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Outcome of functional endonasal sinus surgery with and without CT-navigation*

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SUMMARY

Introduction: *Computer-assisted surgery (CAS) has found widespread use in functional endonasal sinus surgery (FESS) over the past few years. The present study investigates if CAS leads to a better outcome in FESS.*

Material and methods: *All patients who underwent endonasal sphenoethmoidectomy were enrolled in a prospective, non-randomized case-control study. The procedures were done without CAS (group A) in 2003 and with CAS (group B) in 2004, using a Stryker navigation unit. Sixty-two patients (113 sphenoidectomies) were included in group A and 61 patients (109 sphenoidectomies) in group B. The underlying disease was recurrent chronic sinusitis or polyposis nasi in all patients except for inverted papilloma in one patient from group A and in two patients from group B. The follow-up period was 12 months. Symptom scores were assessed preoperatively and at 12 months postoperatively, using a questionnaire. A CT-scan was obtained in all patients preoperatively and at 6 months postoperatively.*

Results: *No significant difference was found between group A and B, neither with respect to symptom scores at 12 months postoperatively, nor in postoperative CT-scans. The operation strategy did not change by the introduction of CAS. The frontal sinuses were entered in group A and B in 59% and 64% of the patients, respectively. All parameters improved significantly postoperatively, compared to the preoperative values. As far as complications are concerned, two anterior orbital injuries and one retrobulbar haematoma occurred in group A and one postoperative lacrimal stenosis in group B.*

Conclusions: *CAS does not lead to a better clinical outcome in FESS. Our data suggest that the rate of complications may be reduced using CAS. However, studies with a much larger number of patients would be necessary in order to definitely answer the question of whether CAS reduce complications in FESS.*

Key words: Computer-assisted surgery (CAS), functional endonasal sinus surgery, chronic sinusitis, nasal polyps

INTRODUCTION

CT-assisted navigation has gained widespread use in functional endonasal sinus surgery (FESS). Improved intraoperative localization of difficult anatomical landmarks may enable more radical surgical removal of disease [(1)]. This should theoretically lead to a better clinical outcome with CT-navigation. The present article investigates this issue.

MATERIAL AND METHODS

Patients

All patients undergoing endonasal sphenoethmoidectomy in our department were enrolled in a prospective control study. From 1.1.2003 until 31.12.2003 the interventions were performed without CT-navigation. A Stryker-Leibinger CT-navigation unit has been available since 2004, and was used for the operations from 1.1.2004 until 31.12.2004.

In total, 63 patients were included in the group without CAS (group A) and 65 patients were included in the group with CAS (group B). One patient from group A and three patients from group B had to be excluded because of incomplete data. Additionally, one patient died from unrelated reasons in group B. Finally, 62 patients (40 males, 22 females) were evaluated in group A and 61 patients (40 males, 21 females) in group B. The average age was 47 years (SD +/-16) and 50 years (SD +/-17) in groups A and B, respectively.

Only patients with a complete sphenoethmoidectomy were included in the study. However, enlargement of the ostium of the frontal sinus was at the surgeons discretion and performed as clinically indicated.

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Surgical procedures

In group A (without CAS) a total of 113 sides were operated (67 times with enlargement of the ostium of the frontal sinus) and in group B (with CAS) the number of operated sides was 109 (70 times with enlargement of the ostium of the frontal sinus). The procedures were performed by using predominantly the operating microscope. Endoscopes were used for special situations such as enlargement of the frontal recess. The surgeons (K.P.T. and E.G.T.) were the same in the two treatment groups. The surgical philosophy was to remove all diseased mucosa of the ethmoids. However, in the sphenoid, maxillary and frontal sinus only the natural ostia were enlarged without any attempt of removing additional mucosa. Blood loss and operation time were registered in all patients.

Image guidance

A Stryker-Leibinger navigation unit was used for image-guidance. This is an optical system with an infrared camera. The unique feature of the system is a mask that is mounted onto the patient's front, nose and orbital rim. The mask contains 31 LEDs and is used for surface matching of the patient's face and the surface of the face in CT-data. During surgery, only 10 LEDs on the patient's front are active. Thus changes of the shape of the nose during the procedure, as in additional septoplasty or rhinoplasty, do not interfere with CT-navigation. The FESS was performed in the usual way in procedures with image-guidance. In all cases the sphenoid sinus, the anterior skull base and the orbit were localized using CT-navigation. Moreover, CT-navigation was additionally used whenever necessary, as judged by the operating surgeon. A curved and a straight pointer were available for intra-operative localization.

Data concerning image-guidance, such as time for set-up of the CT-navigation unit, clinical accuracy and a general judgment by the surgeon were registered in procedures with CT-navigation assistance. The surgeon was asked in a standardized questionnaire if the CT navigation was useless, a little helpful, helpful or very helpful. Any problems related to CAS such as system breakdown or repeated registration procedures were noted in the study protocol. The clinical accuracy was assessed at the level of the roof or the posterior wall of the sphenoid. This is a reliable intra-operative landmark and the most distant point from the level of the surface matching. Inaccuracy is expected to be higher at deeper structures in the operating field because of physical reasons related to surface matching. An inaccuracy of up to 3 mm was tolerated at the level of the sphenoid.

Table 1. Indications for FESS.

	Group A	Group B
Chronic rhinosinusitis	47	40
Polyposis, grade 1	2	1
Polyposis, grade 2	1	14
Polyposis, grade 3	20	24
Polyposis, grade 4	42	28
Inverted papilloma	1	2

Indications for FESS of study group A (without CAS) and group B (with CAS). The number of operated sides is indicated.

The indications for the operation are listed in Table 1. Most patients suffered from chronic sinusitis or nasal polyps, but there were also three cases of inverted papilloma. The extent of nasal polyposis was judged according to Rasp [(2)]. Both study groups were similar with respect to indications ($p > 0.28$). Nasal endoscopy was performed preoperatively in all patients. Widal disease (aspirin intolerance, asthma and sinusitis) was present in one case of group A and in two cases of group B. Eight patients of group A and 7 patients of group B had previous sinus surgery.

Follow-up

All patients were followed-up for one year at intervals as clinically indicated. However, symptoms and general quality of life were assessed using a standardized questionnaire preoperatively and at 12 months postoperatively, using a visual analogous scale (VAS). We asked about nasal obstruction, postnasal drip, smell, headache and recurrent sinusitis. Symptoms were scored according to their severity on a scale from 1 to 10 (1 meaning no symptoms, 10 meaning very severe symptoms).
A CT-scan was obtained in all patients preoperatively and at 6 months postoperatively. Aeration of maxillary sinus, frontal sinus, anterior and posterior ethmoid and sphenoid sinus were assessed. Each sinus was scored as 0 = normally transparent, 1 = partially opacified and 2 = totally opacified.
Postoperatively, all patients administered topical steroids (Budenosid) for at least 3 to 6 months according to clinical findings. Patients with nasal polyps were additionally treated with oral prednisone (20-30 mg every second day) and the antihistaminic desloratadine (5 mg daily) for 4-6 weeks.

Statistics

The Wilcoxon test was used for statistical comparisons using the Statview® program. The level of significance was defined as $p = 0.05$. The differences in the proportion of complications were tested using Fisher's exact test. In addition, the sample size needed to investigate the observed difference with a type II error of 0.2 (power of 0.8) was estimated using a simulation procedure programmed for this particular example in R. Other statistical tests based on approximations would fail because there was no orbital complication at all in group B. For dural complications group A was substituted by the below mentioned study group of our clinic in 1995-2003 (without CT navigation), in order to calculate the sample size.

RESULTS

Figure 1 shows symptom scores and subjective judgement of general quality of life preoperatively and at 12 months postoperatively. Postoperative values for all variables improved significantly in both groups ($p = 0.001$ - 0.002). However, the

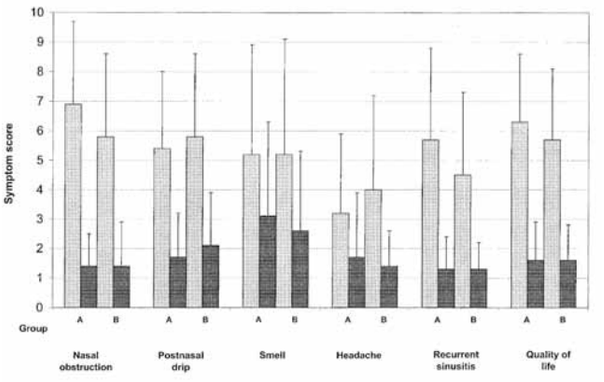

Figure 1. Symptom scores and general assessment of quality of life on the visual analogue scale (1-10), 1 meaning no symptoms and 10 meaning very important symptoms.
Group A = without CT-navigation (n=62 patients), group B - with CT-navigation (n=61 patients). Preoperative scores in grey, scores at 12 months postoperative in black.
The standard deviation is indicated by bars.

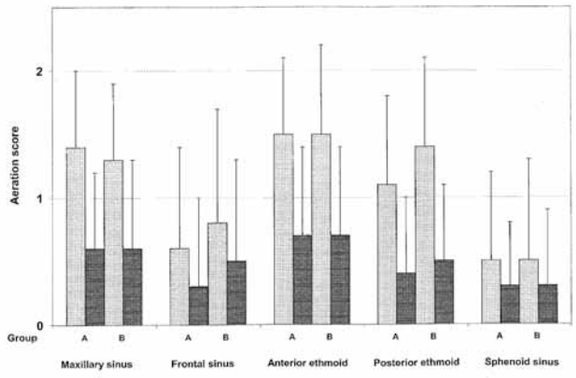

Figure 2. Aeration scores of paranasal CT in patientgroup A (= FESS without CT-navigation; n=62 patients) and group B (=FESS with CT-navigation; n=61 patients). Aeration of maxillary sinus, frontal sinus, anterior and posterior ethmoid and sphenoid sinus were assessed. Each sinus was scored as 0 = normally transparent, 1 = partially opacified and 2 = totally opacified. The average scores are depicted (standard deviation indicated by bars). Preoperative scores in grey and scores at 6 months postoperatively in black.

improvement was similar for group A and B ($p = 0.13$ - 0.62). Findings in CT-scans preoperatively and postoperatively at 6 months are depicted in Figure 2. Aeration improved significantly ($p < 0.001$) for all paranasal sinuses except for the frontal sinus where improvement did not reach the level of significance ($p = 0.19$). There was no significant difference between group A and B ($p > 0.05$).

The operative strategy did not change by introducing CT-navigation. The frontal sinus was entered in 59% of group A and 64% of group B patients. Two patients in group A and three patients in group B needed revision surgery within 12 months of the postoperative follow-up.

Two anterior orbital lesions and one retrobulbar haematoma occurred as complications in group A. The two anterior orbital lesions were mild hematomas in the orbital fat anterior to the eyeball. They manifested as swelling of the upper and lower lid and resolved within two weeks. The retrobulbar haematoma was caused by injury to the anterior ethmoidal artery, which retracted into the orbit in a case with important polyposis nasi and *Aspergillus pansinusitis*. A lateral canthotomy was necessary. Fortunately all orbital complications were without long-term sequelae for the patients. A CT scan was obtained in all cases immediately after the complications and confirmed the diagnosis. In group B one patient developed a lacrimal duct stenosis postoperatively, which required later endonasal dacryocystorhinostomy.
The mean operation time for sphenoidectomy was 73 min. (SD. +/- 46 min.) in group A and 74 min (SD. +/- 29 min.) in group B. Blood loss was 201 ml (SD. +/- 198 ml) and 180 ml (SD. +/- 124 ml), in groups A and B, respectively.

Table 2. Navigational data.

Time for reading of radiological data	3.3 min. (1.1 min.)
Time for mask set-up	2.9 min. (0.9 min.)
Time for surface registration	3.5 min. (0.8 min.)
Mean RSME value between patient and CT surface	0.46 mm (0,24 mm)
Number of activation LEDs	25 (6)

Data from CT navigation of group B (n = 61 patients). Average values are indicated (standard deviation in brackets).

Data concerning CT navigation are summarized in Table 2. The mean time for data transfer, mask set-up and registration was 9.7 min. (SD. +/- 1.6 min.). In one case a second intraoperative registration was necessary. In 6 cases CT navigation was abandoned because of a wrong Gantry tilt in radiological data (1 case), technical problems with patient tracker (2 cases) and inadequate accuracy (3 cases). Thus, a clinical accuracy better than 3 mm at the level of the sphenoid was achieved in 95%. However, it should be noted that the study was initiated at the introduction of the CT-navigation system in our clinic. Technical problems and inadequate radiological data were attributed to lack of familiarity with CT-navigation and did not occur with more experience.

CT navigation was judged as very helpful in 27 cases (44%), helpful in 25 cases (41%) and of little help in 3 cases (5%). CT navigation was obviously judged as useless in the 6 cases (10%) in which navigation had to be abandoned.

DISCUSSION

We did not find articles in the literature that compared outcome of FESS with and without CT-navigation in prospective studies.

Table 3. Power analysis of the complication rates with and without CT-navigation.

Complication	Rate without CT-navigation	Rate with CT-navigation	p-value (Fisher)	sample size (power=0.8)
Anterior orbital injury	0.0177(2/113)	0(0/109)	0.498	446
Retrobulbar hematoma	0.0088(1/113)	0(0/109)	1	880
Dural injury	0.00357(2/560)	0(0/109)	1	836

The necessary sample size for significant conclusions regarding the prevention of complications using CT-navigation was calculated based on the incidence of complications in our clinic in 1995-2003 (without CT-navigation). In addition, we report the sample size needed to investigate the observed difference with a type II error of 0.2 (power of 0.8)

The symptom scores and general quality of life showed significant improvement postoperatively. However, CT-navigation did not lead to a better outcome compared to FESS without CT-navigation. Comparison of the postoperative CT-scans did not demonstrate a more radical operation of paranasal sinuses with CT-navigation. We conclude from these data that the outcome of functional endonasal sphenoethmoidectomy is not improved by CT-navigation.

Operation time was not prolonged by CT navigation. The time for system set-up and patient registration was, on average, 10 minutes. Arapakis et al. [3] reported a set-up time of 10 to 15 min for the same CT navigation system. The Stryker navigation system has user-friendly software and an acceptable set-up time for clinical use.

At the level of the sphenoid, a clinical accuracy of better that 3 mm was obtained in 95%. Using the same Stryker navigation system, previous studies reported an intraoperative accuracy of better than 2.5 mm in all patients [3]. Schlaier et al. [4] found a similar accuracy of 2.8 mm +/-1.6mm for the surface registration by the z-touch® (BrainLab, Heimstetten, Germany).

Fewer complications were observed in the group with navigation (group B). It is worth noting that no orbital injury occurred in group B. The level of significance was not reached with respect to prevention of orbital complications and a type 2 error occurred (Table 3). Both surgeons (K.P.T & E.G.T.) feel that the orbital injuries in group A could have been prevented if CT-navigation had been used. However, the number of operated sinuses in our study is too small for definite conclusions.

Fortunately, the incidence of complications in paranasal surgery is small. The complication rate in our clinic was, for the period 1995-2003, in which no CT-navigation was available, 2.9% anterior orbital injuries, 0.6% retrobulbar haematomas, 0.3% dural injuries and 0.95% postoperative bleedings with revision surgery in a total of 560 operated sinuses (n = 315 patients)[5]. This lies within the range of data in the literature [6].

The results of Fisher's exact test for assessing the difference of the complication rate between group A and B is indicated in Table 3. In addition, the sample size needed to investigate the observed difference with a type II error of 0.2 (power of 0.8) for orbital and dural complication is reported. In summary, a sample size of at least 880 would be necessary to draw reliable conclusions regarding the prevention of major complications using CT-navigation.

Fried et al. [7] found a significantly lower complication rate using CT navigation in a retrospective study of FESS with 61 patients without CT navigation and 35 patients with CT navigation. However, from our point of view, a much larger collective is necessary for definite conclusions, in view of the abovementioned rate of complications.

Reardon et al. [8] compared the complication rate in 800 patients in a retrospective study. Half were operated with and half without CAS. Similar complication rates were found for both groups. However, more patients are necessary in order to draw definitive conclusions about the impact of CAS on complication rates in FESS. In addition, other factors, such as the extent of the disease and the procedures, as well as the experience of the surgeons need to be considered.

In the study of Reardon et al. [8], significantly more frontal sinuses were opened using CT navigation compared to procedures without CT navigation. However, we could not find a change of operating strategy in our data.

When the value of CT navigation is judged, other aspects such as the safety feeling of the surgeon are important. Although this factor may not be easily quantified it was the major reason for 85% of surgeons to use CT navigation in a survey of American otolaryngologists (9). In our study CT navigation was judged as helpful or very helpful in 85% of procedures. From our experience, CT navigation is an important contribution to the safety feeling of even experienced surgeons and is suitable for routine application in endonasal sphenoethmoidectomy.

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