ie, those requiring either hospital admission, visit to the emergency department, or reoperation within 30 days postoperatively. Secondary outcomes evaluated were types of complications (hematoma, infection, VTE, etc.).

Potential Confounders and Risk Factors

Distribution of factors including age, gender, smoking, diabetes mellitus, types of procedures, and combined procedures were compared among different surgical facilities. The dataset included 24 unique cosmetic surgical procedures, and patients underwent anywhere from 1 to 7 procedures resulting in more than 700 procedure combinations. Thus, for the purpose of this study, we categorized all cosmetic procedures into 3 groups based on body region. These groups were face (blepharoplasty, browlift, cheek implant, chin augmentation, facelift, facial resurfacing, hair replacement, otoplasty, rhinoplasty), breast (augmentation, reduction, mastopexy, male breast surgery), and body (abdominoplasty, brachioplasty, buttock lift, calf implant, labiaplasty, liposuction, lower body lift, thigh lift, upper body lift). Patients who underwent more than one cosmetic procedure under the same anesthetic were considered to have combined procedures. In addition, we looked at outcomes in each of the 24 surgical procedures performed as a solitary procedure to offset the potential effect-modification from combining procedures.

Statistical Analysis

Two separate, limited, datasets were obtained from CosmetAssure, one with the enrollment data and the other with claims information. The enrollment dataset contained entries for each unique procedure. Thus, a patient undergoing combined procedures had separate entries for each procedure. A unique identifier was created using the following variables; date of birth, date of surgery, and BMI. Using this unique identifier, the enrollment dataset was restructured such that a patient undergoing combined procedures was counted once with each of the procedures listed as a separate variable. Another unique identifier was created with variables shared between the enrollment and claims datasets; date of birth, date of surgery, and gender. This identifier was then used to match the claims dataset to the restructured enrollment dataset. Of the 2506 patients in the claims dataset, 20 did not match to the enrollment data using the identifier. These cases were manually matched to enrollee's with closest demographic characteristics. Kolmogorov-Smirnov statistic was used to check normal distribution of continuous variables; age and BMI. The only missing data were absent BMI information for 1046 (0.8%) patients. These patients were included in the analysis without replacing these missing data points. Univariate analysis comparing distribution of patient characteristics, types of procedures, and complications among facilities was performed using ANOVA (Analysis of Variance) test or by the Pearson chi-square test. Standard logistic regression analysis was performed to determine complication rates for risk-adjusted patients. For the purpose of multivariate analysis, dummy variables were created to compare complications among all three types of facilities. Outcomes were reported as 30-day incidence rates after the surgery. Unless otherwise noted, probability of type I error of less than 5% ($P < .05$) was used to determine statistical significance. All analyses were performed using IBM SPSS Statistics 23.0 software (IBM Corporation, Armonk, NY).

RESULTS

Between May 2008 and May 2013, a total of 183,914 cosmetic surgery procedures were performed on 129,007 patients enrolled in the CosmetAssure program. Overall, the mean age was 40.9 ± 13.9 years (range, 5-93 years), BMI 24.3 ± 4.6 kg/m^2 (range, 17.0-56.3 kg/m^2), and the majority of patients were women (93.5%).

Most procedures were performed at ASCs (57.4%, n = 73,994), followed by hospitals (26.7%, n = 34,477) and OBSS (15.9%, n = 20,536). From 2008 to 2013, the proportion of cosmetic surgical procedures performed in OBSS stayed relatively stable (16.6% vs 15.9%). On the other hand, utilization of ASCs increased significantly (53.9% vs 58.7%) coupled with decreased use of the hospitals (29.5% vs 25.3%). Figure 1 illustrates yearly trends where cosmetic surgeries were performed.

Demographics

Patients undergoing surgery at an OBSS were older (mean, 42.2 ± 14.0 years), than those in a hospital (mean, 41.6 ± 13.9 years) and ASC (mean, 40.2 ± 13.9 years, $P < .01$). The BMI of OBSS patients (mean, 24.3 ± 4.5 kg/m^2) was intermediate between ASC (mean, 24.0 ± 4.4) and hospital (mean, 25.1 ± 5.1, $P < .01$). There were more men in the OBSS group (7.0%) than hospital (6.4%) and ASC (6.3%, $P < .01$). Patients in OBSS were more likely to be smokers (8.9%) compared to ASCs (8.2%) and hospitals (7.8%, $P < .01$). Diabetes was more prevalent in patients undergoing cosmetic surgery in hospitals (2.4%, $P < .01$) compared to OBSS (1.9%) and ASCs (1.5%). Table 1 summarizes patient demographics across the three different facilities.

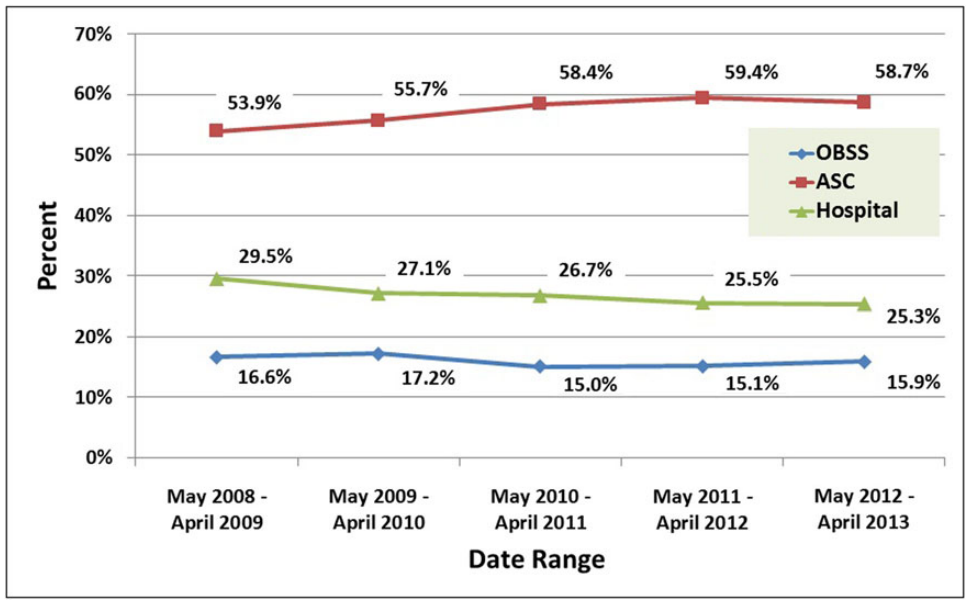

Figure 1. Yearly trends for usage of different types of facilities where cosmetic surgeries were performed. ASC, ambulatory surgery center; OBSS, office-based surgical suite.

Table 1. Patient Demographics Across Different Types of Facilities

	OBSS ($n = 20,536$)	ASC ($n = 73,994$)	Hospital ($n = 34,477$)	*P* value
Age ± SD (mean)	42.2 ± 14.0	40.2 ± 13.9	41.6 ± 13.9	<.01
BMI (kg/m^2) ± SD (mean)	24.3 ± 4.5	24.0 ± 4.4	25.1 ± 5.1	<.01
Gender, male (%)	1444 (7.0)	4697 (6.3)	2216 (6.4)	<.01
Smoker (%)	1828 (8.9)	6102 (8.2)	2691 (7.8)	<.01
Diabetic (%)	398 (16.8)	1127 (1.5)	843 (2.4)	<.01

ASC, ambulatory surgery center; BMI, body mass index; OBSS, office-based surgical suite; SD, standard deviation.

Table 2. Distribution of Cosmetic Procedures, by Body Region, Across Different Types of Facilities

	OBSS (%) ($n = 20,536$)	ASC (%) ($n = 73,994$)	Hospital (%) ($n = 34,477$)
Face	4364 (21.3)	11,472 (15.5)	4,869 (14.1)
Breast	8367 (40.7)	36,300 (49.1)	13,628 (39.5)
Body	5467 (26.6)	15,945 (21.5)	10,710 (31.1)
Face + Breast	231 (1.1)	863 (1.2)	331 (1.0)
Face + Body	458 (2.2)	1447 (2.0)	565 (1.6)
Breast + Body	1580 (7.7)	7625 (10.3)	4242 (12.3)
Face + Breast + Body	47 (0.2)	288 (0.4)	106 (0.3)

ASC, ambulatory surgery center; OBSS, office-based surgical suite.
Face: blepharoplasty, browlift, cheek implant, chin augmentation, facelift, facial resurfacing, hair replacement, otoplasty, rhinoplasty.
Breast: augmentation, reduction, mastopexy, male breast surgery.
Body: abdominoplasty, brachioplasty, buttock lift, calf implant, labiaplasty, liposuction, lower body lift, thigh lift, upper body lift.

Types of Procedures

A total of 41,886 (32.5%) patients underwent combined procedures. Patient operated in an OBSS were less likely to undergo combined procedures (30.3%) compared to ASC (31.8%) and hospital (35.3%, $P < .01$).

By body region, 21.3% of patients at OBSS underwent face procedures, compared to 15.5% of ASC and 14.1% of hospital patients. At ASCs, 49.1% of patients had breast procedures compared to 40.7% of OBSS and 39.5% of hospital patients. Proportionally, more body procedures were performed at hospitals (31.1%) rather than OBSS (26.6%) or ASCs (21.5%). Table 2 summarizes the distribution of cosmetic procedures by body region. Breast augmentation was the most common procedure performed in each type of facility. Liposuction was the second most frequent procedure in OBSS and ASCs, while abdominoplasty was more common at hospitals. The most commonly performed procedures within each facility are depicted in Table 3.

Table 3. Most Commonly Performed Procedures in Each Type of Facility

OBSS (n = 20,536)	n (%)	ASC (n = 73,994)	n (%)	Hospital (n = 34,477)	n (%)
Breast augmentation	6026 (29.3)	Breast augmentation	26,374 (35.6)	Breast augmentation	9436 (27.4)
Liposuction	2758 (13.4)	Liposuction	6135 (8.3)	Abdominoplasty	3906 (11.3)
Blepharoplasty	1268 (6.2)	Breast augmentation + Mastopexy	4979 (6.7)	Liposuction	2597 (7.5)
Breast augmentation + Mastopexy	1234 (6.0)	Abdominoplasty	4047 (5.5)	Abdominoplasty + Liposuction	2563 (7.4)
Facelift	1197 (5.8)	Abdominoplasty + Liposuction	3393 (4.6)	Breast augmentation + Mastopexy	1872 (5.4)
Abdominoplasty	1022 (5.0)	Blepharoplasty	2696 (3.6)	Facelift	1181 (3.4)
Abdominoplasty + Liposuction	990 (4.8)	Facelift	2431 (3.3)	Rhinoplasty	965 (2.8)
Facelift + Blepharoplasty	494 (2.4)	Rhinoplasty	2260 (3.1)	Breast reduction	918 (2.7)
Mastopexy	449 (2.2)	Mastopexy	2046 (2.8)	Blepharoplasty	915 (2.7)
Rhinoplasty	383 (1.9)	Breast reduction	1811 (2.4)	Mastopexy	902 (2.6)

ASC, ambulatory surgery center; OBSS, office-based surgical suite.

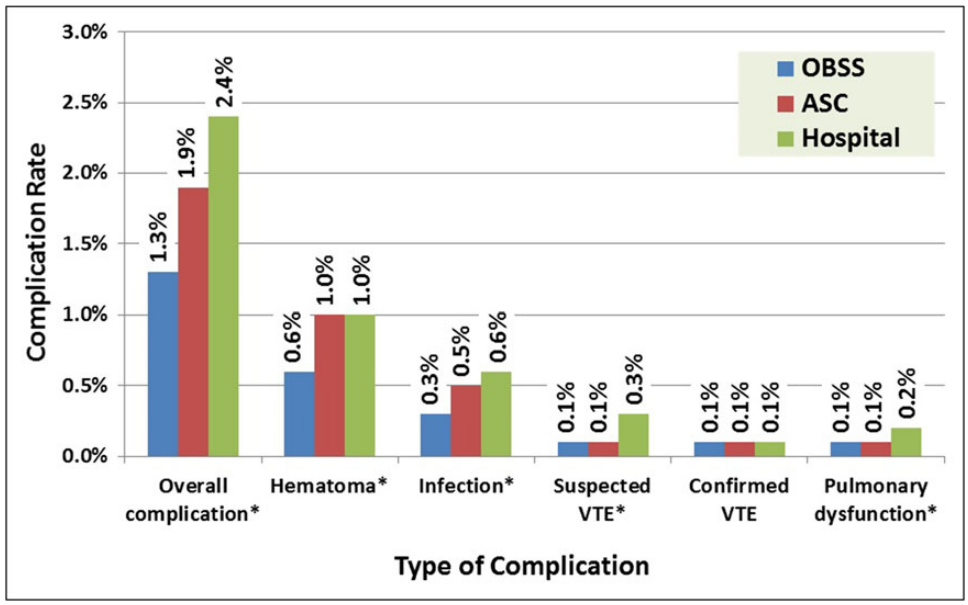

Figure 2. Overall and individual complication rates by type of facility. ASC, ambulatory surgery center; OBSS, office-based surgical suite; VTE, venous thromboembolism.

Univariate Analysis of Complications

Overall, across all facilities, 1.9% (n = 2,506) patients developed at least one major complication. The most common complications were hematoma (0.9%), infection (0.5%), suspected VTE (0.2%), pulmonary dysfunction (0.1%), and confirmed VTE (0.1%).

On univariate analysis, complication rates were lowest in OBSS (1.3%), compared to ASCs (1.9%) and hospitals (2.4%, P < .01). There were fewer hematomas, infections and pulmonary dysfunctions in OBSS (0.6%, 0.3%, and 0.1%) compared to ASCs (1.0%, 0.5%, and 0.1%) and hospitals (1.0%, 0.6%, and 0.2% respectively, P < .03). Interestingly, though hospitals had significantly higher occurrence of *suspected* VTE (0.3%) compared to other facilities (0.1%, P < .01), incidence of *confirmed* VTE was similar across all facilities (0.1%) (Figure 2).

When stratified by body region being operated (breast, body, face, or any combination of regions), body, breast, face, and breast-body combined procedures had lower

Table 4. Multivariate Logistic Regression for any Complication

	Relative Risk	95% CI		*P* value
OBSS/hospital	0.59	0.52	0.68	<.01
OBSS/ASC	0.67	0.59	0.77	<.01
Age	1.01	1.00	1.01	<.01
BMI	1.03	1.02	1.04	<.01
Gender (male)	1.05	0.90	1.23	.54
Smoking	1.19	1.03	1.37	.02
DM	1.24	0.98	1.58	.08
Body procedure	1.57	1.44	1.72	<.01
Combined procedure	1.68	1.55	1.83	<.01

ASC, ambulatory surgery center; BMI, body mass index; CI, confidence interval; DM, diabetes mellitus; OBSS, office-based surgical suite.

Table 5. Multivariate Logistic Regression for Hematoma

	Relative Risk	95% CI		*P* value
OBSS/hospital	0.57	0.46	0.70	<.01
OBSS/ASC	0.57	0.47	0.70	<.01
Body procedure	0.87	0.76	0.99	.03
BMI	1.00	0.99	1.01	.95
Age	1.01	1.00	1.01	.03
Smoking	1.15	0.94	1.41	.16
DM	1.29	0.88	1.87	.19
Combined procedure	1.47	1.29	1.67	<.01
Gender (male)	1.74	1.43	2.11	<.01

ASC, ambulatory surgery center; BMI, body mass index; CI, confidence interval; DM, diabetes mellitus; OBSS, office-based surgical suite.

incidence of complications when performed at OBSS rather than ASCs or hospitals.

Multivariate Analysis

In addition to univariate and stratified analysis, we performed multivariate logistic regression analysis to evaluate the association between type of facility and major complications after adjusting for the effect of age, BMI, smoking, diabetes, gender, type of procedures, and combined procedures. We found that there was a lower risk of developing a complication in an OBSS compared to an ASC (Relative risk (RR) 0.67, 95% confidence interval (CI) 0.59-0.77, $P < .01$) or hospital (RR 0.59, 95% CI 0.52-0.68, $P < .01$) (Table 4). When evaluating individual complication using the same regression model, similar observations were made for hematoma and infection. Risk of hematoma was lower at OBSS compared to ASC (RR 0.57, 95% CI 0.47-0.70, $P < .01$) or hospital (RR 0.57, 95% CI 0.46-0.70, $P < .01$) (Table 5). The relative risk for developing infection in OBSS was 0.71 (95% CI 0.55-0.92, $P = .01$) compared to ASC and 0.74 (95% CI 0.56-0.97, $P = .03$) compared to hospital (Table 6). There was no significant difference between facilities in terms of risk of confirmed VTE. With regards to pulmonary dysfunction and suspected VTE hospitals, but not ASCs, had a higher risk compared to OBSS.

Table 6. Multivariate Logistic Regression for Infection

	Relative Risk	95% CI		*P* value
Gender (male)	0.54	0.36	0.80	<.01
OBSS/ASC	0.71	0.55	0.92	.01
OBSS/hospital	0.74	0.56	0.97	.03
Age	1.01	1.00	1.02	<.01
BMI	1.07	1.06	1.09	<.01
DM	1.58	1.07	2.36	.02
Smoking	1.61	1.24	2.10	<.01
Combined procedure	1.88	1.58	2.23	<.01
Body procedure	2.42	2.00	2.94	<.01

ASC, ambulatory surgery center; BMI, body mass index; CI, confidence interval; DM, diabetes mellitus; OBSS, office-based surgical suite.

DISCUSSION

The practice of outpatient surgery has been around for decades. Natof et al published the first report of outcomes of ambulatory surgery in 1980.[16] Since then, there has been a dramatic increase in procedures performed at ASCs and OBSS. This shift is evident not only in aesthetic surgery but also in subspecialties such as gynecology, urology, vascular surgery, and otolaryngology.[17-21] Unfortunately, there has been a lack of well-designed studies to measure the safety of office-based surgery. While several studies exist, they have been limited to retrospective reviews or surveys. This current study provides data from the prospective CosmetAssure database to evaluate the safety of aesthetic surgery in an OBSS. Furthermore, outcomes in OBSS are compared to ASCs and hospitals, all of which are accredited facilities and the procedures are performed only by ABPS board certified plastic surgeons or ASPS Candidates for Membership who have passed the ABPS Written Examination.

Fleisher et al retrospectively reviewed 564,267 nationally representative Medicare beneficiaries (> 65 years) between 1994 and 1999.[12] They compared mortality, emergency room visits, and hospital admissions between OBSS, ASCs, and hospitals for 16 different types of outpatient surgeries. The majority were general surgery procedures such as umbilical, inguinal or femoral herniorrhaphies, mastectomies, laparoscopic cholecystectomies, etc. Though they found a risk-adjusted increase in hospital admission within 7 days of surgery in OBSS and hospitals compared to ASCs, none of the 16 surgeries were aesthetic surgeries. Thus, their results cannot be generalized to cosmetic surgery patients. Furthermore, Fleisher et al only studied patients over 65 years, which is not representative of aesthetic patients who are typically younger and likely healthier.

Morello et al performed one of the first published studies in 1996 to evaluate safety of office-based surgery in the plastic surgery population.[22] A questionnaire was sent to 418 (57.7% response rate) AAAASF-accredited surgical facilities. From the respondents, 400,675 surgical procedures were tallied between January 1, 1989 and December 31, 1993, of which 63% were aesthetic procedures and the remaining reconstructive procedures. Similar to our study, all respondents were board certified plastic surgeons and operated within an accredited OBSS. Total complications (hemorrhage, hypertensive, wound infection/sepsis, hypotension) were very low (0.47%), as was return to operating room (0.13%) and hospitalization (0.03%). The study demonstrated plastic surgery in accredited OBSS by board-certified plastic surgeons to be safe and very low risk, though selective response to the questionnaire by only those who had low complication rates may have introduced a selection bias. A 6-year retrospective review of 5316 office-based cases, majority being cosmetic surgical procedures, by Byrd et al demonstrated very low complication rates.[23] The complication rates definition by Byrd et al was similar to our study and in their sample 0.73% had reoperation or were hospitalized (compared to 1.3% in our study, though emergency room visit was not included in the Byrd et al study), 0.5% had hematoma (compared to 0.6%), 0.11% had infection (compared to 0.3%), and 0.04% had pulmonary embolus (compared to 0.1% VTE). Furthermore, parallel to this present study hematoma, followed by infection, were the most common complications. Outcomes of these earlier studies are comparable to and support the findings of our study that suggests cosmetic surgery at accredited OBSS is safe. More recent studies using the AAAASF-developed Internet-Based Quality Assurance and Peer Review (IBQAP) database have also demonstrated very low rates of major complications (0.33% to 0.56%) in OBSS.[24,25] Keyes et al reviewed the IBQAP database for mortality in outpatient surgery.[26] In the 1,141,418 procedures performed over 5.5-year period; 23 deaths occurred (0.002%), with the majority (57%) being related to pulmonary embolisms. Other deaths were attributed to postoperative medication abuse (13%), myocardial infarction (8.7%), and other rare events. CosmetAssure does not mandate reporting of deaths. Unless death is preceded by one of the covered major complications, it is unlikely to be reported. Considering this potential limitation, is should be noted that two deaths were reported to CosmetAssure (0.0015%). One occurred in a hospital following a lower body lift and the other in an ASC after combined breast augmentation and liposuction.

The concern about safety of office-based aesthetic procedures first surfaced in a study by Vila et al.[13] Adverse events in office-based procedures were compared to ASCs across several procedural subspecialties using the Florida Board of Medicine adverse incidence reports and Florida Agency for Health Care Administration data. Vila and colleagues reported that there was a significant increase in adverse events and deaths in an office setting. However, this conclusion was quickly refuted by other studies, which pointed out significant methodological flaws in Vila et al analysis.[14,27] Specifically, while Vila et al counted the office surgical deaths from both registered and unregistered offices as incident cases, they only used the number of procedures performed in registered office to calculate the complication rate, thus leading to significant overestimation of death risk. Coldiron and Venkat published several studies in the dermatology literature on safety of office-based surgery using the same Florida databases that were used by Vila et al after addressing their methodological shortcomings.[14,27] The findings of their studies supported the safety of office-based procedures, as they found no statistically significant difference in adverse events compared to ASCs. In a 7-year Florida data follow-up study evaluating outcomes in OBSS alone, Coldiron et al reported that cosmetic procedures contributed to a large portion of adverse outcomes and relayed caution for office-based cosmetic surgery.[28] They reported that cosmetic surgery accounted for 58% (18/31) of deaths and 61% (87/143) of complications. Unfortunately, the proportion of cosmetic procedures to all other procedures in the study was not reported, and therefore should the total number of cosmetic surgeries have accounted for the bulk of all office-based surgeries, even with a low complication rate, the proportion of all major complications attributed to cosmetic surgery would be falsely elevated. It is also worthy of mention that 67% of deaths in Coldiron's study were related to use of general anesthesia, and the majority of cosmetic surgery related deaths were in unaccredited facilities.

It is important to point out that the studies performed by Vila et al, Coldiron et al, and Venkat et al use several different sources to calculate death and adverse event rates between OBSS and ASCs. For example, the "total number of cases" (used as the denominator) for office procedures was estimated from the National Ambulatory Medical Care Survey, while the "number of adverse events" (numerator)

was obtained by the incident reports from the Florida Board of Medicine. Outcomes for ASCs were calculated using different sources than those used for OBSS although the analysis was performed in a similar fashion. As one can imagine, results from these estimates may not be accurate, as demonstrated by the heterogeneity in conclusions between authors. Contrary to these studies, the CosmetAssure database reports incident events from a direct subset of the population at risk, both with a high degree of ascertainment and neither extrapolated from external sources. Our present study demonstrates very low major complication rates in aesthetic surgical procedures performed by board certified plastic surgeons at an accredited OBSS. Contrary to the aforementioned studies, which are limited to data from one state, CosmetAssure is more representative of complication rates across the United States as it is offered in all 50 states. Furthermore, by limiting its source of data to board certified plastic surgeons operating at accredited facilities, CosmetAssure minimizes the heterogeneity that may be introduced from variability of these factors.

In the existing cosmetic plastic surgery literature, several studies have reported the rate of adverse outcomes in OBSS, however without comparing to other types of facilities. This current study takes the reporting of complications a step further by directly comparing these outcomes with those of ASCs and hospitals, on risk adjusted patients, using the same CosmetAssure database. Patients in OBSS were found to fare better than the other two types of facilities in overall complications, hematoma and infection rates. Hospitals had significantly higher occurrence of suspected VTE compared to other facilities but the incidence of confirmed VTE was similar across all facilities. It indicates that patients in hospitals may be subject to a lower threshold when determining the need for VTE workup.

It can be surmised that compared to other facilities, OBSS offer the advantage of cost-effectiveness, increased patient and surgeon convenience, and consistent staffing.[29-32] However, these benefits could be negated if patient safety is compromised with this change in paradigm, given the limited or lack of office-specific regulations. Furthermore, with an aging population and the expected increase in associated comorbidities, we must assure the safety of our patients. The growth in office-based surgery has also been paralleled with an increase in complexity of procedures within these facilities. Intravenous sedation therefore may be inadequate for many of these procedures, resulting in the need for general anesthesia. The question is, does this translate to compromised safety? Hoefflin et al reports no significant anesthetic complications in more than 23,000 consecutive procedures performed in an accredited OBSS.[33] Their study recommends that plastic surgery should be performed at an OBSS which has been properly accredited and appropriately equipped. Unfortunately, in our study, information about the type(s) of anesthesia administered to each patient was not recorded. American Society of Anesthesiologist (ASA) Physical Status class is another important variable that is not available in the database. Patients with significant comorbidities, generally reflected in ASA, may have been preferentially treated in hospitals, thereby possibly contributing to the higher complication rates observed in hospitals. However, the ASA endorses general criteria for patient selection, which should be adhered to irrespective of type of facility. After all, most ASA class III or IV patients are inappropriate candidates for elective cosmetic surgery. Published cosmetic surgery literature demonstrates that the vast majority of patients seeking these procedures are healthy (ASA I and II).[34-36] This is further evident by the fact that the prevalence of risk factors (DM, obesity, smoking) among patients in the CosmetAssure database is significantly lower than in the general population, indicating that patients seeking cosmetic surgery are in better health than the rest of the population.

This present study is the largest, prospective investigation to evaluate the safety of cosmetic surgery in OBSS and compare it to other types of accredited facilities. Our findings demonstrate low major complication rates in OBSS, further adding confidence to the validity of other published literature demonstrating the safety of office-based procedures. In comparing outcomes at OBSS to ASCs and hospitals, factors that may influence outcomes were accounted for such as demographics (BMI, DM, smoking), number of procedures and body region, specifically trunk and extremity procedures as they demonstrated the highest complication rates among all regions evaluated. Furthermore, variability in facility accreditation and board certification was eliminated since all procedures in the CosmetAssure database are performed by ABPS board-certified plastic surgeons or ASPS Candidates for Membership who have passed the ABPS Written Examination at accredited facilities only. This provides a major strength compared to early reports that suggest that office-based cosmetic surgery may not be safe as neither of these factors were adjusted for in those studies. Accordingly, office-based surgery appears to offer advantageous benefits compared to other facilities without compromising patient safety. These findings are reciprocated even in the more complex procedures, as body procedures in this cohort demonstrated similar safety profile. This notion of safety in complex cosmetic surgery is supported by more recent retrospective and literature review studies that demonstrate the safety and effectiveness of abdominoplasty and body contouring performed in OBSS.[36,37]

The CosmetAssure insurance database is a powerful tool for assessment of clinical outcomes of cosmetic surgery. It provides prospectively collected data, which are necessary for determining true incidence of complications and risk factors. It is a multicenter database encompassing hospitals, ASCs and OBSS, making the results generalizable to a wide variety of practice models. Previous studies looking at complications and risk factors often did not differentiate

patients undergoing combined procedures. Our database is robust in establishing baseline complication rates following any procedure combination. A previous study has shown cross-validation of CosmetAssure data with the Tracking Operations and Outcomes for Plastic Surgeons (TOPS) database.[38] Since CosmetAssure offers significant incentive to a surgeon for reporting a complication, in the form of a payment of the claim, this database offers major advantage over TOPS by potentially minimizing the under-reporting of complications. In addition, the dataset is validated by similar patient profiles as that reported by ASAPS.[3]

The database goes a step further by establishing the minimum surgeon qualification (plastic surgeons who are certified by the ABPS or who have passed the ABPS Written Examination), thus avoiding variability in complications attributable to the credentials of the healthcare provider. In today's environment, where cosmetic surgeries are being performed by a variety of healthcare providers, it is essential to demonstrate, and compare, outcomes of these providers with different board affiliations.

While the CosmetAssure database has many advantages, a few of its limitations need to be addressed. The BMI information was missing for 1046 (0.8%) patients in the overall database. We used BMI, along with date of surgery, and date of birth, to create a unique identifier for restructuring the enrollment dataset. Multiple quality control measures were performed to confirm accuracy of the restructuring. It is possible that despite these considerations there may be errors in information on a few patients. Additionally, the database does not register complications occurring after 30 days of the operation. This results in unknown final outcomes after the management of these complications. No information is available on measures such as ASA class, VTE prophylaxis, type of anesthesia, surgical technique, preoperative antibiotics, and duration of surgery and thus their impact cannot be analyzed. Also, even though management of these major complications incur significant costs, it is possible that the plastic surgeon may write it off or be compensated by patient's primary health insurance provider. Either of these scenarios, though very unlikely, may lead to under-reporting of major complications to CosmetAssure. Finally, CosmetAssure is used by a minority of eligible plastic surgeons in the United States.

CONCLUSIONS

In conclusion, OBSS are a reasonable alternative to ASC and hospitals for cosmetic procedures. Accredited OBSS are a safe environment for board-certified plastic surgeons to conduct single, combined, or complex cosmetic surgical procedures. This may translate to reduced costs and better patient satisfaction without compromising safety. However, plastic surgeons should continue to triage their patients carefully for candidacy based on variables such as ASA class and other significant comorbidities that were not measured in this present study.

Disclosures

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