

ORIGINAL ARTICLE

Awake, sedated or anaesthetised for regional anaesthesia block placements?

A retrospective registry analysis of acute complications and patient satisfaction in adults

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BACKGROUND Whether adults should be awake, sedated or anaesthetised during establishment of regional anaesthesia is still debated and there is little information on the relative safety of each. In paediatric practice, there is often little choice but to use sedation or anaesthesia as otherwise the procedures would be too distressing and patient movement would be hazardous.

OBJECTIVE(S) The objective of this study was to evaluate complications related to central and peripheral regional block and patient satisfaction in awake, sedated and anaesthetised adult patients.

DESIGN A retrospective registry analysis.

SETTING The German Network of Regional Anaesthesia database was analysed between 2007 and 2012.

PATIENTS We included data of 42 654 patients and defined three groups: group I awake ($n = 25\,004$), group II sedated ($n = 15\,121$) and group III anaesthetised ($n = 2529$) for block placement.

MAIN OUTCOME MEASURES Odds ratios [OR; 95% confidence interval (CI)] were calculated with logistic regression analysis and adjusted for relevant confounders

to determine the risk of block-related complications in sedated or anaesthetised patients compared with awake patients.

RESULTS Rates of local anaesthetic systemic toxicity were comparable between the groups [awake 0.02% (95% CI: 0.002 to 0.0375), sedated 0.02% (0.003 to 0.042) and anaesthetised 0% (0 to 0.12%)], as were the rates of pneumothorax [awake 0.035% (0 to 0.074), sedated 0% (0 to 0.002) and anaesthetised 0.2% (0 to 0.56)]. Considering peripheral nerve blocks, sedated patients had a decreased risk for multiple skin puncture [adjusted OR: 0.78 (95% CI: 0.71 to 0.85), premature termination [0.45 (0.22 to 0.91)], primary failure [0.58 (0.40 to 0.83)] and postoperative paraesthesia [0.35 (0.28 to 0.45)], but an increased risk for a bloody tap [1.82 (1.50 to 2.21)]. General anaesthesia increased the risk of a bloody tap [adjusted OR: 1.33 (95% CI: 1.01 to 1.78)] and multiple skin puncture [1.28 (1.12 to 1.46)], but decreased the risk for postoperative paraesthesia [0.16 (0.06 to 0.38)]. In neuraxial sites, sedation increased the risk for multiple skin puncture [adjusted OR: 1.18 (95% CI: 1.09 to 1.29)], whereas block placement under general anaesthesia decreased the risk for multiple skin puncture [0.53 (0.39 to 0.72)] and bloody tap

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but significantly increased the risk for postoperative paraesthesia related to a catheter [2.45 (1.19 to 5.02)]. Sedation was associated with a significant improvement in patient satisfaction.

Introduction

Regional anaesthesia is associated with a reduced morbidity and mortality in the peri and postoperative period after some types of surgery.^{1–4} In trauma and orthopaedic surgery, regional anaesthesia provides pain control superior to systemic analgesia and may be associated with reduced postoperative cognitive dysfunction.^{5,6} However, the patients' state of consciousness during regional anaesthesia procedures is still debated. Block placement under general anaesthesia is widely accepted in paediatrics and in noncompliant or disabled patients, to minimise distress and hazardous movements but is only used in a minority of compliant adult patients.^{7–9} Leaving patients responsive during regional anaesthesia procedures is thought to reduce the chance of local anaesthetic systemic toxicity (LAST) because patients should be able to communicate early warning signs.^{10,11} Needle-to-nerve contact or the injection of local anaesthetic into a nerve may be reported immediately as pain or paraesthesia by a responsive patient, and so many anaesthesiologists prefer to perform regional anaesthesia on patients in an awake or lightly sedated state¹² but this is not substantiated by a high level of evidence.^{13,14} On the other hand, patients often require sedation to reduce procedural pain and anxiety, and to improve comfort. Whenever catheter placement is planned for postoperative pain therapy together with a general anaesthesia for surgery, worried patients may ask why the regional anaesthesia procedure is not performed under general anaesthetic. Furthermore, sedation or block placement under general anaesthetic reduces spontaneous patient movements, which are associated with complications, such as unintentional vascular or dural puncture, pneumothorax or multiple skin puncture. Thus, general anaesthesia could contribute to a higher acceptance of regional anaesthesia procedures and improve safety.¹¹

Randomised controlled trials may answer these uncertainties, but are extremely difficult to perform because serious complications remain rare. In 2007, the *German Society for Anaesthesiology and Intensive Care Medicine* and the *Professional Association of German Anaesthesiologists* established a network for safety in regional anaesthesia.¹⁵ Since then, data regarding patients' health status, details of the block procedures and acute complications are collected in a registry. Employing this large multicentre database, we analysed retrospectively the effects of sedation and general anaesthesia on block-related complications and patient satisfaction.

CONCLUSION Sedation may improve safety and success of peripheral nerve block placement. Block placement under general anaesthesia in adults should be reserved for experienced anaesthesiologists and special situations.

Published online 27 June 2016

Materials and methods

The German Network of Regional Anaesthesia (NRA) database was analysed between November 2007 and December 2012. During this 5-year-period, 25 clinical centres participated in the data collection. The retrospective data analysis was conducted at the Saarland University Medical Centre, Germany.

Ethical approval

Ethical approval was provided by the Ethical Committee of the *Ärztekammer des Saarlandes*, Saarbrücken, Germany (number Ha50/11, Chairperson Professor Dr Herrmann Schieffer) on 22 March 2011. The approval did not require written consent, as the data stored in the NRA database are anonymous (regulatory proof of protection of data privacy, Saarland Commissioner, 12 March 2014).

Data collection

The NRA database collects pre, intra and postoperative data related to regional anaesthesia procedures, intravenous patient-controlled analgesia or combinations thereof within the frame of a defined record.¹⁵ Each participating hospital uses an individualised documentation system (digital or machine-readable paper) completed by the anaesthesiologists in charge of the patient and the members of the acute pain service. Each centre transfers the data from all documented treatments anonymously via https-encrypted Extensible Markup Language files regularly to a central registry ensuring data safety. Uploaded data are not automatically checked for completeness, as not all data fields are compulsory. For the present analysis, we extracted all cases with regional anaesthesia procedures from the registry and transferred the data into an Excel data sheet for further editing.

Validation of data

The database included 82 287 regional anaesthesia-related cases in the above-mentioned period, which were comprehensively tested to comply with the predefined inclusion criteria: completeness of demographic data; clear information on whether patients were awake, sedated or anaesthetised and the presence of information about acute complications. The definitions of the block-related acute complications considered in our study are given in Table 1. After exclusion of 37 832 patients not complying with the predefined inclusion criteria and 853 children who were below 14 years of age, the remaining

Table 1 Definition of central and peripheral block-related acute complications and patient satisfaction according to the German Network of Regional Anaesthesia

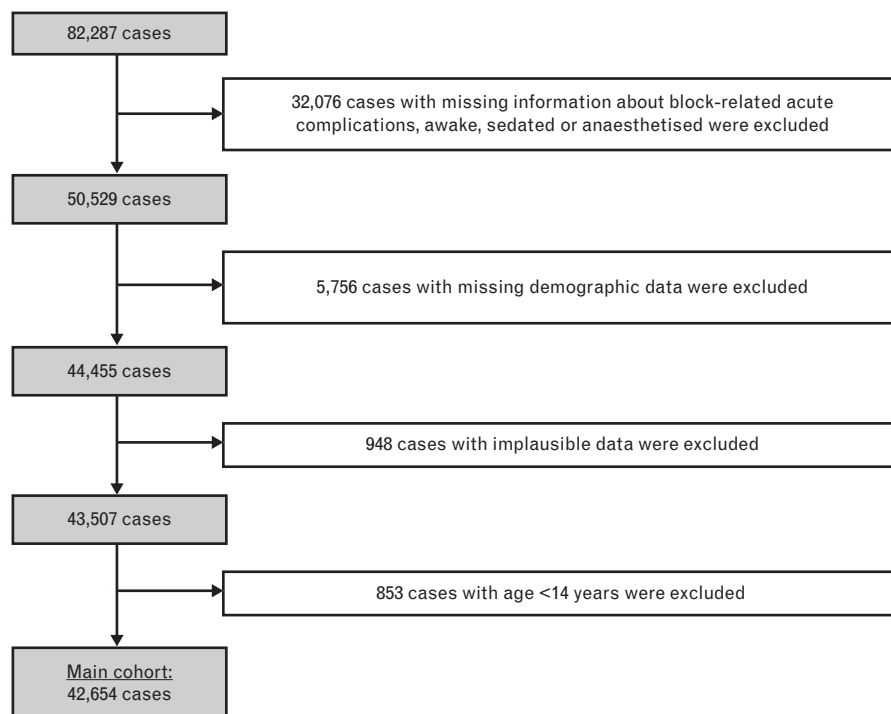
Central and peripheral block-related acute complications	Definition according to the German Network of Regional Anaesthesia
LAST	Symptoms of intoxication (neurologic and/or cardiovascular) after the injection of the local anaesthetic ^{16,17}
Pneumothorax	A puncture-related pneumothorax
Accidental dural puncture	Unintentional tap of the dura mater
Bloody tap	Aspiration of blood through the puncture needle or catheter
Multiple skin puncture	More than one skin puncture for one particular block procedure
Premature termination (of the block procedure)	Either because of unfavourable anatomic conditions or insufficient compliance of the patient
Primary failure (for surgical interventions planned under regional anaesthesia)	Need to change the anaesthetic technique into unplanned general anaesthesia
Postoperative paraesthesia in patients with catheters	An unexpected painful, unpleasant or electrifying sensation within the area supplied by the nerve(s) affected by the regional anaesthesia (without any adequate stimulus)
Patient satisfaction	Satisfaction with the regional anaesthesia therapy reported by the patient at the final round of the acute pain service described by a verbal numeric rating scale ranging from 0 (= completely dissatisfied) to 10 (= completely satisfied)

43 602 cases were subjected to a plausibility check according to predefined rules. The date of birth had to be before the date of the procedure; obstetric procedures were only accepted in women; and age, weight and height needed to be in a plausible relation: the lower limits of height and weight were defined as the third percentile of a 14-year-old woman (150 cm, 39 kg) and man (150 cm, 38 kg); the upper limits to a height of 220 cm, a weight of 250 kg and a BMI of 70 kg m^{-2} . The denominator for pneumothorax rates was defined for periclavicular blocks and thoracic epidurals, and the denominator for

accidental dural puncture rates was defined by the number of epidural blocks. A total of 948 cases had to be excluded because of implausibility with the result of a final study population of 42 654 cases with single shot or continuous regional anaesthesia in both peripheral and neuraxial sites (Fig. 1).

Study population

The final study cohort ($n = 42\,654$) was subdivided into three groups based on state of consciousness at the time of placement of the regional anaesthetic block:

Fig. 1

Flow chart of data selection.

- (1) Awake without any drugs for sedation ($n = 25\,004$)
- (2) Sedated ($n = 15\,121$)
- (3) Anaesthetised and mechanically ventilated ($n = 2529$)

Statistical analysis

Continuous variables are expressed as means and SDs. Categorical variables are presented as absolute and relative frequencies, unless otherwise stated. χ^2 tests were performed for the comparison of frequencies between the groups. For continuous variables, groups were compared by one-way Analysis Of Variance (ANOVA) followed by post hoc analysis including the correction of α error according to Bonferroni. For nonnormal distributed variables, ANOVA for nonparametric values (Kruskal–Wallis test) was used with multiple comparison method (Dunn or Bonferroni method). Statistical significance was accepted at two-sided $P \leq 0.05$. Logistic regression analysis was used to calculate univariate and multivariate odds ratios [ORs and (95% confidence intervals)]. Only statistically significant variables were included in the multivariate logistic regression. Potential confounders were sex, age, BMI, *American Society of Anesthesiologists* physical status score, diabetes mellitus, glomerular filtration rate, use of ultrasound, anti-

coagulation (warfarin, platelet inhibition, high/low molecular heparin), multiple skin puncture, bloody tap and premature termination. These were used to identify the specific confounders for each analysis, which are listed in particular in the results. Collinearity was tested by Pearson or Spearman correlation coefficients. Variables with a positive (>0.3) or negative correlation (<-0.3) were excluded. Goodness of fit for each adjusted model was assessed by Hosmer–Lemeshow tests ($P > 0.05$). All variables were verified with centre analyses to avoid centre effects. For each centre, frequency analyses were performed and OR and 95% confidence interval were calculated by logistic regression. All data analyses were performed using SPSS Statistics 19 (IBM, Ehningen, Germany).

Results

Table 2 presents the demographic factors of the study population. A total of 21 338 peripheral nerve blocks (PNBs) and 21 316 neuraxial blocks were analysed. The majority of PNBs (55.7%) were performed in sedated, followed by awake (33.9%) and anaesthetised patients (10.4%). Ultrasound was frequently used in awake (35.9%) and sedated (41.8%) patients ($P < 0.001$), but only in 23.2% of the anaesthetised patients ($P < 0.001$).

Table 2 General information about demographics and sites

Demographics	Awake ($n = 25\,004$)	Sedated ($n = 15\,121$)	Anaesthetised ($n = 2529$)	P-value awake versus sedated	P-value awake versus anaesthetised
Patient-related data					
Male sex (%)	10 340 (41.4)	7052 (46.6)	1159 (45.8)	<0.001	<0.001
Age (years)	54 ± 19	57 ± 18	55 ± 20	0.01	0.68
BMI (kg m^{-2})	27.6 ± 5.5	27.7 ± 5.5	27.3 ± 5.9	0.09	0.31
ASA 1 (%)	3161 (12.6)	1974 (13.1)	594 (23.5)	0.23	<0.001
ASA 2 (%)	14 834 (59.4)	7703 (50.9)	1363 (53.9)	<0.001	<0.001
ASA 3 (%)	6735 (26.9)	5329 (35.2)	542 (21.4)	<0.001	<0.001
ASA 4 (%)	274 (1.1)	115 (0.8)	30 (1.2)	0.001	0.68
GFR (ml min^{-1})	91 ± 33	89 ± 29	106 ± 33	<0.001	<0.001
Diabetes (%)	2973 (12.0)	1889 (12.5)	324 (12.9)	0.11	0.18
Anticoagulation (%)	8418 (33.7)	5946 (39.3)	1318 (52.1)	<0.001	<0.001
Site					
Peripheral nerve blocks (%)	7226 (28.9)	11 889 (78.6)	2223 (87.9)	<0.001	<0.001
Upper limb					
Interscalene (%)	1658 (6.6)	2565 (17.0)	333 (13.2)	<0.001	<0.001
Infracavicular (%)	590 (2.4)	380 (2.5)	206 (8.1)	0.33	<0.001
Axillary (%)	205 (0.8)	227 (1.5)	13 (0.5)	<0.001	0.05
Lower limb					
Femoral (%)	2292 (9.2)	2967 (19.6)	1000 (39.5)	<0.001	<0.001
Sciatic nerve (%)	1259 (5.0)	2650 (17.5)	435 (17.3)	<0.001	<0.001
Psoas (%)	1064 (4.2)	2954 (19.5)	49 (1.9)	<0.001	<0.001
Other peripheral nerve blocks (%)	158 (0.7)	146 (1.0)	187 (7.4)	<0.01	<0.001
Use of ultrasound (%)	2596 (35.9)	4970 (41.8)	516 (23.2)	<0.001	<0.001
Neuraxial blocks (%)					
Thoracic (%)	8034 (32.1)	1894 (12.5)	145 (5.7)	<0.001	<0.001
Lumbar (%)	5736 (22.8)	607 (4.0)	146 (5.8)	<0.001	<0.001
CSE (%)	2343 (9.4)	405 (2.7)	2 (0.1)	<0.001	<0.001
Intrathecal (%)	1632 (6.5)	311 (2.1)	3 (0.1)	<0.001	<0.001
Caudal (%)	33 (0.1)	15 (0.1)	10 (0.4)	0.36	0.04

Data are presented as mean \pm SD. Categorical variables are presented as a percentage in relation to the respective group, also the percentages of the different sites. GFR calculated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. Anticoagulation comprised warfarin, platelet inhibition and high and low molecular heparin. Peripheral sites with a case number less than 100 (supraclavicular, saphenous and suprascapular nerve blocks) were combined to 'other PNBs'. ASA, American Society of Anesthesiologists; GFR, glomerular filtration rate; PNB, peripheral nerve block.

Table 3 Drugs used in sedated patients (group II)

Drugs used for sedation	Sedated patients (<i>n</i> patients/% patients)
Opioid	6694/44.3%
Opioid + benzodiazepine	3981/26.3%
Opioid + others	288/1.9%
Benzodiazepine	3224/21.3%
Benzodiazepine + others	46/0.3%
Others	494/3.3%
Opioid + benzodiazepine + others	394/2.6%
Total	15 121/100.0%

The choice of sedative(s) and the overall dose administered were a priori decision of the anaesthetist in charge of the patient. 'Others' include propofol, clonidine and ketamine.

Neuraxial blocks were usually performed in awake patients (83.4%); 15.2% of the patients received sedative drugs and only 1.4% of the patients were anaesthetised. Table 3 gives a summary of drugs used for sedation.

Block-related complications in peripheral nerve blocks

Regarding PNBs (Table 4), we found four cases of LAST (0.19/1000) and three cases of pneumothorax after periclavicular blocks (1.48/1000). There was no statistical significance in the rates of LAST and pneumothorax between awake and sedated or anaesthetised patients.

The incidence of bloody tap was significantly higher in sedated (3.3%) and anaesthetised (3.8%) patients (awake 2.2%; $P < 0.001$). After adjustment for relevant confounders (sex, age, anticoagulation, use of ultrasound, multiple skin puncture, premature termination), both sedation [adjusted OR: 1.82 (1.50 to 2.21)] and general anaesthesia [adjusted OR: 1.33 (1.01 to 1.78)] seem to be associated with a significantly increased risk for a bloody tap.

The incidence of multiple skin puncture was found to be significantly lower in sedated (11.2%) and higher in anaesthetised (18.8%) patients (awake 13.9%; $P < 0.001$). Adjusted for relevant confounders (age, diabetes, anticoagulation, use of ultrasound, bloody taps, premature termination), the risk for multiple skin puncture was similarly lower in sedated [adjusted OR: 0.78 (0.71 to 0.85)] and higher in anaesthetised patients [adjusted OR: 1.28 (1.12 to 1.46)].

The overall rate of premature termination was low (0.25%) and sedation was associated with a significantly lower incidence (awake: 0.3%, sedated: 0.1%; $P = 0.01$) and risk [adjusted OR: 0.45 (0.22 to 0.91); adjusted for anticoagulation, use of ultrasound, multiple skin puncture, bloody tap]. Under general anaesthetic, the incidence of premature termination (awake: 0.3%, anaesthetised: 0.5%, $P = 0.21$) and the risk [adjusted OR 1.11 (0.52 to 2.37)] were comparable with awake patients. Unfavourable anatomical conditions were much more often the reason for abandoning the block procedure than insufficient patient compliance.

The incidence of primary failure was significantly lower when the block was performed under sedation (awake: 0.8%; sedated: 0.5%; $P < 0.01$) and as was the risk [adjusted OR: 0.58 (0.40 to 0.83); adjusted for use of ultrasound, multiple skin puncture].

For postoperative paraesthesia, we found a decreased incidence (awake: 3.4%; sedated: 1.2% and anaesthetised: 0.5%; $P < 0.001$) and risk in the group of sedated [adjusted OR: 0.35 (0.28 to 0.45)] and anaesthetised [adjusted OR: 0.16 (0.06 to 0.38)] patients (adjusted for age, anticoagulation, use of ultrasound, multiple skin puncture, bloody tap).

Patient satisfaction with the regional anaesthesia was significantly higher whenever performed under sedation (awake: 8.0 ± 3.4 ; sedated: 9.2 ± 2.1 ; $P < 0.001$). We found no further benefit for patients receiving the block procedure under general anaesthetic (awake: 8.0 ± 3.4 ; anaesthetised: 8.2 ± 3.5 ; $P = 0.6$).

Block-related complications in neuraxial blocks

Regarding neuraxial blocks (Table 5), four cases of LAST (0.19/1000), one case of pneumothorax (0.10/1000) after a thoracic epidural attempt and 96 cases of accidental dural puncture within thoracic (4.9/1000) and lumbar (7.2/1000) epidurals were documented. There was no statistically significant difference in the rates of LAST, pneumothorax and accidental dural puncture between the study groups.

The incidence of bloody tap in neuraxial blocks was comparable between awake and sedated patients, but significantly lower in anaesthetised patients (awake: 1.4%; sedated: 1.2% and anaesthetised 0.0%; $P < 0.001$).

The incidence of multiple skin puncture was significantly higher in sedated (31.4%) and lower in anaesthetised (17.0%) patients (awake 27.0%; $P < 0.001$) as was the risk, being increased under sedation [adjusted OR: 1.18 (1.09 to 1.29)] and decreased under general anaesthetic [adjusted OR: 0.53 (0.39 to 0.72); adjusted for sex, diabetes, anticoagulation, use of ultrasound, bloody taps, premature termination].

The incidence of premature termination for anatomical reasons was much greater than insufficient patient compliance and it was equally distributed between the study groups (awake: 0.6%; sedated: 0.5% and anaesthetised: 0.7%). In contrast to our results in PNBs, neither sedation nor general anaesthesia influenced the risk of premature termination.

The incidence of primary failure was comparable between sedated (0.2%) and awake (0.3%; $P = 0.07$) patients. In contrast to our results in PNBs, sedation did not decrease the risk of primary failure in neuraxial blocks (adjusted for anticoagulation, multiple skin puncture).

Table 4 Peripheral nerve block-related complications

Peripheral nerve block-related complications	Awake (n = 7226)	Sedated (n = 11 889)	Anaesthetised (n = 2223)	P-value awake versus sedated	P-value awake versus anaesthetised	P-value Hosmer– Lemeshow test
Local anaesthetic systemic toxicity						
	7226/2/0.0%	11 889/2/0.0%	2223/0/0.0%	0.62	0.43	
Crude OR (95% CI)	1	0.61 (0.09 to 4.32)	—	0.62	—	
Adjusted OR (95% CI)	1	0.71 (0.10 to 5.17)	—	0.73	—	
Pneumothorax						
Periclavicular	660/2/0.3%	465/0/0.0%	223/1/0.4%	0.24	0.75	
Crude OR (95% CI)	1	—	1.48 (0.13 to 16.43)	—	0.75	
Adjusted OR (95% CI)	1	—	1.61 (0.14 to 18.69)	—	0.70	
Bloody tap						
	7226/161/2.2%	11 889/395/3.3%	2223/84/3.8%	<0.001	<0.001	0.09
Crude OR (95% CI)	1	1.51 (1.25 to 1.82)	1.72 (1.32 to 2.25)	<0.001	<0.001	
Adjusted OR (95% CI)	1	1.82 (1.50 to 2.21)	1.33 (1.01 to 1.78)	<0.001	0.049	
Multiple skin puncture						
	7226/1006/13.8%	11 889/1329/11.1%	2223/418/18.8%	<0.001	<0.001	0.19
Crude OR (95% CI)	1	0.78 (0.71 to 0.85)	1.44 (1.27 to 1.63)	<0.001	<0.001	
Adjusted OR (95% CI)	1	0.78 (0.71 to 0.85)	1.28 (1.12 to 1.4)	<0.001	<0.001	
Premature termination (anatomy)						
	7226/21/0.3%	11 889/13/0.1%	2223/11/0.5%	0.01	0.21	0.13
Crude OR (95% CI)	1	0.38 (0.19 to 0.75)	1.71 (0.82 to 3.54)	0.01	0.15	
Adjusted OR (95% CI)	1	0.45 (0.22 to 0.91)	1.11 (0.52 to 2.37)	0.03	0.80	
Premature termination (compliance)						
	7226/3/0.0%	11 889/5/0.0%	—	0.99	—	0.65
Crude OR (95% CI)	1	1.01 (0.24 to 4.24)	—	0.99	—	
Adjusted OR (95% CI)	1	1.14 (0.27 to 4.80)	—	0.86	—	
Primary failure and change to general anaesthesia						
	7226/60/0.8%	11 889/56/0.5%	—	<0.01	—	0.47
Crude OR (95% CI)	1	0.57 (0.39 to 0.81)	—	<0.01	—	
Adjusted OR (95% CI)	1	0.58 (0.40 to 0.83)	—	<0.01	—	
Postoperative paraesthesia						
	5509/188/3.4%	10 043/118/1.2%	1016/5/0.5%	<0.001	<0.001	0.62
Crude OR (95% CI)	1	0.34 (0.27 to 0.43)	0.14 (0.06 to 0.34)	<0.001	<0.001	
Adjusted OR (95% CI)	1	0.35 (0.28 to 0.45)	0.16 (0.06 to 0.38)	<0.001	<0.001	

Reported as n = group size/number of block-related complications/percentage of block-related complications. Goodness of fit for each adjusted model was assessed by Hosmer–Lemeshow tests. CI, confidence interval; OR, odds ratio.

Regarding the risk of postoperative paraesthesia, we found no influence of sedation, but a significantly higher risk for patients receiving the neuraxial block under general anaesthetic [adjusted OR: 2.45 (1.19 to 5.02); adjusted for multiple skin puncture].

Patients were significantly more satisfied with regional anaesthesia when the neuraxial block was performed under sedation (awake: 7.4 ± 3.8 , sedated: 7.9 ± 3.6 ; $P = 0.01$), whereas those receiving the neuraxial block under general anaesthetic had lower satisfaction (awake: 7.4 ± 3.8 , anaesthetised: 6.5 ± 4.1 ; $P < 0.001$).

Discussion

In contrast to paediatric regional anaesthesia, only a few single-centre studies and anecdotal reports are available for regional anaesthesia performed in anaesthetised adults to assess the balance between comfort and safety.^{18–24} In searching for block-related acute complications, we were able to analyse 21 338 cases with PNBs and 21 316 cases with neuraxial blocks. Our multicentre

analysis of 42 654 cases is the first study to focus upon the patient's state of consciousness during regional anaesthesia procedures and how this may affect the incidence and risk of complications, and patient satisfaction.

We found that LAST and pneumothorax rates were independent of the state of consciousness. The incidence of LAST was low in peripheral and neuraxial puncture sites (0.19/1000), nevertheless close to the range known from literature (0.07 to 1/1000).²⁵ Sedation or block placement under general anaesthetic did not affect the incidence of LAST, so our results for adult patients are in accordance with Taenzer *et al.*'s²² registry analysis in 53 564 paediatric patients. A very low incidence was also found for pneumothorax. Only one of four reported cases was related to a thoracic epidural (0.10/1000), three occurred in the context of periclavicular block placement (1.48/1000) performed without ultrasound guidance. By using the landmark technique or nerve stimulation, the incidence of pneumothorax reported in previous studies ranges from 0.2 to 0.7% for infraclavicular and up to 6.1% for supraclavicular blocks.^{26,27} Gauss *et al.*²⁸ reported only

Table 5 Neuraxial block-related complications

Neuraxial block-related complications						
	Awake (n = 17 778)	Sedated (n = 3232)	Anaesthetised (n = 306)	P-value awake versus sedated	P-value awake versus anaesthetised	P-value Hosmer – Lemeshow test
Local anaesthetic systemic toxicity						
	17 778/3/0.0%	3232/1/0.0%	306/0/0.0%	0.59	0.82	
Crude OR (95% CI)	1	1.83 (0.19 to 17.64)	—	0.60	—	
Adjusted OR (95% CI)	1	1.83 (0.18 to 18.19)	—	0.61	—	
Pneumothorax						
Thoracic epidurals	8034/1/0.0%	1894/0/0.0%	145/0/0.0%	0.63	0.89	
Crude OR (95% CI)	1	—	—	—	—	
Adjusted OR (95% CI)	1	—	—	—	—	
Accidental dural puncture						
Thoracic epidurals	8034/38/0.5%	1894/10/0.5%	145/1/0.7%	0.76	0.71	
Crude OR (95% CI)	1	1.12 (0.56 to 2.25)	1.46 (0.20 to 10.72)	0.76	0.71	
Adjusted OR (95% CI)	1	1.12 (0.56 to 2.28)	2.01 (0.27 to 14.93)	0.75	0.50	
Lumbar epidurals	5736/45/0.8%	607/1/0.2%	146/1/0.7%	0.09	0.89	
Crude OR (95% CI)	1	0.21 (0.03 to 1.52)	0.87 (0.12 to 6.37)	0.12	0.89	
Adjusted OR (95% CI)	1	0.31 (0.04 to 2.34)	2.51 (0.32 to 19.76)	0.26	0.38	
Bloody tap						
	17 778/255/1.4%	3232/40/1.2%	306/0/0.0%	0.38	<0.001	0.01
Crude OR (95% CI)	1	0.86 (0.62 to 1.20)	—	0.38	—	
Adjusted OR (95% CI)	1	0.89 (0.63 to 1.25)	—	0.49	—	
Multiple skin puncture						
	17 778/4801/27.0%	3232/1014/31.4%	306/52/17.0%	<0.001	<0.001	0.09
Crude OR (95% CI)	1	1.24 (1.14 to 1.34)	0.55 (0.41 to 0.75)	<0.001	<0.001	
Adjusted OR (95% CI)	1	1.18 (1.09 to 1.29)	0.53 (0.39 to 0.72)	<0.001	<0.001	
Premature termination (anatomy)						
	17 778/109/0.6%	3232/16/0.5%	306/2/0.7%	0.42	0.93	0.56
Crude OR (95% CI)	1	0.81 (0.48 to 1.37)	1.07 (0.26 to 4.34)	0.42	0.93	
Adjusted OR (95% CI)	1	0.74 (0.43 to 1.28)	1.59 (0.39 to 6.53)	0.28	0.52	
Premature termination (compliance)						
	17 778/13/0.1%	3232/3/0.1%	—	0.71	—	0.45
Crude OR (95% CI)	1	1.27 (0.36 to 4.46)	—	0.71	—	
Adjusted OR (95% CI)	1	1.00 (0.22 to 4.45)	—	0.99	—	
Primary failure and change to general anaesthesia						
	17 778/61/0.3%	3232/6/0.2%	—	0.07	—	0.76
Crude OR (95% CI)	1	0.54 (0.23 to 1.25)	—	0.15	—	
Adjusted OR (95% CI)	1	0.61 (0.26 to 1.42)	—	0.25	—	
Postoperative paraesthesia						
	15 739/187/1.2%	2823/29/1.0%	291/8/2.7%	0.46	0.11	0.43
Crude OR (95% CI)	1	0.86 (0.58 to 1.28)	2.35 (1.15 to 4.82)	0.46	0.02	
Adjusted OR (95% CI)	1	0.85 (0.57 to 1.26)	2.45 (1.19 to 5.02)	0.42	0.02	

Reported as n = group size/number of block-related complications/percentage of block-related complications. Goodness of fit for each adjusted model was assessed by Hosmer–Lemeshow tests. CI, confidence interval; OR, odds ratio.

four pneumothoraces in 6366 ultrasound-guided periclavicular blocks and attributed the reduced incidence of pneumothorax to the ability to visualise the pleura and the advancing needle tip by ultrasound. According to our data, additional sedation or block placement under general anaesthetic seems not to influence the incidence of pneumothorax. Underreporting is possible, because the diagnosis of pneumothorax is not systematically excluded in clinical routine. In our study, the incidence of pneumothorax and LAST was too low to draw any firm conclusions regarding the patients' state of consciousness during regional anaesthesia procedures but we feel that, based on these data, there is no strong reason to withhold sedation from patients or not to perform regional anaesthesia under general anaesthesia as long as appropriate vigilance is maintained for these complications.

In PNBs, the risk of a bloody tap increased significantly under sedation or general anaesthesia possibly because of the vasodilatation caused by anaesthetics and sedative drugs. When nerve stimulation instead of ultrasound is used, the vessels cannot be detected.²⁹ Surprisingly, in our analysis, the increased risk of a bloody tap was independent of the use of ultrasound, even though ultrasound per se is known to reduce the rate of vascular punctures.³⁰ But venous blood vessels in particular can be easily compressed by the transducer and can be overlooked. Although we expected underreporting of the incidence of bloody tap, there was no positive correlation between the increased incidence of bloody tap under sedation or general anaesthetic and the incidence of LAST. The increased risk for a bloody tap caused by sedation and general anaesthesia seen in PNBs was not

confirmed in neuraxial blocks. Although we expect underreporting, the incidence of bloody tap in neuraxial blocks is obviously lower than in PNBs. A possible reason for this phenomenon could be the fact that PNBs are usually performed under continuous aspiration; therefore, a puncture of even a small vessel will be immediately detected. On the other hand, neuraxial blocks are performed using continuous positive pressure to detect the loss of resistance reaching the epidural space. In this case, only a vascular puncture of the epidural veins can be visualised, provided that there is sufficient bleeding to passively fill the needle used for the neuraxial block, which is usually thicker than a needle used for PNBs. But overall, the incidence of documented bloody taps in our network is too low to reach a reliable conclusion.

Multiple skin puncture is a risk factor for infectious complications and has to be avoided whenever possible.³¹ Our hypothesis, that sedation during block performance could enhance the operating conditions and therefore reduce the incidence and the risk of multiple skin puncture, was confirmed in PNBs. Surprisingly, instead of the expected further reduction, performing PNBs in anaesthetised patients increased the risk. In literature, there is no evidence for this phenomenon, but one possible hypothesis could be the 'human factor': when performing PNBs in anaesthetised patients who are not able to report the pain produced by the skin puncture, the threshold for rectifying the needle position with a new skin puncture may be lower than in awake or sedated patients. Our results concerning multiple skin puncture in neuraxial blocks are in contrast to our findings in PNBs. We can only speculate why sedation significantly increases the incidence and risk for multiple skin puncture in neuraxial blocks, whereas block placement under general anaesthetic decreases it. The incidence of multiple skin puncture in neuraxial blocks is much greater than the incidence in PNBs, and is most likely because of the necessity to try different levels if there are anatomical difficulties. Our data show that sedation is less common for neuraxial techniques than for PNBs and we expect it to be used particularly in difficult block placement, which is associated itself with an increased risk for multiple skin puncture.³² Performing neuraxial blocks in anaesthetised patients constituted an exception in our network data and it is certainly reserved for very experienced anaesthesiologists or specific situations (e.g. ICU). This may explain the lower risk for multiple skin puncture in this subgroup of patients.

Sedation significantly reduced the risk of premature termination of the PNB as well as the risk of primary failure. Our results confirm the hypothesis that sedation can enhance the operating conditions for the anaesthesiologist performing the block and can reduce the risk of a required change in anaesthetic techniques. Moreover, we observed no benefit in terms of circumventing anatomical difficulties when general anaesthesia was used.

Considering that anatomical problems were the most reported cause for abandoned neuraxial blocks, it seems logical that improving the operating conditions by peri-procedural sedation may also reduce complications in neuraxial blocks. This hypothesis was not proven for accidental dural puncture being comparable between awake, sedated and anaesthetised patients. Although the sample size particularly in the group of anaesthetised patients is too small for a reliable statement, our results (which revealed a mean of 0.39% for accidental dural puncture) are close to the rates reported in the literature (0.4 to 0.7%).^{33–35} Additional sedation or block placement after induction of general anaesthesia in neuraxial blocks did not influence the risk for premature termination or primary failure, which confirms our impression that additional sedation in neuraxial blocks does not have the same beneficial value than in PNBs. This can also be applied to the risk of postoperative paraesthesia after epidural catheter placement not being influenced by sedation. Caution should be exercised performing neuraxial catheter placements under general anaesthetic. The risk for postoperative paraesthesia may be raised, but the power of our present analysis is too low to be definitive in this setting.

Although the NRA database does not provide information on long-term outcomes of acute complications, there is evidence that paraesthesia extending beyond the normal residual effects of the peripheral regional anaesthesia is a serious warning sign and has to be monitored closely.^{36,37} In our analysis, the mean incidence for postoperative paraesthesia in patients with continuous regional anaesthesia was 1.05% for neuraxial block and 1.46% for PNB. This is comparable with the previously reported incidences because early transient postoperative neurologic symptoms are very common in the first days and decline with time.^{38–40} Our results show that both sedation and general anaesthesia reduce significantly the incidence and the risk of postoperative paraesthesia in PNBs and may therefore contribute to increased safety in continuous peripheral regional anaesthesia.

Our multicentre analysis confirms results from previous investigations that patient satisfaction with peripheral or neuraxial regional anaesthesia is significantly higher when the block is performed under sedation.^{41,42} In line with previous studies, which reported that 15 to 57% of patients received sedation during regional anaesthesia procedures, our study found that 56% of PNBs and 15% of neuraxial blocks were performed in sedated patients, which may represent current practice in German hospitals.^{11,41} However, we found that performing nerve blocks after induction of general anaesthesia did not improve patient satisfaction further. In our analysis, anaesthetised patients account for 10.4% of PNBs and 1.4% of neuraxial blocks, but in the literature, there is a high variability in the percentages of patients receiving regional anaesthesia in an anaesthetised state.^{13,32,43} This

suggests uncertainty among clinicians on this issue and should encourage further research to develop guidance on best practice.

Limitations

Our investigation was not designed to clarify possible mechanisms of interaction. Data in our registry do not provide information on long-term outcomes of acute complications or on persistent nerve damage. It is necessary to study a large number of patients to reliably determine the incidence of rare complications and to elucidate risk factors in their production. During the long observation period of 5 years, progress in medicine, technique or anaesthesia methods may have caused bias of the results and represents an important limitation in a registry study. All medical centres participating in this registry are enthusiastic proponents of regional anaesthesia, which could have biased our findings.¹⁵ Other confounding factors such as the use of tourniquet in trauma and orthopaedic surgery represent a further limitation. Many other ill-described factors (posture, surgery type, catheter misplacement detection) may also be responsible for unknown bias. Registries critically depend on the quality of data entry and handling and we could not provide external validity. The distribution of complications, however, seems to be plausible.

Conclusion

Additional sedation for peripheral regional anaesthesia procedures offers a number of benefits to the patient and the anaesthesiologist and should be recommended to all those patients where there are no contraindications. Performing PNBs under general anaesthetic does not enhance the risk of major complications, but particular precaution should be taken to avoid multiple skin puncture and bloody taps in anaesthetised patients. Procedural sedation for neuraxial blocks enhanced patient comfort without further beneficial effects. Performing neuraxial blocks in anaesthetised patients should be reserved for special situations and for experienced anaesthesiologists because of the increased risk of postoperative paraesthesia.

Acknowledgements relating to this article

Assistance with the study: we thank all hospital centres that are part of the NRA and have collected data for the present study: Bad Saarow – Helios Klinikum, SPW; Bad Wildbad – Sana Klinik, Dr Jens Döffert; Berlin – Charité CCM und CVK, Professor Claudia Spies; Berlin – DRK Kliniken Westend, Professor Arnd Timmermann; Bochum – Knappschafts Krankenhaus, Professor Michael Adamzik; Dresden – Universitätsklinikum, Professor Thea Koch; Erfurt – Helios Klinikum, Dr Gerald Burgard and Professor Andreas Meier-Hellmann; Frankfurt – BGU, Dr Rolf Teßmann; Frankfurt – Orthopädische Uniklinik, Professor Paul Kessler; Hamburg – Universitätsklinikum Eppendorf, Professor Alwin E. Goetz; Hannover – Diakoniekrankenhaus Friederikenstift gGmbH, Professor André Gottschalk; Jena – Uniklinikum, Professor Konrad Reinhart; Marburg – Universitätsklinikum,

Professor Hinnerk Wulf; Memmingen – Klinikum, Professor Lars Fischer; Siegen – St. Marien-Krankenhaus, Professor Werner Hering; Solingen – Klinikum, Professor Thomas Standl; Ulm – Rehabilitationskrankenhaus, Dr Peter M. Geiger. We thank Karen Schneider and Ralf Heckmann for their critical revision of the manuscript and language correction.

Financial support and sponsorship: the analysis was supported by institutional funds. The German Network of Regional Anaesthesia database is supported by the Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin e.V., Berufsverband Deutscher Anästhesisten e.V. and Deutsche Forschungsgemeinschaft.

Conflicts of interest: none.

Presentation: preliminary data for this study were presented as a poster presentation at the European Society of Regional Anaesthesia (ESRA) Annual Meeting, 5 September 2013, Glasgow.

Details of authors contributions: CK, KS, NA, NRA Investigators HB and TV had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Together with TS, TS, AG, WM, SPW, JB, AR, JS, PK and SG, they made substantial contributions to the concept and the design of the study; the acquisition; the analysis and the interpretation of data and drafting the article and revising it critically for important intellectual content.

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