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Patient safety with orthognathic surgery in an outpatient setting

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Abstract. Orthognathic surgery is traditionally performed in inpatient care. The question is whether patient safety is maintained when orthognathic surgery is performed in outpatient care. This retrospective cohort study was conducted to investigate patient safety in selected single-jaw orthognathic surgeries performed in outpatient care compared to inpatient care. Postoperative infection, postoperative bleeding, postoperative pain, plate removal, and re-operation, as well as emergency visits/phone calls and postoperative admission during the first 12 months after surgery were recorded. Predictor variables were sex, age, smoking, general disease, antibiotics, operation type, and operation time. Of the 165 patients included, 58 were treated in inpatient care and 107 in outpatient care. No significant difference was found between the groups regarding postoperative bleeding, pain, plate removal, re-operation, or emergency visits/phone calls. Ninety-four percent of outpatients (n = 101) were able to leave the hospital on the day of surgery as planned. There was an increased risk of postoperative infection in the outpatient care group (odds ratio 2.46, P = 0.049). Selected single-jaw orthognathic surgery can be performed in the outpatient setting, with maintained patient safety. The reason for the increased risk of postoperative infection among patients operated in outpatient care should be investigated in further studies.

Keywords: Orthognathic surgery; Outpatient care; Ambulatory care; Day care; Inpatients; Patient safety; Postoperative complications.

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For patients with large dentofacial deformities, a combination of orthodontic treatment and orthognathic surgery may be required to achieve a good and sustainable outcome.[1–3] The skeletal deviation can be corrected with surgery to either the maxilla, the mandible, or both jaws. Midfacial deformities are often corrected with a Le Fort I osteotomy (LFI), while deformities in the lower jaw can be corrected with a vertical ramus osteotomy or bilateral sagittal split osteotomy (BSSO).[4–8] The surgery is performed under general anaesthesia, either as a single-jaw or bimaxillary procedure.

In Sweden, orthognathic surgery is traditionally performed in an inpatient care setting, with the patient normally remaining hospitalized for 1–2 days after the surgery. More recently, in the Department of Oral and Maxillofacial Surgery at Karolinska University Hospital (KUH), selected single-jaw orthognathic interventions have been performed in an outpatient care setting. This move to the outpatient setting occurred as a result of recent changes in the handling of selected single-jaw interventions in Sweden. To ensure

patient safety, experience from other surgical specialties points to the need for specific anaesthesia management adapted for outpatients.[9] Moreover, standardized care programmes with clear discharge criteria are required, and the patients and relatives should be well informed. Previous studies reviewing orthognathic cases treated in outpatient care have reported satisfied patients and few unexpected complications.[10,11]

Since outpatient single-jaw orthognathic surgery is a relatively new way of managing skeletal malocclusion in Sweden, it is imperative to evaluate the treatments carried out. The aim of this study was therefore to investigate patient safety when performing orthognathic surgery in an outpatient setting compared with inpatient care, with the hypothesis that selected orthognathic surgery procedures can be performed in outpatient care with maintained patient safety.

Materials and methods

Study design

This retrospective cohort study investigated patient safety when performing orthognathic surgery in an outpatient setting compared with inpatient care. The orthognathic surgery procedures included BSSO, LFI, and surgically assisted rapid maxillary expansion (SARME) performed under general anaesthesia and as a single-jaw procedure.

Study population

The study population consisted of two exposure groups: a study group that included outpatient surgeries conducted between June 2014 and December 2017 and a control group that consisted of inpatient surgeries conducted between May 2012 and May 2014. Patients who underwent orthognathic surgery in the Department of Oral and Maxillofacial Surgery at Karolinska University Hospital (KUH) between May 2012 and December 2017 were identified through the surgical planning program Orbit (TietoEVRY, Espoo, Finland) and patient record system CGM TakeCare (CompuGroup Medical, Koblenz, Germany). The orthognathic surgeries were performed at KUH Huddinge and KUH Solna – the two different clinical sites of the hospital. The outpatient surgery department was at KUH Huddinge. To reduce the risk of bias, only the inpatient care patients operated in KUH Huddinge were selected for the study.

Inclusion criteria were single-jaw procedures (i.e., SARME, LFI, and BSSO), consent for outpatient surgery, medical history ASA I or II (American Society of Anesthesiologists), patient socially and psychologically capable of managing and cooperating with the planned treatment, well-informed family members, and stable home circumstances. Reasons for exclusion were age less than 16 years, segmental maxillary surgery in combination with LFI osteotomy, vertical ramus osteotomy, genioplasty, bimaxillary surgery, and compromised medical history (ASA III or more).

The primary outcome was patient safety, including complications, emergency visits/phone calls, admission of an outpatient surgery patient to the hospital, and readmission of an already discharged patient. Complications included postoperative infection (localized swelling, redness, purulent drainage, or wound dehiscence, and conditions that required antibiotic therapy), postoperative bleeding (bleeding that occurred after surgery and that needed surgical packing or revision surgery to find the source and perform haemostasis), postoperative pain (uncontrolled pain with prescribed analgesics and in need of dose adjustment or in need of an additional prescription), plate removal, and reoperation. The study period for the safety evaluation was the first 12 months after surgery. Patient data regarding complications were retrieved from the patient records.

Other recorded variables were sex, age in years at the time of the operation, smoking (yes or no), general disease (yes or no), antibiotics (type and dose the day of surgery), operation type (SARME, LFI, or BSSO), and duration of the operation (minutes).

Patients treated in inpatient care underwent surgery in the Central Operation Department at KUH Huddinge and were monitored in a nearby recovery ward before being transported to the inpatient ward for overnight observation.

Patients treated in the outpatient setting underwent surgery in the Department of Outpatient Surgery co-located with the Department of Oral and Maxillofacial Surgery, KUH Huddinge. The operation room was fully equipped for orthognathic surgery and for anaesthetic care.

The patients received intravenous (IV) antibiotic prophylaxis within 30 min before surgery: 3 g benzylpenicillin (or 600 mg clindamycin if allergic to penicillin) initially and then every 8 h for the first 24 h. The majority of patients operated in outpatient care received one or two doses of antibiotic, while most patients in the inpatient care group received three or four doses of IV antibiotic.

After the operation in outpatient care, the patient was transported to a recovery room nearby. A nurse regularly monitored vital signs, physical signs, and oxygen saturation. Before leaving the hospital for home, the patient was evaluated by the anaesthesiologist and the responsible surgeon. The criteria for discharge were as follows: completely awake patient oriented in person, place and time, pain intensity manageable in a home setting, oxygen saturation > 92% without oxygen, adequate nutrition orally, and no difficulty in urinating. In addition to these discharge criteria, the patient had to be willing and motivated to go home, be able to follow postoperative instructions, and have an escort home to provide adequate home care. Patients who did not meet the discharge criteria were kept under observation for another 1–3 h on the inpatient ward or were transferred to inpatient care and remained on the ward overnight.

All patients operated in the inpatient and outpatient care setting received prescriptions for postoperative medication, written postoperative information, the phone number of the oral and maxillofacial surgeon on call, and a follow-up appointment within 1–2 weeks. The prescribed postoperative medications were mainly paracetamol, non-steroidal anti-inflammatory drugs (NSAID), and short-term opioids or morphine. No postoperative antibiotics were prescribed routinely.

Statistical analyses

The associations between inpatient and outpatient care and the outcome variables were analysed using the χ^2 test and binary logistic regression analysis. Odds ratios (OR) were calculated with a confidence interval of 95% (95% CI). Statistical significance was defined as a *P*-value less than 0.05 for both statistical tests. Inpatient and outpatient were the main exposure variable, and

adjustment was made for sex, age, smoking, general disease, antibiotics, operation type, and duration of the operation. Age, antibiotics, and operation time were each categorized into three groups: age into 16–19 years, 20–29 years, and 30–59 years, antibiotics into one dose IV, two doses IV, and three or four doses IV, and operation time into 41–102 min, 103–134 min, and 135–224 min. The differences between the study variables for inpatient care and outpatient care were tested with the Pearson χ^2 test for the categorical variables, and with the independent samples *t*-test for the continuous variables. For missing data on smoking, multiple imputation was used (five times). All statistical analyses were performed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA).

Results

Between May 2012 and December 2017, 870 patients were operated in the Department of Oral and Maxillofacial Surgery at KUH, of whom 165 met the inclusion criteria; 58 of these patients were treated in inpatient care and 107 in an outpatient setting. Fig. 1 shows a flowchart of the study population. Descriptive data for the study population are presented in Table 1.

Data on smoking were missing for seven patients (4.2%), all in the inpatient care group. To address the missing data, multiple imputation was used. Missing values for the covariate smoking were assumed to be missing at random, and multiple imputation was used to impute missing data (five imputations). The Markov chain Monte Carlo (MCMC) method was used during the imputation and all covariates were included.[12,13]

All but one patient in the inpatient group received antibiotics before surgery. In the inpatient group, the majority received three to four doses of IV antibiotics on the day of surgery (first 24 h), while the majority in the outpatient group received one to two doses ($P < 0.001$).

The study period for follow-up was 12 months. Data were collected for 12 months after surgery or to the first journal record 12 months after surgery. Patients who underwent SARME were only followed up for a few weeks postoperatively until the orthodontist took over the responsibility for further treatment. A total of 13 patients were treated with SARME, four patients in inpatient care and nine patients in outpatient care. Thirteen of the 165 patients (7.9%) were missing from the final control, six patients in the inpatient group and seven patients in the outpatient group. Three patients had moved away from Stockholm at the time for follow-up and 10 patients did not turn up.

The association between inpatient and outpatient care and the primary outcome variables (complications, emergency visits, and phone calls) are presented in Tables 2 and 3. A significantly higher incidence of postoperative infection ($P = 0.029$) was found in the outpatient care group, while there was a higher incidence of postoperative pain ($P = 0.035$) in the inpatient care group (Table 2). A postoperative infection had developed in 24.1% of the inpatient care group compared to 41.1% of the outpatient care group after 12 months of follow-up. All infections were regarded as uncomplicated and were easily handled with antibiotics alone or together with drainage, and without an impact on the surgical outcome. Postoperative pain was registered in 15.5% of the inpatient care group and 5.6% of the outpatient care group.

The risk of developing a postoperative infection was significantly higher for patients in the outpatient care group when compared to those in inpatient care in both the unadjusted and adjusted analysis (crude OR 2.20, $P = 0.031$; adjusted OR 2.46, $P = 0.049$), while the risk of postoperative pain was significantly lower in the outpatient group when compared to the inpatient group in the unadjusted analysis (crude OR 0.32, $P = 0.042$) (Table 3). No significant difference in the risk of postoperative bleeding, plate removal, re-operation, emergency visit, or emergency phone call was observed between the inpatient and outpatient care groups.

Of the 107 patients treated in the outpatient setting, 97 (90.7%) could be discharged home within office hours on the day of surgery. Four patients (3.7%) did not meet the discharge criteria and were admitted to the ward. After recovering for 1–2 h on the ward, they were able to go home. Overall, 101 of the 107 patients (94.4%) were able to leave the hospital on the day of surgery as planned. The other six patients (5.6%) needed full hospital admission and stayed overnight. The patients in inpatient care were discharged home 1–3 days after surgery. Two of the 58 patients (3.4%) treated in inpatient care were readmitted within the first 2 weeks after surgery due to postoperative nausea and vomiting and postoperative infection. The assessment of patient safety and risk linked to the type of care is presented in Table 3.

Discussion

As modern healthcare faces growing patient volumes and limited economic means, organizational changes to patient care may be needed to increase the efficiency of care, reduce the time from diagnosis to surgical treatment, and streamline the use of resources. These types of changes to patient care, however, require meticulous follow-up to ensure that patient safety and treatment outcomes are maintained. In Sweden, patients undergoing orthognathic surgery have routinely been admitted to hospital for 24–48 h of postoperative observation. Tradition rather than evidence-based concern for serious postoperative complications has been the strongest argument for this precaution. A reorganization at KUH based around patient value care called for many surgical procedures, including selected orthognathic procedures, to be moved from inpatient care to an outpatient setting. The purpose of the current study was to investigate whether patient safety has been maintained when orthognathic surgery has been performed in an outpatient care setting.

The results of this study showed no significant difference between patients operated in inpatient care and those operated in outpatient care regarding emergency visits and calls, re-operations, plate removal, or postoperative bleeding. However, the risk of developing a postoperative infection was higher in patients operated in outpatient care than in those operated in inpatient care. Moreover, the risk of postoperative infection in patients operated in the outpatient setting was higher after BSSO (OR 3.96, 95% CI 1.69–9.29; $P = 0.002$) and with increasing operation time (103–134 min vs 41–102 min: OR 3.63, 95% CI 1.28–10.31, $P = 0.015$; 135–224 min vs 41–102 min: OR 3.85, 95% CI 1.40–10.59; $P = 0.009$).

All of the infections were considered uncomplicated, limited to the oral cavity, and were managed without any

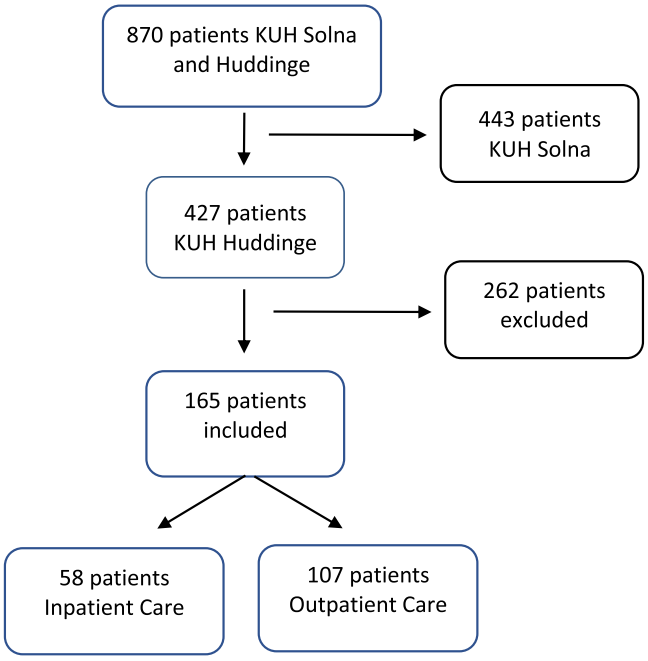

Fig. 1. Flowchart of the study population selection process.

impact on the final treatment result. Orthognathic surgery is classified as a clean-contaminated surgery with an expected incidence of postoperative infection of 10–15%.[11] Therefore, it is noteworthy that the overall infection rate in this study was 35.2% (inpatient care 24.1% and outpatient care 41.1%), which is higher than the rates found in other studies.[14–18] This needs to be addressed in the continuing quality assessment of the study department.

The large difference in infection rate between the two groups could be due to one or more of the identified confounding factors, namely the difference in types of surgical procedure performed, the detected high particle values measured in the outpatient operating room, and that most inpatient care patients received one or two extra doses of antibiotic on the day of surgery.

The new outpatient operating rooms initially had problems with ventilation and elevated particle values (CFU/m^3). These values were eventually normalized with, for example, revised clothing rules, fewer people in the operating room, and less entering and leaving the room to avoid doors being opened and closed.[19] Other relevant factors are the proportion of BSSO within and between the two groups and the number of participating surgeons.

In this study, an increased risk of postoperative infection in the mandible after BSSO compared to surgery in the maxilla was observed, which is consistent with other studies.[18,20,21] In the outpatient care group, 61.7% of the operations were BSSO, compared to 43.1% in the inpatient care group.

At a university hospital such as KUH, with a clinical care mission and responsibility for teaching and research, many participating surgeons can be involved in patient care. A total

Table 1. Descriptive statistics.

Study variable	Inpatient care group	Outpatient care group	*P*-value[a]
	Mean ± SD (range), or *n* (%)	Mean ± SD (range), or *n* (%)	
Sample size, *n*	58	107	
Sex			0.173
Female	25 (43.1%)	58 (54.2%)	
Male	33 (56.9%)	49 (45.8%)	
Age (years)	24 ± 9 (18–59)	23 ± 7 (16–57)	0.330
Smoker[b]			0.540
Yes	8 (15.7%)	13 (12.1%)	
No	43 (84.3%)	94 (87.9%)	
General disease	22 (37.9%)	38 (35.5%)	0.758
Type of surgery			0.037*
SARME	4 (6.9%)	9 (8.4%)	
Le Fort I	29 (50%)	32 (29.9%)	
BSSO	25 (43.1%)	66 (61.7%)	
Operation time (min)	126 ± 31 (48–224)	113 ± 35 (41–215)	0.021*
Antibiotic protocol			< 0.001*
1 dose IV	1 (1.7%)	29 (27.1%)	
2 doses IV	5 (8.6%)	75 (70.1%)	
3 or 4 doses IV	51 (87.9%)	3 (2.8%)	
Follow-up duration (days)	313 ± 162 (15–714)	342 ± 225 (5–848)	0.388

IV, intravenous; BSSO, bilateral sagittal split osteotomy; SARME, surgically assisted rapid maxillary expansion; SD, standard deviation.

[a] χ^2 test for categorical variables and independent samples *t*-test for continuous variables.

[b] Data missing for seven patients, all in the inpatient care group.

* Statistically significant difference between the groups, $P < 0.05$.

Table 2. Comparison of primary outcome variables between the inpatient and outpatient care groups.

	Inpatient care group	Outpatient care group	*P*-value[a]
Complications			
Postoperative infection	14 (24.1%)	44 (41.1%)	0.029*
Postoperative bleeding	3 (5.2%)	1 (0.9%)	0.091
Postoperative pain	9 (15.5%)	6 (5.6%)	0.035*
Plate removal	7 (12.1%)	22 (20.6%)	0.171
Re-operation	2 (3.4%)	5 (4.7%)	0.709
Emergency visits per patient			0.748
0	40 (69.0%)	79 (73.8%)	
1	14 (24.1%)	23 (21.5%)	
2 or more	4 (6.9%)	5 (4.7%)	
Emergency phone calls per patient			0.549
0	40 (69.0%)	64 (59.8%)	
1	11 (19.0%)	23 (21.5%)	
2	5 (8.6%)	11 (10.3%)	
3 or more	2 (3.4%)	9 (8.4%)	

[a]χ^2 test.
*Statistically significant difference between the groups, $P < 0.05$.

of 11 consultants and 14 residents in oral and maxillofacial surgery were involved in the care of the patients included in this study. The number of participants and different levels of experience may affect the length of the operation and thus the risk of postoperative complications (postoperative infection). With many individuals involved, there is also a greater risk of a lower compliance with routines, which contribute to bias.

The duration of care for an outpatient surgery patient was a mean 528 min (range 285–660 min). Before the operation starts, the patient receives one dose of IV antibiotic prophylaxis; the second dose is given after 8 h. Patients with a shorter operation time and a stay of less than 8 h in the clinic only receive one dose of antibiotic, while patients in inpatient care receive three doses of antibiotic on the day of surgery (first 24 h). The difference in antibiotic regimen between the two groups may explain why the outpatient patients had more postoperative infections than patients in inpatient care.[15] Antibiotics were not prescribed routinely after surgery, in accordance with the recommendations of the Swedish Medical Products Agency and Public Health Agency of Sweden.[22]

In a previous study on 87 patients who underwent orthognathic surgery in outpatient care, 84% could be discharged on the day of surgery, 12.6% were observed for 23 h or less, and 3.4% required full admission to the hospital.[23] Another study reported that 47% (94/205) of orthognathic surgery patients operated in an outpatient setting could be discharged on the day of surgery, 51% were observed for less than 23 h, and 2% were fully admitted to the hospital.[24]

In the present study, most of the patients (97/107, 90.7%) operated in the outpatient setting could be discharged on the day of surgery. Four patients (3.7%) did not meet the discharge criteria at closing time for the outpatient surgery department and had to remain another 1–2 h on the ward before going home later the same day. Six patients (5.6%) required full hospital admission.

Bleeding is of great concern with orthognathic surgery, particularly in LFI procedures.[24] In this study, the mean ± standard deviation perioperative bleeding in outpatient care was 167 ± 110 ml (range 25–580 ml), and 183 ± 146 ml (range 25–580 ml) for LFI. None of the study patients, whether operated in inpatient or outpatient care, required a blood transfusion perioperatively or postoperatively.

Swelling that affects the airways after orthognathic surgery is another important issue. Haber-Cohen and Rothman (1988)[25] reported a respiratory complication rate of 0.38% after oral and maxillofacial surgery. In the present study, no patient was admitted due to bleeding problems or

Table 3. Summary of patient safety for orthognathic surgery: outpatient surgery compared to inpatient surgery.

	Crude (Inpatient vs Outpatient)			Adjusted (Inpatient vs Outpatient)		
	OR	95% CI	P	OR	95% CI	P
Complications						
Postop infection	2.20	1.08 4.48	0.031*	2.46	1.00 6.03	0.049*
Postop bleeding	0.17	0.02 1.70	0.133	0.39	0.02 9.80	0.564
Postop pain	0.32	0.11 0.96	0.042*	0.41	0.11 1.55	0.191
Plate removal	1.89	0.75 4.73	0.176	2.33	0.72 7.54	0.159
Re-operation	1.37	0.26 7.31	0.710	1.31	0.13 13.17	0.817
Emergency visits per patient	0.79	0.39 1.59	0.506	0.55	0.23 1.35	0.193
Emergency phone calls per patient	1.49	0.76 2.94	0.246	1.16	0.51 2.64	0.726

*Binary logistic regression, statistically significant $P < 0.05$.

swelling threatening the airways, or due to poor social circumstances with fear and anxiety.

An important aspect for orthognathic surgical treatment in the outpatient setting is that the patient and relatives are provided with appropriate information and are well-informed about the procedures and postoperative care. They need to understand the extent of the surgical intervention and the postoperative course, which is the same regardless of the form of care.

A limitation of this study is the retrospective study design; only data from the various medical systems and patient records of the hospital were available for investigation. The number of possible patients in the inpatient care group was also limited since the overall change to outpatient surgery was completed in mid-2014. From that point on, selected single-jaw orthognathic surgery was performed in outpatient care.

In this study, most patients undergoing surgery in outpatient care could be discharged on the day of surgery. No significant difference was found between the groups in terms of postoperative emergency visits or phone calls, or in postoperative complications, except for the 2.5-times higher risk of developing a postoperative infection for the patients operated in outpatient care compared with inpatient care.

The advantage of performing selected orthognathic surgery in an outpatient setting is early patient mobilization and ability to recover in a familiar home environment surrounded by family. This reduces the psychological stress that a hospital environment can cause. There is also a decreased risk of being exposed to hospital-borne infections and a lower risk of cancelled operations. Hospital resources are freed up for other patient groups in need of inpatient care.

This study confirms that selected single-jaw orthognathic surgery procedures can be done in the outpatient care setting with maintained patient safety, but it presupposes a well-defined care programme adapted to outpatient surgery, staff who feel confident with the treatment protocol, patients with orderly home circumstances and where it is safe to be discharged the day of surgery, and that the distance to care is reasonable in the case of an emergency.

The reason for the increased risk of postoperative infection overall and among patients operated in the outpatient care setting should be followed up in new studies.

Ethical approval

The study was approved by the Regional Ethics Review Board, Karolinska Institute, Stockholm, Sweden (dnr: 2017/594–31/2).

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Competing interests

None.

Patient consent

Not required.

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