



The catheter-over-needle assembly offers greater stability and less leakage compared with the traditional counterpart in continuous interscalene nerve blocks: a randomized patient-blinded study

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To the Editor,

Continuous peripheral nerve blocks are susceptible to various complications, including leakage from the catheter insertion site which increases the risk of leakage of the bolus of injectate. This has the potential to disrupt the adhesive dressing and may further compromise the sterility of the surgical field if leakage occurs during the operation. Continuous interscalene brachial plexus blocks are commonly administered for pain control following shoulder and upper arm surgery. A prior study of complications of continuous interscalene analgesia showed a 9.3% incidence of leakage at the catheter site.¹ We conducted a prospective randomized study to test the hypothesis that interscalene catheter-over-needle (CON) assemblies are clinically less prone to leakage at the insertion site compared with conventional catheter-through-needle (CTN) counterparts. The primary outcome of the study was leakage from the catheter insertion site. Secondary outcomes were block performance time (the time from the initial skin puncture to first application of Tegaderm™ dressing) and pain scores in recovery and at 24 and 48 hr post-surgery. An 11-point visual analogue scale in which 0 indicated “no pain” and 10 indicated “worst pain imaginable” was used to record pain scores.

The study was conducted from May 2012 to September 2012 at the University of Alberta Hospital. Following approval from the University of Alberta Health Research

Ethics Board (January 2012) and informed written consent, adult patients admitted for shoulder surgery or surgery of the proximal humerus were randomly assigned using sealed envelopes to the CON (catheter-over-needle: study) or CTN (catheter-through-needle: control) group. Patients were blinded to the allocation, as was a member of the research team who collected follow-up data.

Ultrasound-guided interscalene brachial plexus blocks using the CTN and CON methods were performed as previously described.² All blocks were performed by staff regional anesthesiologists or by supervised regional anesthesia trainees. After insertion of the catheter, general anesthetic was administered to patients in both groups. A nerve block catheter remained in each of the patients in both groups throughout the operation and in the postoperative period with local anesthetic infusion with bolus dose for two to three days.

Ten patients, six in the CON group and four in the CTN group, were approached and consented to participate in the trial. After the fourth CTN patient, the study was terminated at the request of our surgical colleagues (see below). None (0/6) of the CON patients experienced leakage around the catheter, and none required catheter manipulation or fortification during the perioperative period (Table). Based on the “rule of three”,³ the 95% confidence interval for the occurrence of leakage in CON patients was 0 to 0.5. In contrast, all CTN patients (4/4) experienced leakage around the perineural catheter during the perioperative period. One CTN catheter migrated out on postoperative day one, and two CTN catheters required fortification with gauze to address leakage. One CTN catheter was removed just before surgery due to excessive leakage; this case has been described previously.² Following this case, the study had to be terminated earlier than anticipated at the surgeon’s request due to

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Table Summary of patient demographics and study data

Study #	Sex	Age (yr)	BMI	Allocation group	Surgery‡	Block performance time (sec)	Leakage at catheter site?	Pain†			
								Preop	PARR	24 hr post-surgery	48 hr post-surgery
1	M	69	49.3	CON	TSA	628	N	9	0	1	0
2	M	74	29.1	CTN	TSA	532	Y	N/A	8	0	0
3	F	76	39.9	CON	TSA	570	N	8	0	7	7
4	F	69	32.9	CON	TSA	550	N	1	0	0	1
5	M	54	24.0	CON	TSA	465	N	2	5	4	1
6	M	79	38.3	CON	TSA	750	N	0	0	0	1
7	M	74	33.3	CTN	TSA	520	Y	2	0	2	0
8	F	61	44.7	CTN	TSA	660	Y	0	0	6	3
9	F	38	20.2	CON	ORIF proximal humerus	390	N	7	9	2	1
10*	M	62	31.0	CTN	TSA	781	Y	N/A	N/A	N/A	N/A

† Pain was measured on a 0-10 visual analogue scale (0 = no pain; 10 = worst pain imaginable)

BMI = body mass index; CTN = catheter-through-needle; CON = catheter-over-needle; ‡TSA = total shoulder arthroplasty; ORIF = open reduction/internal fixation; PARR = postanesthesia recovery room

* Patient 10's CTN catheter was removed in the operating room before surgery and was replaced with a CON catheter after surgery

the risk of surgical site contamination posed by the CTN catheters. Other data, including block performance time and pain scores, are provided in the [Table](#).

Continuous peripheral nerve blocks are performed routinely with CTN catheters, and it is acknowledged in the literature that leakage at the catheter insertion site is a common complication with continuous interscalene blocks.^{1,4} The results of our randomized study suggest that interscalene CON catheters are clinically less prone to leakage compared with traditional CTN catheters. This is especially apparent given that all patients who received a CTN catheter experienced leakage compared with none of the patients who received a CON catheter. Indeed, our prior experience with CON catheter assemblies shows their stability and effectiveness at mitigating the problems of leakage and dislodgement.⁵

Unfortunately, the problem of leakage led to a premature termination of the study, leaving us with a relatively small sample size. Although this renders us unable to perform an adequate statistical analysis comparing the two catheterization methods, it is perhaps more significant that, in light of the observable superiority of the CON assembly in preventing leakage, our institution's orthopedic surgeons have requested that all future continuous interscalene blocks be performed with CON catheters. In the months following this study, we have been using the CON assembly exclusively for continuous interscalene blocks with great success. We are currently undertaking further randomized controlled studies to show the superiority of the CON method in administering other peripheral nerve blocks.

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Conflict of interest/other associations The Pajunk MultiSet 211156-40E is modified and re-designed by Ban Tsui. Dr. Tsui also has a patent-licensing agreement with Pajunk.

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