European Annals of Otorhinolaryngology, Head and Neck diseases (2010) **127**, 2—6

Available online at ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com

ORIGINAL CLINICAL RESEARCH

Surgical-site infections and surgery of the salivary glands

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Available online 24 March 2010

KEYWORDS
Surgical-site infection;
Case-control;
Salivary gland surgery

Summary
Objectives: To determine the surgical-site infection (SSI) incidence rate targeted on salivary gland surgery over a 2-year period (from January 2007 to December 2008). Then identify any risk factors associated with SSI in all the patients operated with no antibiotic prophylaxis in accordance with French Anesthesiology Society guidelines.
Population and methods: Ninety-three patients were operated during the standard SSI surveillance period. A case-control (one case for five controls) study was then conducted aiming to identify risk factors.
Results: The SSI incidence rate was 9.7%. The case-control study failed to identify any relevant risk factor with univariate analysis.
Conclusion: As no risk factors could be identified, we suggest that surgical antibioprophylaxis could be relevant in salivary glands surgery and should be evaluated in this setting.

Introduction

Within the surgical-site infection (SSI) monitoring program proposed by the Nosocomial Infection Alert, Investigation, and Monitoring French Network and the Professional Practices Assessment Program (Réseau d'alerte, d'investigation et de surveillance des infections nosocomiales; RAISIN) defined at the Toulouse University Hospital, the ENT surgical team opted for targeted monitoring of salivary gland surgery.

Today's RAISIN database has no French data specific to this type of surgery, with the head and neck incidence rate at 0.7% for head and neck surgeries on noncancerous lesions and 7.5% for cervicofacial oncology surgeries, including the pharynx/larynx and trachea [1]. The rare data found in the literature report SSI rates varying from 0 to 7%.

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1879-7296/$ – see front matter © 2010 Published by Elsevier Masson SAS.
doi:10.1016/j.anorl.2010.02.001

The objective of this study was first to assess the incidence of SSIs after salivary gland surgery and then in a second phase to search for possible risk factors associated with SSIs.

We report the results of each of these two phases.

Population and methods

Monitoring surgical-site infection

The methodology and the data collection materials were designed by RAISIN [2]; the study's objective was to include 100 consecutive patients. The intraoperative data (type of surgery, contamination class, American Society of Anesthesiologists [ASA] score, and duration of surgery [from incision to closure, in minutes]) were collected in the operating room; the follow-up (presence of a SSI and if so its characteristics, date of last contact) was carried out by the referring surgeon in liaison with colleagues. A SSI is an infection occurring within 30 days following the intervention [2]. The SSI diagnostic criteria retained in the study were essentially the presence of signs of local infection such as pain, redness, heat, purulent discharge with or without collection, sometimes associated with general signs such as fever. Bacterial samples were not collected systematically, but they are not indispensable to confirm a SSI. Exhaustivity was verified by comparison with operative lists of the corresponding period.

Inclusion in the study began on 15 January 2007 and ended on 31st December 2008, with the objective of including 100 interventions.

Data entry and analysis were carried out using EPIINFO software made available by RAISIN. In absence of specific references for salivary gland surgery, the National Nosocomial Infection Surveillance (NNIS) score was calculated taking the 75th percentile as the surgery duration parameter, as found in the longitudinal monitoring database.

For practical reasons, inclusions were stopped on 31st December 2008, in agreement with the surgical team. Possible risk factors were then sought through a case-control analysis.

Case-control study

In the database established throughout the longitudinal monitoring process, the controls were randomly selected, with a maximum of five controls for every case.

A data collection tool was elaborated specifically to record the following information:

- the usual criteria: age, sex, date of surgery, duration of surgery, ASA anesthetic score, and contamination class;
- specific data on the patient (initial disease based on the pathology, examination of the excised specimen, associated pathologies such as diabetes, medications modifying hemostasis, a history of radio- or chemotherapy), data on the surgical intervention (surgeon, type of surgery [submaxillectomy, partial parotidectomy, total parotidectomy, ligature of the salivary canal, existence or absence of hematoma]), place of preoperative cutaneous debridement (unit or operating room) and the product used, need for surgical revision the same day as the intervention, presence of bleeding and/or inflammation, and presence of edema;
- the NNIS score calculated based on three parameters: the ASA score, the contamination class, and the duration of the intervention.

The statistical analysis was done using STATA 9.2 SE software. We conducted a bivariate analysis between the confounding factors and the dependent variables and the endpoint (the presence of a SSI). The confounding factors chosen were age, sex, and diabetes and correspond to patient characteristics. These confounding factors are factors that, although not directly influential factors, have a probable influence that can lead to confounding bias. The factors studied were initial disease, taking medications modifying hemostasis, history of radio- or chemotherapy, the NNIS score, and the factors relative to the surgical intervention. The means of the quantitative variables (age and duration of surgery) were compared using the Student *t*-test or a Wilcoxon's nonparametric test; the distributions of the qualitative variables were compared using the Chi^2 test or the Fisher's exact test. A multivariate analysis (logistic regression) was planned taking into account the factors associated with the onset of a SSI with significance set at $P < 0.25$ in bivariate analysis.

Results

Longitudinal study

On 31st December 2008, 93 interventions on the salivary glands had been included, with 42 interventions in 2007 and 51 interventions in 2008.

The patients' mean age was 56 ± 18 years, the sex ratio was 1.7:

- 27% of the patients were classified ASA 1;
- 53% were classified ASA 2;
- 20% were classified ASA 3.

The 75th percentile was defined at 123 min. The NNIS score was distributed as follows:

- 34%, NNIS 0;
- 49%, NNIS 1;
- 15%, NNIS 2;
- 2%, NNIS 3.

Seventy-seven interventions involved the parotids and 16 the submandibular glands. Twenty-four interventions followed cancer, 34 pleomorphous adenoma, 23 another benign tumor, and 12 lithiasis.

Nine SSIs occurred, leading to an overall SSI rate of 9.7% (95% confidence interval [95% CI]: 4.5; 17.6); this rate was 9% (95% CI: 3.7; 17.8) for parotid surgery and 13% (95% CI: 1.6; 38.3) for submandibular gland surgery.

The mean time to SSI was 26 ± 34 days. Of the nine SSIs, five (55.6%) occurred within 8 days, two between 8 and 30 days, and two later; the latter two were nonetheless

Table 1 Bivariate analysis according to confounding factors.

	Controls ($n=47$)		Cases ($n=9$)		P^{a}
	n	%	n	%	
Age (years)					
18–54	18	38.3	1	11.1	0.097
55–66	13	27.7	6	66.7	
67–85	16	34.0	2	22.2	
Sex					
Male	30	63.8	7	77.8	0.70
Female	17	36.2	2	22.2	
Diabetes	4	8.5	1	11.1	1.00

[a] Fisher's exact test.

retained because they were authenticated by the surgeons (excluding them, the overall SSI rate would be 7.5% [95% CI: 3.1; 14.9]). Five SSIs required surgical revision. From the bacteriological point of view, *Staphylococcus aureus* was found in two cases, *Streptococcus intermedius* in one case, *Streptococcus milleri* in one case, and *Corynebacterium* spp. in one case; the four remaining cases had no microbiological documentation.

Search for risk factors

Nine infected patients were compared to 47 randomly selected noninfected controls (1:5 controls).

Fifty-six patients were studied: 66% males and 34% females. In the infected patients, the mean age was 60.9 ± 10.3 years and in the controls the mean age was 57.7 ± 17.1 years (range: 18–85 years). The mean duration of surgery was 159.8 ± 84.4 min for the cases and 165.6 ± 98.7 min for the controls.

None of the 56 patients had preoperative antibiotic treatment.

Confounding factors

Of the possible confounding factors, there was no significant difference between the cases and the controls for mean age (60.9 years vs. 57.7 years; $P=0.94$) or presence of diabetes. The bivariate analysis of the confounding factors is presented in Table 1.

The dependent variables

Of the dependent variables, an inflammatory syndrome and the presence of a hematoma or an edema were more frequently found in the infected patients. All the other dependent variables did not show a significant difference between cases and controls. The bivariate analysis of the factors studied is presented in Table 2.

After adjustment for age, the probability of SSI onset was more frequent in presence of edema/hematoma or an inflammatory syndrome, with odds ratios (OR) of 11.6 (95% CI: 1.8; 72.3) and 20.4 (95% CI: 2.0; 219.9), respectively. These measures were not adjusted for the NNIS score or the contamination class because of the imbalance in the distribution of these two variables.

Discussion

Salivary gland surgery is rarely individualized within head and neck surgeries in the databases constructed based on the required monitoring data; it accounts for only a small part of the activity in our unit and therefore a long inclusion period was used in the study, although this did not solve the study's problems of statistical power.

The overall SSI rate, 9.7%, would have been 7.5% if two of the SSIs had been excluded because of delayed onset longer than 30 days for surgery that did not involve implantation of foreign material, which placed the SSI rate in this study at the upper limit of the rates reported in the literature, 3–7% [3,4] for varied head and neck surgeries. More specifically for salivary gland surgery, two retrospective studies are interesting. One reports 325 interventions and found a 0.9% infection rate for parotidectomies and 1% for submandibulectomies [5]; however, nearly one-fourth of the patients received antibiotics in the perioperative period. The other, covering a period of 11 years, on parotid and benign tumor surgery, reported a 7% infection rate [6] and identification of three independent risk factors: ligature of the salivary canal, total ablation of the parotid gland, and patient age greater than 60 years, factors that we were not able to identify, perhaps because of insufficient statistical power in our study.

Malignant tumors account for approximately 8–18% of salivary gland tumors [7]. Of the benign tumors, pleomorphous adenomas account for more than 50% of the parotid tumors and are observed at all ages, with a maximum frequency between 30 and 60 years, with no predominance of either sex; cystadenolymphomas, or Warthin's tumors, account for 5–10% of the parotid tumors [7]. Parotid tumors account for 90% of the salivary gland tumors [8].

Salivary lithiases are frequent ailments; submandibular lithiasis is by far the most often encountered and is observed at all ages. It very frequently presents infectious signs [7]. Therefore, submandibulectomies are infected more often than parotidectomies.

Previous chemotherapy is also a risk factor for postoperative infection [9–11].

The contamination class (clean for parotidectomies and clean-contaminated for submandibulectomies), the duration of surgery, and the ASA score are independent risk factors of SSI onset, grouped in a NNIS score that is highly predictive of SSI [12]. In our study, the NNIS score did not differ between infected and noninfected patients, with most patients in the NNIS 0 category, an even stronger indication given that 75th percentile value was calculated on the population of cases and controls, making this parameter less discriminatory. The only factors that we observed to be significantly associated with infection were the presence of an inflammatory syndrome and the presence of hematoma or edema. These two factors are highly related and finally only announce infection, since the conditions for infection to develop are undoubtedly already present: should they lead to implementing probabilistic curative antibiotic therapy?

Hematoma and edema are associated with SSI; however, they are noted after the intervention and are more a symptom of the infectious complication of the surgical site than an associated risk factor and also have no predictive value.

Table 2 Bivariate analysis according to dependent factors.

	Controls			Cases			P[a]
	n	*N*	%	*n*	*N*	%	
Disease							
Cancer	8	47	17.0	2	9	22.2	0.78
Pleomorphous adenoma	17	47	36.2	2	9	22.2	
Benign tumor	15	47	31.9	3	9	33.3	
Lithiasis	7	47	14.9	2	9	22.2	
Experienced operator	31	47	66.0	5	9	55.6	0.71
Debridement in operating room	5	47	9.6	1	9	11.1	1.00
Type of surgery							
SM	9	47	19.1	2	9	22.2	1.00
PP	9	47	19.1	2	9	22.2	
PT	29	47	61.7	5	9	55.6	
Side of surgery							
Right	25	44[b]	56.8	4	8	50.0	1.00
Left	19	44[b]	43.2	4	8	50.0	
Class of contamination							
1	45	47	95.7	8	9	88.9	0.18
2	2	47	4.3	0	9	0.0	
3	0	47	0.0	1	9	11.1	
4	0	47	0.0	0	9	0.0	
NNIS score							
0	19	47	40.4	4	9	44.4	0.20
1	20	47	42.6	4	9	44.4	
2	8	47	17.0	0	9	0.0	
3	0	47	0.0	1	9	11.1	
Salivary canal ligature	5	47	10.6	1	9	11.1	1.00
Hematoma/edema	6	47	12.8	5	9	55.6	0.01
Any change in hemostasis	10	47	21.3	3	9	33.3	0.42
Bleeding	6	47	12.8	2	9	22.2	0.60
Inflammatory syndrome	7	47	14.9	5	9	55.6	0.02
		N	$m \pm \sigma$		*N*	$m \pm \sigma$	P[c]
Duration of intervention (min)		47	165.6 ± 98.7		9	159.8 ± 84.4	0.97

SM: submaxillectomy; PP: partial parotidectomy; PT: total parotidectomy; NNIS: National Nosocomial Infection Surveillance; ttt: treatment.
[a] Fisher's exact test.
[b] For three patients, the side of surgery was unknown
[c] Wilcoxon's test.

With the exception of advancing the indications for preoperative antibiotic prophylaxis [13], our study did not provide the means for improving preventive strategies. However, the awareness campaign at the beginning of 2008 aimed at the surgical team through the dissemination of the results for 2007 had a positive effect (six out of 43 SSI patients in 2007, three out of 50 in 2008) [14].

Conclusion

This study found the SSI incidence rate following salivary gland surgery close to the rates reported in the literature but did not identify particular risk factors. The lack of statistical power stemming from the small numbers of infections found could easily be resolved in a multicenter study. Finally, this study raises the question of the benefit of preoperative antibiotic prophylaxis in this type of surgery, particularly in submandibulectomies for lithiasis.

Conflict of interest statement

The authors have not communicated conflicts of interest.

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