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Patient well-being after general anaesthesia: a prospective, randomized, controlled multi-centre trial comparing intravenous and inhalation anaesthesia

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Background. The aim of this study was to assess postoperative patient well-being after total i.v. anaesthesia compared with inhalation anaesthesia by means of validated psychometric tests.

Methods. With ethics committee approval, 305 patients undergoing minor elective gynaecologic or orthopaedic interventions were assigned randomly to total i.v. anaesthesia using propofol or inhalation anaesthesia using sevoflurane. The primary outcome measurement was the actual mental state 90 min and 24 h after anaesthesia assessed by a blinded observer using the Adjective Mood Scale (AMS) and the State-Trait-Anxiety Inventory (STAI). Incidence of postoperative nausea and vomiting (PONV) and postoperative pain level were determined by Visual Analogue Scale (VAS) 90 min and 24 h after anaesthesia (secondary outcome measurements). Patient satisfaction was evaluated using a VAS 24 h after anaesthesia.

Results. The AMS and STAI scores were significantly better 90 min after total i.v. anaesthesia compared with inhalation anaesthesia (P=0.02, P=0.05, respectively), but equal 24 h after both anaesthetic techniques (P=0.90, P=0.78, respectively); patient satisfaction was comparable (P=0.26). Postoperative pain was comparable in both groups 90 min and 24 h after anaesthesia (P=0.11, P=0.12, respectively). The incidence of postoperative nausea was reduced after total i.v. compared with inhalation anaesthesia at 90 min (7 *vs* 35%, P<0.001), and 24 h (33 *vs* 52%, P=0.001).

Conclusion. Total i.v. anaesthesia improves early postoperative patient well-being and reduces the incidence of PONV.

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General anaesthesia can be provided by i.v. or inhaled volatile anaesthetics. In current practice, both propofol for total i.v. and sevoflurane for inhalation anaesthesia are frequently administered because of their pharmacological properties providing fast recovery after anaesthesia.[1–5] Clear indications for the use of one or the other method with respect to 'minor' outcomes such as postoperative nausea and vomiting (PONV) and quality of anaesthesia are lacking. Therefore, preference in daily practice continues to be based on tradition, consideration of costs or clinical impression of anaesthesiologists and patients rather than on large trial evidence.

This randomized, double-blind multi-centre study was designed to assess the effect of total i.v. anaesthesia with propofol compared with inhalation anaesthesia with sevoflurane on postoperative patient well-being and major adverse events in the postoperative period. In addition, we intended to define preoperative risk factors predicting

reduced postoperative patient well-being and increased occurrence of PONV. Our hypothesis was that total i.v. anaesthesia would show improved postoperative patient well-being and improved patient satisfaction.

Methods

Patients and interventions

With ethics committee approval in-patients presenting for minor elective gynaecological or orthopaedic interventions were screened for study eligibility at the Triemli City Hospital and the University Hospital Zurich, Switzerland. Patients were admitted to the study according to the following criteria: (i) ASA classification I or II; (ii) age between 20 and 80 yr; (iii) German speaking; (iv) absence of psychiatric diagnosis or psychiatric medication and drug or alcohol abuse; (v) planned minor gynaecological intervention (laparoscopic, hysteroscopic, vaginal, or transabdominal procedures and breast tumour surgery) or minor orthopaedic surgery on extremities (arthroscopy, meniscectomy, minor internal fixation, removal of metal work, or minor tumour resection); (vi) no specific anaesthetic technique (i.e. regional anaesthesia, total i.v. or inhalation anaesthesia) requested or preferred.

Primary and secondary outcome measures

The primary outcome measure was patient well-being assessed by the Adjective Mood Scale (AMS)[6] and the short form of the State-Trait-Anxiety Inventory (STAI).[7 8] Additionally, patient satisfaction was assessed to establish a possible correlation to patient well-being as a quality indicator of anaesthesia. Additional secondary outcome measures were the cumulative incidence of PONV and the level of postoperative pain.

Study sequence

Preoperative period

On the day before surgery, 1 h after the routine preoperative visit, written informed consent was obtained and the preoperative interview was performed by an independent observer (Fig. 1). Patient characteristics (age, gender, social, and educational status), basic medical history, history of previous general anaesthesia and previous PONV, and the relevant findings of a physical examination were recorded. Subsequently, the patient's preoperative emotional state (e.g. patient well-being) was evaluated using the psychometric test sequence (AMS and STAI).

Randomization and blinding

After the interview, the patients were assigned randomly to receive total i.v. anaesthesia with propofol or inhalation anaesthesia with sevoflurane: computer-generated randomization, stratified by centre and intervention, was developed by a statistician (R.K.). Allocation concealment was ensured by enclosing assignments in sealed, sequentially numbered envelopes distributed to both centres. For each patient, the corresponding envelope was attached to the pre-medication notes and was opened the next day in the operating room before induction of anaesthesia. Study personnel (independent observer) and patients were blinded to group assignment for the time from allocation until after the second postoperative interview 24 h after anaesthesia.

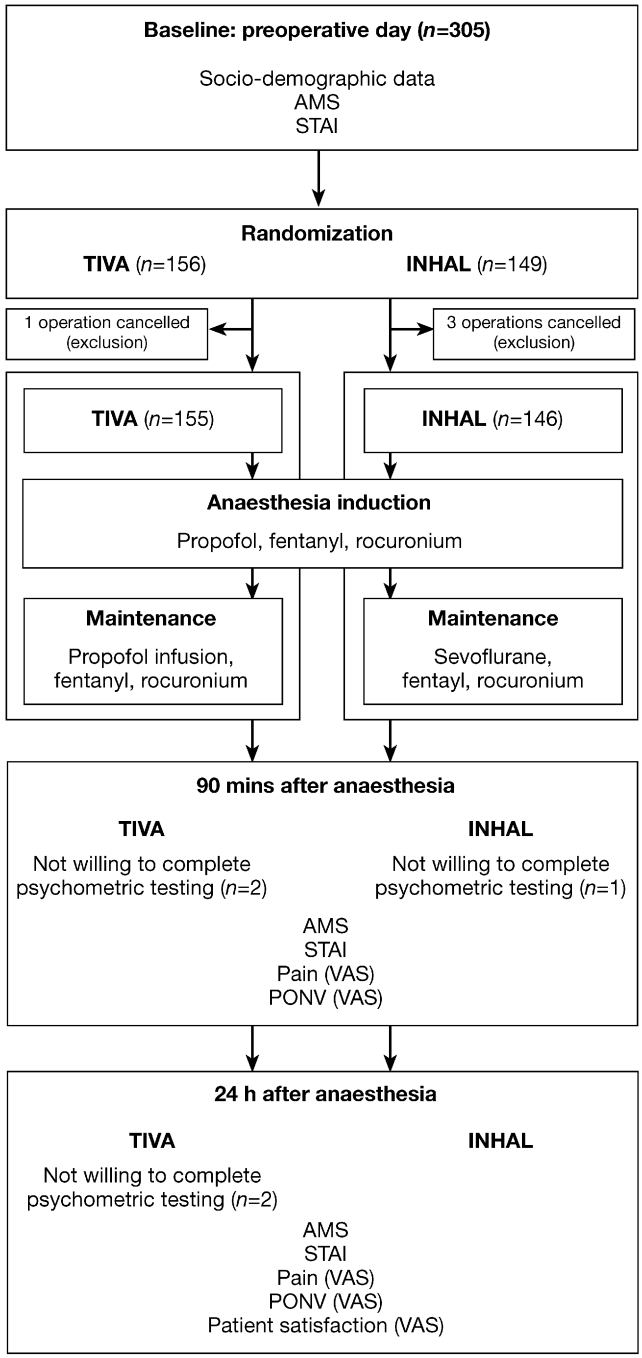

Fig 1 Study profile. TIVA=total i.v. anaesthesia group; INHAL=sevoflurane inhalation anaesthesia group.

Anaesthesia

The patients received pre-medication with oral midazolam 7.5 mg 1 h before induction of anaesthesia. After application of routine monitoring, standardized anaesthesia induction for all patients was performed using sequential boluses of i.v. fentanyl (3 μg kg^{-1}), lidocaine 1% (10 mg) and propofol (1.4 mg kg^{-1}). Rocuronium (0.6 mg kg^{-1}) was given for neuromuscular block after loss of the eyelash reflex and the trachea was intubated. Anaesthesia was maintained with an i.v. propofol infusion 2–8 mg kg^{-1} h^{-1} or inhaled sevoflurane titrated to keep haemodynamic variables within 10% of pre-induction levels. Before skin incision, fentanyl 3 μg kg^{-1} i.v. was given in both groups. In the case of inadequate depth of anaesthesia indicated by movement, swallowing, sweating, tachycardia, or increase in arterial pressure (>10% of pre-induction level), the end-expiratory concentration of sevoflurane or the rate of propofol infusion were increased. If this was not sufficient, additional fentanyl (1.5 μg kg^{-1}) i.v. was given. Controlled mechanical ventilation with oxygen/air (inspired oxygen fraction=0.5) was applied. Before completion of surgery, all patients received pro-paracetamol 2 g i.v. No prophylactic anti-emetics were given. The duration of surgery and anaesthesia and the dosages of drugs were recorded on a separate evaluation sheet by the anaesthesiologist in charge of the patient.

Postoperative period

Ninety minutes after the termination of anaesthesia a second interview (psychometric test sequence) was carried out by the same independent observer who performed the pre-operative tests. The occurrence of both postoperative nausea or vomiting (yes/no) was recorded. The intensity of pain was assessed using a Visual Analogue Scale (VAS) based on a total score between 0 and 10 (0=no pain and 10=worst pain). On the first postoperative day, 24 h after anaesthesia, the interview with AMS, STAI, assessment of postoperative nausea, vomiting and postoperative pain was repeated by the same observer. Additionally, patient satisfaction was evaluated using a VAS (0=not satisfied, 10=completely satisfied). After the interview, use of analgesics and anti-emetics within 24 h after the operation was recorded from the charts. Subsequently, all data were entered in a Microsoft Access 2000® database.

Psychometric tests

AMS

The Zerssen AMS[6] proved to be a valid instrument in the assessment of affective state in German[9] and French-speaking patients.[10] It has been successfully used in patients after anaesthesia.[11] The questionnaire consists of 28 paired items representing different dimensions of affects. Each pair is rated by the patient and the answers are scored ('rather happy'=0 points, 'rather unhappy'=2 points, 'neither of both'=1 point). Therefore, scoring ranges from 0 to 56 points with decreased well-being represented by higher scores.

STAI

The Spielberger STAI is a reliable and sensitive measure of anxiety in applied psychology research and in anaesthesia.[12] In contrast to the original version with 40 items,[8] the validated short form of the inventory[7] to assess state has six items ('calm', 'tense', 'feel upset', 'relaxed', 'feel content', 'worried'). Every item is rated by the patient and answers are scored ('not at all'=1 point, 'somewhat'=2 points, 'moderately'=3 points, 'very'=4 points). Scoring ranges from 6 to 24 points, and higher scores indicate increased anxiety.

Practicability and reliability of the AMS and STAI 90 min after general anaesthesia was tested in a pilot study performed in 50 patients at the Triemli City Hospital during March 2000. All 50 patients were able to answer the test sequence in an adequate manner. The preoperative mean (SD) value for AMS in this pilot study was 13.1 (11.5) (median 11, range 0–46). It increased 90 min after general anaesthesia to 20.8 (11.4) (21, 0–43) ($P<0.01$). The preoperative mean value for STAI was 17.8 (3.8) (16, 6–24), decreasing to 15.8 (3.3) (15, 6–21) ($P<0.001$) 90 min after anaesthesia. The Crohnbach α statistic for AMS was 0.93 and for STAI 0.85, that is the test reliability was high for this setting.

Statistics

Sample size calculation

All statistical analyses were performed using SPSS for Windows 9.0. Assuming a difference of 0.5 SD in the psychometric test sequence (AMS and STAI) with an α-error level=0.05 (one-sided) a sample size of 75 patients for each group (total i.v., inhalation anaesthesia and gynaecologic, orthopaedic procedures, respectively) was calculated to yield a test power of greater than 80%. Therefore, a minimum of 300 patients had to be included in the study.

Data analysis

Data were analysed (two-sided) according to a pre-established plan by a statistician. Differences in the results of psychometric testing (AMS and STAI) between total i.v. and inhalation anaesthesia were compared using the Mann–Whitney *U*-test for independent samples adjusted for multiple comparisons (Bonferroni–Dunn correction). The incidences of postoperative nausea and also vomiting between groups were compared using the χ^2-test. A predefined subgroup analysis for primary and secondary outcome measurements was performed for gynaecological and orthopaedic procedures. Differences in patient satisfaction and in postoperative pain were tested using the *t*-test for independent samples. Risk factor analysis predicting reduced postoperative patient well-being (postoperative increased AMS and STAI as continuous variables) was

performed on the basis of pre- and intraoperative variables by multiple regression analysis. A risk factor analysis to predict PONV (nominal variables yes/no) was done using logistic regression. Data are presented as mean (SD). In addition median and range are indicated for psychometric test results.

Results

A total of 305 patients were included in the study between July 4, 2000 and July 10, 2001, 145 at the Triemli City Hospital Zurich and 160 at the University Hospital Zurich. Four patients were excluded from the study protocol after randomization as a result of cancelled surgery. 155 patients had general anaesthesia with propofol and 146 patients inhalation anaesthesia using sevoflurane. Five patients were not willing to complete the psychometric testing in the postoperative period; these patients were included in the statistical analysis (Fig. 1). The two study groups were comparable with respect to baseline patient, clinical and psychological characteristics, and the distribution of planned interventions. In both groups the duration of surgery and anaesthesia were comparable. Similar dosages of propofol for induction and of fentanyl during anaesthesia were given. The dosage of propofol for maintenance in the TIVA group was 1446 (896) mg, and the mean end-expiratory concentration of sevoflurane was 1.3 (0.5) MAC (MAC=minimal alveolar concentration) (Table 1).

Table 1 Patient characteristics; surgery and anaesthesia data. TIVA=total i.v. anaesthesia group; INHAL=sevoflurane inhalation anaesthesia group; MAC=minimal alveolar concentration. Data are presented as mean (SD or range) or *n* (%), respectively

	TIVA (*n*=155)	**INHAL (*n*=146)**
Age, yr	46 (20–77)	48 (20–79)
Male/female ratio, *n* (%)	43/112 (28/72)	42/104 (29/71)
ASA I/II, *n* (%)	86/69 (56/44)	78 (53/47)
Previous general anaesthesia, *n* (%)	121 (78)	112 (77)
Previous PONV, *n* (%)	35 (23)	33 (23)
Fear of anaesthesia, *n* (%)	82 (53)	81 (56)
Gynaecological procedures, *n* (%)	73 (47)	69 (47)
Orthopaedic procedures, *n* (%)	82 (53)	77 (53)
Duration of surgery, min	88 (47)	93 (49)
Duration of anaesthesia, min	155 (54)	157 (54)
Dosage of propofol (induction), mg	122 (41)	120 (41)
Dosage of propofol (maintenance), mg	1446 (896)	–
Mean sevoflurane concentration, MAC	–	1.3 (0.5)
Dosage of fentanyl (induction), mg	0.2 (0.1)	0.2 (0.1)
Dosage of fentanyl (maintenance), mg	0.5 (0.3)	0.5 (0.1)

Table 2 Primary outcome measurement: patient well-being. TIVA=total i.v. anaesthesia group; INHAL=sevoflurane inhalation anaesthesia group. Data are presented as mean (SD) (median/minimum/maximum)

	TIVA (*n*=155)	**INHAL (*n*=146)**	***P***
AMS			
Baseline	12.0 (10.0) (10/0/46)	11.5 (9.2) (9/0/40)	0.83
90 min after anaesthesia	20.9 (10.8) (21/0/45)	23.6 (11.1) (23/0/48)	0.02
24 h after anaesthesia	13.3 (9.6) (12/0/44)	13.7 (10.4) (11/0/42)	0.90
STAI			
Base line	11.3 (3.7) (10/6/24)	11.4 (3.2) (11/5/19)	0.37
90 min after anaesthesia	10.6 (3.5) (10/6/21)	11.5 (4.0) (11/6/24)	0.05
24 h after anaesthesia	9.7 (2.8) (9/6/18)	9.8 (2.4) (9/6/18)	0.78

Primary outcome measurements

The AMS levels were comparable for both groups at baseline (P=0.83). They increased in both groups 90 min after anaesthesia and decreased again after 24 h to approximately the baseline values. A significantly lower AMS 90 min after total i.v. anaesthesia indicated improved well-being as compared with inhalation anaesthesia (P=0.02). This difference between groups disappeared after 24 h (Table 2). The test reliability during the study period was high (Crohnbach α=0.89–0.92). The baseline STAI was also similar for both anaesthetic groups (P=0.37). Ninety minutes after total i.v. anaesthesia STAI decreased, whereas STAI decreased only 24 h after inhalation anaesthesia. There was a significant difference between the two anaesthetic techniques 90 min after anaesthesia (P=0.05) indicating lower anxiety after total i.v. anaesthesia. The test reliability for both psychometric tests was high (Crohnbach α=0.79–0.82). The changes in both psychometric tests during the test period (baseline, 90 min and 24 h after anaesthesia) were comparable for gynaecological and orthopaedic procedures. There was a significantly lower AMS for the gynaecology patients 90 min after anaesthesia (P=0.03).

Secondary outcome measurements

Patient satisfaction assessed by a VAS 24 h after anaesthesia was similar in both groups (9.6 (1.0) for the TIVA group *vs* 9.4 (1.5) for the inhalation anaesthesia, P=0.26). Occurrence of both nausea and vomiting was significantly higher 90 min and 24 h after anaesthesia in the inhalation compared with the total i.v. anaesthesia group (Table 3). Also, anti-emetic drugs were more frequently given after inhalation anaesthesia (Table 4). The cumulative incidence of PONV increased for both techniques in the first 24 h after anaesthesia. For gynaecological procedures, the incidence of PONV was significantly reduced 90 min and 24 h after total i.v. anaesthesia compared with inhalation anaesthesia (P<0.001 and P=0.006, respectively). For orthopaedic procedures, this effect was only significant for postoperative nausea 90 min after total i.v. anaesthesia (P=0.002): at 24 h, no difference between the two anaesthetic regimens could be shown (P=0.38). Postoperative pain levels were similar for both anaesthetic techniques. However, the use of opioids

Table 3 Secondary outcome measurements: incidence of postoperative nausea and vomiting; postoperative pain. TIVA=total i.v. anaesthesia group; INHAL=sevoflurane inhalation anaesthesia group; VAS=visual analogue scale (0=no pain, 10=strong pain). Data are presented as mean (SD) or *n* (%), respectively

	TIVA (*n*=155)	INHAL (*n*=146)	*P*
Cumulative incidence of postoperative nausea			
90 min after anaesthesia, *n* (%)	10 (7)	43 (31)	< 0.001
24 h after anaesthesia, *n* (%)	50 (33)	75 (52)	0.001
Cumulative incidence of postoperative vomiting			
90 min after anaesthesia, *n* (%)	4 (3)	13 (9)	0.01
24 h after anaesthesia, *n* (%)	34 (23)	50 (35)	0.01
Postoperative pain (VAS)			
90 min after anaesthesia	3.8 (2.5)	4.3 (2.4)	0.11
24 h after anaesthesia	3.8 (2.4)	4.2 (2.6)	0.12

Table 4 Postoperative medication. TIVA=total i.v. anaesthesia group; INHAL=sevoflurane inhalation anaesthesia group; NSAIDs=non-steroidal anti-inflammatory drugs

	TIVA (*n*=155)	INHAL (*n*=146)	*P*
Acetominophen, *n* (%)	122 (79)	118 (81)	0.42
NSAIDs, *n* (%)	28 (18)	23 (16)	0.23
Opioids, *n* (%)	105 (68)	113 (77)	0.04
Anti-emetics, *n* (%)	33 (21)	55 (37)	0.001

was significantly more frequent after inhalation anaesthesia (Tables 3 and 4). There were no differences between the gynaecological and the orthopaedic groups regarding postoperative pain.

Risk factor analysis

In terms of increased postoperative AMS the following independent pre- and intraoperative determinants of impaired postoperative patient well-being were identified: preoperatively increased STAI, gynaecological procedures, inhalation anaesthesia with sevoflurane, duration of anaesthesia and female gender (Table 5).

The predictability of multiple regression analysis (adjusted r^2) using the AMS was 31%, whereas the predictability using the STAI was only 14%. Independent risk factors for PONV for the entire study population were inhalation anaesthesia with sevoflurane, gynaecological interventions, and a preoperatively increased AMS (Table 6). In patients with a history of general anaesthesia, previous PONV was an additional risk factor (OR=3.12, 95% CI=1.32–7.40). The inclusion of postoperative factors in the risk analysis revealed use of postoperative opioids not to be significantly associated with PONV (OR=1.59, 95% CI=0.70–3.61).

Table 5 Risk factors for decreased postoperative patient well-being. Adjusted r^2=0.31, *P*=0.01, β=standardised regression coefficient

	β	*P*
Decreased preoperative well-being	0.44	<0.001
Gynaecological procedures	0.28	<0.001
Use of sevoflurane	0.15	0.003
Duration of anaesthesia	0.13	0.01
Gender (male *vs* female)	–0.16	0.01
Increased preoperative anxiety	0.10	0.10
Fear of anaesthesia	0.08	0.17
Smoking	–0.04	0.43
Age (⩽50 *vs* >50 yr)	0.4	0.48
Obesity (BMI ⩾35 *vs* <35)	0.03	0.51

Table 6 Risk factors for postoperative nausea and vomiting. OR=odds ratio; CI=confidence interval

	OR	95% CI
Use of sevoflurane	7.80	3.48–13.51
Gynaecological procedures	3.0	1.23–7.26
Decreased preoperative well-being	1.06	1.02–1.11
Age (⩽50 *vs* >50 yr)	1.01	0.99–1.04
Duration of anaesthesia	1.00	0.99–1.01
Fear of anaesthesia	2.1	0.92–4.82
Increased preoperative anxiety	0.90	0.79–1.02
Gender (female *vs* male)	2.1	0.65–6.78
Obesity (BMI ⩾35 *vs* <35)	0.47	0.16–1.41
Smoking	0.43	0.19–0.96

Discussion

This trial demonstrates that total i.v. anaesthesia with propofol was associated with improved early postoperative well-being as compared with inhalation anaesthesia using sevoflurane. The occurrence of PONV was significantly lower after total i.v. anaesthesia. Improved well-being and reduced incidence of PONV after total i.v. anaesthesia was particularly pronounced in the group of patients undergoing gynaecological procedures. The intensity of postoperative pain was comparable using both techniques and patient satisfaction was similarly high after inhalation and total i.v. anaesthesia.

Well-being represents the subjective patient condition[6 9 10] and has been proposed as a useful surrogate endpoint in anaesthetic quality assessment.[11] However, in the context of general anaesthesia, an attempt to evaluate possible differences of quality only between different anaesthetic techniques has never been made. In the present study, an established psychometric test, Zerssen's AMS[6] was used to assess subjective patient state before and after anaesthesia. Being a central issue in the perioperative subjective experience, anxiety was specifically determined by Spielberger's STAI.[7] The combination of both tests allowed the assessment of different qualities of the patient's affective state perioperatively, whereas most studies on

quality of anaesthesia did not discriminate between affective and cognitive patient perception.[13 14] Both tests revealed a significantly better affective state in the early postoperative period after total i.v. anaesthesia compared with inhalation anaesthesia.

The reduction of PONV may be the main determinant of this improved affective state. PONV remains a major patient complaint related to anaesthesia[15] and a frequent endpoint in studies comparing total i.v. with inhalation anaesthesia.[16–18] A significantly reduced incidence of PONV after i.v. anaesthesia was suggested in a number of studies.[19 20] However, most studies revealed a variety of methodological and statistical problems (small study populations, case mix, use of different anaesthetics, non-standardized use of opioids, heterogeneous definition of PONV). Two large meta-analyses showed evidence of a significantly reduced incidence of PONV up to 6 h after total i.v. anaesthesia.[19 20] This effect was also observed recently in a large controlled trial for up to 24 h postoperatively by Visser and co-workers.[17] However, some confounding factors in this study have to be considered when interpreting the results, these are the use of nitrous oxide as a potential risk factor for PONV in the inhalation group only, inclusion of both inpatients and outpatients, and use of different anaesthetic induction regimens and techniques. In the present study, the effect on PONV of total i.v. and inhalation anaesthesia was evaluated without the use of nitrous oxide in inpatients only with one standardized induction regimen. Still, a high overall incidence of PONV was observed. The occurrence of PONV in the total i.v. anaesthesia group was significantly reduced in the early postoperative period, then increased in the first 24 h postoperatively, but remained significantly lower compared with the inhalation anaesthesia group. The anti-emetic effect of propofol in subanaesthetic concentrations may be responsible for this finding.[21]

Pain, another important patient complaint in the postoperative period, may affect well-being. Opioid use was significantly higher in the sevoflurane anaesthesia group to achieve a comparable intensity of postoperative pain. This finding may indicate that patients had more pain after inhalation anaesthesia and this may have influenced well-being in the early postoperative period. Furthermore, increased opioid analgesic usage is known to promote PONV.[22] However, this postoperative use of opioid analgesics was not an independent determinant of PONV in the risk factor analysis.

This study did not address any aspects of costs and economy. However, today clinicians are faced with the need to improve patient outcome at minimal costs. Total i.v. anaesthesia is supposed to be more expensive than inhalation anaesthesia.[17 23 24] Cost assessment and cost-benefit analysis in anaesthesia have proved to be complex. Comparing costs of anaesthetic drugs alone (direct costs) is inappropriate, as postoperative adverse events—such as PONV—may be associated with secondary expenses (indirect costs). Thus, identification of risk groups for adverse outcome appears to be desirable. The preoperative risk factor analysis of the present study revealed that patients undergoing gynaecological procedures are at highest risk for impaired postoperative well-being. They also suffer from PONV in more than 60% of cases after inhalation anaesthesia. In contrast, significantly improved well-being and a significantly reduced incidence of PONV in this group was demonstrated after total i.v. anaesthesia. We believe the use of this more expensive anaesthetic drug in this specific risk group to be justified not only from the medical but also from the economical point of view.

In contrast to the present results, many studies comparing propofol with sevoflurane anaesthesia failed to show any difference between the two anaesthetic techniques in terms of improved patient outcome (e.g. recovery, patient satisfaction, PONV).[1 3 5 25] Study designs with a pragmatic approach of daily clinical practice,[25] but also shortcomings of surrogate endpoints[1 3] may be responsible for these findings. However, applying a strict anaesthetic regimen with minimal variations, which may in part not reflect common practice, revealed a significant difference in psychometric testing.

In conclusion, when compared with sevoflurane we have shown that propofol for maintenance of general anaesthesia improves early postoperative patient well-being and reduces, but does not eliminate the risk of PONV, especially in the subgroup of patients undergoing gynaecological procedures.

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