Randomized Controlled Trial of Needleless Jet Injected (J-Tip) Lidocaine in Children Undergoing Regional Anesthesia Prior to Knee Arthroscopy

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DATE:	August 28, 2019
TO:	Daryl Osbahr, MD
FROM:	Orlando Health IRB #2
PROJECT TITLE:	[747969-9] Randomized, Controlled Trial of Needleless Jet Injected (J-Tip) Lidocaine in Children Undergoing Regional Anesthesia prior to knee arthroscopy.
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Thank you for your submission of Closure/Final Report materials for this project. The submission was reviewed and approved by the Orlando Health IRB #2.

Study records must be maintained in a secure location. For the length of time the records must be stored, follow any applicable regulations/policies from Orlando Health, the state of Florida, and the federal government, as well as any requirements the study sponsor might have.

If you have any questions, please contact the IRB Office at (321) 841-5895. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Orlando Health IRB #2's records.

Randomized, Controlled Trial of Needleless Jet Injected (J-Tip) Lidocaine in Children Undergoing Regional Anesthesia prior to knee arthroscopy.

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List of Abbreviations:

VAS=Visual Analog Scale
FNB=Femoral Nerve Block
SNB=Sciatic Nerve Block

1. Research Synopsis

Purpose of this study is to investigate the pain outcomes and satisfaction of pain relief for pediatric patients receiving needleless jet-injected (J-Tip) lidocaine prior to regional anesthesia with femoral and/or sciatic nerve block and general anesthesia for arthroscopic knee surgery compared to femoral nerve block and/or sciatic nerve block with needle injected lidocaine prior to regional and general anesthesia.

1.1 Study Title

Randomized Prospective Trial of Needleless Jet Injected (J-Tip) Lidocaine in Children Undergoing Regional Block Anesthesia prior to knee arthroscopy.

1.2 Study Population

Children of both sexes, between the ages of 11 and 17 undergoing arthroscopic knee surgery will be eligible for this study.

1.3 Study Design

This study is a prospective and randomized project.

1.4 Sample Size

A sample size of 50 per group, two groups, for a total of 100 patients is the goal. An additional 15 patients will be enrolled to account for withdrawals, bringing total enrolled to 115.

1.5 Study Duration

This study is estimated to take 3 years to complete, including the length of time to review charts, data collection, and analysis of study data.

1.6 Primary Objective

The primary objective is to measure the change in pain from a femoral or sciatic nerve block with the use of J-tip injected lidocaine compared to needle injected lidocaine for local anesthesia prior to the regional nerve block.

1.7 Secondary Objectives

- To evaluate the difference in pain from local anesthetic infiltration with J-tip needleless injection compared to needle injection.
- To evaluate efficacy of femoral and/or sciatic nerve block after J-tip lidocaine injection compared to needle injected lidocaine post operatively by tracking pain levels to post operative day three.
- To assess patient and parent satisfaction with J-tip use.
- To assess changes in post operative pain medication amounts with J-tip use.
- To evaluate changes in post operative nausea and/or vomiting with J-tip use.
- To evaluate changes in post operative anti-nausea/anti-emetic mediation use with J-tip use.
- To evaluate changes in time of PACU stay.

- To assess any differences in outcomes or pain after J-tip or needle injected lidocaine with respect to BMI, thigh circumference, gender, ethnicity or operative time in pain reporting measures, satisfaction or medication usage.

2. Background and Significance:

Lower extremity regional nerve block anesthesia has been shown to decrease post-operative pain and length of hospital stay after arthroscopic knee surgery (Nowicki, Micalizzi, Schloss). The introduction of the nerve block needle is still a source of pain and anxiety for the pediatric patient. The pain experienced during the nerve block procedure may cause difficulty in technique allowing for the most efficient nerve blockade. Infiltration of the subcutaneous tissues with local anesthetic is usually performed prior to nerve block needle introduction. This is performed by standard techniques with needle and syringe and is associated with the pain usually experienced with one or more needle sticks required to fully deposit the local anesthetic. It has also been suggested that post block complications are higher in pediatric patients receiving nerve blocks while awake or sedated compared to patients already under general anesthesia (Taenzer). For this and other reasons, many of these blocks are performed with the patient already in the operating room under a general anesthetic. This can increase operating room time and expense for each surgical case

Patients have benefited from the increasing use of lower extremity regional block anesthesia for arthroscopic knee surgeries. This benefit has been realized by patients with regard to decreased pain post operatively. The health care system and patients share the benefit of decreased length of hospital stay and significantly fewer patients admitted to inpatient status. Current practices with anesthesia for pediatric patients undergoing knee surgery is variable. General anesthesia is the norm during arthroscopic knee surgery, but the introduction and timing of regional blocks is physician and institution dependent. In some cases femoral and sciatic blocks are used and in others only femoral blocks are used. Some are introduced prior to leaving the preoperative area, after general anesthesia has been administered, while still under general anesthesia after the procedure is complete, or in the post anesthesia care unit with the general anesthetic effects diminishing. Most blocks at Arnold Palmer medical center are administered in the preoperative area prior to patient transfer to the operating room.

The J-tip has not been reported for use prior to regional block anesthesia prior to femoral or sciatic nerve blocks. The use of the J-tip for lidocaine introduction prior to femoral or sciatic blocks at Arnold Palmer Medical Center has been up to the discretion of the anesthesiologist. It has been anecdotally reported at our institution to have equal or better pain relief for the regional nerve blocks as needle introduction of lidocaine.

While there has been much attention appropriately directed to post operative pain control after arthroscopic surgery, minimal concern has been shown to decrease pain from regional block needle introduction. Needle insertion is the most common pain provoking procedure in the hospital setting. The American Academy of Pediatrics has addressed acute pain states with a policy statement expressing the need to anticipate, assess and manage pain caused by medical procedures. (AAP) There have been many advancements

to minimize the pain due to needle introduction for procedures such as venipuncture, intravenous cannulation and lumbar puncture (Ferayorni). It has been shown that anesthetic introduction by eutetic mixture of local anesthetics (EMLA) cream or needleless jet injection of local anesthetic reduces reported and observed pain and anxiety score validated measures when used prior to these procedures. There has been a demonstrated advantage in time to anesthesia and pain relief with needleless jet injection of lidocaine compared to EMLA cream use prior to venipuncture (Jimenez, Spanos, Zsigmond IJCPT 99). A decrease in pain has also been shown with jet-injected lidocaine over jet-injected placebo prior to needle insertions (Auerbach, Peter, Zsigmond *JCA* 99).

Limiting the use of pain medications and thus their potential side effects is becoming a greater point of emphasis in medicine. The use of opiate based medication to control acute pain from orthopaedic surgery is common. Utilization of these medications comes with possible pitfalls ranging from physiologic side effects to addiction. The most common side effects are manifested as nausea and vomiting. Control of these side effects often requires the administration of another pharmacologic agent. Within the field of orthopaedics, the use of regional block anesthesia prior to arthroscopic knee surgery has shown to decrease post-operative pain. This has lead to decreased opioid requirements. In turn this could provide for fewer medication-related side effects (Schloss). Local anesthesia prior to regional blockade may allow for a more effective block and permit the use of fewer pain medications and occurrence of side effects for those medications.

3. Objectives:

3.1 Primary Objective

The primary objective is to measure the change in pain from femoral and/or sciatic nerve block with the use of the J-tip injector by visual analogue scales (VAS) for pain reporting.

3.2 Secondary Objectives

- To evaluate the difference in pain from local anesthetic infiltration with J-tip needleless injection compared to needle injection by use of VAS.
- To evaluate efficacy of femoral nerve block after J-tip lidocaine injection post operatively by use of VAS.
- To assess patient and parent satisfaction with J-tip use by satisfaction questionnaire.
- To assess changes in post operative pain medication amounts with J-tip use.
    - 1)Type and amount in PACU
    - 2) Home log of amount taken daily for post operative days one through three (Standard opiate based pain medication prescription given to each patient). Measured in number of pills/tablets taken each day.
- To evaluate changes in post operative nausea and/or vomiting with J-tip use.
    - Calculated as “Present” or “Absent”
- To evaluate changes in post operative anti-nausea/anti-emetic mediation use with J-tip use.
    - 1)Type and amount in PACU

- 2) Home record log of amount taken daily (Standard medication prescription given to each patient). Measured in number of pills/tablets taken each day.

- To evaluate time in PACU with use of J-tip compared to needle use group prior to regional block. PACU stay time recorded in minutes.

4. Study design/methodology:

This study will be submitted to the Institutional Review Board of Orlando Health in Orlando, Florida, and will be conducted at Arnold Palmer Hospital from June 2015 to September 2017. Patients' age 11-17 years old undergoing knee arthroscopies are eligible for the trial. A single surgeon will perform all arthroscopic knee surgeries in this study. A femoral and/or sciatic block will be performed prior to the knee arthroscopic surgery. A single anesthesiologist will perform all J-tip or needle local anesthesia injections and nerve blocks in this study. Written consent is to be obtained from the parents or legal guardians, and written assent is to be obtained from the patients. The J-tip injector by National Medical Products, INC. will be used for needleless injection of 0.25 mL of 1% plain lidocaine or 1.5 mL of 1% plain lidocaine will be injected by syringe and 25-gauge needle into the subcutaneous tissues of the proximal anterior thigh near the inguinal crease prior to the femoral nerve block and the proximal posterolateral thigh near the gluteal fold or the posterolateral thigh prior to the sciatic regional nerve block. The location for the sciatic regional block along the course of the nerve will be chosen at the discretion of the performing anesthesiologist as is customary for sciatic nerve block procedures.

Patients with a known allergy to lidocaine, preoperative analgesic treatment with medications other than nonsteroidal anti-inflammatory drugs and acetaminophen, current use of chemotherapeutic agents, coagulation disturbance affecting coagulation abilities, any signs of skin infection or pathology at the injection site, neurosensory deficit at area of injection, developmental delay diagnosis precluding pain scale completion, and patients who received any other local anesthesia in the area of the regional block needle introduction prior to the regional block procedures will meet the exclusion criteria for this trial.

The J-tip will not be used for any IV insertions on patients in this study. There is currently variable use of the J-tip prior to IV insertions currently at Arnold Palmer Medical Center.

Demographics and anthropometric measurements considered in this study will be age, gender, ethnicity, thigh circumference and body mass index (BMI). Thigh circumference on the surgical side will be measured as 1/3 the distance distal to the ASIS to the superior pole of the ipsilateral patella.

Randomization to form the two trial groups will be performed by utilizing the computer program 'Research Randomizer' to create the randomization list. Randomization will be 50/50 or 1 to1. The assignments will be printed out and placed into numbered envelopes.

The envelopes will be kept in a box in the Dr. Zelaya's office. Group 1 will receive 0.25 mL of 1% buffered lidocaine delivered by the J-tip injector. Group 2 will be formed by subjects receiving 1.5 mL of 1% plain lidocaine injected by syringe and 25 gauge needle. The site of administration for this trial will be standard femoral and/or sciatic nerve block locations. The regional block will be performed under ultrasound guidance and with the assistance of nerve stimulation. General anesthesia will be given when the patient is in the operating room. This is done after the regional blocks have already been completed.

Administration of sedative and anxiolytic medications before or during the regional nerve block procedures will be based on nervous and pain VAS scores and anesthesiologist graded anxiety scores. If anxiety levels are indicated to be less than four, no sedation will be administered prior to the nerve block procedure. If anxiety scores are four to seven, then two mg to a maximum of four mg of versed IV will be administered just prior to the local anesthesia administration. If anxiety scores are greater than seven, then two mg to a maximum of four mg of IV Versed will be administered just prior to the local anesthesia administration. If anesthesiologist observed anxiety levels remain above 7, then 20 mcg to a max of 40 mcg of IV Precedex will subsequently be administered.

The current observations of clinical efficacy in the delivery of local anesthesia by either needle or J-tip introduction have shown that the superficial and subcutaneous tissues are adequately anesthetized. Pain is usually encountered as the touhy needle, nerve block needle, penetrates the fascia of the muscle. The fascia is a barrier to the deeper tissues and is not anesthetized with any local anesthetic. Additional medications may be administered during the needle insertion through the fascia during the regional block. If pain VAS is greater than four, and IV Versed was not administered due to anxiety scores between four and seven, then two mg to a maximum of four mg of IV Versed will be administered. If pain continues to be above four and IV Precedex was not administered due to anxiety levels greater than seven, then 20 mcg to a max of 40 mcg IV Precedex will be administered. If pain continues to be greater than four, then 25 mcg Fentanyl to a maximum of 50 mcg will be administered. If pain values continue to be above seven, then 100 mg of IV propofol will be given. No matter what amount and type of sedative or anxiolytic is administered during the nerve block procedure, the first VAS measure at each time point will be the one of record for analysis in this study.

Patients will indicate their level of nervousness by completing a visual analogue scale, after admission to the preoperative area, for how nervous they are prior to their procedure. The anesthesiologist through observational measurement on a scale of 0-10 will also measure patient anxiety levels. A level of ten will be the highest observed measure of anxiety. These scores will assist in identifying patients that may need more general types of anesthesia prior to the nerve block. This will also allow for further evaluation of limitations due to the amount of pre-op anesthesia of patients in the study.

Femoral nerve blocks will be performed on all arthroscopic procedures. Single injection sciatic nerve blocks will be utilized in addition to femoral catheter nerve blocks for patients undergoing arthroscopic surgery with ACL reconstruction or if lateral meniscus repair is expected to be performed. The site or sites of injection on the operative lower extremity will be chosen, a timeout taken and sterile preparation performed by the

anesthesiologist prior to local anesthetic infiltration and the regional blockage needle introduction. After sterile preparation, the J-tip injector will be placed on the skin at the selected site of the regional block needle introduction. Firm pressure will be placed with the J-tip injector on the site for the chosen block, the safety ring slid down, the trigger pressed and the tip held firmly on the skin for three seconds. One quarter of a milliliter of one percent lidocaine will be injected with the characteristic “pop” and “hissing” sounds inherent to the J-tip injector. There is the possibility of medication leak and spray from under the J-tip. This is known to happen with use of the device and can be minimized with firm pressure of the device on the skin. Ninety seconds after the J-tip discharge, the regional block will be administered. The same initial timeout and sterile prep procedure will be followed for the use of local syringe and 25 gauge needle injection of 1% lidocaine ninety seconds prior to introduction of the regional block needle. The parents will be out of the room to reduce any effect on pain levels they could have by contact with the patient. Having the parents outside of the room is currently the standard during nerve block procedures at Arnold Palmer Hospital. No music, television, or video screen will be allowed to be on in the room from the time of the timeout to the completion of the post nerve block VAS completion to minimize confounders that could alter pain perception. Currently, there is no specific attention paid to whether or not music, television, or video screen is on during the procedure. There is varied and inconsistent use at this time.. If the sciatic regional block needle introduction is felt by the anesthesiologist to be an inadequate location, the procedure of local anesthesia and VAS questionnaires will be restarted and completed again for a new location. The new location will be at least two centimeters from the previous location. This will take into effect the local tissue dispersion of lidocaine shown to be about 1.8cm in diameter in previous needless injector studies (Hardison, Bennett). National Medical Products, INC. describes the dispersion of the medication delivered by the J-tip to usually be the size of the front diameter of the J-tip device, which measures one centimeter. The number of attempts with needle sticks for the regional block needle will be recorded for further analysis.

Times will be recorded for; time of J-tip administration, time of regional block performance, operating room arrival time, incision time, surgical end time, PACU arrival time and PACU discharge time. The amount of time from regional block to arrival in operating room and to incision time will be calculated. The surgical procedure time and amount of time in PACU will also be calculated.

Visual analogue pain scales will be completed prior to and immediately after J-tip use or needle local anesthesia infiltration. The scale immediately after will be with regard to pain felt at time of J-tip use or needle introduction. The scale will be completed once again prior to and immediately after needle introduction for each regional blockade. The scale immediately after will be with regard to pain felt at time of regional block needle introduction. Visual analogue pain scale will be recorded in PACU. All scoring will be performed on separate VAS assessments without patient access to previous scores.

The patient will record visual analogue pain scales on post-operative days one through three. The anesthesiologist will collect telephone verbal pain scores on a 0-10 scale on post-operative days one and two. This is current standard procedure for all patients who

receive a regional block. The femoral nerve block catheter, when utilized, is left in place for 40 hours from the initial femoral nerve block procedure. The number of days until the post-operative visit will be recorded. Another visual analogue pain scale will be completed at the first post-operative visit. An Arthroscopic Surgery Satisfaction Questionnaire will be completed by the patient and a parent or guardian at the first post-operative visit. The questionnaire will be specific to the patient's randomized treatment group. If the patient was randomized to receive the J-Tip, the patient and parent will receive the J-Tip questionnaire and if the patient was randomized to receive the traditional needle and syringe, the patient and parent will receive the needled syringe questionnaire. The sex of the parent or guardian completing the form will be recorded.

It will also be recorded if intra-articular analgesic injection is given intra-operatively. The amount and type of pain and anti-nausea/emetic and pain medication use will be recorded in PACU and by the patient on the first three post-operative days.

5. Study Population:

The 15 patients enrolled to account for withdrawals will cover patients who wish to self-select to the J-tip or needle group and do not wish to be randomized. These patients will not be in the final analysis. Patients who wish to switch groups after being randomized will be allowed to switch, but will be withdrawn from final analysis. If a patient does not wish to have either method of local anesthesia delivery prior to the regional block, they will be withdrawn from final analysis.

5.1 Inclusion /Exclusion Criteria

Inclusion:

- Subjects between the ages of 11 and 17 undergoing arthroscopic knee surgery.
- Able to independently complete the VAS pain scales.
- Subjects who are neurologically intact at area of injection.
- English speaking.

Exclusion:

- Subjects with known allergies to lidocaine.
- Presence of developmental delay.
- Subjects with blood disorders affecting coagulation.
- Subjects on blood thinners.
- Subjects receiving chemotherapeutic agents.
- Those who use or receive analgesia prior to procedure, except for acetaminophen or NSAIDs.
- Any other local sedation at the area of nerve block injection.
- *Non-English Speaking
- Subjects with signs of skin infection or pathology at the injection site.

*The consent form and other documents for this study are not available in any other language. Non-English speaking families may not fully understand the study.

6. Study Duration/ Study Timeline:

Stage 1, enrollment of patients: 12 to 24 months.
Stage 2, data collection and data analysis: 3-6 months.
Stage 3, presentation and publication: 6-12 months.
Goal is to conclude data analysis by: September 2017

7. Statistical Analysis Plan:

Analyses will vary by specific aim. To evaluate our hypotheses, we will use exact and non-parametric hypothesis testing procedures. Confidence intervals (95%) of differences will be computed. Regression analysis will be employed when adjustment between comparison groups is considered necessary.

8. Informed Consent Process:

IRB approval will be obtained prior to patient recruitment. Patients will be identified as they present to the orthopaedic pediatric service of Arnold Palmer Hospital / Orlando Health Inc. with a qualifying injury to determine their interest in participating in the study. The study will be explained to them, they will have an opportunity to read the consent, have their questions answered. If they agree to participate, they will be randomized to a treatment arm as described above.

9. Privacy and Confidentiality:

Any PHI will be kept on a password protected database and will be linked only with a study identification number for this research. All data will be entered into a computer that is password protected. Data will be stored in a locked office of the investigators and maintained for a minimum of five years after the completion of the study.

10. Risk/Benefit:

10.1 Possible Risk to participants:

- Allergic reaction to lidocaine with a previously unknown allergy.
- Blood reflux at injection point.
- Skin wheal.
- Skin bruising.

10.2 Possible Benefits to Participants

- Decreased pain from local anesthesia infiltration compared to needle injected local anesthetic at nerve block site.
- Decreased pain during femoral and/or sciatic nerve block procedure.
- Possible increased efficacy of femoral nerve block leading to decreased post-operative pain, medication use and pharmacologic side effects.

11. Data Safety Monitoring:

Monitoring is an ongoing review of the study throughout its duration.
Safeguards to protect research participant data and identity include but are not limited to restricting access to data to the principal, sub investigators and the study coordinators. Identifiable PHI will not be used in any manuscript and any data containing PHI will be stored in a password protected computer.

12. Conflict of Interest:

This is not a sponsored study. There is no additional benefit to the investigator(s) beyond academic publication or presentation. No direct financial support for the study will be provided from any entity. No royalties will be received from any implants implanted at Orlando Health.

13. Publication and Presentation Plans:

This project will be presented at Orthopaedic meetings and the manuscript is to be presented for publication in a peer reviewed Orthopaedic journal.

14. References:

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15. Appendices :

"Nervous" Visual Analogue Scale (VAS)
Pain Visual Analogue Scale (VAS)
Arthroscopic Surgery Satisfaction Questionnaire Parent (J-Tip)
Arthroscopic Surgery Satisfaction Questionnaire Child (J-Tip)

Arthroscopic Surgery Satisfaction Questionnaire Parent (Needle)
Arthroscopic Surgery Satisfaction Questionnaire Child (Needle)
Home medication logs

Results:

Descriptive Statistics: Visual Analogy Scores (VAS) After Local Femoral and Local Sciatic Nerve Blocks

As seen in Table 1, the mean VAS immediately after local femoral for is 1.54 with a standard deviation 1.524 and the mean VAS immediately after local femoral for Needle Injections is 3.57 with a standard deviation 2.133. The mean VAS immediately after local femoral for J-Tip injections is 2.03 less than the mean VAS immediately after local femoral for Needle Injections. The difference time shows a large time gap and variation between the two injection types.

As seen in Table 1, the mean VAS immediately after local sciatic for is 2.272 with a standard deviation 2.1631 and the mean VAS immediately after local sciatic for Needle Injections is 4.5 with a standard deviation 2.4553. The mean VAS immediately after local sciatic for J-Tip injections is 2.228 less than the mean VAS immediately after local sciatic for Needle Injections. The difference time shows a large time gap and variation between the two injection types.

	Injection Type	N	Mean	Standard Deviation	Standard Error Mean
VAS Immediately After Local Femoral	Needle	54	3.57	2.133	.290
	J-Tip	57	1.54	1.524	.202
VAS Immediately After Local Sciatic	Needle	54	4.500	2.4553	.3341
	J-Tip	57	2.272	2.1631	.2865

Table 1: Group Statistics

Two-Sample T Test: Visual Analogy Scores (VAS) After Local Femoral and Local Sciatic Nerve Blocks

VAS Immediately After Local Femoral:

H_0 : No statistically significant difference exists between the mean of the VAS Immediately After Local Femoral for Needle Injections and the mean of VAS Immediately After Local Femoral in the J-Tip Injections.

H_a: A statistically significant difference exists between the mean of the VAS Immediately After Local Femoral for Needle Injections and the mean of VAS Immediately After Local Femoral in the J-Tip Injections.

The VAS Immediately After Local Femoral for J-Tip Injections exceeds the mean VAS Immediately After Local Femoral for Needle Injections to a statistically significant degree, $t(95.525) = 5.792$, $p < .01$, CI [1.328, 2.732], as indicated within Table 2.

VAS Immediately After Local Sciatic:

> H_0 : No statistically significant difference exists between the mean of the VAS Immediately After Local Sciatic for Needle Injections and the mean of VAS Immediately After Local Sciatic in the J-Tip Injections.
>
> H_a: A statistically significant difference exists between the mean of the VAS Immediately After Local Sciatic for Needle Injections and the mean of VAS Immediately After Local Sciatic in the J-Tip Injections.

The VAS Immediately After Local Sciatic for J-Tip Injections exceeds the mean VAS Immediately After Local Sciatic for Needle Injections to a statistically significant degree, $t(109) = 5.080$, $p < .01$, [1.3587, 3.0974], as indicated within Table 2.

		Levene's Test for Equality of Variances		**T-Test For Equality of Means**					**95% Confidence Interval of the Difference**	
		F	**Significance**	**t**	**df**	**Significance (2-tailed)**	**Mean Difference**	**Standard Error Difference**	**Lower**	**Upper**
VAS Immediately After Local Femoral	Equal Variances Assumed	4.491	.036	5.792	109	.000	2.030	.351	1.336	2.725
	Equal Variances Not Assumed			5.741	95.525	.000	2.030	.354	1.328	2.732
VAS Immediately After Local	Equal Variances Assumed	.515	.474	5.080	109	.000	2.2281	.4386	1.3587	3.0974

Sciatic	Equal Variances Not Assumed			5.062	105.576	.000	2.2281	.4401	1.3554	3.1007

Table 2: Independent Samples Test

Ordinary Least Squares Regression: Visual Analogy Scores (VAS) After Local Femoral and Local Sciatic Nerve Blocks

No statistical significance when comparing means Injection Type the following variables: 1st Type of Sedation, 1st Total Quantity of sedation used (mg), 2nd Type of Sedation Used, Total Quantity 2nd Type of sedation used (mcg), 3rd Type of Sedation Used, Total Quantity 3rd Type of sedation used (mcg), Visual Analog Scale (VAS) prior to local femoral, VAS prior to femoral, VAS immediately after femoral, VAS prior to local sciatic, VAS prior to sciatic, VAS immediately after sciatic, VAS prior to PACU Discharge.

VAS Immediately After Local Femoral:

Ordinary Least Squares Regression is utilized to determine if the Visual Analog Scale (VAS) immediately after local femoral for Needle Injections is significantly different from J-Tip Injections. This regression is run to determine if the injection type can statistically predict VAS immediately after local femoral. There is an independence of residuals, as assessed by a Durbin-Watson statistic, of 1.688 (Table 4). The assumptions of linearity, independence of errors, homoscedasticity, unusual points, and normality of residuals were met. The model is statistically significant, $F(6, 100) = 10.215$, $p \leq .001$, adj. $R^2 = .343$. Injection type statistically significantly predicts VAS immediately after local femoral, as seen in Table 3, $\beta = -2.020$, $t = -6.266$, $p \leq .001$. The beta explains that if a J-tip injection was given it would decrease the VAS immediately after local femoral by approximately 2. Regression coefficients and standard errors can be found in Appendix.

Variable	**Adjusted R^2**	**Model**			**Injection Type**		
VAS Immediately After Local Femoral	.343	**df**	**F**	**Sig.**	**Beta**	**T**	**Sig.**
		6	10.215	.000	-2.020	-6.266	.000

Table 3: Beta Explanation for VAS Immediately After Local Femoral

Model	**R**	**R^2**	**Adjusted R^2**	**Standard Error of the Estimate**	**Durbin-Watson**
1	.616[a]	.380	.343	1.656	1.688

a. Predictors: (Constant), Thigh Circumference (cm), Ethnicity, Injection Type, Age, Gender BMI

b. Dependent Variable: VAS Immediately After Local Femoral

Table 4: Model Summary

Model		Sum of Squares	dF	Mean Square	F	Sig.
1	Regression	168.140	6	28.023	10.215	.000[b]
	Residual	274.327	100	2.743		
	Total	442.467	106			

a. Dependent Variable: VAS Immediately After Local Femoral
b. Predictors: (Constant), Thigh Circumference (cm), Ethnicity, Injection Type, Age, Gender BMI

Table 5: ANOVA[a]

Model		Unstandardized Coefficients		Standardized Coefficients			95% Confidence Interval for B	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
1	(Constant)	9.774	2.119		4.613	.000	5.570	13.977
	Injection Type	-2.020	.322	-.496	-6.266	.000	-2.660	-1.381
	Gender	.504	.340	.124	1.481	.142	-.171	1.179
	Age	-.250	.105	-.193	-2.367	.020	-.459	-.040
	Ethnicity	-.021	.117	-.014	-.177	.860	-.253	.212
	BMI	-.079	.065	-.186	-1.225	.223	-.208	.049
	Thigh Circumference (cm)	-.021	.038	-.083	-.545	.587	-.097	.055

a. Dependent Variable: VAS Immediately After Local Femoral

Table 7: Coefficients[a]

VAS immediately after local sciatic:

Ordinary Least Squares Regression is utilized to determine if the Visual Analog Scale (VAS) immediately after local sciatic for Needle Injections is significantly different from J-Tip Injections. This regression is run to determine if the injection type can statistically predict VAS immediately after local sciatic. There is an independence of residuals, as assessed by a Durbin-Watson statistic, of 1.798 (Table 9). The assumptions of linearity, independence of errors, homoscedasticity, unusual points, and normality of residuals were met. The model is statistically significant, $F(6, 100) = 6.178$, $p \leq .001$, adj. $R^2 = .227$. Injection type statistically significantly predicts VAS immediately after local sciatic, as seen in Table 8 $\beta = -2.248$, $t = -5.191$, $p \leq .001$. The beta explains that if a J-tip injection was given it would decrease the VAS) immediately after local sciatic by approximately 2. Regression coefficients and standard errors can be found in Appendix.

Variable	Adjusted R^2	Model			Injection Type		
		df	F	Sig.	Beta	T	Sig.
VAS Immediately After Local Sciatic	.277	6	6.178	.000	-2.248	-5.191	.000

Table 8: Beta Explanation for VAS Immediately After Local Sciatic

Model	R	R^2	Adjusted R^2	Standard Error of the Estimate	Durbin-Watson
1	.520[a]	.270	.227	2.2247	1.798

c. Predictors: (Constant), Thigh Circumference (cm), Ethnicity, Injection Type, Age, Gender BMI

d. Dependent Variable: VAS Immediately After Local Sciatic

Table 9: Model Summary

Model		Sum of Squares	dF	Mean Square	F	Sig.
1	Regression	183.449	6	30.575	6.178	.000[b]
	Residual	494.930	100	4.949		
	Total	678.379	106			

c. Dependent Variable: VAS Immediately After Local Sciatic

d. Predictors: (Constant), Thigh Circumference (cm), Ethnicity, Injection Type, Age, Gender BMI

Table 10: ANOVA[a]

		Unstandardized Coefficients		Standardized Coefficients			95% Confidence Interval for B	
Model		**B**	**Std. Error**	**Beta**	**t**	**Sig.**	**Lower Bound**	**Upper Bound**
1	(Constant)	9.130	2.846		3.208	.002	3.484	14.777
	Injection Type	-2.248	.433	-.446	-5.191	.000	-3.107	-1.389
	Gender	.826	.457	.164	1.807	.074	-.081	1.179
	Age	-.236	.142	-.147	-1.665	.099	-.517	-.040
	Ethnicity	.005	.157	.003	.033	.973	-.307	.212
	BMI	-.029	.087	-0.54	-.329	.743	-.201	.049
	Thigh Circumference (cm)	-.028	.051	-.090	-.543	.588	-.130	.055

b. Dependent Variable: VAS Immediately After Local Sciatic

Table 11: Coefficients[a]