

# **ORIGINAL ARTICLE**

# Patient satisfaction with intravenous regional anaesthesia or an axillary block for minor ambulatory hand surgery

A randomised controlled study

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**BACKGROUND** Intravenous regional anesthesia (IVRA) and the axillary brachial plexus block are popular alternatives to general anaesthesia in ambulatory hand surgery. Although both have proven their effectiveness, patients' preferences have never been evaluated.

**OBJECTIVES** We investigated patient satisfaction with both techniques and hypothesised that satisfaction after IVRA is noninferior compared with axillary brachial plexus block.

**DESIGN** A prospective, randomised controlled trial.

**SETTING** Ambulatory surgical day care centre, University Hospitals of Leuven, Belgium, from September 2016 to November 2017.

**PATIENTS** One hundred and twenty adults undergoing minor ambulatory hand surgery were included in this study.

**INTERVENTION** Patients received either IVRA with 300 mg lidocaine or an axillary block with 280 mg mepivacaine.

MAIN OUTCOME MEASURES The primary endpoint was the evaluation of patient satisfaction using the 'Evaluation du Vécu de l'Anésthesie Locoregional' (EVAN-LR) questionnaire. Secondary outcomes included different procedural times, block quality, tourniquet discomfort, the incidence of block failure and postoperative nausea and vomiting (PONV), the severity of postoperative pain and the need for postoperative analgesics during the first 24 h.

**RESULTS** Noninferiority of IVRA was shown for the median [IQR] total score on the EVAN-LR questionnaire, IVRA-group: 92 [87 to 96] vs. axillary brachial plexus block-group: 91 [87 to 97]; Hodges–Lehmann estimator (95% confidence interval (CI)] for the shift: -0.25 (-2.60 to 2.20). Induction of anaesthesia and time to discharge, requiring partial recovery of the motor block, were significantly longer in the axillary brachial plexus block group. The IVRA-group had a lower block quality, a higher incidence of tourniquet-discomfort and higher median intra-operative and postoperative pain scores on day 0; 0 [0 to 2] vs. 0 [0 to 0] and 0.8 [0 to 1.8] vs. 0 [0 to 0.25], respectively, but no increase in the need for supplementary analgesics or conversion rate to general anaesthesia.

**CONCLUSION** IVRA and axillary brachial plexus block result in comparably high patient satisfaction in ambulatory hand surgery.

CLINICAL TRIAL REGISTRATION EudraCT 2016-002325-11.

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## Introduction

Regional anaesthesia has become an increasingly popular alternative to general anaesthesia in ambulatory hand surgery. Regional anaesthesia allows faster recovery and reduces time to discharge from the hospital, resulting in lower hospital costs.<sup>1</sup>

For hand surgery, two important regional techniques are traditionally used: intravenous regional anaesthesia (IVRA) or Bier's Block and the axillary brachial plexus block.

IVRA was first described in 1908 by the German surgeon August Karl Gustav Bier.<sup>2</sup> It is a simple technique, with a

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high success rate, a low incidence of complications and rapid onset and resolution of the block, which enables early discharge from the hospital.<sup>3</sup> Possible downsides of IVRA include a limited duration of action, incomplete muscle relaxation and the risk of local anaesthetic systemic toxicity (LAST).<sup>4</sup>

Axillary brachial plexus block was first performed by Hirschel in 1911.<sup>5</sup> With the widespread use of ultrasound, it has become very popular in clinical practice.<sup>6</sup> The use of ultrasound (US) guidance, in comparison with nerve stimulation, results in a higher success rate of this technique and reduces the dose of local anaesthetic necessary to achieve an adequate block.<sup>7</sup> In so doing, it decreases the risk of intravascular injection and LAST but the impact of ultrasound on neurological damage remains unclear.8 Compared with IVRA, the axillary brachial plexus block has a longer analgesic effect and a reduced need for postoperative analgesia but may increase the time to hospital discharge.<sup>1,9</sup> Other disadvantages include a slower onset than IVRA, a longer learning curve, a higher failure rate,<sup>10</sup> risk of arterial puncture, nerve damage and LAST.

Traditionally regional anaesthesia techniques have been studied and compared with respect to analgesic efficacy and safety, but patients' preferences have not been thoroughly evaluated in this setting. Patient satisfaction is influenced by multiple factors and not only by the chosen anaesthetic technique.<sup>11,12</sup> Moreover, we have recently demonstrated that even moderate postoperative pain does not decrease patient satisfaction after ambulatory anaesthesia.<sup>13</sup> Hence, we hypothesised that satisfaction in patients undergoing ambulatory hand surgery with regional anaesthesia was similar following IVRA and ultrasound-guided axillary brachial plexus block.

### Methods

#### Study design and population

This randomised controlled trial was approved by the ethics committee of the University Hospitals of Leuven (EC S59319, 22 July 2016), and the Federal Agency for Medicines and Health Products (27 July 2016). It was registered in the publicly accessible European Clinical Trials Database of the European Medicine Agency (EudraCT 2016-002325-11). Patients were enrolled between September 2016 and November 2017.

We enrolled adults undergoing carpal tunnel release, resection of a wrist cyst or Dupuytrens release (with a maximum of two strands) under regional anaesthesia in an ambulatory setting. We included only patients with American Society of Anesthesiologists physical status I to III, who were at least 18 years of age and scheduled for elective surgery in the day surgery unit (DSU). Exclusion criteria were refusal of consent, allergy to any of the medications used, contraindications to paracetamol or nonsteroidal anti-inflammatory drugs (NSAID), preoperative uncontrolled hypertension (SBP >170 mmHg), peripheral neuropathy, epilepsy, bilateral operations, puncture site infections, contraindication for the use of a tourniquet, coagulation disorders or the use of anticoagulant therapy (vitamin K antagonists, new oral anticoagulants) or antiplatelet drugs (thienopyridines).

Written informed consent was obtained on arrival during preoperative preparation. The randomisation list was generated using the Sealed Envelope <sup>TM</sup> program (Sealed Envelope Ltd, Clerkenwell, London, United Kingdom). Allocation concealment was ensured by enclosing assignments in sealed, opaque, sequentially numbered envelopes, which were opened only before induction of anaesthesia.

#### **Study intervention**

In patients allocated to receive an axillary block, regional anaesthesia was performed in the preoperative preparation and block room. The arm for surgery was abducted at  $90^{\circ}$  and the forearm flexed to a  $90^{\circ}$  angle. With the use of ultrasound, the following four nerves were identified as hyperechoic structures: the median, ulnar and radial nerve surrounding the axillary artery and the musculocutaneous nerve in the fascial layers between the biceps and coracobrachialis muscles. Local anaesthesia of the puncture site was achieved with a subcutaneous injection of 2 ml lidocaine 1%. The needle (Stimuplex Ultra 360 0.71× 50 mm; G 22; B. Braun Medical Inc., Melsungen, Hessen, Germany) was inserted in the axilla under ultrasound guidance with the probe in plane.<sup>14</sup> Both ultrasound and neurostimulation were used to detect the nerves and to decrease the risk of intraneural puncture or injection. After the initial motor response was obtained in the median nerve (set at 0.5 mA), the needle was slowly advanced towards the stimulated nerve and the intensity was decreased to 0.3 mA. If a motor response was still present, the needle was slightly withdrawn, to reduce the risk of intraneural injection. Afterward, the needle was redirected to the musculocutaneous nerve and the radial nerve, using the same technique.

A total volume of 28 ml mepivacaine 1% was administered, divided over three injections: two into the neurovascular sheath (10 ml each above and under the axillary artery) and one outside the sheath (8 ml around the musculocutaneous nerve). Before injection of the LA, aspiration was performed to check that the needle position was not intravascular.<sup>15</sup>

The sensory block was assessed by evaluation of the loss of cold sensation (yes/no) for the different nerves supplying the forearm (anterior and posterior: musculocutaneous distribution) and hand (palmar: ulnar and median distribution, dorsal: radial distribution). The motor block was evaluated in a dichotomous way (complete/incomplete) for the different nerves (finger movements: radial and ulnar nerve, flexing the elbow: musculocutaneous

nerve, arm extension: radial nerve). When the sensory block was adequate in all areas, the patient was transported to the operating room and surgery was started.

In patients allocated to the IVRA-group, all anaesthetic techniques took place in the operating room. A cannula (22 G, BD Insyte-W; Becton, Dickinson Benelux N.V., Erembodegem, Belgium) was inserted into a vein on the back of the hand on the operative side. A tourniquet with a double cuff was attached around the upper arm. Then, an Esmarch bandage was wrapped tightly while lifting the arm, exsanguinating the arm.<sup>3</sup> Subsequently, the proximal cuff of the tourniquet was inflated to 250 mmHg, and the Esmarch bandage was removed. Three hundred milligrams of lidocaine in a total volume of 40 ml was injected slowly through the intravenous catheter, which was removed afterwards.

The quality of the sensory and motor block was examined in the same way as in the axillary brachial plexus blockgroup. When the sensory block was adequate (loss of cold sensation in the different areas), surgery was started.

#### Anaesthetic and peri-operative management

Before the start of the regional anaesthesia procedure an intravenous (i.v.) cannula was inserted and midazolam 2 mg with crystalloid fluid was given. Standard monitoring, including electrocardiography, noninvasive blood pressure measurement and pulse oximetry was used in all patients. Before insufflation of the tourniquet, an i.v. bolus of  $0.5 \text{ mg kg}^{-1}$  ketorolac with a maximum of 30 mg, was administered. In addition, all patients received an i.v. bolus of  $15 \text{ mg kg}^{-1}$  paracetamol with a maximum of 1000 mg during surgery.

If the block was insufficient [numeric rating scale (NRS)  $\geq$ 4], patients received an i.v. bolus of 5 µg sufentanil repeated once if necessary. If pain was persistent or the block failed, general anaesthesia was induced with 2 mg kg<sup>-1</sup> propofol. A laryngeal mask was inserted and anaesthesia was maintained with sevoflurane 1.5 to 2.0% in a 40% O<sub>2</sub>/air mixture.

If there was tourniquet pain (NRS  $\geq$ 4) in the IVRA-group more than 15 min after injection, the distal cuff was inflated and the proximal cuff was released. If tourniquet pain (NRS  $\geq$  4) was present directly after inflation or persisted after a switch of the cuffs in the IVRA-group, or tourniquet pain in the axillary brachial plexus blockgroup, sufentanil, and propofol were administered using the same sequence as for block failure. Following conversion to general anaesthesia or adverse events (hypotension, bradycardia or symptoms of LAST), patients were monitored in the postanaesthesia care unit (PACU) until the problem resolved, otherwise they were admitted immediately after surgery to the day care unit (DCU).

At the PACU or the DCU, postoperative pain [visual analogue scale (VAS)  $\geq$ 4] was treated with tramadol 50 to

100 mg per orum. Postoperative nausea or vomiting (PONV) was treated with i.v. ondansetron 4 mg.

Patients were discharged home when the following criteria were fulfilled: a postanaesthesia discharge score (PADS) at least 9<sup>16</sup> (Supplementary digital file Addendum 1, http://links.lww.com/EJA/A321) and recovery of the motor block at the elbow. Once at home, the oral analgesic regimen consisted of paracetamol 1 g four times daily. and ibuprofen 400 mg three times a day.

#### Study outcomes

#### Primary outcome

Patient satisfaction was evaluated using the 'Evaluation du Vécu de l' Anesthésie LocoRegional' (EVAN-LR) questionnaire, which was specially developed for the evaluation of patient satisfaction after regional anaesthesia<sup>17</sup> (Addendum 2, http://links.lww.com/EJA/A322). In addition, patients were asked if they would choose the same anaesthetic technique in the future. All questions were completed just before discharge, except for those items, which are home-related (questions 12, 13 and 14). These questions were asked during a postoperative phone call interview at day 1 during which patients were also asked for the occurrence of adverse events and postoperative pain (see below).

#### Secondary outcomes

Different time intervals were measured: anaesthesia induction time (defined as the time between administration of midazolam and readiness for surgery), duration of surgery (defined as the time between incision and completion of bandage), tourniquet time, time to achieve a stable PADS score of at least 9 and discharge time (defined as the time between end of surgery and criteria met for discharge). The quality of the block (4-point scale, Addendum 3, http://links.lww.com/EJA/A323),<sup>18</sup> incidence of tourniquet discomfort, intra-operative need for supplementary analgesia and the conversion rate to general anaesthesia (block failure rate) were noted. NRS pain scores, VAS pain scores, and required doses of analgesics were measured intra-operatively, postoperatively and 24 h after surgery.

#### Adverse events

The incidences of hypotension, bradycardia, PONV, symptoms of LAST and neurological damage were noted. When adverse events were present at postoperative day 1 (assessed by a phone call), patients were repeatedly contacted via phone until the resolution of these events or until consultation with the orthopaedic surgeon.

#### Statistical analysis

#### Sample size calculation

The required sample size was based upon a noninferiority test (with alpha = 0.025) for the comparison of two means assuming no difference in mean satisfaction between

groups. This corresponds to a two-sided *t*-test with alpha = 5%, and the assumed standard deviation was set at 8 points. Our assumptions were derived from a historical cohort study of 50 patients undergoing hand surgery under axillary block in our unit. In this cohort, we observed a mean satisfaction score of 91.8 and a standard deviation of 7.15. The range for noninferiority was defined as a maximal difference of 5 points in the mean EVAN-LR score. To reach a power of 80%, at least 42 patients in each group were needed. To compensate for possible dropouts, 60 patients were randomised to each group.

#### Data analysis

All analyses were performed using SAS software, version 9.4 (64-bit) of the SAS System for Windows, using SAS/ STAT 14.2 (SAS Institute Inc., Cary, North Carolina, USA).

The study aimed to assess whether IVRA was noninferior to the axillary block with regard to the EVAN-LR scores (total and dimension scores), with the noninferiority limit set at -5. Hodges–Lehman estimators for the shift, with associated 95% confidence interval, for the difference between IVRA and axillary brachial plexus block, were calculated. If the lower 95% confidence limit was above -5, IVRA was deemed to be noninferior to the axillary block. Noninferiority was also assessed in the following subgroups using the same methodology: sex (man, woman), age (<55 years, at least 55 years), ASA classification (I, II and III).

Continuous variables were summarised by mean  $\pm$  SD, or median [IQR] if severe deviations from normality were observed. Comparisons between randomised groups were made using a two-sample *t*-test or Wilcoxon rank-sum test in case of nonnormality.

Categorical data were summarised by observed frequencies and percentages per category. Comparisons between randomised groups were made using a  $\chi^2$  test or Fisher's exact test, as appropriate.

Continuous repeated data were analysed using a longitudinal generalised estimating equations (GEE) model using an identity link and normal distribution for the residuals.<sup>19</sup> The model included group allocation, time and their interaction as factors in the model. For intraoperative data, the pretreatment measure was included as a covariate in the model. A joint score test of the randomised group and interaction was performed to assess whether there was an effect of group allocation.

Kaplan–Meier methodology was used to estimate the proportion of patients with PADS at least 9 and the proportion of patients discharged. For the former, patients were censored at the time of discharge. A comparison of the proportions between the two groups was performed using a log-rank test. Unless specified otherwise, all statistical tests were twosided and assessed at a significance level of 5%. Due to the exploratory nature of the study, no adjustments were made to the significance level for multiple testing.

#### Results

We enrolled 60 patients in each group, and all received the allocated technique, but two in each group were lost to follow-up after 24 h (Fig. 1). Patients' characteristics were similar between both groups (Table 1).

#### **Primary outcome**

The total response rate to the EVAN-LR questionnaire was 98%. Noninferiority of the IVRA was shown for the median [IQR] total score on the EVAN-LR questionnaire; IVRA-group: 92 [87 to 96] vs. axillary brachial plexus block-group: 91[87 to 97]; Hodges-Lehman estimators for the shift (95% CI), -0.25 (-2.60 to 2.20). In addition, the sub-scores for the different dimensions (attention, information, discomfort, waiting, pain) were also noninferior. However, evaluation of satisfaction in the different prespecified subgroups of patients (defined by sex, age or ASA classification), demonstrated that noninferiority of the IVRA technique could not be proven in the group of young and healthy men. Detailed results are shown in Fig. 2.

The statistical analysis of the additional question (if patients would choose the same technique for a future intervention) also revealed no significant difference between both groups, IVRA-group (n=58): 96.67% vs. axillary brachial plexus block-group (n=57): 95%, P=1.0.

#### Secondary outcomes

Anaesthesia induction time was significantly longer in the axillary brachial plexus block-group (Table 2). Tourniquet time was significantly longer in the IVRA-group, whereas surgical times were similar between groups (Table 2).

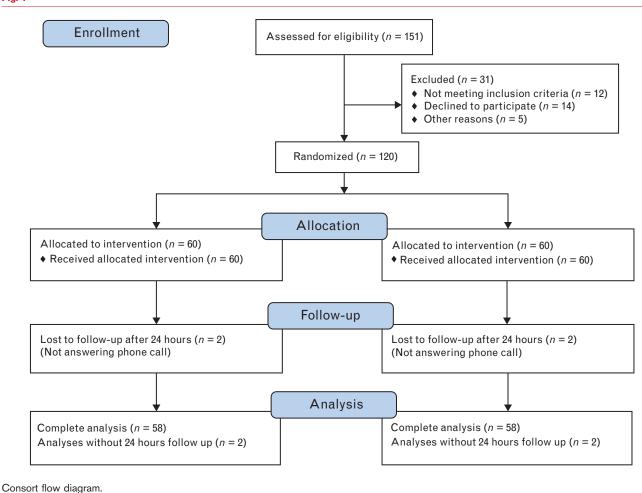
The quality of the block differed significantly between both groups but only at the start of surgery (Fig. 3). Intraoperative NRS pain scores and the incidences of tourniquet discomfort were significantly higher in the IVRA group (Table 3). However, these differences did not result in an increased need for extra sufentanil and did not affect the conversion rate to general anaesthesia (Table 3).

In the PACU or DCU, VAS scores were significantly higher in the IVRA-group without increasing the need for extra analgesics. Time to reach a stable PADS at least 9 was significantly longer in the IVRA-group, but discharge times were significantly longer in the axillary brachial plexus block-group (Table 2, Figs. 4 and 5).

After 24 h, there were no significant differences between groups in pain scores or the need for additional analgesics (Table 3).







#### Adverse events

Groups were similar at all times in haemodynamic status, the incidence of PONV and the need for antiemetic. No

#### Table 1 Patient characteristics

	IVRA-group ( <i>n</i> =60)	Axillary brachial plexus block-group (n=60)	Total ( <i>n</i> =120)
Age (years)	53 (16)	50 (15)	52 (16)
Female (n)	31 (52)	32 (53)	63 (53)
Male (n)	29 (48)	28 (47)	57 (47)
Weight (kg)	$75\pm15$	$76\pm15$	$75\pm15$
Height (cm)	$170\pm8$	$171\pm10$	$171\pm9$
ASA			
ASA 1 (n)	24 (40)	32 (53)	56 (47)
ASA 2 (n)	26 (43)	24 (40)	50 (42)
ASA 3 (n)	10 (17)	4 (7)	14 (12)
Indication			
ECTR (n)	18 (30)	18 (30)	36 (30)
Wrist cyst (n)	16 (27)	19 (32)	35 (29)
Dupuytren's disease (n)	26 (43)	23 (38)	49 (41)
History of PONV (n)	8 (13)	5 (8)	13 (11)

Data are presented as mean  $\pm$  SD or as frequency (%). ASA, American Society of Anesthesiologists; ECTR, endoscopic carpal tunnel release; IVRA, intravenous regional anesthesia; PONV, postoperative nausea and vomiting.

serious adverse events or persistent neurological damage were noted. An overview of all adverse events is listed in Table 4.

#### Discussion

The results confirm our hypothesis that satisfaction after IVRA is noninferior when compared with an axillary brachial plexus block. Although we observed no significant difference between groups in block failure rate, induction and discharge times were longer in the axillary brachial plexus block-group.

To our knowledge, this is the first study that compares patient satisfaction with two popular regional anaesthesia techniques for hand surgery. Because of the extremely low morbidity and mortality associated with ambulatory anaesthesia per se, patient satisfaction as an outcome of anaesthesia and peri-operative care becomes increasingly important.<sup>20</sup> Although regional anaesthesia has been associated with certain benefits in ambulatory surgery, such as better analgesia and faster discharge, the relationship between patient satisfaction and regional anaesthesia is unclear.<sup>12</sup> Patient satisfaction after ambulatory

Fig. 2

EVAN–LR	IVRA	Axillary Block	HL (95% CI)	IVRA	IVRA
Scores	(n) Median (Q1;0	Q3) (n) Median (Q1;Q3)	Bier's – Axillary	Inferior	Not Inferior
Total Score	(60) 92 (87; 96)	(60) 91 (87; 97)	-0.25 (-2.60; 2.20)		┆┝╼╇┙
Attention	(60) 100 (94; 100)	(60) 100 (95: 1 (0)	0.00 (0.00; 0.00)		. •
Information	(58) 93 (86; 99)	(60) 92 (86; 98)	0.00 (-2.00; 4.00)		i 🖛 🛶
Discomfort	(60) 94 (88; 100)	(60) 96 (89; 100)	0.00 (-3.75: 0.00)		¦⊷-•
Waiting	(60) 90 (73; 100)	(60) 90 (79; 100)	0.00 (-5.00; 5.00)		∳ŧı
Pain	(60) 93 (84; 98)	(60) 94 (89; 98)	-2.50 (-5.00; 0.00)		┝╼┥
Gender					
Male	(29) 91 (87; 98)	(28) 94 (90; 98)	–1.55 (–5.75; 2.00)	ŀ	┊╼┼┥
Female	(31) 94 (87; 96)	(32) 90 (87; 95)	-1.23 (-2.13; 4.20)		i ⊢ <mark>¦∎</mark> ⊸i
Age					
< 55 years	(29) 90 (83; 95)	(36) 91 (87; 96)	-2.14 (-6.20: 1.70)	F	┊╼┼╸
≥ 55 years	(31) 94 (89; 98)	(24) 92 (86; 97)	0.98 (–2.15; 4.70)		
ASA Scorev					
I	(24) 92 (82; 97)	(32) 92 (89; 97)	–1.50 (–5.53: 2.25)		┊──■┼┥
П	(26) 92 (89; 95)	(24) 91 (86; 98)	0.23 (-3.45; 4.25)		·
111	(10) 92 (86; 98)	(4) 81 (77; 89)	8.03 (-4.60; 19.80)		₀

HL = Hodges-Lehmann estimator for shirt.

Note: Confidence intervals that lie entirely within the shaded non-inferiority region provide evidence of statistical non-inferiority of IVRA versus Axillary Block.

Results of the 'Evaluation du Vécu de l' Anesthésie Locoregional' questionnaire in both groups: analysis of total, subdimension and subgroup scores.

surgery has been evaluated in several trials in which, however, overall satisfaction scores or nonvalidated questionnaires were most frequently used.<sup>21</sup> We, instead, used the EVAN-LR questionnaire, which to our knowledge, is the first validated peri-operative questionnaire that evaluates patient satisfaction after regional anaesthesia in a multidimensional way, addressing preoperative, intra-operative and postoperative items.<sup>12,17</sup>

Patient satisfaction with peri-operative care is a multidimensional concept that is influenced by several factors, with anaesthesia being only one,<sup>22,23</sup> but in our study, the choice for a particular anaesthetic technique did not influence overall satisfaction. Moreover, 95% of our patients would choose the same technique for future operations, which is an additional indicator for satisfaction with the anaesthetic technique.

Even within the different sub-dimensions, the EVAN-LR questionnaire could not reveal any significant differences between both groups. These results indicate that neither the longer induction and discharge times in the axillary brachial plexus block-group nor the higher pain scores in the IVRA-group affected patient satisfaction. As long as nurses and doctors pay attention to patient's complaints and discuss the need for treatment ('patientcentred care'), patient satisfaction need not be influenced by pain.<sup>24</sup> These results re-affirm the fact that patient satisfaction is an interplay of many influencing factors.

Evaluation of satisfaction in the different prespecified subgroups of patients (defined by sex, age or ASA classification), demonstrated that the noninferiority of the IVRA technique was not proven in the group of young and healthy men. The fact that patient characteristics

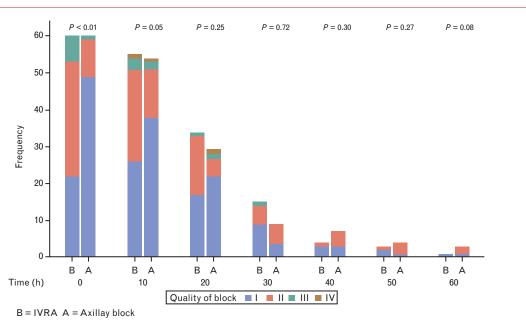
#### Table 2 Time characteristics

	IVRA-group ( <i>n</i> =60)	Axillary brachial plexus block-group ( $n=60$ )	P value
Anesthesia induction time (min)	8 [7 to 10]	34 [29 to 40]	<0.001
Tourniquet time (min)	34 [30 to 40]	25 [17 to 35]	< 0.001
Duration of surgery (min)	15 [11 to 24]	17 [10 to 23]	0.828
Discharge time (min)	52 [40 to 63]	104 [69 to 128]	<0.001

Data are presented as median [IQR]. IVRA, intravenous regional anesthesia. Bold values indicate a P-value <0.05.

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Fig. 3



Evolution of intra-operative block quality.

influence satisfaction has already been demonstrated in the literature.<sup>23,25,26</sup> However, in contrast to our results, male patients usually have a higher satisfaction score in most studies. We cannot explain these unexpected results as the lower total satisfaction scores could not be attributed to a specific dimension of the EVAN-LR questionnaire. This is in contrast to our findings in young patients in whom lower dimensional scores regarding pain and information did result in less overall patient satisfaction. Although the pain scores were higher in the IVRA-group, the difference was not clinically important and pain scores remained beneath the threshold for treatment.<sup>27,28</sup> As a result there were no important differences in the need for supplementary analgesics. The IVRA-group also experienced more tourniquet discomfort, probably as the skin underneath the tourniquet was not anaesthetised. In the axillary brachial plexus block group; however, we selectively blocked the musculocutaneous nerve

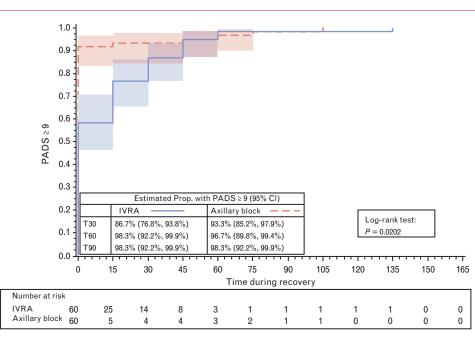
#### Table 3 Intraoperative and postoperative data

	IVRA-group ( <i>n</i> =60)	Axillary brachial plexus block-group ( $n=60$ )	<b>P</b> value
Intraoperative data			
NRS pain score	0 [0 to 2]	0 [0 to 0]	<0.001
Need for supplementary sufentanil	12 (20)	9 (15)	0.632
Indications:			0.417
Operative pain	9 (75)	5 (56)	
Tourniquet discomfort	3 (25)	3 (33)	
Panic attack	0 (0)	1 (11)	
Conversion to general anaesthesia	1 (2)	2 (3)	1.000
PONV medication	0 (0)	2 (3)	0.496
Postoperative day 0			
VAS pain score	0.79 [0.00 to 1.76]	0.00 [0.00 to 0.25]	<0.001
Supplementary analgesics	5 (8)	4 (7)	1.000
PONV medication	1 (2)	1/60 (2)	1.000
Postoperative day 1	n=58	n=58	
NRS pain score	2.00 [0 to 3]	2.00 [0 to 3]	0.973
Supplementary analgesics	44 (76)	48 (83)	0.492
PONV medication	1 (2)	O (0)	1.000

Data are presented as median [IQR] or as frequency (%). NRS, numeric rating scale; PONV, postoperative nausea and vomiting; VAS, visual analogue scale. Bold values indicate a *P*-value <0.05.

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Fig. 4

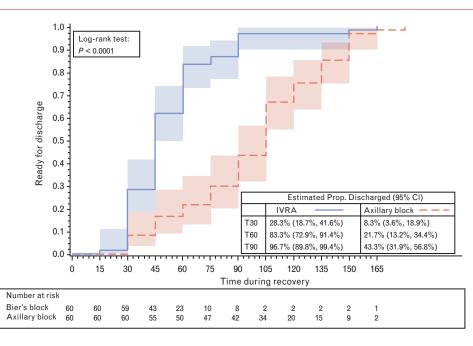


Time to reach a PADS at least 9 in both groups.

resulting in upper arm anaesthesia. Most complaints about tourniquet discomfort (20/23) could be solved by changing the inflated cuff to the distal one, but in doing so increased the risk of mistakes or tourniquet failure, and therefore, the risk of LAST.

Our results show a discrepancy between the time to reach a stable PADS score and the discharge time in both groups. This has a number of explanations. First, in the IVRA-group, the median time between administration of midazolam at induction of anaesthesia and arrival

Fig. 5



Discharge times in both groups.

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#### Table 4 Adverse events

	IVRA-group ( <i>n</i> =60)	Axillary brachial plexus block-group ( $n=60$ )	P value	
Intra-operative data				
Venous congestion	2 (3)	0 (0)	0.496	
Panic attack	0 (0)	1 (2)	1.000	
Hyperventilation	1 (2)	0 (0)	1.000	
Postoperative day 0				
Vertigo	2 (3)	0 (0)	0.496	
Tinnitus	2 (3)	0 (0)	0.496	
Syncope	1 (2)	0(0)	1.000	
Postoperative day 1	n=58	n=58		
Tingling of the hand/fingers	1 (2)	4 (7)	0.364	
Coldness of the hand/fingers	0 (0)	1 (2)	1.000	
Numbness of the hand/fingers	7 (12)	3 (5)	0.322	
Haematoma at the tourniquet site	1 (2)	0 (0)	1.000	

Data are presented as frequency (%).

at DCU (first measurement of PADS score) was significantly shorter (IVRA vs. axillary brachial plexus block: 46 vs. 110 min, P < 0.0001), resulting in greater sedation and more dizziness on arrival in the DCU, which could have delayed normalisation of the PADS score in the IVRAgroup. Second, the absorption of lidocaine into the systemic circulation after releasing the tourniquet might induce some systemic reaction like dizziness or lightheadedness, prolonging the time to reach a PADS at least 9. These two factors might have resulted in a shorter time to reach a stable PADS score in the axillary brachial plexus block-group when compared with the IVRA-group (Table 4). Third, according to our hospital policy, patients after regional anaesthesia were only discharged home after partial recovery of the block. This policy results in an increased discharge time following axillary block, whereas block offset times of 2 to 8 min are described for the IVRA technique and up to 230 min for an axillary block.<sup>29,30</sup>

Unfortunately, there are no clear guidelines concerning discharge policy after regional anaesthesia. Although in some centres, patients are only discharged home after complete recovery of the sensory and motor block,<sup>31</sup> in others, discharge is permitted without a full return of sensation.<sup>32</sup> A less strict discharge protocol in our setting would have influenced our results and reduced patients' discharge times in the axillary brachial plexus block-group.

The observed difference in block quality was mainly because of the difference in the motor block between both groups (partial motor block: IVRA-group vs. axillary brachial plexus block-group: 83 vs. 47%; P < 0.001). As complete motor block was not mandatory for the selected surgery block efficacy was unaffected (effective block: IVRA-group vs axillary brachial plexus block-group: 88.3% vs. 98.3%; P = 0.06). IVRA might prove inadequate for surgery that required a complete motor block.

Failure rate defined as the need for conversion to general anaesthesia in our study was low for both techniques

(Table 3). While the reported success rate of IVRA (98.6%) is comparable to our results (98.3%),<sup>33</sup> the reported success of an axillary brachial plexus block varies between 80% and 90% which is lower than observed in our study (96.7%).<sup>7,34</sup> The fact that a single anaesthetist experienced in Regional anaesthesia performed all blocks using ultrasound and neurostimulation may have contributed to our higher success rate.

There were no long-lasting neurological complications with either technique. All complaints of numbness or tingling after D1 disappeared over the following week or were attributed to the surgical intervention and not related to the anaesthetic technique. Two patients in the IVRA-group complained of tinnitus after deflation of the tourniquet, which can be a minor symptom of LAST (Table 4).

We acknowledge that our study has several limitations. First, for obvious reasons, neither investigators nor patients could be blinded during the procedure and because of these procedural differences between both groups, a performance bias cannot be excluded.

Second, two different local anaesthetics were used in the two groups, namely lidocaine, a short-acting drug, in the IVRA-group and mepivacaine, an intermediate-acting drug, in the axillary brachial plexus block-group. Lidocaine is the most commonly used local anaesthetic in IVRA because of its low toxicity.<sup>35</sup> Mepivacaine can also be used for IVRA. However, because of its vascular effects, vasoconstriction with decreased reactive post ischaemic hyperaemia, mepivacaine is not considered to be the local anaesthetic of choice in IVRA,<sup>36</sup> but both lidocaine and mepivacaine are considered suitable drugs for day case axillary brachial plexus block.<sup>37,38</sup> Both local anaesthetics have a fast onset but duration of analgesia is longer after mepivacaine when used for peripheral nerve blocks.<sup>39</sup> In our hospital setting, in which block rooms are used, we have observed that analgesia was sometimes insufficient at the end of surgery when lidocaine had been use used for an axillary brachial plexus block. Therefore,



we opted for mepivacaine as local anaesthetic in the axillary brachial plexus block-group.

Third, we only included patients undergoing minor hand surgery. Therefore, caution is warranted when extrapolating our results to patients undergoing major hand surgery.

Last, it should be noted that the present trial was powered only for the primary outcome. All other results concerning secondary endpoints should, therefore, be interpreted with caution.

In conclusion, the results of this randomised controlled trial demonstrate that patient satisfaction is not inferior after IVRA compared with an axillary brachial plexus block for ambulatory hand surgery. No other clinical important differences could be demonstrated except for a faster induction and discharge time after the IVRA, which are essential requirements for ambulatory surgery.

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#### References

- 1 Chan VW, Peng PW, Kaszas Z, et al. A comparative study of general anesthesia, intravenous regional anesthesia, and axillary block for outpatient hand surgery: clinical outcome and cost analysis. Anesth Analg 2001; 93:1181–1184.
- 2 van Zundert A, Helmstädter A, Goerig M, Mortier E. Centennial of intravenous regional anesthesia. Bier's Block (1908–2008). *Reg Anesth Pain Med* 2008; **33**:483–489.
- 3 Barry LA, Balliana SA, Galeppi AC. Intravenous regional anesthesia (Bier block). *Techniques in regional anesthesia and pain management* 2006; 10:123–131.
- 4 Guay J. Adverse events associated with intravenous regional anesthesia (Bier block): a systematic review of complications. J Clin Anesth 2009; 21:585-594.
- 5 Mian A, Chaudhry I, Huang R, et al. Brachial plexus anesthesia: a review of the relevant anatomy, complications, and anatomical variations. *Clin Anat* 2014; 27:210-221.
- 6 Klaastad O, Sauter AR, Dodgson MS. Brachial plexus block with or without ultrasound guidance. Curr Opin Anaesthesiol 2009; 22:655–660.
- 7 Chan VWS, Perlas A, McCartney CJL, et al. Ultrasound guidance improves success rate of axillary brachial plexus block. Can J Anesth 2007; 54:176– 182.
- 8 Ecoffey C, Oger E, Marchand-Maillet F, et al. Complications associated with 27 031 ultrasound-guided axillary brachial plexus blocks: a web-based survey of 36 French centres. *Eur J Anaesthesiol* 2014; 31:606–610.
- 9 Brill S, Middleton W, Brill G, Fisher A. Bier's Block; 100 years old and still going strong!. Acta Anaesthesiol Scand 2004; 48:117–122.
- 10 Neal JM, Barrington MJ, Brull R, et al. The Second ASRA Practice Advisory on neurologic complications associated with regional anesthesia and pain medicine: executive summary 2015. *Reg Anesth Pain Med* 2015; 40:401–430.

- 11 Bleich SN, Ozaltin E, Murray CKL. How does satisfaction with the healthcare system relate to patient experience? *Bull World Health Organ* 2009; 87:271–278.
- 12 Wu CL, Naqibuddin M, Fleisher LA. Measurement of patient satisfaction as an outcome of regional anesthesia and analgesia: a systematic review. *Reg Anesth Pain Med* 2001; 26:196–208.
- 13 Teunkens A, Vanhaecht K, Vermeulen K, et al. Measuring satisfaction and anesthesia related outcomes in a surgical day care centre: a three-year single-centre observational study. J Clin Anesth 2017; 43:15–23.
- 14 Ranganath A, Srinivasan KK, lohom G. Ultrasound guided axillary brachial plexus block. *Med Ultrason* 2014; **16**:246–251.
- 15 Tran DQH, Russo G, Muñoz L, et al. A prospective, randomized comparison between ultrasound-guided supraclavicular, infraclavicular, and axillary brachial plexus blocks. Reg Anesth Pain Med 2009; 34:366-371.
- 16 Chung F, Chan VW, Ong D. A postanesthetic discharge scoring system for home readiness after ambulatory surgery. J Clin Anesth 1995; 7:500–506.
- 17 Maurice-Szamburski A, Bruder N, Loundou A, et al. Development and validation of a perioperative satisfaction questionnaire in regional anesthesia. Anesthesiology 2013; 118:78-87.
- 18 Mehrotra MS, Mehrotra MM. Regional block anaesthesia how effective is it for extremity trauma? Med J Armed Forces India 2002; 58:205-209.
- 19 Zeger SL, Liang KY. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics* 1986; 42:121–130.
- 20 Herrera FJ, Wong J, Chung F. A systematic review of postoperative recovery outcomes measurements after ambulatory surgery. *Anesth Analg* 2007; **105**:63–69.
- 21 Chanthong P, Abrishami A, Wong J, *et al.* Systematic review of questionnaires measuring patient satisfaction in ambulatory anesthesia. *Anesthesiology* 2009; **110**:1061–1067.
- 22 Whitty PM, Shaw IH, Goodwin DR. Patient satisfaction with general anaesthesia. Too difficult to measure? *Anaesthesia* 1996; **51**:327–332.
- 23 Caljouw MAA, van Beuzekom M, Boer F. Patient's satisfaction with perioperative care: development, validation, and application of a questionnaire. *Br J Anaesth* 2008; **100**:637–644.
- 24 Comley AL, DeMeyer E. Assessing patient satisfaction with pain management through a continuous quality improvement effort. J Pain Symptom Manage 2001; 21:27-40.
- 25 Jlala HA, Caljouw MA, Bedforth NM, Hardman JG. Patient satisfaction with perioperative care among patients having orthopedic surgery in a university hospital. *Local Reg Anesth* 2010; 3:49–55.
- 26 Ironfield CM, Barrington MJ, Kluger R, Sites B. Are patients satisfied after peripheral nerve blockade? Results from an international registry of regional anesthesia. *Reg Anesth Pain Med* 2014; **39**:48–55.
- 27 Walder B, Maillard J, Lübbeke A. Minimal clinically important difference: a novel approach to measure changes in outcome in perioperative medicine. *Eur J Anaesthesiol* 2015; **32**:77–78.
- 28 Farrar JT, Pritchett YL, Robinson M, et al. The clinical importance of changes in the 0 to 10 numeric rating scale for worst, least, and average pain intensity: analyses of data from clinical trials of duloxetine in pain disorders. J Pain 2010; 11:109–118.
- 29 Rosenberg PH. 1992 ASRA Lecture. Intravenous regional anesthesia: nerve block by multiple mechanisms. *Reg Anesth* 1993; 18:1-5.
- 30 Bouaziz H, Narchi P, Mercier FJ, et al. The use of a selective axillary nerve block for outpatient hand surgery. Anesth Analg 1998; 86:746-748.
- 31 Chung F. Are discharge criteria changing? J Clin Anesth 1993; 5:64S-68S.
- 32 Marshall SI, Chung F. Discharge criteria and complications after ambulatory surgery. *Anesth Analg* 1999; **88**:508–517.
- 33 Dunlop DJ, Graham CM, Waldram MA, et al. The use of Bier's block for day case surgery. J Hand Surg Br 1995; 20:679–680.
- 34 Qin Q, Yang D, Xie H, et al. Ultrasound guidance improves the success rate of axillary plexus block: a meta-analysis. Braz J Anesthesiol 2016; 66:115– 119.
- 35 Flamer D, Peng PW. Intravenous regional anesthesia: a review of common local anesthetic options and the use of opioids and muscle relaxants as adjuncts. *Local Reg Anesth* 2011; **4**:57–76.
- 36 Kalman S, Björhn KC, Tholén EK, Lisander B. Mepivacaine as an intravenous regional block interferes with reactive hyperemia and decreases steady-state blood flow. *Reg Anesth* 1997; 22:552–556.
- 37 Satapathy AR, Coventry DM. Axillary brachial plexus block. Anesthesiol Res Pract 2011; 2011:173796–173805.
- 38 Allegri M, Delazzo MG, Grossi P, Borghi B. Efficacy of drugs in regional anesthesia: a review. Eur J Pain Suppl 2009; 3:41–48.
- 39 Covino BG. Comparative clinical pharmacology of local anesthetic agents. Anesthesiology 1971; 35:158–167.