Influence of anatomic conditions on efficacy and safety of combined intermediate cervical plexus block and perivascular infiltration of internal carotid artery in carotid endarterectomy: a prospective observational trial

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INFLUENCE OF ANATOMIC CONDITIONS ON EFFICACY AND SAFETY OF COMBINED INTERMEDIATE CERVICAL PLEXUS BLOCK AND PERIVASCULAR INFILTRATION OF INTERNAL CAROTID ARTERY IN CAROTID ENDARTERECTOMY: A PROSPECTIVE OBSERVATIONAL TRIAL

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Abstract—Ultrasound-guided intermediate cervical plexus blockade with perivascular infiltration of the carotid artery bifurcation perivacular block (PVB) is a reliable technique for regional anesthesia in carotid endarterectomy (CEA). We investigated the effect of the carotid bifurcation level (CBL) on PVB efficacy and safety in patients undergoing CEA. This prospective observational cohort study included 447 consecutive CEA patients who received PVB over a 6-y period. Vascular and neurologic puncture-related complications were recorded. The CBL was localized at the low level (C4 and C5 vertebra, low-level [LL] group) in 381 (85.2%) patients and at the high level (C2 and C3 vertebra, high-level [HL] group) in 66 (14.8%) patients. Local anesthetic supplementation by surgeons was necessary in 64 (14.3%) patients in the LL group and 38 (59.4%) patients in the HL group (p < 0.001) and was associated with a higher rate of central neurologic complications in the HL group (p = 0.031). Therefore, the efficacy of the PVB may be influenced by the CBL. (E-mail: thomas.roessel@ukdd.de)

Key Words: **Carotid surgery, Regional anesthesia, Ultrasound, Carotid artery, Local anesthetic, Ropivacaine, Carotid endarterectomy, Observational trial.**

INTRODUCTION

The treatment of internal carotid artery (ICA) stenosis depends on various factors, such as the degree of stenosis or the occurrence of neurologic symptoms, and includes conservative therapy, carotid artery stenting and carotid endarterectomy (CEA). According to the current guidelines, CEA significantly reduces the risk of ischemic stroke for asymptomatic patients with stenosis by 60%−99% (Aboyans et al. 2018). How carotid artery stenting will influence the therapy of ICA stenosis in the future is still debated (Brott et al. 2016; Bonati et al. 2018). Yet the optimal anesthetic procedure during CEA remains controversial (GALA Trial Collaborative Group et al. 2008). The major advantage of regional anesthesia is its simple, immediate and highly sensitive and specific neurologic monitoring (Tangkanakul et al. 1997). However, because of the complex anatomic conditions of the lateral neck region, severe puncture-related complications (*e.g.*, brain stem anesthesia, accidental intravascular local anesthetic application and different nerves paralysis such as laryngeal or phrenic nerve paralysis) may occur (Pandit et al. 2007; Feigl et al. 2020). These puncture-related complications can lead to the inability to monitor neurologic symptoms properly. In the last decade, the application of ultrasound-guided regional anesthesia has increased patient safety and processual quality. New regional anesthetic techniques were also developed (Roessel et al. 2007;

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Leblanc et al. 2016). However, these trials involved only small numbers of patients (Roessel et al. 2007; Leblanc et al. 2016; Seidel et al. 2018).

In 2013, Rössel et al. described a new regional anesthetic technique for CEA: The combination of ultrasound-guided intermediate cervical plexus (CP) block, where local anesthetic is administered between the superficial and deep cervical fascia, with a ventral and dorsal infiltration of the carotid artery bifurcation, aiming for a local anesthetic spread along the ICA (the so-called perivascular block [PVB]) (Rössel et al. 2013). This study demonstrated a high level of block success and low puncture-related complications, but only 40 patients were enrolled in this study. Based on our clinical experience with more than 1500 CEAs using different regional anesthesia techniques in the past, we saw that various factors have an influence on both the blockade and the surgery. These factors included the ability to turn and recline the head, neck circumference and the level of bifurcation, but also the experience of the anesthesiologist and the surgeon. Among these factors, the location of the bifurcation appeared to be of particular interest to us. The height of the bifurcation has an influence on the complexity of the operation and the complications, which has already been described by Blaisdell et al. (1966, 1967). However, Blaisdell's proposed imaginary line between the angle of the jaw and the mastoid as border for feasibility of the CEA is a very general description and appears to be very cranially located, with no strict anatomic relation to the vertebrae (Blaisdell et al. 1966, 1967; Brott and Thalinger 1984). As a result, we hypothesize that the level of the carotid bifurcation has an effect on block performance and puncture-related complications.

The primary objective of this study was to identify the effect of the anatomic level of the common carotid artery (CCA) bifurcation on the efficacy of the PVB in terms of requiring additional local anesthetic supplementation by the surgeon and necessary conversion to general anesthesia. The secondary aim was to evaluate the influence of the anatomic carotid artery level on the safety by means of puncture-related complications and patient satisfaction.

METHODS

Approval was obtained from the Ethics committee of the Technische Universität Dresden, Germany (EK255122004), and written informed consent was obtained from the participants. Over a 6-y period, this prospective observational cohort trial enrolled consecutive patients scheduled for CEA who received an intermediate CP block combined with perivascular infiltration of the ICA in the University Hospital Carl Gustav Carus at the Technische Universität Dresden, Germany. Criteria for exclusion were a history of anaphylactic reaction to local anesthetics, local infection, presumed limitations of the patients' compliance and refusal of regional anesthesia. The manuscript is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al. 2014). A detailed checklist is provided in Table S1 of the supplemental digital content.

Sonoanatomy

Patients were placed in the supine position on the operation table with their heads turned 30 degrees to the contralateral side. Before performing the block, the anatomic conditions of the neck region were investigated using a 12.5 MHz linear ultrasound transducer (Philips HD 11 or Philips Affiniti 70G, Philips Medicine Systems GmbH, Hamburg, Germany). First, the transverse process from C7 to C2 with the corresponding nerve root were visualized (Fig. 1). The transverse processes were distinguished by their different shape, the course of the associated nerve roots and relation to the vertebral artery. Subsequently, the nerves of CP, the internal jugular vein, the CCA, the external carotid artery (ECA), the ICA and the carotid bifurcation were identified. The carotid bifurcation was defined as the first image obtained in cranial direction (short axis) showing the ICA and ECA as separated vessels. The carotid bifurcation level (CBL) defined as height of the carotid bifurcation in relation to the transverse process level of the respective vertebra was determined. Moreover, the distance between the skin and the CBL was recorded (Fig. 2). Patients were allocated with respect to the CBL according to the corresponding vertebra in two groups: a high-level group (HL group) with a CBL at C2 or C3 and a low-level group (LL group) with a CBL at C4 or C5.

Regional anesthesia

We administered remifentanil up to 0.05 μg/kg/min (Ultiva, Janssen-Cilag GmbH, Neuss, Germany) during puncture and surgery in all patients for their comfort.

The ultrasound-guided PVB was performed as described by Rössel et al. (2013). The puncture for perivascular infiltration was performed at the CBL (Fig. 3). The bevel of the needle tip was orientated slightly in a cranial direction, aiming a cranial spread of local anesthetic along the ICA. Local anesthetic was administered on both the ventral and dorsal side of the arterial vessel. For all patients, 3−5 mL of ropivacaine 0.5% were injected in the perivascular region of the carotid artery bifurcation. The blockade of plexus cervicalis was undertaken at the level of the Erb's point. At this level, 10−20 mL ropivacaine 0.5% was applied between superficial and deep cervical fascia. The total amount of injected ropivacaine (Naropin, Aspen Germany GmbH, Munich, Germany) was recorded. The success of the

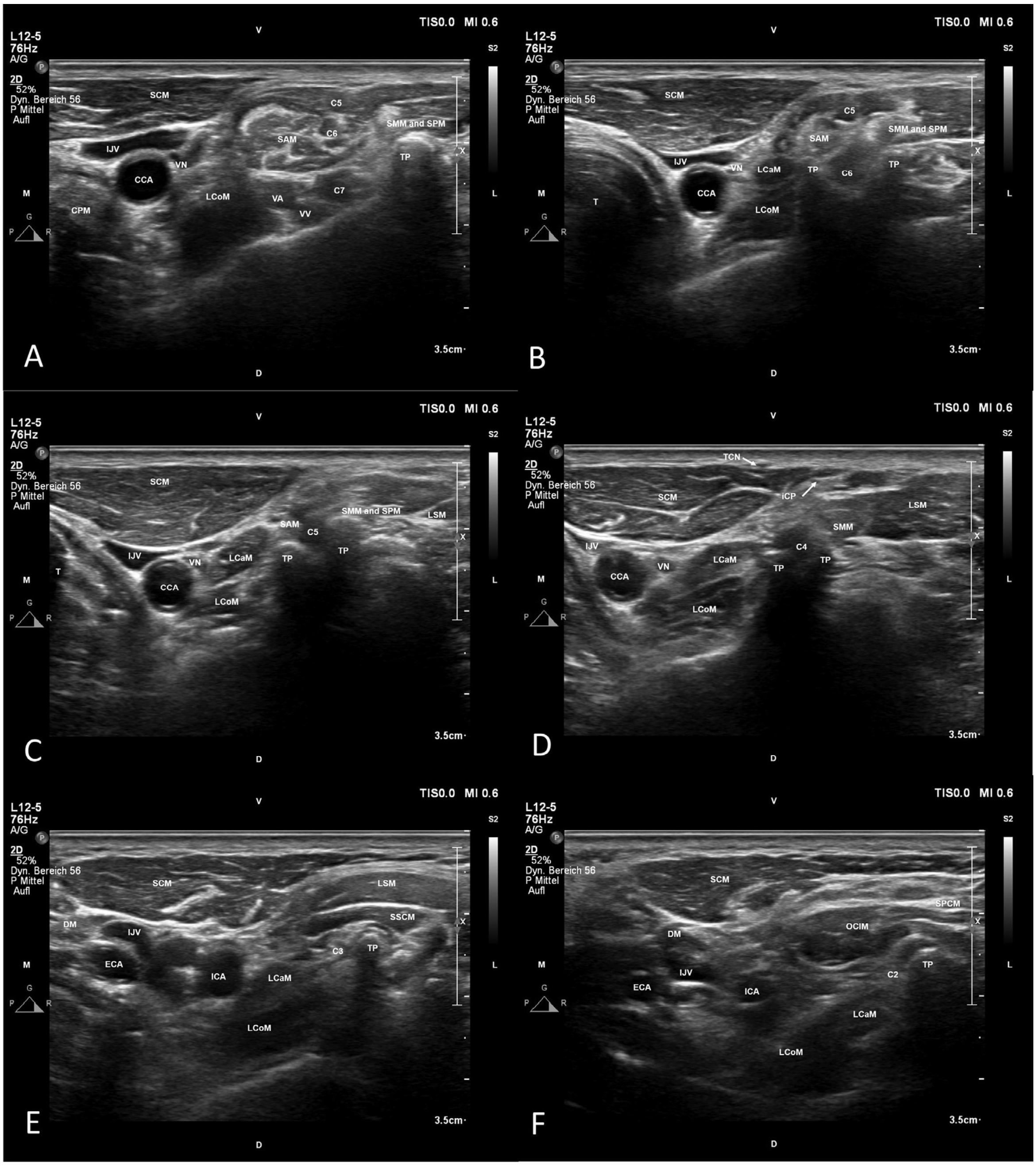

Fig. 1. Sonoanatomy of the neck. This figure shows the typical ultrasound examination for identification of the carotid bifurcation level starting at vertebra C7 (a), which can be recognized by its typical unimodal shape of the processus transversus and the moniliform ordered nerve roots C7, C6 and C5. The transducer is then moved cranial, showing vertebra C6 (b), which is the first vertebra with a characteristic bimodal shaped processus transversus. While further advancing the transducer cranial to the respective vertebra C5 (c), C4 (d), C3 (e) and C2 (f) appear. On C2 level a determination of anatomic structures with ultrasound might be difficult because of the close anatomic relations. C2−C7, respective nerve roots; CCA = common carotid artery; CPM = constrictor pharyngis muscle; DM = digastricus muscle; ECA = external carotid artery; ICA = internal carotid artery; IJV = internal jugular vein; LCaM = longus capitis muscle; LCoM = longus colli muscle; LSM = levator scapulae muscle; OCIM = obliquus capitis inferior muscle; SAM = scalene anterior muscle; SCM = sternocleidomastoid muscle; iCP = intermediate part of cervical plexus; SMM = scalene medius muscle; SPM = scalene posterior muscle; SSCM = semispinalis capitis muscle; T = trachea; TCN = transversus colli nerve; TP = transverse processus; VA = vertebral artery; VV = vertebral vein; VN = vagal nerve; L = lateral; M = medial; V = ventral; D = dorsal. Pictures were acquired using a using a 12.5 MHz linear ultrasound transducer (Philips L12-5, Philips Affiniti 70G, Philips Medicine Systems GmbH, Hamburg, Germany). Depth in cm.

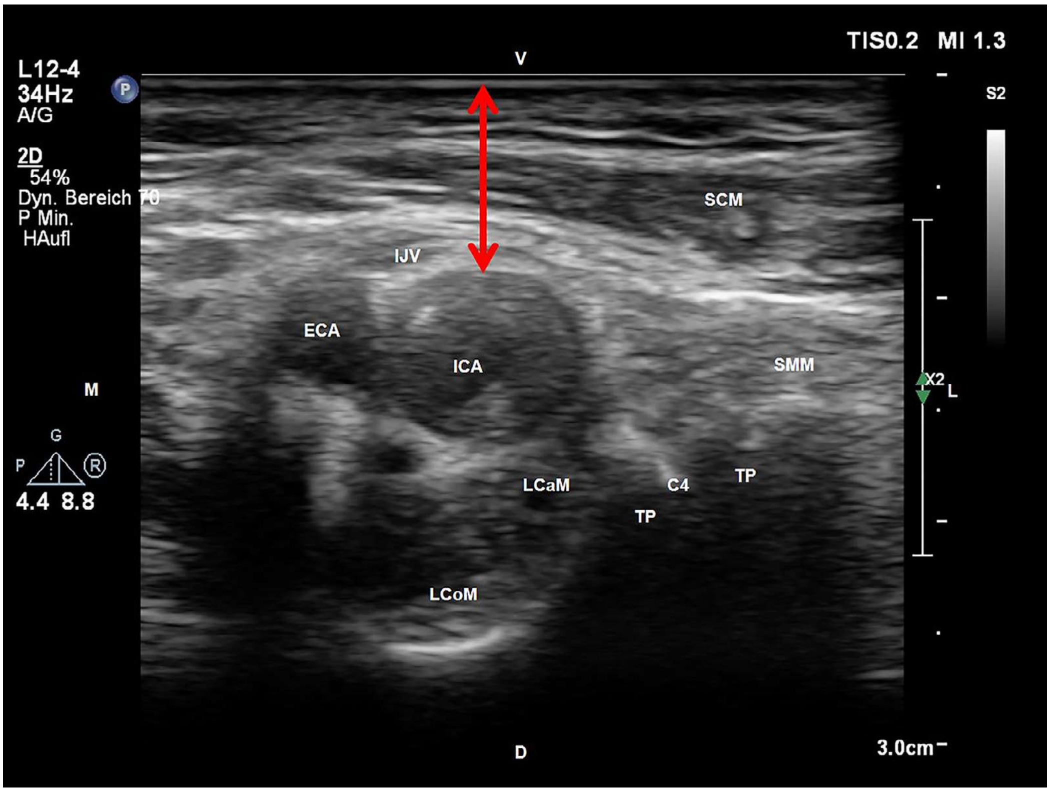

Fig. 2. Measurement of carotid bifurcation level depth. This image shows the method of the skin to vessel distance determination (*red arrow*) at C4 vertebra level. C4 = nerve root C4; ECA = external carotid artery; ICA = internal carotid artery; LCaM = longus capitis muscle; LCoM = longus colli muscle; SCM = sternocleidomastoid muscle; SMM = scalene medius muscle; TP = transverse process of C4; L = lateral; M = medial; V = ventral; D = dorsal. Pictures were acquired using a using a 12.5 MHz linear ultrasound transducer (Philips L12-5, Philips Affiniti 70G, Philips Medicine Systems GmbH, Hamburg, Germany). Depth in cm.

skin block was evaluated 20 min after regional anesthesia by pin prick test in the dermatomes C2 to C4. Puncture-related complications, such as hoarseness, respiratory distress, hypoglossal nerve palsy or Horner's syndrome were also assessed. Surgery was started when the surgical site had been sufficiently anesthetized. Pain was evaluated according to the Numeric Analgesia Scale (NAS) graded from 0 (no pain) to 10 (worst pain) during the performance of regional anesthesia and during skin incision, retractor placement, dissection, cross-clamping and skin closure. If patients reported intra-operative pain of NAS >2, an additional local infiltration of 1% lidocaine (Xylocitin-loc 1%, mibe GmbH, Brehna, Germany) was administered by the surgeon. The total amount of lidocaine 1% was recorded. Post-operatively, patients' satisfaction regarding anesthesia was assessed on a subjective scale ranging from 1−5 (1, very good; 2, good; 3, reasonable; 4, poor; 5, very poor).

Neurologic Monitoring

The neurologic function was continuously monitored by assessment of consciousness and the adequate response to verbal commands. During carotid cross-clamping, the patient was requested to squeeze a squeaking rubber toy with the contralateral hand every minute and to answer simple questions for close assessment of neurologic function. A temporary shunt was placed if any signs of neurologic dysfunction occurred during carotid cross-clamping. In addition, the function of recurrent laryngeal nerve, hypoglossal nerve and facial nerve before and 30 min after regional anesthesia, as well as before and after carotid cross-clamping and end of surgery, were monitored. After surgery, patients with symptomatic stenosis as well as patients with intra-operative neurologic complications were monitored post-operatively in the post-anesthesia care unit or intermediate care unit, as appropriate. An independent neurologist examined all patients before hospital discharge.

Hemodynamic monitoring

In the holding area, a 5-lead electrocardiogram including ST-segmental analysis, a pulse oximetry and a peripheral venous access, as well as an arterial line for continuous monitoring of arterial blood pressure, were

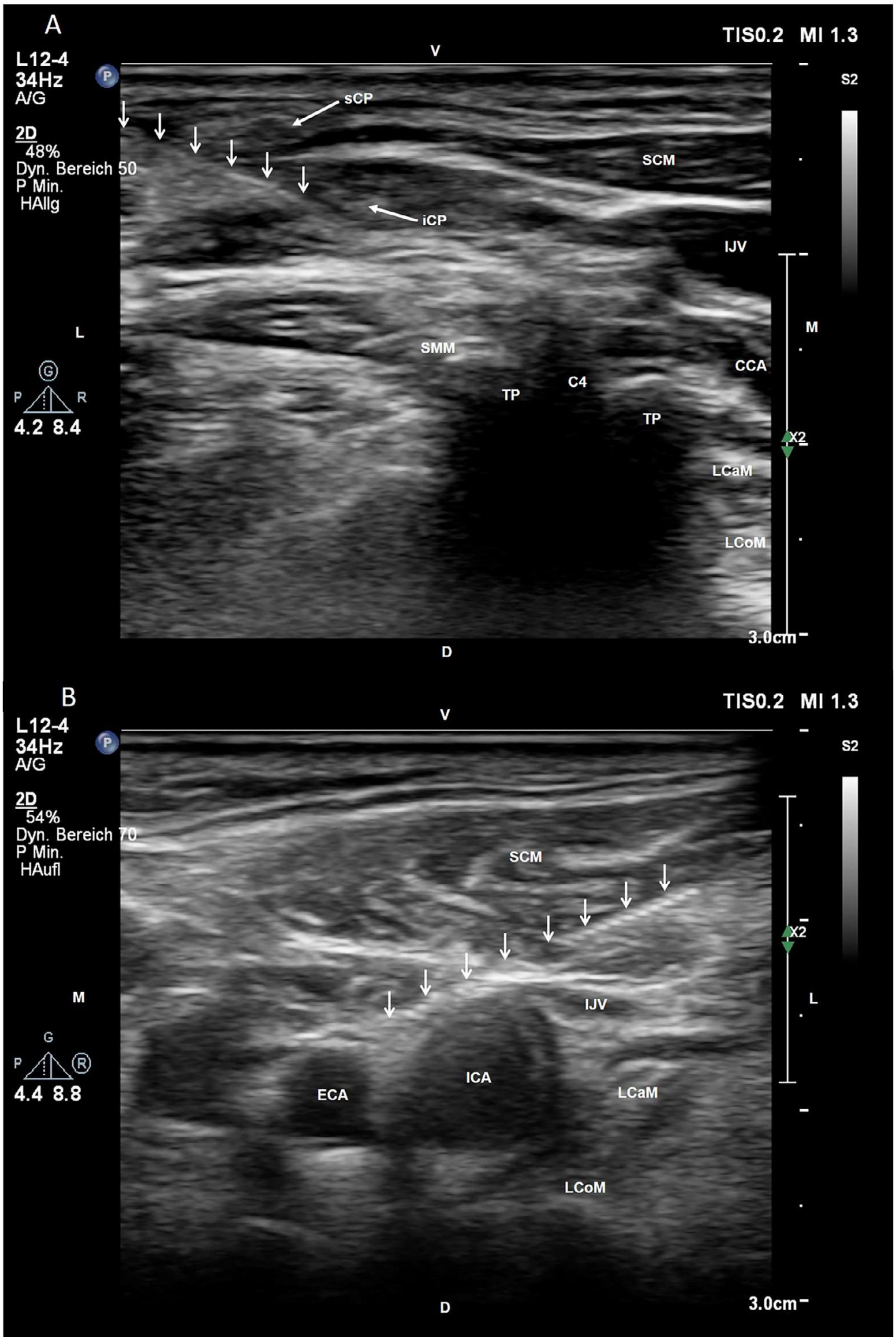

Fig. 3. Perivascular block. (a) Needle guidance (*arrows line*) during intermediate cervical block of level C4. (b) Needle guidance (*arrows line*) during perivascular infiltration of carotid bifurcation level. C4 = nerve root C4; CCA = common carotid artery; ECA = external carotid artery; ICA = internal carotid artery; IJV = internal jugular vein; iCP = intermediate part of cervical plexus; LCaM = longus capitis muscle; LCoM = longus colli muscle; sCP = superficiale part of cervical plexus; SCM = sternocleidomastoid muscle; SMM = scalene medius muscle; TP = transverse process of C4; L = lateral; M = medial; V = ventral; D = dorsal. Pictures were acquired using a using a 12.5 MHz linear ultrasound transducer (Philips L12-5, Philips Affiniti 70G, Philips Medicine Systems GmbH, Hamburg, Germany). Depth in cm.

applied. The following data were recorded using a Philips Intellivue MP 70 (Philips Medicine Systems GmbH, Hamburg, Germany): pulse oximetry, heart rate, ST-segmental analysis and arterial blood pressure. The desired mean arterial pressure was ±20% from baseline. Urapidil (Urapidil Stragen i.v., Stragen Pharma GmbH, Köln, Germany) in cases of hypertension and noradrenaline (Arterenol, Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany) in cases of hypotension were administered to reach the specified target range for arterial pressure.

Emergency management

In case of severe complications before carotid cross-clamping (*e.g.,* strong agitation, local anesthetic intoxication or severe pain), general anesthesia was performed by administering propofol, sufentanil and rocuronium. In those cases, neurologic monitoring was applied using near infrared spectroscopy or somatosensory evoked potentials (SEP) of the median nerve (Pennekamp et al. 2009; Nwachuku et al. 2015). SEPs were monitored using the Neuropack 2 system (Nihon Kohden Deutschland GmbH, Rosbach, Germany). Standard variables for stimulating and recording were used (Florence et al. 2004). The electric stimulus (a square wave of 0.1 ms duration and 10 Hz frequency with intensity just over the motor threshold) was generated with the electrode on the median nerve at the wrist. The amplitude and latency of the N20-P25 complex and the peak to peak amplitude of the cervical potential were measured online.

Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics version 20 (IBM Deutschland GmbH, Ehningen, Germany). Graphs were computed using GraphPad Prism version 6.01 (GraphPad Software Inc., La Jolla, CA, USA). Values were given as total numbers and percentage, mean and standard deviation or median and lower and upper quartile were given as appropriate. Statistical significance was accepted at $\alpha = 0.05$. Normal distribution was assessed visually using Q-Q plot of standardized residuals. Frequency distributions were analyzed with a X^2 test or Fisher's exact test as appropriate. Students' *t*-test or Mann-Whitney *U* test were used for independent parameters with parametric or non-parametric distribution, respectively. A sample size calculation was not performed since this is an exploratory trial, and no data on distribution of the level of the carotid bifurcation among patients with ICA stenosis were available.

RESULTS

Over a period of 6 y, 447 patients undergoing CEA were enrolled in this study. The pre-operative risk factors and indications for surgery are described in Table 1. The identification of the CP between the superficial and deep cervical fascia of the neck and the CCA bifurcation using ultrasound was successful in all patients. The CBL were localized at the low level (C4/5) in 381 (85.2%) patients and at high level (C2/3) in 66 (14.8%) patients. The distance between the skin and the CCA bifurcation was 1.8 (1.7, 1.9) cm in the HL group compared with 1.3 (1.3, 1.5) cm in the LL group ($p < 0.001$, Table 2), despite a lower BMI in the HL group (26.0 [16.0, 23.0, 29.0, 38.0] kg/m^2 vs. 27.0 (19.0, 24.0, 29.5, 41.0), kg/m^2, $p = 0.042$, Table 1). The spread of the local anesthetic could be observed in all patients around the nerves of CP between the superficial and deep cervical fascia of the neck, as well as at the CCA bifurcation, including the proximal ICA area. In few cases, a pronounced vascular calcification restricted ultrasound imaging of the cranial local anesthetic spread adjacent to the carotid vessel wall. The overall time required to perform the anesthetic induction (PVB and arterial line) was 15 (5, 10, 24, 85) min independent of group (15 [5, 15, 25, 85] min vs. 15 [5, 15, 25, 85] min; $p = 0.355$; HGL vs. LL; median [minimum, 25th percentile; maximum, 75th percentile], respectively).

The sensitive testing in dermatome C3 resulted in sufficient blockade after 20 min for all patients. The influence of the CBL on the PVB effectiveness as well patients' satisfaction is shown in Table 2. During surgery, 64 (14.3%) patients reported pain of NAS >2. For these 64 patients, a local anesthetic infiltration by the surgeon was required ($n = 38$ [57.6%] HL group *vs.* $n = 26$ [6.8%] LL group, $p < 0.001$). The amount of supplemental lidocaine 1% was higher in the HL group compared with the LL group ($p < 0.001$).

A conversion to general anesthesia was necessary in eight patients without group difference ($n = 3$ HL group, $n = 5$ LL group, $p = 0.100$). The reason for conversion ranged from a new intra-operative neurologic deficit ($n = 2$ HL group; $n = 3$ LL group), an epileptic seizure after local anesthetic supplementation by the surgeon ($n = 1$ HL group) to insufficient regional anesthesia during surgery ($n = 2$ HL group). Puncture-related complications are summarized in Table 2. The duration of surgery and the cross-clamping time were comparable between groups. The incidence of post-operative complications and the length of hospital stay and hospital mortality are described in Table 3.

DISCUSSION

The present study is the first trial investigating the efficacy and safety of ultrasound-guided PVB in relation to the anatomic conditions of the CCA bifurcation in a large cohort of 447 patients undergoing CEA. This trial was conducted as a prospective observational study

Table 1. Patient characteristics

	HL group (*n* = 66)	LL group (*n* = 381)	Total (*n* = 447)	*p* value
Age	67.0 (43.0, 61.5, 75.0, 88.0)	70.0 (35.0, 64.0, 76.0, 90.0)	70.0 (35.0, 64.0, 76.0, 90.0)	0.880*
Sex				0.552†
Male	46 (69.7)	279 (73.2)	325 (72.7)	
Female	20 (30.3)	102 (26.8)	122 (27.3)	
Height (m)	1.70 ± 0.10	1.70 ± 0.08	1.70 ± 0.08	0.759‡
Weight (kg)	74.0 (50.0, 64.8, 85.8, 114.0)	78.0 (48.0, 70.0, 86.0, 120.0)	77.0 (48.0, 70.0, 86.0, 120.0)	0.065*
BMI (kg/m^2)	26.0 (16.0, 23.0, 29.0, 38.0)	27.0 (19.0, 24.0, 29.5, 41.0)	27.0 (16.0, 24.0, 29.0, 41.0)	0.042*
Stenosis grade,	80.0 (60.0, 75.0, 80.0, 90.0)	80.0 (50.0, 75.0, 80.0, 95.0)	80.0 (50.0, 75.0, 80.0, 95.0)	0.470*
Symptomatic	30 (45.5)	184 (48.3)	214 (47.9)	0.691†
Asymptomatic	36 (54.5)	197 (51.7)	197 (52.1)	
Site				0.894†
Right	34 (51.6)	202 (53.0)	236 (52.8)	
Left	32 (48.5)	179 (47.0)	221 (47.2)	
Stenosis on other site	24 (36.4)	131 (34.4)	155 (34.7)	0.780†
Stenosis grade other site	60.0 (40.0, 51.3, 67.5, 100.0)	60.0 (40.0, 51.3, 67.5, 100.0)	60.0 (35.0, 50.0, 70.0, 100.0)	0.759*
Urgency of Procedure,				
Elective	66 (14.8)	381 (85.2)	447 (100.0)	n.a.
Urgent	0 (0.0)	0 (0.0)	0 (0.0)	
ASA				0.081§
I	1 (1.5)	0 (0.0)	1 (0.2)	
II	11 (16.7)	79 (20.7)	90 (20.1)	
III	53 (80.3)	291 (76.4)	344 (77.0)	
IV	1 (1.5)	11 (2.9)	12 (2.7)	
Comorbidities				
Arterial hypertension	63 (95.5)	368 (95.5)	431 (96.4)	0.716†
Diabetes mellitus	22 (33.3)	141 (37.0)	163 (36.5)	0.678†
HLP	59 (89.4)	338 (88.7)	397 (88.8)	1.000†
PAOD	26 (39.4)	121 (27.1)	147 (32.9)	0.256†
CAD	16 (24.2)	98 (25.7)	114 (25.5)	0.879†
AMI	5 (7.6)	52 (13.6)	57 (12.8)	0.230†
Cardiac insufficiency	23 (34.8)	134 (35.2)	157 (35.1)	1.000†
Cardiac arrhythmias	20 (30.3)	178 (46.7)	198 (44.3)	0.015†
COPD	13 (19.7)	42 (11.0)	55 (12.3)	0.065†
Epilepsy	1 (1.5)	11 (2.9)	12 (2.7)	1.000†
Liver disease	5 (7.6)	27 (7.1)	32 (7.2)	0.800†
Kidney disease	17 (25.8)	88 (23.1)	105 (23.5)	0.639†
Anemia	2 (3.0)	28 (7.3)	30 (6.7)	0.286†
Nicotine abuse	18 (27.3)	119 (31.2)	137 (30.6)	0.566†
Alcohol abuse	5 (7.6)	50 (13.1)	55 (12.3)	0.308†

AMI = acute myocardial infarction; ASA = American Society of Anesthesiology physical status; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; HL = high level (level of carotid bifurcation on vertebrae level 2 or 3); HLP = hyperlipoproteinemia; LL = low level (level of carotid bifurcation on vertebrae level 4 or 5); PAOD = peripheral artery occlusive disease.

Values are given as mean ± standard deviation, median (minimum, 25th percentile; maximum, 75th percentile) or absolute number (percentage per column by group or percentage in relation to total [n = 447]) as appropriate. Differences between groups were tested using a Student's *t*-test (‡) or Mann-Whitney *U* test (*) as appropriate. Frequencies were analyzed using X^2 (§) or Fisher's exact test (†), as appropriate. Statistical significance was accepted at $\alpha = 0.05$.

providing "real life" data on puncture-related complications and success of regional anesthesia. Although the combination of ultrasound-guided intermediate CP block with perivascular infiltration shows a good overall clinical efficacy with a high level of puncture safety and patient satisfaction, our main results of this study may be summarized as follows:

- The CBL is an important factor influencing block efficacy and patient satisfaction.
- A higher CBL is associated with an increased rate of additional local anesthetic supplementation by surgeons and more post-operative irritation of the hypoglossal and facial nerve.
- A higher CBL is associated with more puncture complications with respect to local anesthetic intoxication
- The combination of ultrasound-guided intermediate CP block with perivascular infiltration has an overall high level of puncture safety with good clinical efficacy and a high level of patient satisfaction, especially in patients with a CBL at C4 or below.

Role of regional anesthesia in CEA

The CEA is still the gold standard of treatment for the prevention of ischemic stroke owing to stenosis of carotid artery. However, surgical intervention is associated with different possible perioperative complications. The

Table 2. Intra-operative characteristics

	HL group ($n = 66$)	LL group ($n = 381$)	Total ($n = 447$)	p value
Amount of ropivacaine (mg)	122.5 (80.0, 100.0, 150.0, 220.0)	120.0 (55.0, 100.0, 150.0, 300.0)	120.0 (55.0, 100.0, 150.0, 300.0)	0.971
Depth of the bifurcation to skin (cm)	1.8 (1.3, 1.7, 1.9, 2.7)	1.3 (0.9, 1.3, 1.5, 2.6)	1.4 (0.9, 1.3, 1.6, 2.7)	<0.001*
Additional local anesthesia injection (no.)	38 (57.6)	26 (6.8)	64 (14.3)	<0.001*
Amount of additional local anesthetic (mL)	8.0 (2.0, 5.8, 10.0, 24.0)	4.5 (1.0, 2.0, 4.5, 8.0)	6.0 (1.0, 3.0, 8.0, 24.0)	<0.001*
Conversion to general anesthesia (no.)	3 (4.5)	5 (1.3)	8 (1.8)	0.100†
Puncture complications (no.)				
N. facialis paresis	1 (1.5)	3 (0.8)	4 (0.9)	0.473†
N. hypoglossus paresis	1 (1.5)	3 (0.8)	4 (0.9)	0.473†
N. glossopharyngeus paresis	2 (3.0)	7 (1.8)	9 (2.0)	0.627†
Seizure	1 (1.5)	1 (0.3)	2 (0.4)	0.274†
Local anesthetic intoxication	3 (4.5)	1 (0.3)	4 (0.9)	0.011†
Horner's syndrome	1 (1.5)	8 (2.0)	9 (2.0)	1.000†
Additional block before surgery (no.)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	n.a.
Operation time (min)	90.0 (55.0, 75.0, 110.0, 170.0)	90.0 (45.0, 75.0, 110.0, 185.0)	90.0 (45.0, 75.0, 110.0, 185.0)	0.781*
Clamping time (min)	30.0 (10.0, 22.3, 35.0, 50.0)	30.0 (5.0, 25.0, 37.8, 95.0)	30 (5.0, 25.0, 36.0, 95.0)	0.153*
Transient hemispheric neurologic symptoms during clamping (no.)	6 (9.0)	22 (5.7)	28 (6.3)	0.280†
New central neurologic deficit (no.)´				
End of procedure	4 (6.0)	6 (2.0)	10 (2.2)	0.045†
Discharge	3 (4.5)	6 (2.0)	9 (2.0)	0.134†
Shunt (no.)	3 (4.5)	11 (2.9)	14 (3.1)	0.445†
Planned	1 (1.5)	1 (0.3)	2 (0.4)	0.273†
Unplanned	2 (3.0)	10 (2.6)	12 (2.7)	1.000†
Amount of anesthetics (no.)				
Opiates	58 (87.9)	338 (88.7)	396 (88.6)	1.000†
Sedatives	9 (13.6)	51 (13.4)	60 (13.4)	1.000†
Vagolytics	12 (18.2)	63 (16.5)	75 (16.8)	0.860†
Beta blockers	4 (6.0)	35 (9.2)	39.0 (8.7)	0.488†
Catecholamines	54 (81.8)	322 (84.5)	369 (82.6)	0.585†
Antihypertensive drugs	40 (60.6)	270 (70.9)	310 (69.4)	0.112†
Patient satisfaction‡				
1	20 (30.3)	260 (68.2)	280 (62.6)	<0.001†
2	9 (13.6)	88 (23.1)	97 (21.7)	
3	24 (36.4)	26 (6.8)	50 (13.1)	
4	8 (12.1)	6 (1.6)	14 (3.1)	
5	3 (4.5)	0 (0.0)	3 (0.7)	
Missing§	2 (3.0)	1 (0.3)	3.0	

HL = high level (level of carotid bifurcation on vertebrae level 2 or 3); LL = low level (level of carotid bifurcation on vertebrae level 4 or 5); PVB = intermediate cervical block with perivascular infiltration of the internal carotid artery; n.a. = not applicable.

Values are given as median (minimum, 25th percentile; maximum, 75th percentile) or absolute number (percentage per column by group or percentage in relation to total [n = 447]) as appropriate. Differences between groups were tested using Mann-Whitney *U* test (*) or Fisher's Exact test (†), as appropriate. Statistical significance was accepted at $\alpha = 0.05$. ‡Patient's satisfaction was analyzed summarizing grade 1 + 2 versus grade 3 + 4 + 5, respectively. §Missing values owing to three patients with stroke who were unable to assess their satisfaction.

Table 3. Post-operative complications

	HL group (n = 66)	LL group (n = 381)	Total (n = 447)	p value
Nerval lesion or paresis (no.)				
End of surgery				
N. facialis	16 (24.3)	21 (5.5)	37 (8.3)	<0.001†
N. hypoglossus	27 (40.1)	17 (4.5)	44 (9.8)	<0.001†
N. glossopharyngeus	1 (1.5)	3 (0.8)	4 (0.9)	0.473†
N. laryngeus recurrens	2 (3.0)	10 (2.6)	12 (2.7)	0.694†
Horner’s syndrome	0 (0.0)	2 (0.5)	2 (0.4)	1.000†
Discharge				
N. facialis	8 (12.1)	13 (3.4)	21 (4.7)	0.006†
N. hypoglossus	5 (7.5)	9 (2.3)	14 (3.1)	0.041†
N. glossopharyngeus	0 (0.0)	2 (0.5)	2 (0.4)	1.000†
N. laryngeus recurrens	1 (1.5)	0 (0.0)	1 (0.2)	1.000†
Horner’s syndrome	0 (0.0)	0 (0.0)	0 (0.0)	1.000†
Outpatient control‖				
N. facialis	2 (3.0)	3 (0.8)	5 (1.1)	0.160†
N. hypoglossus	2 (3.0)	1 (0.3)	3 (0.7)	0.054†
N. glossopharyngeus	0 (0.0)	0 (0.0)	0 (0.0)	1.000†
N. laryngeus recurrens	0 (0.0)	0 (0.0)	0 (0.0)	1.000†
Horner’s syndrome	0 (0.0)	0 (0.0)	0 (0.0)	1.000†
Surgical complications (no.)				
Hematoma	3 (4.5)	7.0 (1.8)	10 (2.2)	0.473†
Laryngeal hematoma	0 (0.0)	2 (0.5)	2 (0.4)	1.000†
Re-occlusion	0 (0.0)	8 (2.1)	8 (1.8)	0.609†
Neuroradiologic intervention	0 (0.0)	3 (0.8)	3 (0.7)	1.000†
Hyperperfusion syndrome	0 (0.0)	4 (1.0)	4 (0.9)	1.000†
Seizures	0 (0.0)	4 (1.0)	4 (0.9)	1.000†
Hypertensive crisis [no.]	1 (1.5)	23 (6.0)	24 (5.4)	0.230†
Dyspnea (no.)	0 (0.0)	1 (0.3)	1 (0.2)	1.000†
Delirium (no.)	0 (0.0)	0 (0.0)	0 (0.0)	n.a.
Cardiac complications‡ (no.)	0 (0.0)	3 (0.8	3 (0.7)	1.000†
Pulmonary complications§ (no.)	0 (0.0)	0 (0.0)	0 (0.0)	n.a.
Hospital length of stay (days)	6.0 (3.0, 5.0, 7.0, 30.0)	5.0 (3.0, 5.0, 6.0, 27.0)	5.0 (3.0, 5.0, 6.0, 30.0)	0.276*
Mortality within 24 h after surgery (no.)	0 (0.0)	0 (0.0)	0 (0.0)	n.a.
Hospital mortality (no.)	0 (0.0)	3 (0.8)	3 (0.7)	1.000†

HL = group, high level (level of carotid bifurcation on vertebrae level 2 or 3); LL = low level (level of carotid bifurcation on vertebrae level 4 or 5); n.a. = not applicable.

Values are given as median (minimum, 25th percentile; maximum, 75th percentile) or absolute number (percentage per column by group or percentage in relation to total [n = 447]) as appropriate. Differences between groups were tested using Mann-Whitney U test (*) or Fisher’s exact test (†), as appropriate. Statistical significance was accepted at $\alpha = 0.05$. ‡Cardiac complications included myocardial ischemia, new arrhythmias, or decompensated heart failure.

§ Pulmonary complications involved pneumonia, lung edema, bronchospasm, acute respiratory failure, acute respiratory distress syndrome or pleural effusions. ‖Outpatient control approximately 3 mo after operation.

perioperative risks of CEA include stroke, myocardial ischemia, cranial nerve injury or acute respiratory distress by phrenic nerve paralysis or airway obstruction by neck hematoma (Ferguson et al. 1999). Neurologic complications can have various perioperative causes such as thromboembolism during surgical manipulation and hypoperfusion or hyperperfusion during and after carotid cross-clamping (GALA Trial Collaborative Group et al. 2008). Selective shunting is a reliable method for preventing cerebral ischemia during carotid cross-clamping. However, neurologic monitoring with a high level of sensitivity and specificity is necessary for detecting cerebral ischemia during CEA with selective shunting. Several techniques using SEP, transcranial duplex sonography, electroencephalography and near infrared spectroscopy are described to measure brain function and collateral blood flow during carotid cross-clamping (Tangkanakul et al. 2000; GALA Trial Collaborative Group et al. 2008). Each of these methods has its own advantages and pitfalls, mostly represented by insufficient sensitivity and specificity in real-time detection of ischemic episodes. Furthermore, all these techniques require technical equipment and experienced examiners with the ability to interpret the measured values. Over the last decade, various authors advocate the awake patient as the best neurologic monitoring in carotid surgery (Guay 2008; Rössel et al. 2008; Patelis et al. 2018). However, in Germany the majority of CEAs continue to be performed under general anesthesia mainly because of fear of intraoperative discomfort of the patient and complications of regional anesthesia that may limit the neurologic monitoring (Qualitätssicherung 2007; Guay 2008; Patelis et al. 2018). For this reason, recently many studies compared the efficacy and safety of different regional anesthetic techniques for CEA.

Role of ultrasound-guided CP block in CEA

Before the introduction of ultrasound-guided regional anesthesia, CP blocks were performed based on external landmarks with or without electric nerve stimulation for the identification of target nerves (Mehta and Juneja 1992; Merle et al. 1999). The most common regional anesthetic techniques without ultrasound guidance are superficial and deep cervical block. Despite the different puncture site, the effectiveness of the deep and superficial cervical block seems to be comparable (Pandit et al. 2000). Both regional anesthetic techniques have required local or systemic supplementation in 30%−80% of cases of the regional anesthesia (Davies et al. 1997) owing to the complex innervation in the lateral neck triangle, especially in the region of the carotid bifurcation and the ICA ("neurovascular sheath") (Seidel et al. 2018).

In contrast to the superficial CP block, serious complications have been reported for deep blockade, such as spinal anesthesia or vascular punctures with or without local anesthetic intoxication (Pandit et al. 2007). Reasons for higher complication rates of deep cervical block is the proximity of the puncture site to vulnerable structures like the vertebral artery and the epidural and intrathecal space.

Recently, the application of ultrasound in regional anesthesia has increased safety and enabled new regional anesthetic techniques (Rössel et al. 2013; Seidel et al. 2016). The major advantages of ultrasound-guided regional anesthesia are the visualization of the needle advancement and local anesthetic spread in relation to the target space with adjacent structures, resulting in fewer puncture-related complications. Surprisingly, despite visualization of the needle and the puncture site, the ultrasound-guided deep or superficial cervical block also required a high level of local anesthetic infiltration by surgeons in CEA (Rössel et al. 2019). Barone et al. (2010) examined the ultrasound-guided intermediate CP block with 10 mL of ropivacaine 0.75% in 183 patients, requiring an intra-operative supplementation by surgeons in 32% of cases. Alilet et al. (2017) compared the ultrasound-guided intermediate cervical block versus the superficial cervical block. In this study, the local anesthetic supplementation by surgeons was 77% for intermediate block and 93% for superficial block (Alilet et al. 2017). Comparable results regarding intra-operative local anesthetic supplementation were obtained by Calderon et al. (2015) in 57% of the cases (n = 116). The reason for insufficient anesthesia on an almost regular basis is the complex innervation of the lateral neck region. Pain in the mandibular region during skin incision and insertion of the retromandibular retractor might be caused by the anastomoses between the facial nerve and the CP (Seidel et al. 2015; Litz and Feigl 2016; Seidel 2018). In addition, the tissue attached to the ICA is not only innervated by the CP but also by branches of the vagal and glossopharyngeal nerves, which may cause pain in the auricular and pharyngeal region during surgical preparation of the vessel sheath (Seidel et al. 2015; Litz and Feigl 2016; Seidel et al. 2016; Seidel 2018).

Assessment of the perivascular block

In a previous study, we introduced a combination of ultrasound-guided perivascular regional anesthesia of the ICA and an intermediate CP block for CEA, resulting in decreased intra-operative supplementation of local anesthetic in less than 20% of cases (Rössel et al. 2013). Other trials investigating perivascular infiltration with superficial or intermediate CP block comparing a similar technique versus local anesthesia alone showed a demand of intra-operative local anesthetic supplementation of 19% up to 28% (Hoefer et al. 2015; Madro et al. 2016). While the present study was performed in a teaching hospital, the overall supplementation rate was 14.3%, which is even lower than previously reported. In contrast, Seidel et al. (2016) observed a supplementation rate by the surgeon of 65% for PVB on the C4 level. One explanation for these controversial results may be the different localization of perivascular infiltration within or around the neurovascular sheath. According to our experience, an infiltration only at the level of carotid bifurcation seems inadequate. For this reason, we targeted for a cranial spread of the local anesthetic along the ICA. However, the specific place of the perivascular infiltration site was not exactly described in the previously mentioned trials (Hoefer et al. 2015; Madro et al. 2016; Seidel et al. 2016) and requires further investigation. In this context, needle tip position regarding fascia alaris and vagina carotica might be of major impact for local anesthetic spread. Challengingly, the visualization of the perivascular infiltration might be compromised by motion artefacts and acoustic shadowing behind calcified plaques (Seidel et al. 2018). Furthermore, anatomic variations regarding contributed nerves within the neurovascular sheath may influence the complexity of the perivascular block.

The analgesic effect of PVB is highly influenced by the CBL. Although in this study the local anesthetic supplementation for all patients was 14.3%, the rate of supplementation increases up to 59.4% for a CBL above the C4 vertebra, and is temporarily associated with more central neurologic complications. In our opinion, the main reason for increased supplementation is the change of anatomic conditions above C4 (Supplementary Figs. S1−S3, online only). The tissues attached to the ICA are not only innervated by the CP but also by branches of the glossopharyngeal and vagus nerves. Despite the high safety of ultrasound-guided PVB, a block of these nerves was not desired because a complete block of the N. glossopharyngeus is associated with considerable discomfort owing to impairment of swallowing. In addition, local anesthetic supplementation could also be necessary if the local anesthetic/puncture needle did not penetrate the turquoise fascia alaris (Feigl et al. 2020). Because of its thin layer and acoustic shadowing artefacts, visualization of the turquoise fascia alaris with ultrasound is challenging. Beside the level of the bifurcation, various factors are conceivable that have an influence. These factors included the ability to turn and recline the head, the level of bifurcation, complex pathology (*e.g.,* aneurysmatic dilation of the ICA), the BMI and the experience of the anesthesiologist and surgeon (Supplementary Fig S4−S7, online only). Furthermore, the BMI only allows limited conclusions to be drawn about difficulties during regional anesthesia or surgery. To assess the possible influence of the patient's weight, it would probably have been more useful to determine the circumference and mobility of the neck. In particular, severely restricted reclination of the head can make surgery considerably more difficult.

Influence of CCA bifurcation level

The innervation of the lateral neck triangle is very complex. While the skin is supplied by the plexus cervicalis, a large number of nerves, such as sympathetic trunk and vagus and the glossopharyngeal nerves, are involved in the innervation of the deep cervical structures. The objective of perivascular infiltration is only the anesthetization of the sensitive end fibers of the nerves, without the complete block of these nerves. In the present study, only for patients with CBL on C4 or C5, the use of the perivascular infiltration reduced the additional supplementation during dissection of the neurovascular sheath. However, numerous patients with CBL above C4 still reported pain despite perivascular infiltration. In many cases this pain is localized in the face, ear or teeth. These symptoms may be triggered by irritation of the trigeminal or tympanic nerves during the dissection of distal ICA or by pulling the retractor. The reason might be the close spatial relationships between nerves and ICA or ECA, respectively, in the case of high bifurcation. The difficult anatomic conditions could also explain the higher rate of N. hypoglossal paresis in the HL group. These pareses can be caused either directly by mechanical irritation or by the infiltration of local anesthetics. To avoid this complication, it can be argued that the PVB may lack sufficient analgesia above C3 level, and its use should be discussed critically.

Limitations

The present trial has several limitations. First, the present trial was an exploratory observational study. Therefore, no sample size calculation was performed. Second, the level of the CBL was not evenly distributed between groups, which could influence comparability. Third, there may be differences between the anatomic variations of the position of the ECA in relation to the ICA, which could influence PVB performance independent of the anatomic level of the CBL (Rössel et al. 2013). Fourth, the higher BMI in the LL group could be confounding the results. On the other hand, we would expect a higher supplementation rate in the LL group if this is the case. Fifth, our patient population consisted mainly of white people, and the distribution of the anatomic CBL could be varying among other ethnic groups. Sixth, we did not measure ropivacaine blood plasma levels routinely during CEA to detect potential side effects of perivascular infiltration. Seventh, the setting of a university teaching hospital may lead to a higher complication rate because of residents in anesthesiology or vascular surgery learning the PVB or CEA technique, respectively. However, the overall local anesthetic supplementation rate and surgical complications in our trial were lower than previously reported (GALA Trial Collaborative Group et al. 2008; Rössel et al. 2013; Madro et al. 2016; Seidel et al. 2016).

Implications for further studies

Future prospective randomized controlled trials investigating the effects of anatomic conditions on regional anesthesia efficacy and puncture safety are warranted. The present trial may provide a basis for sample size calculation. However, the evaluation of peripheral nerve paresis in regional anesthesia for CEA is difficult in a randomized controlled design owing to rare events (Davies et al. 1997; Stoneham et al. 1998; GALA Trial Collaborative Group et al. 2008). A prospective observational multi-center trial focusing on the occurrence of peripheral nerve paresis dependent of the regional anesthetic technique may help to further investigate these complications. The adaption of the data entry in national databases for CEA regarding the specific regional anesthetic technique and type of anesthetic may help researchers access a larger data set for a retrospective trial.

CONCLUSION

The combination of ultrasound-guided intermediate cervical block and perivascular infiltration of ICA is an efficient and safe regional anesthetic technique. The efficacy of the block is highly influenced by the level of the CCA bifurcation. A bifurcation level above the C4 vertebra is associated with increased need of local anesthetic supplementation as well as surgical and anesthetic complications.

Conflict of interest disclosure—All authors declare no conflicts of interest regarding this manuscript.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ultrasmedbio.2021.05.014.

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