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Surgical site complications after parotid gland surgery for benign tumors in a centralized setting: A Clavien-Dindo class cohort analysis

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ABSTRACT

Background: Surgical resection is the standard of care for parotid gland tumors. Comprehensive reports on the surgical complications of parotidectomy are lacking. This study focuses on surgical wound complications of parotid gland surgery.
Patients and methods: In the period 2002–2012, 390 consecutive patients (395 procedures) who underwent parotid gland surgery were selected for retrospective analysis. Based on subsequent management, the impact of surgical site complications was graded by the Clavien-Dindo Classification (CDC).
Results: In 83 (21.0%) of the procedures, at least one complication was registered. In total, 118 complications were described. Rated to CDC, 61 patients (15.4%) were graded as class 2 or higher. This implies therapy was dictated. Fortyfive (11.4%) of the complications were surgical site infections (SSI). In 9 patients (2.3%) surgical complications required a surgical intervention under general anesthesia (CDC class 3b), and in 19 patients (4.8%) other invasive treatment (CDC class 3a) was needed.
Conclusions: The Clavien-Dindo Classification proved to be very useful for retrospective registration of surgical complications. Of the 61 patients, 33 were managed by conservative therapy. No risk profile was found for patients at risk for direct surgical complications.
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Introduction

Parotid gland tumors are the most frequently occurring neoplasia of the head and neck region, with a reported incidence of 3–4 per 100,000 [1,2]. Roughly 80% of these tumors are benign and they are more frequently located in the superficial lobe of the gland [3]. The standard treatment of both benign and malignant tumors of the parotid gland is surgical resection. For benign disease, the surgical procedure has changed from extirpation of the total gland to today's standard of nerve-conserving partial superficial parotidectomy (PSP) [4].

Although it is one of the commonly performed surgeries, there is no comprehensive report on perioperative complications in the current literature. Many studies have reported on postoperative facial nerve function and the presence of Frey's syndrome [5]. However, surgical site complications are less often and inaccurately described. Table 1 shows a review of literature, selected as of more than 100 patients each, reporting on surgical site complications [6]. They report rates varying from 4% to 40% [1,7]. However, none of these articles have analysis of wound complications as primary objective and they are not comprehensive.

The objective of this study is to analyze and report incidence and management of surgical wound complications. Standardized surgical classification of Clavien-Dindo (CDC) was utilized to ensure uniformity [8].

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Table 1
Literature review of studies with >100 patients, concerning parotidectomy surgical site complications.

Author	Year	Procedures	Hemorrhage	Hematoma	Seroma/sialocele	SSI	Dehiscence	Necrosis	Fistula
Leverstein [14]	1997	246	–	–	–	–	–	–	0.4%
Harney [1]	2002	108	1.9%	–	–	–	–	–	1.9%
O'brien [15]	2003	363	–	3.8%	4.4%	1.9%	–	–	–
Umapathy [16]	2003	168	4.8%	–	–	10.3%	–	–	2.7%
Lim [17]	2003	118	–	–	–	5.9%	–	–	–
Bova [18]	2004	170	–	3.5%	6.6%	2.3%	–	–	–
Guntinas [19]	2006	963	6.0%	–	–	3.0%	–	–	1.0%
Drivas [20]	2007	131	–	1.5%	–	3.0%	–	–	3.1%
Van Lierop [21]	2007	199	3.0%	–	3.0%	5.0%	–	–	2.0%
Upton [22]	2007	237	3.8%	–	–	3.8%	–	–	6.3%
Lin [23]	2008	271	1.5%	2.6%	1.5%	0.7%	–	–	–
Takahama [24]	2009	369	–	–	–	–	–	–	–
Witt [25]	2009	120	–	–	32.5%	–	–	–	6.6%
Ali [2]	2010	112	1.7%	–	1.7%	–	–	–	–
Koch [26]	2010	492	–	–	–	9.3%	–	–	9.1%
Papadogeorgakis [27]	2010	156	–	*12.2%	^8.9%	*12.2%	–	*12.2%	^8.9%
Maddox [28]	2012	341	–	2.3%	6.5%	6.2%	–	–	1.8%

All studies included different forms of parotid surgery and studies are performed with various objectives.
* = combined percentage for these 3 complications. ^ = combined percentage for these 2 complications.

Patients and methods

A retrospective cohort study of consecutive patients, treated between 2002 and 2012 in the Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital is analyzed. To study the exclusive surgical outcomes of pure parotidectomy and not of additional neck dissection, only patients with benign tumors were included.

Both the institutional tumor registry and the registry of surgical procedures were searched.

Patients with malignant tumors (primary or metastasis of other (skin) malignancies) and duplicate entries were excluded. To analyze a uniform group of patients undergoing primary surgery, patients with previous surgery to the parotid area or current infection of the parotid were excluded. This resulted in 395 surgical procedures to the parotid area in 390 patients. In five patients both sides were operated in separate sessions.

Procedures took place at the main hospital or at a collaborative center. All were performed or strictly supervised by a group of ten head and neck surgeons (mean experience >10 years). No standard antibiotic prophylaxis was given. Closed suction drainage (CSD) was used as standard. Anticoagulant therapy was paused preoperatively and after CSD removal restarted. In 2002, patients were admitted the day before surgery and discharged one day after successful CSD removal (i.e. by drain production of $\leq$15 cc per 24 h). This evolved slowly to the current protocol, in which patients were admitted at the day of surgery and are usually dismissed the next day – with CSD in situ.

All medical records were thoroughly examined to register each deviation of the postoperative course, including hemorrhage, hematoma, infection, seroma, dehiscence, necrosis and fistula. Focusing on these wound complications, facial nerve function and Frey's syndrome were not objectives of this study. Subsequently, the management of the complication was recorded and used to grade according to the surgical Clavien-Dindo Classification (CDC), see Table 2. The CDC grades 'backwards' – meaning the complication is graded based on the severity of the required intervention [9,10]. In case of a cascade of complications, grading was based on the most extensive intervention.

Wound infections were classified according to the common Centers for Disease Control definitions of surgical site infection (SSI), i.e. superficial incisional for infection limited to skin and subcutaneous tissue and deep incisional for infection in deeper soft tissue [11].

Fisher's exact test was used to test categorical variables independently for their relation with binary outcomes of complications. Continuous variables were tested by Mann–Whitney *U* test. In order to assess for independent risk factors for a surgical complications dictating therapy (i.e. CDC $\geq$2), multivariable logistic regression was performed by using the backward stepwise selection procedure. And ROC curve and Akaike Information Criterion (AIC) were determined to test for a predictive model, that was subsequently checked by interval internal 10-fold cross validation.

All statistical analyses were performed using Statistical Package for the Social Science (SPSS) version 21.0 (SPSS Inc., Chicago, IL, USA).

Results

In total 390 patients were included for analysis, 220 females and

Table 2
Clavien-Dindo Classification system.

Grade	Definition
1	Any deviation from the normal postoperative course **without** the need for pharmacological **treatment** or surgical, endoscopic, or radiological **interventions**.
2	Requiring pharmacological **treatment with drugs** other than those permitted for grade I complication.
3	**Requiring surgical, endoscopic, or radiological intervention**
3a	Intervention **not under** general anesthesia
3b	Intervention **under** general anesthesia
4	**Life-threatening complication** (including complications of the central nervous system) that requires management in a high dependency or intensive therapy unit
4a	Single organ dysfunction (including dialysis)
4b	Multiorgan dysfunction
5	**Death**

Table 3
Patient characteristics.

Patients	
- Total	390
- Female	220 (56.4%)
- Male	170 (43.6%)
Age (year)	
- Mean (standard deviation)	52.1 (5.3)
- Range	10–87
Tobacco consumption (N = 392)	
- None	229 (58.4%)
- Yes	163 (41.6%)
Alcohol consumption (N = 391)	
- None	110 (28.1%)
- Yes	281 (71.9%)
ASA score (N = 394)	
- I	242 (61.4%)
- II	137 (34.8%)
- III	14 (3.6%)
- IV	1 (0.3%)
Diabetes mellitus	33 (8.4%)
Cardiovascular disease	69 (17.5%)
Procedures (number)	395
Location of tumor (N = 395)	
- Superficial lobe	323 (81.8%)
- Deep lobe	72 18.2%)
Size of tumor (millimeters) (N = 381)	
- Mean (standard deviation)	22.8 (10.6)
- Range	7.0–30.0
Histology (N = 395)	
- Pleiomorphic adenoma	246 (62.3%)
- Warthin's tumor	120 (30.4%)
- Other adenoma	14 (3.5%)
- Myoepithelioma	9 (2.3%)
- Oncocytoma	4 (1.0%)
- Other	2 (0.5%)
Type of incision (N = 357)	
- Cervicomastoidfacial	315 (88.2%)
- Facelift	42 (11.8%)
Duration of surgery (minutes) (N = 222)	
- Mean (standard deviation)	152.0 (52.8)
- Range	44–425

Overview of characteristics of patients, tumor and surgery.

170 males and a total of 395 procedures were studied (Table 3). Mean age at time of surgery was 52.1 years, with a range of 10–87 years.

Complications

Postoperative course was complicated in 83 (21.0%) of the 395 procedures. Fifty-five of these procedures had only one complication and in 22 cases two complications were registered. In total, 118 complications were recorded (Table 4). Fortyfive (11.4%) of the procedures were complicated by an SSI, mostly superficial incisional infections (N = 33). Oral antibiotics were sufficient in 42 of the total of 45 infections. In 12 patients, the SSI was part of a cascade of complications.

Eleven (2.8%) patients suffered from postoperative bleeding. Nine required re-intervention under general anesthesia (i.e. CDC 3b). The other two bleedings were managed conservatively, yet the following hematoma still required percutaneous drainage (i.e. CDC 3a). In a total of 16 (4.1%) procedures a hematoma developed, 6 of them (including above mentioned) required percutaneous drainage. No significant relation to the use of anticoagulants was seen.

Percutaneous drainage was also necessary in 13 of the 16 (4.1%) seroma/sialocele patients (amylase was not tested for all). And four patients needed fibrin glue injections to enhance tissue layer adherence. Twenty (5.1%) patients developed a (salivary) fistula postoperatively. One was the consequence of a malfunctioning CSD,

Table 4
Overview of complications.

Clavien-Dindo (N = 395)	
Clavien-Dindo Classification	
- Grade 1	334 (84.6%)
- Grade ≥2*	*61 (15.4%)*
- Grade 2	33 (8.4%)
- Grade 3a	19 (4.8%)
- Grade 3b	9 (2.3%)
Types of complication	
Hemorrhage	11 (2.8%)
Hematoma	16 (4.1%)
Seroma	16 4.1%)
Surgical Site Infection	
- Total	*45 (11.4%)*
- Superficial	33 (8.4%)
- Deep	9 (2.3%)
- Organ	0 (0%)
- Unknown	3 (0.8%)
Wound dehiscence	9 (2.3%)
Skinflap necrosis	1 (0.3%)
Fistula	20 (5.1%)
Total complications^	118

* Grade ≥2 implies complication requiring treatment.
^ Total number of complications higher than complicated procedures due to multiple complications per procedure.

another required secondary CSD placement. Dehiscence of the wound was noticeable in nine (2.3%) patients; in three of them conservative care was sufficient (i.e. CDC 1), in others the dehiscence occurred as part of a cascade of complications. Partial necrosis of skin flap occurred in one patient – subsequently after infection.

By using therapies, the complications were translated to a Clavien-Dindo grade per patient. Intervention requiring complications – CDC class 2 or higher – were seen in 61 patients (15.4%). Thirty-three patients (8.4% of total population) received pharmacological treatment (CDC 2), while 28 (7.1%) patients needed invasive intervention. Most of the interventions (N = 19, 4.8%) did not require general anesthesia, however in 9 patients (2.3%) general anesthesia (CDC 3b) was required.

Risk factors

Most patients were ASA scale grade I (61.4%) and grade 2 (34.8%). An ASA score of 2 or higher, was associated with an CDC grade of 2 or higher (p = 0.045; Table 5).

Hundred and sixty three patients (41.3%) were active tobacco consumers. Though, complications (i.e. CDC ≥2) were not more frequent in this population.

The mean tumor diameter was 22.8 mm and 81.6% of them were located in the superficial lobe. Deep lobe tumors required a longer surgery (148 versus 101 min, p = <0.001). However, tumor size (p = 0.527) and location (p = 1.000) were in this study not

Table 5
Patient and tumor characteristics versus complication by Clavien Dindo Classification.

Characteristic	CDC 1 (N = 334)	CDC ≥2 (N = 61)	P
Age (mean in years)	51.8	53.7	0.318 *
Tobacco consumption (yes)	140 (42.3%)	23 (37.7%)	0.573 ^
Alcohol consumption (yes)	233 (70.2%)	48 (81.4%)	0.085 ^
ASA (≥2)	121 (36.3%)	31 (50.8%)	0.045 ^
Diabetes mellitus (yes)	26 (7.9%)	7 (11.5%)	0.323 ^
Tumor size (mean in cm)	2.30	2.17	0.527 *
Lobe (deep)	61 (18.3%)	11 (18.0%)	1.00 ^
Incision (modified facelift)	31 (10.3%)	11 (20.0%)	0.065 ^

* Mann-Whitney *U* test, ^ Fisher exact test.

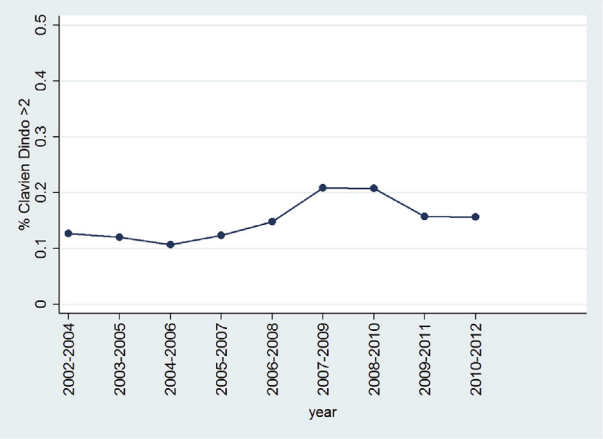

Fig. 1. Smoothed 3-year period incidence of Clavien-Dindo class ≥2.
Running means of incidence of complications graded Clavien-Dindo 2 or higher per 3-year interval.

correlated to a CDC ≥2.

Cervico-mastoid-facial (CMF) incision was the approach of choice in 315 patients (79.7%), while 42 patients (10.6%) underwent the procedure per rhytidectomy or modified facelift (MF) incision. Younger age was significantly more often related with the MF incision (Mann Whitney *U* test, p = 0.005). MF incision showed a higher level of SSI (Fisher test, p = 0.014). Yet, it did not result in a significant difference in interventions, graded by CDC ≥2.

Multivariable logistic regression was performed for both CDC ≥2 and for SSI. Selecting the clinically more important variables, models were created. However, by internal validation they proved to be of low prognostic value (figure not shown).

Admission

Mean post-surgery hospital admission time for the whole period was 2.57 days, ranging from 1 to 7 days (N = 378). For the year 2002 mean admission duration was 3.09 days (range 2–4 days), compared to 2.20 days (range 2–5) for 2012. Testing mean and median hospital admission time by resulted in a significant difference per year (ANOVA, p = <0.001; Kruskal Wallis, p = <0.001).

In spite of this reduction in admission time, not significantly more complications (both CDC ≥2 and overall surgical site complications) were seen over the years (per 2 year linear-by-linear association, p = 0.16 and p = 0.26). The incidence of CDC ≥2 was smoothed per 3-year period in Fig. 1. It shows no clear linear trend.

Discussion

Although parotid gland surgery has been universally performed for many years, a glance at Table 1 demonstrates the lack of consistent registration of complications and thereby the inability of literature comparison.

One of the disadvantages inherent to retrospective studies is the lack of integrity of data. Our study overcomes this problem by making use of the corresponding management, graded by the standard surgical Clavien-Dindo Classification. In the context of medical legislation, therapy always needs to be registered in patient's records, also when concerning a complication. Using therapies lead to a very reliable registration, without any misinterpretation of complications. A secondary benefit is that the use of therapy helps to classify the severity of the complications. E.g., a small wound hematoma without further consequences for the healing process is differently graded than a hematoma requiring drainage or resulting into a SSI.

Although rarely used in head and neck surgery, CDC has become the standard tool to classify surgical complications, due to its reliability [9,10,12,13].

In this study, a gross surgical site complication rate of 21% is found. However, transformed by CDC to clinically relevant complications, a rate of 15.4% is seen. As stated above, it is difficult to place this result in the varying incidences of literature.

The (superficial) surgical site infection was most common in this study (11.4%), often easily managed by oral antibiotics. In 4.8%, a local intervention such as needle drainage or fibrin glue injection was needed, while only nine complications (2.8%) dictated re-intervention under general anesthesia. Besides ASA score ≥2, no other variables tested an elevated risk of complications. Combining these variables for modeling towards risk identification did not result in a suitable model for our data. Therefore, no specific risk group was found to prescribe antibiotics to reduce the 11.4% SSI.

Patient counseling is important prior to surgery. In this study a MF incision showed more SSI's, a finding not earlier described in literature. However, MF incision required not significantly more interventions. Facial nerve function was no objective of this study, however, no inadvertent permanent function loss was seen. Since we did not routinely test for Frey's syndrome by iodine-starch test, we deem these figures do not contribute to the already wide variety of incidences in literature.

Over years the admission time was reduced to almost one day post-surgery, without influencing the incidence of complications (CDC ≥2).

Conclusion

This study is primarily conducted to report on surgical site complications, with a stable incidence as outcome. Therefore, it should be the new standard reference regarding complications after parotid gland surgery. Because two-thirds of these complications are SSI's, it is important for patient counseling to mention that most of them are well treated by oral antibiotics.

Transformation to more selective resection and shortened hospital admission did not lead to more complications in our population. This will pave the way to safely try further strategies making the procedure more patient friendly, e.g. by day-care or even drainless surgery.

The standardized Clavien-Dindo Classification proved in this study to be very useful to evade the difficulties of retrospective data collecting, making it a convenient tool to obtain uniformity and reliability in complication grading and thereby for inter-study comparison. We propose to make it the standard in complication registration, not only for parotidectomy but for all head and neck surgery, retrospective and prospective [9].

Declaration of competing interest

We have no conflict of interest.

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