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Reduced hemidiaphragmatic paresis with extrafascial compared with conventional intrafascial tip placement for continuous interscalene brachial plexus block: a randomized, controlled, double-blind trial

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Abstract

Background. The incidence of hemidiaphragmatic paresis with continuous interscalene brachial plexus block (CISB) can approach 100%. We tested the hypothesis that extrafascial placement of the catheter tip reduces the rate of hemidiaphragmatic paresis compared with intrafascial tip placement for CISB while providing effective analgesia.

Methods. Seventy patients undergoing elective major shoulder surgery under general anaesthesia were randomized to receive an ultrasound-guided CISB plexus block for analgesia with the catheter tip placed either within (intrafascial group) or immediately outside (extrafascial group) the brachial plexus sheath midway between the levels of C5 and C6. Catheters were bolus dosed with ropivacaine 0.5% 20 ml before surgery, followed by an infusion of ropivacaine 0.2% at 4 ml h^{-1} for the first 2 days after surgery. The primary outcome was hemidiaphragmatic paresis measured by M-mode ultrasonography on postoperative day (POD) 1. Secondary outcomes included forced vital capacity, forced expiratory volume in 1 s, and rest pain scores.

Results. The incidence of hemidiaphragmatic paresis on POD 1 was significantly reduced in the extrafascial group {intrafascial, 41% [95% confidence interval (CI) 25–59%]; extrafascial, 15% (95% CI 5–32%); $P=0.01$}. We were unable to detect a difference between groups in any of the functional respiratory outcomes or in rest pain scores [numerical rating scale (1–10): intrafascial, 3 (95% CI 2–3); extrafascial, 3 (95% CI: 2–4); $P=0.93$] on POD 1.

Conclusions. Placement of the catheter tip immediately outside of the brachial plexus sheath reduced the incidence of hemidiaphragmatic paresis on POD 1 associated with ultrasound-guided CISB while providing effective analgesia after major shoulder surgery. Our results do not support the routine placement of the catheter tip within the brachial plexus sheath for CISB.

Clinical trial registration. NCT02433561.

Key words: brachial plexus block; diaphragm; Analgesia, Patient-Controlled; regional anaesthesia

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Editor's key points

- Hemidiaphragmatic paresis is a frequent complication of interscalene brachial plexus block that might be reduced by specific extrafascial injection of local anaesthetic.
- Patients undergoing major shoulder surgery were randomized to either extrafascial or intrafascial catheter tip placement for continuous interscalene block using ultrasound guidance.
- Extrafascial catheter placement had a lower incidence of diaphragmatic hemiparesis but equivalent analgesia.

An incidence of hemidiaphragmatic paresis on postoperative day (POD) 1 of up to 100% after continuous interscalene block (CISB) has been reported.[1] We have previously demonstrated that needle tip placement outside of the brachial plexus sheath ('extrafascial') provides similar effectiveness of analgesia[2] while reducing the rate of hemidiaphragmatic paresis by 70%[3] compared with conventional needle tip placement within the brachial plexus sheath ('intrafascial') after single-injection ultrasound (US)-guided interscalene block (ISB) for shoulder surgery. Instead of highly concentrated, large-volume local anaesthetic solutions used for single-shot ISB to achieve surgical anaesthesia, continuous catheter-based techniques use small volumes of local anaesthetic at lower concentrations to achieve prolonged analgesia. Therefore, increasing the distance between the target nerves and catheter tip for CISB might not produce effective analgesia or might not reduce the rate of hemidiaphragmatic paresis, or both, as we have shown for single-injection ISB.

The objective of this randomized, controlled, double-blind trial was to test the hypothesis that placement of the catheter tip outside of the brachial plexus sheath (extrafascial) reduces the incidence of hemidiaphragmatic paresis on postoperative day 1 when compared with conventional catheter tip placement inside of the brachial plexus sheath (intrafascial) for CISB while providing effective analgesia after major shoulder surgery.

Methods

Recruitment and randomization

After approval by the Ethics Committee of the Lausanne University Hospital (Commission d'Ethique Romande, protocol number 319/14), this trial was prospectively registered on clinicaltrials.gov (NCT02433561). All patients aged 18–85 yr undergoing elective shoulder arthroplasty or open rotator cuff repair between November 2015 and September 2016 at Lausanne University Hospital were eligible to participate in this study. Exclusion criteria included an existing neurological deficit in the upper limb, a history of neck surgery or radiotherapy, moderate to severe pulmonary disease, chest deformity, contraindications to peripheral nerve block (e.g. allergy to local anaesthetics, coagulopathy, infection in the area), contraindications to non-steroidal anti-inflammatory drugs, and pregnancy. After providing written informed consent, participating patients were randomly allocated on the day of surgery to either the experimental group (extrafascial placement of the catheter tip) or the control group (intrafascial placement of the catheter tip) using a computer-generated randomization table. Assignments were concealed in sealed opaque envelopes.

Interscalene block procedure

Ultrasound-guided CISB was performed before surgery in a dedicated block procedure room either directly by or supervised by one of the authors (E.A.) who had no further involvement in the study protocol. Patients were positioned supine, with the head turned 45° to the non-operative side. ECG, pulse oximetry, and blood pressure monitors were applied, and supplemental nasal oxygen was provided. Peripheral i.v. access was established, and midazolam 1–4 mg i.v. was administered for anxiolysis and sedation as needed. The catheter insertion site was sterilized with a solution of chlorhexidine 2% in isopropyl alcohol 70%. In sterile conditions, a high-frequency linear array transducer (13–6 MHz, SonoSite S-Nerve; SonoSite, Inc., Bothell, WA, USA) was placed over the interscalene region to view the carotid artery and brachial plexus in the short-axis view. The C5, C6, and C7 roots were identified in accordance with the description by Martinoli and colleagues.[4] The brachial plexus sheath was recognized as the linear hyperechoic layer surrounding the roots of the brachial plexus. After infiltration of the skin with lidocaine 1% 1–3 ml, a 25-gauge 190 mm insulated catheter-over-needle device with 15° bevel needle (Contiplex®C; B. Braun Medical AG, Melsungen, Germany) was inserted in-plane with the US beam on the lateral side of the transducer. The catheter was then advanced under direct US guidance through the middle scalene muscle and towards the lateral border of the brachial plexus sheath. For the extrafascial group, the final catheter-over-needle tip position was immediately lateral to the brachial plexus sheath at a level equidistant between C5 and C6 roots, without puncturing the fascia (Fig. 1). For the intrafascial group, the final catheter-over-needle tip position was within the brachial plexus sheath in between the C5 and C6 nerve roots. After correct positioning of the catheter-over-needle device, the needle was withdrawn and ropivacaine 0.5% 20 ml was injected through the catheter in 5 ml increments with intermittent aspiration. No dose adjustments were made based on patient age. The catheter tip was not withdrawn, except if patients complained of paraesthesia during injection.

Assessment of sensory and motor block was performed by a blinded research assistant every 5 min for up to 30 min after injection. Sensory block was tested in the C5 and C6 dermatomes using a blunt tip needle pinprick test. Motor block was tested using arm abduction (C5) and forearm flexion (C6). A successful block was defined as complete sensory and motor block in the distribution of the C5 and C6 nerve roots within 30 min of injection. In case of block failure or spontaneous catheter dislodgment before initiation of the local anaesthetic infusion (see '*Postoperative procedure*', below), the catheter was repositioned within the plexus according to routine institutional practice. Data for these subjects were analysed on an intention-to-treat basis.

Intraoperative procedure

After application of routine monitors in the operating theatre, subjects received a standard general anaesthetic administered by an anaesthetist who was blinded to group allocation. Anaesthesia was induced using fentanyl 1–2 $\mu g\ kg^{-1}$ i.v. and propofol 2–4 mg kg^{-1} i.v., with tracheal intubation facilitated by rocuronium 0.6 mg kg^{-1} i.v. Maintenance of anaesthesia was with inhaled sevoflurane 1.6–2.4 vol % in a 40:60 mixture of

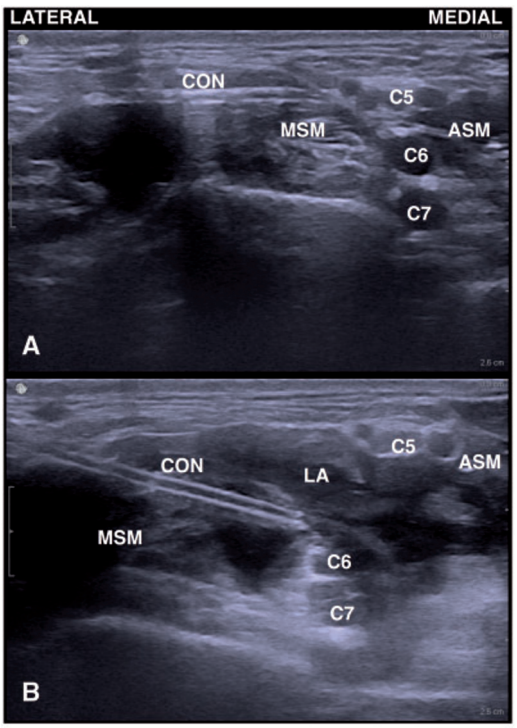

Fig 1 Continuous ultrasound-guided interscalene brachial plexus block with an extrafascial catheter tip position lateral to the brachial plexus before (A) and after (B) bolus injection of local anaesthetic (LA). ASM, anterior scalene muscle; C5, C5 root; C6, C6 root; C7, C7 root; CON, catheter-over-needle after needle withdrawal; MSM, middle scalene muscle.

oxygen and air. Positive pressure ventilation was initiated with tidal volume and rate adjusted to maintain an end-tidal partial pressure of CO_2 of 4.6 – 5.3 kPa. Fentanyl 25–50 μg i.v. was administered as needed to treat increases in blood pressure or heart rate of >15% above pre-induction baseline values. According to our routine institutional practice, all subjects received magnesium sulphate 50 mg kg^{-1} i.v.[5] and dexamethasone 0.15 mg kg^{-1} i.v.[6] for multimodal analgesia, with ondansetron 4 mg i.v. and droperidol 1 mg i.v. as antiemetic prophylaxis. Neuromuscular block was antagonized with neostigmine 50 μg kg^{-1} and glycopyrrolate 5–10 μg kg^{-1} at the end of surgery.

Postoperative procedure

In phase 1 recovery, pain [numerical rating scale (NRS) >3 or patient request for analgesia] was treated with morphine 1–2 mg every 10 min as needed. Once oral intake was initiated, patients received paracetamol 1000 mg p.o. every 6 h, ibuprofen 400 mg p.o. every 8 h, and oxycodone 5 mg p.o. every 3 h, as needed. The catheter was connected to an electronic pump and infused with ropivacaine 0.2% at a rate of 4 ml h^{-1} with patient-controlled boluses of 4 ml available every 30 min, upon arrival in phase 1 recovery after confirmation of block success. The acute pain service visited subjects twice daily. For NRS >3, the infusion was increased to 6 ml h^{-1} after injection of 10 ml of lidocaine 1% with epinephrine 1:200 000. In the event of biceps weakness, the infusion was decreased to 2 ml h^{-1}. In the event of an absence of sensory block despite injection of lidocaine 1% with epinephrine 1:200 000, the catheter was considered non-functional and removed. Antiemetic medications on the ward included ondansetron 4 mg i.v. and metoclopramide 10 mg i.v., administered on request. The catheter was withdrawn on the morning of POD 2.

Hemidiaphragmatic excursion and functional respiratory function assessment

To obtain a baseline value, hemidiaphragmatic excursion was assessed before the CISB procedure with a low-frequency curvilinear transducer (2–5 MHz; SonoSite S-Nerve; SonoSite, Inc.) using a subcostal approach as described by Gerscovich and colleagues.[7] Briefly, patients were examined in the supine position and the hemidiaphragm was identified as a hyperechoic line with breathing-related movements using the liver or spleen as an acoustic window. Hemidiaphragmatic excursion was measured by real-time M-mode ultrasonography from the resting expiratory position for deep and quiet inspiration.

Respiratory function was also assessed before the regional procedure with a bedside spirometer (EasyOne™ Spirometer; ndd Medical Technologies, Andover, MA, USA). After standard instructions, subjects in a sitting upright position were asked to inspire maximally and blow into the device as fast and strong as possible. The test was repeated three times and the best value recorded.

Outcomes

The primary outcome was the presence of hemidiaphragmatic paresis on POD 1, defined as a reduction in hemidiaphragmatic excursion of >75% compared with the pre-procedure value.[8 9] Secondary outcomes were functional respiratory- and pain-related outcomes. Functional respiratory-related outcomes were forced vital capacity, forced expiratory volume in 1 s, and peak expiratory flow. Pain-related outcomes were intraoperative fentanyl consumption; pain scores at rest (NRS 0–10) and on movement (NRS 0–10); cumulative postoperative opioid consumption (converted to equivalent doses of morphine i.v.);[10] and satisfaction with overall anaesthetic management (NRS 0–10). All subjects were hospitalized after surgery. The catheter was withdrawn on the morning of POD 2 at 07.00 h by the acute pain service according to routine practice. All primary and secondary outcomes were measured 2 h after the surgery in phase 1 recovery and once daily up to POD 2 at 11.00 h, except for pain scores, which were measured twice daily (at 11.00 and 18.00 h). In addition, postoperative supplemental oxygen requirements (for oxygen saturation <92% during routine nurse control) and duration of stay in hospital were recorded. Subjects were also contacted on POD 7 to capture any block-related complications, such as haematoma, infection, persistent paraesthesia, or weakness in the upper limb. Subjects, phase 1 recovery nurses, ward nurses, and the research assistant measuring or collecting data were blinded as to group allocation.

Sample size calculation

Based on previous reports in the literature, we expected the incidence of hemidiaphragmatic paresis on POD 1 hours with conventional intrafascial needle tip placement for CISB to be 71%.[11] Assuming that extrafascial catheter tip placement reduces the absolute incidence of ipsilateral hemidiaphragmatic paresis to 50%, corresponding to a relative reduction of 35%, we calculated

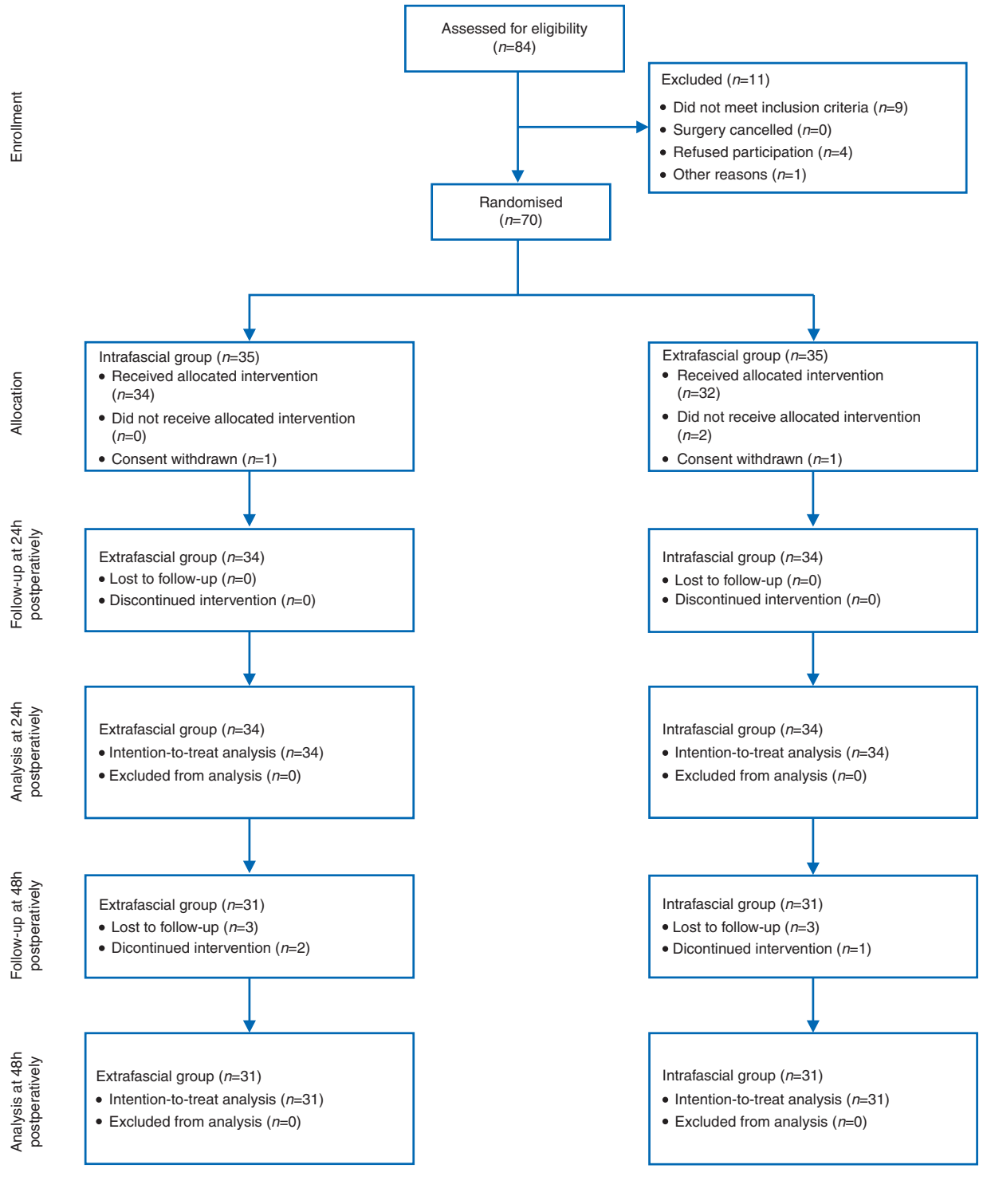

Fig 2 Study flow chart.

Table 1 Subject characteristics and clinical data presented as the mean (95% confidence interval) or the absolute number, as appropriate

Characteristic	Intrafascial group	Extrafascial group	P-value
Gender (male/female)	15/19	14/20	0.81
Age (yr)	63 (59–68)	63 (60–67)	1.00
Height (cm)	167 (164–171)	167 (163–170)	0.78
Weight (kg)	79 (74–84)	78 (73–83)	0.79
ASA physical status (I/II/III)	15/8/11	18/1/15	0.45
Pre-procedure respiratory data			
Diaphragmatic excursion (cm)	4.8 (4.3–5.4)	4.3 (3.9–4.8)	0.15
Forced vital capacity (litres)	3.2 (2.8–3.5)	3.1 (2.9–3.4)	0.77
Forced expiratory volume in 1 s (litres)	2.5 (2.2–2.8)	2.4 (2.2–2.7)	0.76
Peak expiratory flow (litres s^{-1})	5.8 (5.1–6.4)	5.9 (5.1–6.7)	0.79
Duration of surgery (min)	114 (105–124)	106 (97–115)	0.11
Surgical procedure			0.06
Shoulder arthroplasty	19	19	
Rotator cuff repair	11	15	
Other	4	0	

that 29 subjects would be required for each group (total 58) in order to detect this difference with an α error of 0.05 and a power of 80%. Allowing for a 20% drop-out rate, we planned to recruit a total of 70 subjects.

Statistical analysis

Categorical variables are presented as mean values with 95% confidence intervals (CI), computed using the Clopper–Pearson exact method. Continuous variables are summarized as mean values with 95% CI. Continuous Gaussian and non-Gaussian data were compared using Student's unpaired *t*-test or the Mann–Whitney *U*-test, respectively. Categorical and dichotomous data were compared using Fisher's exact test or the Pearson test, as appropriate. Data were analysed on an intention-to-treat basis. An additional per protocol analysis was also performed for the primary outcome. Significance was considered at $P<0.05$ based on a two-tailed probability. Statistical analysis was performed using the Stata Software (v.14.2; StataCorp, College Station, TX, USA).

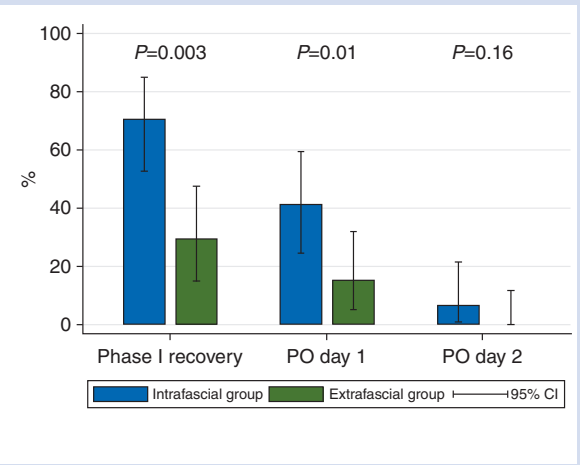

Fig 3 Hemidiaphragmatic paresis in phase 1 recovery, and on postoperative day (POD) 1 and 2. Data are expressed as a percentage with 95% confidence interval (CI).

Results

Seventy subjects were recruited and 68 completed the study for the primary outcome, because two subjects withdrew consent. At 30 min after local anaesthetic injection, all subjects in both groups had a successful block, except for one subject in the extrafascial group. According to routine institutional practice, the catheter was reinserted within the plexus in phase 1 recovery before initiation of the local anaesthetic infusion. Another subject in the extrafascial group had the catheter dislodged during transfer from the operating theatre to phase 1 recovery before initiation of the infusion; this subject also had the catheter re-sited within the plexus in phase 1 recovery. Both of these subjects received a second bolus of ropivacaine 0.5% 20 ml during their catheter replacement procedure, and data for both were analysed on an intention-to-treat basis. Spontaneous postoperative catheter dislodgment occurred in three subjects on POD 1 after study outcomes were measured and collected on that day (intrafascial group, $n=2$; extrafascial group, $n=1$). Catheters were not replaced, and data from these subjects were also analysed on an intention-to-treat basis at 48 h. All other catheters were functional. Finally, three subjects in each group were discharged early (on the afternoon of POD 1) after study outcomes were measured and collected on that day. Fifteen other subjects were discharged on POD 2. Figure 2 depicts the flow chart and Table 1 presents subject characteristics.

The incidence of subjects with hemidiaphragmatic paresis on POD 1 was significantly reduced in the extrafascial group [15% (95% CI 5–32%)] compared with the intrafascial group [41% [95% CI 25–59%); $P=0.01$; Fig. 3]. A per protocol analysis revealed that the incidence of subjects with hemidiaphramatic paresis on POD 1 was 13% (95% CI 4–29%) and 42% (95% CI: 26–59%) in the extra- and intrafascial groups ($P=0.008$), respectively. No subjects in either group required supplemental oxygen after phase 1 recovery.

All subjects except two in the intrafascial group recovered fully from diaphragmatic paresis 4 h after the infusion was

Table 2 Functional respiratory outcomes. Data are presented as the mean and 95% confidence interval

Parameter	Intrafascial group	Extrafascial group	P-value
Phase 1 recovery			
Forced vital capacity (litres)	2.1 (1.8–2.3)	2.2 (1.9–2.4)	0.44
Forced expiratory volume in 1 s (litres)	1.6 (1.4–1.8)	1.7 (1.5–1.9)	0.50
Peak expiratory flow (litres s^{-1})	3.8 (3.3–4.3)	4.1 (3.4–4.7)	0.51
Percentage reduction from baseline value			
Forced vital capacity (%)	36 (33–40)	31 (25–36)	0.09
Forced expiratory volume in 1 s (%)	35 (29–39)	29 (22–34)	0.16
Peak expiratory flow (%)	32 (25–39)	27 (18–37)	0.43
Postoperative day 1			
Forced vital capacity (litres)	2.3 (2.0–2.6)	2.5 (2.1–2.8)	0.53
Forced expiratory volume in 1 s (litres)	1.8 (1.6–2.1)	1.9 (1.7–2.2)	0.57
Peak expiratory flow (litres s^{-1})	4.8 (4.1–5.6)	4.7 (4.0–5.5)	0.84
Percentage reduction from baseline value			
Forced vital capacity (%)	29 (22–36)	23 (17–28)	0.15
Forced expiratory volume in 1 s (%)	29 (23–36)	22 (17–28)	0.12
Peak expiratory flow (%)	20 (12–29)	20 (12–27)	0.87
Postoperative day 2			
Forced vital capacity (litres)	2.6 (2.2–3.0)	2.8 (2.4–3.1)	0.44
Forced expiratory volume in 1 s (litres)	1.9 (1.6–2.3)	2.1 (1.8–2.4)	0.45
Peak expiratory flow (litres s^{-1})	4.8 (4.0–5.6)	5.0 (4.2–5.7)	0.73
Percentage reduction from baseline value			
Forced vital capacity (%)	25 (16–35)	18 (9–28)	0.29
Forced expiratory volume in 1 s (%)	27 (18–37)	19 (9–29)	0.23
Peak expiratory flow (%)	22 (11–33)	19 (7–31)	0.70

Table 3 Acute pain-related outcomes. Data are presented as the mean and 95% confidence interval. NRS, numerical rating scale

Outcome	Intrafascial group	Extrafascial group	P-value
Phase 1 recovery			
Pain scores in phase 1 recovery (NRS, 0–10)	1 (0–1)	0 (0–1)	0.73
I.V. morphine equivalent consumption (mg)	1 (0–2)	1 (0–1)	0.43
Postoperative day 1			
Pain scores at rest, morning (NRS, 0–10)	3 (2–3)	3 (2–4)	0.93
Pain scores on movement, morning (NRS, 0–10)	4 (3–5)	4 (3–5)	0.87
Pain scores at rest, afternoon (NRS, 0–10)	2 (2–3)	3 (2–4)	0.28
Pain scores on movement, afternoon (NRS, 0–10)	4 (3–5)	4 (3–5)	0.79
Cumulative i.v. morphine equivalent consumption (mg)	7 (5–9)	6 (3–9)	0.75
Postoperative day 2			
Pain scores at rest, morning (NRS, 0–10)	2 (1–3)	2 (1–3)	0.45
Pain scores on movement, morning (NRS, 0–10)	4 (3–4)	3 (2–4)	0.56
Pain scores at rest, afternoon (NRS, 0–10)	2 (1–2)	1 (1–2)	0.54
Pain scores on movement, afternoon (NRS, 0–10)	3 (2–4)	3 (2–3)	0.28
Cumulative i.v. morphine equivalent consumption (mg)	17 (12–23)	20 (11–29)	0.58
Satisfaction score (NRS, 0–10)	9 (9–10)	9 (9–10)	0.80

stopped on POD 2 [incidence of hemidiaphragmatic paresis in the intrafascial group, 6% (95% CI 1–21%); extrafascial group, 0% (95% CI 0–12%); $P=0.16$; Fig. 3]. We were unable to detect a difference in any of the functional respiratory outcomes on POD 0, 1, or 2, and reductions from baseline values were similar in both groups throughout the course of the study (Table 2).

No difference between groups was detected regarding mean intraoperative fentanyl consumption [intrafascial group, 147 μg (95% CI 128–166 μg); extrafascial group, 161 μg (95% CI 142–180 μg); $P=0.28$]. We were unable to demonstrate superiority of one approach on pain outcomes and satisfaction (Table 3). The duration of stay in hospital was 3.1 (95% CI 2.2–4.0) and 2.8 (95% CI 2.0–3.5) days in the intrafascial and extrafascial groups, respectively ($P=0.58$). No subjects developed haematoma, infection, persistent paraesthesia, or weakness in the upper limb up to 7 days after the procedure.

Discussion

This randomized, controlled, double-blind trial suggests that extrafascial catheter tip placement for US-guided CISB reduces the rate of hemidiaphragmatic paresis on POD 1, while providing

effective analgesia when compared with an intrafascial catheter tip placement. We were unable to detect any differences in other functional respiratory outcomes after surgery, which is not entirely surprising. Indeed, the contribution by the contralateral diaphragm and compensation by intercostal and abdominal muscles of breathing can mask the functional impact of hemidiaphragmatic paresis on the operative side.[12–14] The presence of a shoulder immobilization sling after surgery could also have restricted chest excursion in both groups.[14] Finally, bedside spirometry might not be a sensitive enough measure to evaluate the functional impact of hemidiaphragmatic paresis,[15] because unilateral diaphragmatic excursion reportedly accounts for only up to 30% of total minute ventilation at rest.[16]

This trial has several limitations. We did not formally assess the catheter tip location by US contemporaneously with the measurement of the primary outcome. In order to see the catheter tip on POD 1, we would have to remove the adhesive wound dressing, with the risk of inadvertently manipulating or even dislodging the catheter tip. Moreover, we do not commonly assess catheter tip position on POD 1 during routine clinical practice. We also recognize that patients may not be hospitalized after elective major shoulder surgery in many North American centres; nonetheless, we believe that our results are arguably generalizable to ambulatory surgery with home catheters. Finally, we did not measure either the daily volume of local anaesthetic infused or the number of patients requiring an increase in infusion rate. This could be included in a non-inferiority trial to assess properly and confirm the equivalence of analgesia between approaches.

In conclusion, placement of the catheter tip immediately outside of the brachial plexus sheath reduces the hemidiaphragmatic paresis associated with US-guided CISB on POD 1, while providing effective analgesia after major shoulder surgery. Our results do not support routine placement of the catheter tip within the brachial plexus sheath for CISB.

Authors' contributions

Study design: E.A., R.B.
Study registration: E.A.
Patient recruitment, data collection: A.J.-G.
Statistical analysis: E.A., N.F.
Data interpretation: E.A., R.B.
Manuscript preparation: E.A.
Manuscript editing: I.B., A.F., R.B.

Declaration of interest

E.A. has received grants from the Swiss Academy for Anaesthesia Research (SACAR), Lausanne, Switzerland to support his clinical research. E.A. has also received an honorarium from B. Braun Medical AG.

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