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Effect of a balanced anaesthetic technique using desflurane and remifentanil on surgical conditions during microscopic and endoscopic sinus surgery*

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SUMMARY

Objectives: *Controlled hypotension is used to improve surgical conditions during microscopic and endoscopic sinus surgery. Several drug combinations are suitable to provide deep and predictable level of anaesthesia combined with an exact control of intraoperative blood pressure. However, only little is known about the relative importance of the level of hypnosis on the one hand and analgesia on the other hand.*

Study design: *Prospective, randomized, patient and observer-blinded study.*

Methods: *All 100 consecutive patients received a balanced anaesthesia technique using desflurane and remifentanil. Anaesthesia was desflurane-accentuated with remifentanil-supplementation (DARS-group: 1 MAC desflurane; remifentanil: 0.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$) or remifentanil-accentuated with desflurane-supplementation (RADS-group: desflurane: 0.5 MAC; remifentanil: 0.4 $\mu g \cdot kg^{-1} \cdot min^{-1}$). Administration of anaesthetics performed to maintain a sufficient level of anaesthesia and to keep mean arterial pressure between 60 and 70 mmHg (8-9.3 hPa). The attending ENT-surgeons were unaware of the type of anaesthesia and rated general surgical conditions and the dryness of the operating site on a visual analogue scale (0-10 cm) and on a verbal rating scale immediately after surgery.*

Results: *Blood pressure and heart rate was not different between the two groups. Dryness of the operating site was rated significantly better ($p < 0.0001$) in the DARS-group (median; 25th/75th-percentile: 2.0; 1.5-3.5 vs. RADS-group: 2.6; 2.0-4.0) but the overall rating of the surgical conditions did not differ between the groups (DARS-group: 2.0; 1.0-2.4 vs. RADS-group: 2.2; 1.5-3.2). Immediate postoperative recovery times were increased in the RADS-group, but there was no difference with respect to fit-for-discharge criteria one hour after surgery.*

Conclusion: *Balanced anaesthesia using high dose of desflurane offers small but statistically significant advantages with respect to dryness of the operating site compared to an opioid-accentuated anaesthesia technique. However, since the opioid-accentuated anaesthetic group had a faster immediate recovery both techniques are equally effective for microscopic and endoscopic sinus surgery.*

Key words: surgical conditions, microscopic and endoscopic sinus surgery, balanced anaesthesia, desflurane, remifentanil, controlled hypotension

INTRODUCTION

Surgery for chronic sinusitis is mainly performed microscopically and endoscopically via the transnasal route. Even small areas of bleeding in inflammatory sites can reduce visibility and considerably impair surgical conditions. General anaesthesia for this type of surgery is often used to improve patient's comfort and to reduce intraoperative haemorrhages. The proposed main mechanism is reduction of systemic blood pressure during anaesthesia. Controlled hypotension is frequently induced to lower mean arterial blood pressure (MAP) to values between 50-60 mmHg. Several pharmacological approaches have been used to induce controlled hypotension. E.g.,

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vasodilators such as sodium nitroprusside [1-3], nicardipine [1], nitroglycerine [1], beta-adrenergic antagonists (esmolol) [1,3,4], and high doses of inhalation anaesthetics like isoflurane [5] have been studied in this context. However these approaches are not unequivocally accepted. First, each hypotensive technique is associated with specific disadvantages. Reflective tachycardia, rebound hypertension on termination of hypotensive agents, tachyphylaxis, and cyanide intoxication during administration of sodium nitroprusside, or the possibility for myocardial depression in patients receiving esmolol are major side effects. High doses of older and high soluble inhalation anaesthetics are likely to prolong recovery from anaesthesia and can delay the patient's discharge. Second, controlled hypotension is associated with a certain incidence of morbidity and mortality. The latter was found to result in 20 to 60 deaths in 100,000 patients, mainly as a consequence of ischemic organ failure [6].

During the last decade the introduction and dissemination of newer anaesthetic agents like propofol, desflurane, and remifentanil have widened the therapeutic options to provide a stable and predictable anaesthesia along with the induction of a mild controlled hypotension. Several drug combinations have been investigated in the last years and some have found to be highly effective compared to older anaesthetic techniques. The main underlying mechanism in all successful trials was that the new short acting drugs allow the maintenance of a deep level of anaesthesia and analgesia without a clinically significant delay in recovery times, the latter extremely important for an efficient OR-management. Deep level of anaesthesia and analgesia during the surgery lowers arterial blood pressure and heart rate by blocking any sympathetic stimulation. Despite the decreased cardiac output the risk for organ ischemia is extremely low because the oxygen consumption of the body is also reduced during deep anaesthesia.

While there have been several studies comparing different drug combinations for endoscopic sinus surgery, only little attention has been paid to answer the question whether an anaesthesia should primarily focus on deep hypnosis (usually achieved by an inhalation anaesthetic or propofol) or profound analgesia (usually achieved by the administration of an opioid). For this purpose we have designed the following study, where the "balance" between the two main components of a typically balanced anaesthesia technique was shifted from deep hypnosis in a "desflurane-accentuated" group to pronounced analgesia in a "remifentanil-accentuated" group.

MATERIALS AND METHODS

Patients

The local ethics committee approved this prospective and randomized study. Patients with ASA grade 1 (a normal, otherwise healthy patient) or ASA grade 2 (a patient with mild systemic diseases) undergoing endoscopic surgery for chronic sinusitis (see table 1 for details) were consecutively included into the study after they had given their informed written consent. Patients were excluded if there was a known allergy against one of the drugs used perioperatively. In case of intolerance to acetyl salicylic acid the patients were only included if there was evidence that this intolerance did not include other NSAID, like diclofenac or metamizole. There was no difference in the staging or degree of sinusitis between the two groups. All patients received oral benzodiazepine premedication with 20 mg clorazepate on the evening before and the morning of surgery. Antihypertensive medication taken before was continued throughout the study.

Surgery

After insertion of an i.v.-line and applying routine monitoring (pulse oximetry, ECG, automatic non-invasive blood pressure) general anaesthesia was induced in both groups with remifentanil (0.1-0.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$) and propofol (1.5-3 $mg \cdot kg^{-1}$) until loss of consciousness. After successful mask ventilation endotracheal intubation was facilitated with 0.6 $mg \cdot kg^{-1}$ rocuronium and lungs were ventilated with air-oxygen (FiO_2: 0.4-0.5) with a fresh gas flow of 1 $l \cdot min^{-1}$. In all patients anaesthesia depth was measured using a processed electroencephalogram (EEG). A commercially available apparatus (BIS®, Aspect Medical Systems, Newton, MA, USA) was used that provides an easy to use parameter (no unit) between 0 (flat line EEG = extreme deep anaesthesia) and 100 (patient awake) [7]. It is generally accepted that BIS-values below 50 indicate that the patient is sufficiently anaesthetized and intraoperative awareness is unlikely [8]. Maintenance of anaesthesia was performed according to instructions located in sealed envelopes that were opened immediately before start of anaesthesia to ensure allocation concealment.

- Desflurane-accentuated (remifentanil-supplemented) technique (DARS-group): maintenance with 1 MAC of desflurane (corrected for age according to the normogram of Nickalls [9]. A continuous infusion of remifentanil was titrated to achieve adequate level of anaesthesia and hemodynamic stability.
- Remifentanil-accentuated (desflurane-supplemented) group (RADS-group): Maintenance with 0.5 MAC desflurane (corrected for age according to the normogram of Nickalls [9]. A continuous infusion of remifentanil was started with 0.2-0.4 $\mu g \cdot kg^{-1} \cdot min^{-1}$ and then titrated to achieve adequate level of anaesthesia and hemodynamic stability.

Adequate level of anaesthesia was defined as a BIS-value of 50 or lower. Blood pressure was aimed as systolic arterial pressure $<$ 12 hPa (90 mmHg) and mean arterial pressure between 8-9 hPa (60 and 68 mmHg) in both groups. Routine antiemetic prophylaxis was performed with 8 mg dexamethasone and 12.5 mg dolasetrone i.v. Patients received a diclofenac suppository (100 mg) after induction of anaesthesia and a slow intravenous infusion of 30 $mg \cdot kg^{-1}$ metamizole (dipyrone), a centrally acting non-steroidal analgesic at the end of surgery. In both

groups administration of desflurane and remifentanil was continued until the surgical dressings were completed. This time point was defined as zero, the remifentanil-infusion was stopped, desflurane was removed with a fresh gas flow of 10 $L \cdot min^{-1}$, and times until parameters of immediate postoperative recovery were recorded using a standardized postoperative recovery score [10].

Preoperatively, in both groups the pharynx was packed with a bandage to prevent passive ingestion of blood into the stomach. The nasal mucosa was then decongested by introducing neurosurgical gauze soaked in naphazoline nitrate solution (1:1000) into the nasal cavity. Thus, only topical vasoconstrictors were employed, whereas the preoperative use of nasal vasoconstrictors was not controlled. However, most patients in both groups used such drugs occasionally. The attending rhinologic surgeon was blind to the relative dosage of drugs applied to maintain anaesthesia. At the end of surgery he rated surgical conditions and dryness of the operation site on a 10 cm visual analogue scale (0 = best possible operating conditions and dryness of the surgical field; 10 = worst possible conditions). In order to make ratings comparable they also used a six-point scale used previously in several other trials [11-13].

0: no bleeding
1: slight bleeding – no suction of blood required
2: slight bleeding – occasional suctioning required. Surgical field not threatened
3: slight bleeding – frequent suctioning required. Bleeding threatens surgical field a few seconds after suctioning is removed
4: moderate bleeding – frequent suctioning required. Bleeding threatens surgical field directly after suction is removed
5: severe bleeding – constant suctioning required. Bleeding appears faster than can be removed by suction. Surgical field severely threatened.

Blood loss was estimated by subtracting the amount of saline used for flushing from the amount of fluid suctioned from the operating field and adding the portion of blood that was sucked into the tamponades.

All adverse events that could have hampered the surgical condition, e.g. movement of the patient or coughing, were recorded. Indicators for immediate postoperative recovery were recorded (times from finishing the dressing or tamponade until removal of the endotracheal tube and leaving the operating theatre, time until patients were judged to be fit for discharge to the ward according to a modified Aldrete score [10]. Finally, the patients were asked to give their subjective impression with respect to the tolerability of anaesthesia 24 hours after surgery on a 10 cm visual analogue scale.

Power estimation and statistic analysis

Assessment of the dryness of the surgical site using the 10-cm visual analogue scale was prospectively defined as the main end point of this study. Results from our previous trial revealed a standard deviation of 50% of the actual means and 80% of the observed difference between the two groups. Using these assumption for a power analysis revealed that fifty patients per group offered a chance of 90% to detect a difference between the two groups of 1.5 (centimetres) on a 10 cm visual analogue scale with a type I error of 5 % using a two-sided t-test (power calculation with PASS 2002, Number Cruncher Statistical Systems, Kaysville, UT, USA).

After normal distribution of the data deriving from the VAS-scale was verified using the Kolmogorov-Smirnov procedure, a Student t-test was performed. Ordinal ratings on the Likert scale (0-5) were analyzed using Mann-Whitney's U-test. All calculations were performed using the JMP 5.1. statistical package for Windows (SAS institute Inc., Cary, NC, USA).

RESULTS

Of 100 patients that were randomized, data of 95 could be analyzed. Two patients were not considered due to major violation of the study protocol (use of sevoflurane instead of desflurane). In two patients the BIS-recordings could not be used due to intraoperative removal of the electrodes that need to be placed on the patient's forehead and temple. In one patient the recordings were incomplete. Since no patient had to be withdrawn from the study due to treatment failure or adverse events and the great majority of 95% of the included patients completed the trial no separate intention to treat analysis was performed.

The demographic data, duration of surgery and anaesthesia, and the distribution of the ENT-surgeons did not show relevant differences between the two groups (Tables 1 and 2).

In all 95 patients, the aimed control of arterial blood pressure and level of anaesthesia could be achieved using the allowed doses of anaesthetics. Thus, no difference with respect to the intraoperative arterial pressure and heart rate was observed, nor was there any deterioration of these hemodynamic values during the entire operating time.

However, a statistically significant trend towards increased dryness of the surgical field in the desflurane-accentuated group was noted ($p = 0.037$ using Student's t-test). This result is confirmed by the rating on the 6-point Likert scale ($p = 0.025$ using Mann-Whitney's U-test). However, having a critical look at the underlying absolute difference of 0.76 (rating of intraoperative bleeding) and 0.52 (general assessment of operating conditions) respectively each made on a 10-cm visual analogue scale it remains unclear whether these differences really reflects clinically relevant improved operating conditions. Figure 1 shows a box and whisker plot of the VAS-ratings of the dryness of the operating site.

There was no significant reduced blood loss in one of the two groups (Table 2). Despite a high correlation between the rating of the dryness of the operating site and the general assessment of the operating conditions the latter showed no statistical significant difference between the groups ($p = 0.085$). Immediate postoperative recovery occurred faster after the remifentanil-accentuated anaesthesia technique (Table 3).

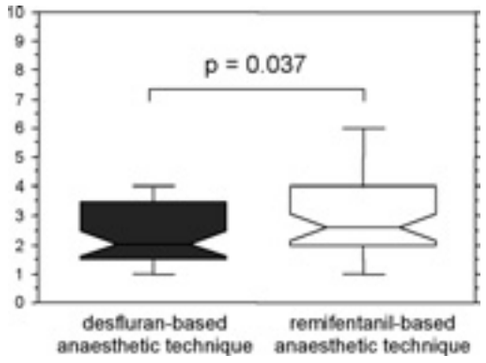

Figure 1. Rating of the blinded ENT-surgeons on a 10-cm visual analogue scale (VAS). The box and whisker plot shows the 90th, 75th, 50th (median), 25th, and 10th percentile of the ratings (from top to bottom) and the 95%-confidence interval of the median (indented area). Low values mean excellent operating conditions; high values represent an impaired surgical site.

In two patients of the desflurane-accentuated group intraoperative movements were observed after the neuromuscular function had recovered but this did not affect the surgeon's general assessment of the operating conditions (VAS-rating 2.0 and 3.0). This observation is in accordance to the results of an analysis where the surgeons' general level of satisfaction and the assessment of intraoperative bleeding were compared. There was a nearly perfect correlation between both ratings (Pearson's correlation coefficient $r^2 = 0.86$; $p < 0.0001$) indicating that the perceived level of intraoperative bleeding is of utmost concern to the otolaryngological surgeon and the top determinate for their satisfaction with anaesthesia.

There was no difference in the ratings of the patients of the overall tolerability of anaesthesia (Table 4). Most of the patients with low rating suffered from nausea and vomiting postoperatively.

DISCUSSION

Several combinations of anaesthetic drugs have been studied with respect to the intraoperative conditions for the ENT-surgeons. Unanimously all these trials have shown that administering newer short acting drugs offer clinically relevant advantages to traditionally used anaesthesia techniques. In this context remifentanil, a new ultra-short-acting μ-opioid receptor agonist, seem to play a major role. Remifentanil is a fentanyl derivative with an ester linkage that can be broken down by

Table1. Demographic data of patients in the two groups. Continuous values are presented as median and 25th / 75th percentile (in parentheses) and dichotomous data as absolute and relative frequency (in parentheses).

Postoperative complications		**Desflurane-accentuated / Remifentanil-supplemented anaesthesia n = 49**	**Remifentanil-accentuated / desflurane-supplemented anaesthesia n = 46**
females	[n=]	15 (31)	16 (35)
males	[n=]	34 (69)	30 (65)
age	[years]	36 (31-54)	45 (37-51)
height	[cm]	173 (168-179)	173 (166-180)
weight	[kg]	80 (72-88)	79 (70-90)
body-mass-index	[kg•m^{-2}]	25.9 (24.2-27.7)	26.1 (23.4-30.1)
ASA*-classification 1	[n=]	32 (65)	27 (59)
ASA*-classification 2	[n=]	17 (35)	19 (41)
duration of surgery	[min]	80 (60-135)	85 (65-105)
duration of anaesthesia	[min]	100 (75-160)	105 (80-135)
diffuse polypoid pansinusitis (treated by sphenoethmoidectomy & fenestration of the maxillary sinus in the middle meatus)	[n=]	26 (53)	23 (50)
chronic, recurrent sinusitis (treated by ethmoidectomy and fenestration of the maxillary sinus in the middle meatus)	[n=]	14 (29)	12 (26)
infundibulopathy (treated by infundibulotomy)	[n=]	9 (18)	11 (24)
patients receiving additional septoplasty for concomitant septal disease	[n=]	36 (73)	33 (72)
patients receiving additional anterior turbinoplasty for turbinate hyperplasia	[n=]	17 (35)	17 (37)
patients receiving widening of the frontal recessus due to total opacification of the sinus	[n=]	5 (10)	4 (9)
median desflurane concentrations	[Vol.%)]	6.5 (5.5–7.0)	2.62 (1.76-3.73)
total consumption of remifentanil	[mg]	1.20 (0.81-1.63)	0.40 (0.31-0.61)
dose of remifentanil	[μg•kg^{-1}•min^{-1}]	0.19 (0.14-0.23)	3.0 (2.8–3.3)
mean arterial pressure	[mmHg]	64 (61 / 70)	67 (63 / 72)
mean arterial pressure	[hPa]	8.7 (8.1 / 9.3)	8.9 (8.4 / 9.6)
systolic arterial pressure	[mmHg]	90 (85-97)	90 (88-95)
systolic arterial pressure	[hPa]	12 (11.3-12.9)	12 (11.7-12.7)
mean heart rate	[min^{-1}]	55 (50-60)	50 (49-59)

* ASA (American Society of Anesthetists)-classification: general rating of global health status
(ASA 1 = normal healthy person; ASA 2=patient with mild systemic disease

Table 2. Rating of the surgical field by the five blinded ENT-surgeons. High ratings on the visual analogue scale (from 0 to 10) and the verbal ratings scale (from 0 to 5) represent impaired operating conditions. The continuous values are presented as median and 25th / 75th percentile (in parentheses) and dichotomous data as absolute and relative frequency. Asterisks indicate statistical significant differences between the two groups ($p \leq 0.05$).

Postoperative complications		**Desflurane-accentuated / Remifentanil-supplemented anaesthesia n = 49**	**Remifentanil-accentuated / desflurane-supplemented anaesthesia n = 46**
Patients treated by surgeon #1	[n=]	9 (18)	11 (24)
Patients treated by surgeon #2	[n=]	8 (16)	10 (22)
Patients treated by surgeon #3	[n=]	8 (16)	6 (13)
Patients treated by surgeon #4	[n=]	9 (18)	6 (13)
Patients treated by surgeon #5	[n=]	15 (31)	13 (28)
Rating of the dryness of the operating site using a VAS-scale		2,0* (1.5-3.5)	2.6* (2.0-4.0)
Surgeon # 1		1.6 (1.0-2.6)	2.6 (1.7-3.4)
Surgeon # 2		2.3 (1.8-3.3)	2.0 (1.5-2.5)
Surgeon # 3		3.0 (2.0-3.5)	3.8 (3.1-6.0)
Surgeon # 4		1.8 (0-4.0)	4.5 (0-8.5)
Surgeon # 5		2.1 (1.7-3.4)	3.0 (2.0-4.3)
Rating on a 6-point scale (0-5)		2 (1 / 2)	2 (2 / 3)
Surgeon # 1		2 (1 / 4)	2 (2 / 4)
Surgeon # 2		2 (1 / 2)	2 (2 / 2)
Surgeon # 3		1.5 (1-2)	2 (2-4)
Surgeon # 4		2 (0.5-3)	4 (1-4)
Surgeon # 5		2 (2-2)	2 (2-3)
Estimated blood loss	[ml]	140 (80 / 260)	180 (120 / 290)
Rating of the overall operating condition using a VAS-rating		2.0 (1.0-2.4)	2.2 (1.5-3.2)
Surgeon # 1		1.0 (0.9-2.1)	1.5 (1.1-2.2)
Surgeon # 2		1.8 (1.3-2.5)	1.9 (1.7-2.3)
Surgeon # 3		3.0 (1.8-3.3)	3.5 (2.4-5.4)
Surgeon # 4		1.5 (0.3-2.2)	2.5 (0.4-5.0)
Surgeon # 5		2.0 (1.9-2.9)	2.5 (2.1-3.3)

non-specific plasma esterases, making clearance independent from hepatic or renal diseases, gender, age, and body weight. This unique form of metabolism and a low volume of distribution of 25-40 litres are responsible for the short duration of action. Even after infusion of several hours time to recover from respiratory depression by 50% is only 6 minutes. Since the relative potency of the main metabolic product of ester hydrolysis is only 0.1-0.3%, residual effects are negligible [14].

Remifentanil has been administered in different doses during otolaryngological surgery. The lowest dose that is usually administered in these types of surgery is 0.15-0.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$ [13,15-18] and the upper limit in most trials is 0.5 $\mu g \cdot kg^{-1} \cdot min^{-1}$ [13,15,16,19,20] but has been described as high as 0.8 [17] or even 1.5 $\mu g \cdot kg^{-1} \cdot min^{-1}$ [21]. All these authors report stable and easy adjustable hemodynamic conditions during the procedures. However, despite the increasing number of studies using remifentanil with various anaesthetic agents to provide hypnosis (e.g. desflurane [15,21], sevoflurane [15,21], or propofol [17-19,21-23] no trial so far has directly compared the impact of the relative weight of the hypnotic part of anaesthesia on the one hand and analgesia on the other hand. An answer to this question is of importance since hypnotic drugs (e.g. propofol or inhalation agents) can be replaced within a wide limit by a potent opioid analgesic and vice versa.

The results from this study demonstrate that it is of minor importance whether an opioid-based anaesthesia technique is performed or an opioid is replaced to some extend by increasing the dose of the inhalation agent. Both modifications of the desflurane-remifentanil combination provided good and comparable operating conditions with only minor differences with respect to the dryness of the surgical field that was better in the desflurane-accentuated group.

In both groups no patient required additional vasodilatators to achieve moderate controlled hypotension. Heart rate and both mean and systolic blood pressure were comparable between the two groups. Meanwhile, it is well accepted that intraoperative blood pressure and bleeding on the surgical site are not necessarily correlated [24]. There is good evidence that decreasing MAP below 70 mmHg can even increase intraoperative bleeding. On the one hand this can happen due to local vasodilatation [3,25] but on the other hand it can also be a result of an increased cardiac output during controlled hypotension resulting from reflex tachycardia, especially when a pure vasodilatator, e.g. sodium nitroprusside, is used [26].
These are the main reasons why simply comparing mean arterial pressure is more a surrogate endpoint in a study seeking for the optimal technique for providing optimal surgical conditions for the otolaryngological surgeon.

Table 3. Immediate postoperative recovery times. All differences are statistically significant using Mann-Whitney's U-test ($p < 0.0001$).
Data are presented as median with 25^{th}-75^{th} percentile and mean ± standard deviation.

Postoperative complications		**Desflurane-accentuated / Remifentanil-supplemented anaesthesia n = 49**	**Remifentanil-accentuated / desflurane-supplemented anaesthesia n = 46**
Median time from completing the surgery until …			
… extubation	[min]	12 (10-14)	9 (7-11)
… leaving the operating theatre	[min]	14 (12-17)	12 (10-15)
… ability to discharge patient to the ward	[min]	23 (20-27)	18.5 (16-22)
Mean time from completing the surgery until …			
… extubation	[min]	12.6 ± 4.8	9.3 ± 3.3
… leaving the operating theatre	[min]	15.3 ± 5.4	10.6 ± 3.2
… ability to discharge patient to the ward	[min]	24.4 ± 6.0	19.3 ± 5.4
percentage of patients who were ready for discharge one hour postoperatively	[n=]	45 (92%)	43 (93%)

The immediate markers of postoperative recovery were in favour for the remifentanil-accentuated group. The differences in mean times until extubation, eye opening or achieving fast-track eligibility were between 3 and 5 minutes. However, it should be mentioned that the study protocol did not allow reduction of the dose of anaesthetics at the end of surgery and thus the results obtained here are somewhat artificial and do not represent the every day practice.

One hour postoperatively, a comparable fraction of more than 90% of the patients were ready for discharge using a validated post-anaesthesia recovery score [10]. Furthermore, postoperative global rating of the tolerability of anaesthesia was not different between the two groups.

CONCLUSION

Balanced anaesthesia with desflurane and remifentanil allows moderate controlled hypotension in patients undergoing microscopic and endoscopic sinus surgery without the use of additional vasoactive drugs. The dryness of the operating site was rated significantly better by the ENT-surgeons when the balance between the opioid analgesic remifentanil and the hypnotic desflurane was shifted towards the desflurane-accentuated technique. However, the underlying absolute difference is of questionable clinical importance. The immediate postoperative recovery was faster in the remifentanil-accentuated group. Taking into account the subjective rating of the patients 24 hours after surgery did not differ between the two groups, both modifications of the desflurane-remifentanil combination can be regarded as clinically equivalent.

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