## Anesthesia & Pain Research

## iPACK Block and Adductor Canal Catheter vs Adductor Canal Catheter for Total Knee Arthroplasty: A Randomized Controlled Trial

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Received: 02 Jun 2024; Accepted: 01 Jul 2024; Published: 08 Jul 2024

**Citation:** Pamela A. Chia, Eva K. Boyd, Natale Naim, et al. iPACK Block and Adductor Canal Catheter vs Adductor Canal Catheter for Total Knee Arthroplasty: A Randomized Controlled Trial. Anesth Pain Res. 2024; 8(3): 1-5.

#### ABSTRACT

**Background:** Regional anesthetic techniques including the adductor canal catheter (ACC) have aided management of post-operative pain for total knee arthroplasty (TKA). The interspace between the popliteal artery and posterior capsule of the knee (iPACK), has been introduced to address posterior knee pain that is not well covered by the ACC. Studies have looked at the addition of the iPACK block to subjects who received an ACC with and without periarticular local infiltration with varying results. We hypothesized that adding the iPACK block to subjects who also received an ACC and periarticular injection (PAI) would significantly decrease opioid consumption compared to the ACC alone in TKA.

**Methods:** Sixty subjects were randomized to receive an ACC alone (control group) or ACC plus single shot iPACK block (iPACK group) for TKA. All subjects were operated on by the same surgeon and received the same PAI. For the primary outcome of postoperative pain, we used opioid consumption as measured by morphine milligram equivalent (MME). Secondary outcomes included pain scores determined by the visual analog scale (VAS), distance ambulated, time to physical therapy (PT) and length of hospital stay.

**Results:** We did not observe a significant difference between groups for opioid consumption, pain scores, distance ambulated (p > 0.05 across all time points), length of hospital stay (p = 0.64), or time to PT (p = 0.32).

*Conclusion:* When combined with an ACC and PAI, the iPACK block did not significantly decrease opioid consumption, pain scores, time to first PT session or increase distance ambulated.

#### Keywords

Arthroplasty, Replacement, Knee, Nerve Block, Analgesics, Opioid, Pain, Postoperative, Injections, Peri-Articular, Popliteal Artery.

#### Introduction

The use of multimodal analgesia has become an increasingly important approach to pain management in response to the overreliance on opioids that has led to the current crisis. Strategies to minimize opioid requirements are especially important in the perioperative period when opioids are often prescribed for pain control. Total knee arthroplasty (TKA) is a surgical procedure that can be associated with significant postoperative pain. An important component of recovery is early participation in physical therapy (PT) to improve range of motion. Poor pain control delays early mobility and rehabilitation, leading to a longer length of stay [1]. Systemic opioids are well known for their adverse effects, including constipation, pruritis, nausea, dependence, and somnolence, which can also contribute to delays in physical therapy.

Regional anesthetic techniques have helped manage post-operative pain as well as minimize narcotic use. The application of femoral and sciatic nerve blocks has been shown to decrease opioid use; however, both of these blocks are associated with significant muscle weakness that delays early mobility and increases the risk of falls [2]. Adductor canal blocks (ACB) have gained favor for providing superior analgesia over opioids alone while avoiding quadriceps muscle weakness [3]. Similarly, blocks to the interspace between the popliteal artery and posterior capsule of the knee (iPACK) have recently been introduced to help address pain in the posterior aspect of the knee that is not well covered by the ACB alone, without the concomitant muscle weakness that occurs with a sciatic nerve block [4].

Studies have shown that subjects who received an ACB with iPACK block for total knee replacements have decreased pain scores and improved rehabilitation ability compared to ACB alone [5]. To date, there are only a few randomized control trials that have looked at the addition of the iPACK block to subjects who received an adductor canal catheter (ACC) [6,7]. One study also included the addition of a periarticular injection (PAI), but used levo-bupivacaine for the iPACK block [8]. We hypothesized that adding the iPACK block to subjects who also received an ACC and PAI would significantly decrease opioid consumption as measured by morphine milligram equivalents (MME). We also hypothesized that the iPACK block would decrease pain score as measured by the visual analog scale (VAS), time to ambulation and PT, and hospital length of stay.

### Methods

#### Subjects

We obtained Institutional Review Board approval (IRB#18-001490) prior to initiation of this study, and the study was registered at ClinicalTrials.gov (Identifier: NCT03774966) on December 4, 2018. Patients scheduled to undergo elective primary unilateral total knee replacement by a specific surgeon at our institution were approached to participate in the study. Subjects were screened preoperatively and excluded from enrollment if they were taking any opioids within one month of surgery. All subjects were interviewed and consented by a member of Regional Anesthesia and Acute Pain Service in the preoperative unit.

Sixty subjects were enrolled in the study from February 12, 2019 to May 28, 2019, and randomized to receive an ACC alone (control group) or ACC plus single shot iPACK block (iPACK group). Subjects were randomized in a 1:1, two-arm, parallel assignment, using a permuted block design with a block size

of four. The randomization list was generated using R V 3.6.1 (www.r-project.org Vienna, AU) using the 'blockrand' package [9]. The assignments to either the control or iPACK group were enclosed in sequentially numbered, opaque, sealed envelopes. The regional anesthesiologist was not blinded to study, but the surgeon and assessor of outcomes were blinded. There were no important changes to methods after trial commencement.

All regional techniques were performed in the preoperative unit by an anesthesia resident or a regional anesthesia fellow under direct supervision by a regional anesthesiologist. Prior to the subjects receiving regional anesthesia, standard American Society of Anesthesiologists (ASA) monitors were applied, and they received fentanyl and/or midazolam as needed. ACC placement and iPACK single shot were performed under ultrasound guidance with direct visualization of the needle.

The blocks were performed using a linear ultrasound probe that was used to identify the sartorius muscle, femoral artery, and adductor canal. A 17G Tuohy needle was inserted via an in-plane technique in a lateral to medial direction with the final needle tip positioned beneath the sartorius muscle and lateral to the femoral artery in the adductor canal space. Fifteen milliliters of 0.25% ropivacaine was injected through the Tuohy needle and, after expanding the adductor canal space, a 19G StimuCath continuous nerve block catheter (Arrow International, PA) was inserted. The catheter was placed approximately 4 to 5 cm in the canal. A test dose of 5 mL of lidocaine 1.5% with epinephrine (1:200,000) was injected to confirm the correct location of the catheter under direct visualization. The adductor canal catheter was secured using 2-octyl cyanoacrylate, liquid adhesive, thin adhesive bandages, and transparent film dressings. Upon arrival to the post-anesthesia care unit (PACU), an infusion of 0.2% ropivacaine at 6 ml/hr was initiated through the catheter (ON-Q Pump with Select-A-Flow Variable Rate Controller, Avanos, USA). The ACCs were typically removed on post-operative day (POD) 3 approximately 72 hours after the infusion was started.

The iPACK single shot injection was performed using a 21G 4-inch Stimuplex insulated needle under direct visualization. The patient placed in supine position with the knee bent and a high frequency linear probe was placed in the popliteal fossa. After the medial and lateral condyles of distal femur and popliteal artery were identified, the needle was then inserted in-plane using a lateral to medial trajectory in the space between the popliteal artery and the shaft of the femur where 15 ml of 0.25% ropivacaine was injected.

#### **Perioperative Course**

Both groups followed a total joint protocol for knee arthroplasty. Preoperatively, subjects received acetaminophen (1000 mg), celecoxib (400 mg), a gabapentinoid, and tramadol (50 mg) orally. Subjects who were less than 70 years of age received a scopolamine patch for post-operative nausea and vomiting (PONV).

Intraoperatively, subjects received neuraxial anesthesia as the main anesthetic technique unless contraindicated. Per study

protocol, subjects received ondansetron (4 mg), famotidine (20 mg), and dexamethasone (0.1mg/kg) intravenously (IV) for PONV intraoperatively. Subjects were also allowed to receive additional doses of midazolam, fentanyl or both prior to spinal placement. All subjects were operated on by the same surgeon and received the same PAI of ketorolac (15 mg), morphine (10 mg), ropivacaine (150 mg) and epinephrine (300 mcg).

Post-operatively, subjects were seen in person by the Regional Anesthesia and Acute Pain Service until discharge from hospital and received phone calls until the ACC was removed on POD 3. Subjects received a multimodal analgesic regimen including three doses of ketorolac, unless contraindicated due to renal insufficiency or allergy, celecoxib (200 mg once daily) and acetaminophen (650 mg every 6 hours) while in the hospital. Hydromorphone, oxycodone, and tramadol were available for subjects as needed. Physicians who were part of the treatment team were able to modify orders if clinically indicated.

#### **Outcome Measurements**

For the primary outcome of postoperative pain of opioid consumption, we converted the total opioids consumed into morphine milligram equivalents. For secondary outcomes, we assessed pain scores as determined by the visual analog scale (VAS), distance ambulated, time to PT and length of hospital stay [10]. There were no changes to trial outcomes after the trial commenced.

#### **Statistical Analysis**

Patient characteristics and study outcomes were summarized between groups using frequency (%) or mean  $\pm$  SD. Patient demographics were compared between groups using a *t*-test (age, BMI) and chi-square test (gender, ASA score). Our outcomes of

interest (MME, VAS, distance ambulated, time to PT, length of hospital stay) were compared between groups at specific time points (e.g. intraop, POD 0, POD 1, etc.) using t-tests. Statistical analyses were performed using SPSS V25 (IBM Corp. Armonk, NY) and SAS V9.4 (SAS Institute, Cary, NC). P-values < 0.05 were considered statistically significant. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of California, Los Angeles [11,12]. After reviewing the relevant literature on the iPACK procedure for TKAs, we found effect sizes ranging from 0.84 to 2.29 between groups for outcomes such as pain scores, range of motion, distance walked, and length of stay [5,13,14]. Therefore, for our study we decided that to reliably detect effect sizes of 0.84 or larger, a minimal sample size of 25 patients per group would be required to provide adequate power (>80%, two-sided alpha = 0.05, two-sample t-test) stay [5,13,14].

#### Results

Sixty subjects were enrolled into this study from February 12, 2019 to May 28, 2019 and randomly assigned to either the control (ACB + ACC) or iPACK (ACB + ACC + iPACK) group (Figure 1). Enrollment ended once 30 subjects were assigned to each group, to ensure there would be adequate power for analysis. Four subjects were excluded including one subject due to postoperative cardiac ischemia, one subject due to catheter misplacement, and two subjects for receiving a local anesthetic that deviated from the study protocol. Thus, 56 subjects were included in the data analysis. The demographics between the two groups were well-matched, and there were no statistically significant differences in age, gender, BMI and American Society of Anesthesiologists (ASA) class (Table 1). Additionally, preoperative and intraoperative medications and intraoperative anesthetic management were similar between groups.

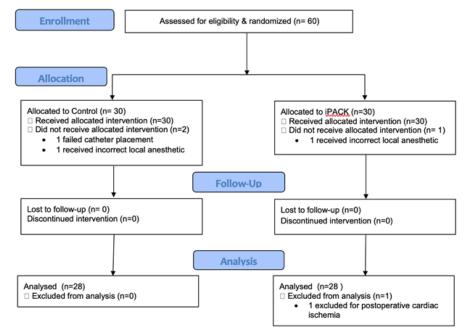


Figure 1: CONSORT diagram. Sixty subjects were enrolled into this study and randomly assigned to the control or iPACK group. Four subjects were excluded from the final data analysis including one patient due to misplacement of the catheter, two subjects for receiving local anesthetic that deviated from the study protocol, and one subject for postoperative cardiac ischemia.

Demographics		Control (n=28)	iPACK (n=28)	<i>p</i> -value
Age (y)		$67.1 \pm 9.7$	$66.9 \pm 7.9$	0.94
BMI (kg/m <sup>2</sup> )		$29.8\pm6.0$	$31.7 \pm 5.4$	0.21
Gender	Male	10 (35.7%)	10 (35.7%)	1.00
	Female	18 (64.3%)	18 (64.3%)	
ASA Score	2	15 (53.6%)	15 (53.6%)	1.00
	3	13 (46.4%)	13 (46.4%)	

**Table 1:** Demographics table. Groups were well matched for age, BMI, gender and American Society of Anesthesiologists (ASA) class. Values for age and BMI are reported as mean  $\pm$  SD, and for gender and ASA class as mean (percent). BMI: body mass index.

**Primary outcomes: Post-operative pain as measured by MME** We observed no significant difference in MME between the iPACK group and the control group (p > 0.05 across all time points, Table 2).

# Secondary outcomes: Pain scores determined by the VAS during hospital stay, distance ambulated, time to PT, length of hospital stay

There were no significant between-group differences observed in pain scores, distance ambulated, time to PT or length of hospital stay (p > 0.05 across all time points, Table 2).

Outcome	Time	Control	iPACK	<i>p</i> -value
	Intraop	$5.20 \pm 17.06$	$4.82 \pm 14.89$	0.93
	PACU	$5.21 \pm 12.90$	$4.66 \pm 12.13$	0.87
	POD 0	$18.63 \pm 28.58$	$14.75 \pm 17.18$	0.54
MME (mg)	POD 1	$23.66 \pm 26.06$	$20.80 \pm 21.33$	0.66
	POD 2	$23.64 \pm 18.59$	$28.18 \pm 31.55$	0.68
	POD 3	$5.00 \pm 7.07$	-	-
	Total	$62.34 \pm 65.47$	$56.11 \pm 53.05$	0.70
	POD 0	$1.39 \pm 1.36$	$1.34 \pm 1.28$	0.90
VAS	POD 1	$2.08 \pm 1.69$	$2.00 \pm 1.54$	0.86
	POD 2	$2.34 \pm 2.07$	$3.35 \pm 2.01$	0.26
	POD 3	$2.15 \pm 3.04$	-	-
	POD0	$40.36 \pm 37.37$	$64.79 \pm 56.97$	0.06
	POD1	$370.61 \pm 347.85$	$276.96 \pm 144.66$	0.19
Distance Walked (ft)	POD2	$360.45 \pm 333.13$	$154.55 \pm 143.53$	0.07
	POD3	$275.00 \pm 318.20$	-	-
	Total	572.21 ± 574.15	$402.46 \pm 232.50$	0.15
Average length of	Total	1.46 ± 0.64	$1.39 \pm 0.50$	0.64
stay (d) Time to PT (min)	Total	493.0 ± 272.7	420.9 ± 266.7	0.32

**Table 2:** Primary and secondary outcomes for all time points. There was no significant difference between groups for MME, VAS, distance walked or length of stay. Values are reported as mean  $\pm$  SD. MME, morphine milligram equivalent; VAS, visual analog scale; PT, physical therapy.

#### Discussion

We found in our randomized controlled study that the iPACK block did not significantly decrease opioid consumption, pain scores, time to first PT session, length of hospital stay or increase distance ambulated at our institution. Recently published randomized controlled trials found improvement in pain scores 6 hours after surgery and in PACU, respectively, but also did not find the addition of the iPACK block to decrease opioid consumption or length of hospital stay [6,7]. It is unclear why our study did not show similar short term benefit from the iPACK block, but published results have been mixed regarding its effectiveness [5,6,7,13,15,16].

Subjects in both groups of our study also received a PAI by the surgeon intraoperatively. The PAI by the surgeon and the ACC are part of the multimodal analgesic regimen of the joint protocol at our institution. This study assessed the effectiveness of the addition of an iPACK block to a multimodal postoperative pain management pathway for total knee replacements. One study which also looked at the efficacy of the iPACK block added to local infiltration saw improvement in range of motion during early recovery, but noted the study was not powered for that outcome [8]. A recent metaanalysis concluded the addition of the iPACK block to an ACB for a TKA did not improve analgesic or functional outcomes [17]. It is possible that the periarticular injection provided a similar benefit to the iPACK block, masking our ability to see either short or long term benefit. We anticipated the ultrasound-guided iPACK block would have provided more clinical or functional improvement due to the consistent manner in which the block was performed.

Initial studies published on the iPACK block suggested a more significant impact on decreasing opioid consumption, improvement in physical therapy and decrease length of hospital stay [5,13]; While more recently published results [6,7] from randomized control trials have not found the iPACK to have a significant clinical impact, a block that provides selective analgesia could still be indicated as a rescue block for posterior knee pain or as an alternative to a surgical periarticular injection [4,6,7].

One limitation to this study included the lack of a sham procedure. During design of this research study and under the guidance of the Institutional Review Board, it was decided that a sham procedure would not be performed. Blinding of participants is important to minimize bias and the potential for influencing results. Without a sham procedure we could not blind the participants and the authors acknowledge this could introduce the risk of bias in this study. Another limitation was that this was a single-center study which utilized a multimodal analgesic approach that was unique to the institution.

Overall, the iPACK block has not consistently been shown to improve patient outcomes in subjects who received an ACC for total knee replacement surgeries. It is important to highlight these patients also received a multimodal regimen perioperatively and participated in a total joint protocol that facilitated early physical therapy which is also a key component in recovery [1,3]. Regional techniques such as the ACC have been well documented to be very effective, and it is essential to continue to investigate novel regional techniques such as the iPACK block that can complement its benefit. Based on this small study, the iPACK block does not appear to have a benefit for total knee arthroplasty. Future studies should look at the addition of adjuvants that may prolong the duration the block or its effectiveness as a rescue block for posterior knee pain.

#### Conclusions

When combined with an ACC and PAI, the iPACK block did not significantly decrease opioid consumption, pain scores, time to first PT session, length of hospital stay or increase distance ambulated in total knee arthroplasty patients. However, other randomized control trials demonstrated short term improvement in pain scores suggesting that more studies may reveal improved clinical and functional benefit and may be useful as a rescue block to target the posterior aspect of the knee postoperatively.

#### **Author Contributions**

PC, SM and NN conceived and designed the study. EZ performed the surgeries. PC, EB, NN, DB, KW, PJ, AL and SM collected the data. PC, TG, and LL analyzed and interpreted the results. PC, SM, EB, and KW wrote the manuscript. PC, SM and EB supervised the study.

#### **Data Availability**

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

#### **Disclosures**

Dr. Naim is a current consultant and Dr. Boyd has been a past consultant for Avanos Medical. Avanos Medical provided no financial support for this study. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

#### Acknowledgments

The authors would like to acknowledge Michael Workman and Andrew Hudson for critical reading and editing of the manuscript.

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