TO EXSANGUINATE OR NOT: A COMPARATIVE STUDY AMONG FILIPINO TOTAL KNEE ARTHROPLASTY PATIENTS WITH TOURNIQUET APPLIED AFTER LEG ELEVATION VERSUS MANUAL EXSANGUINATION WITH ELASTIC BANDAGE.

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ABSTRACT

BACKGROUND

Osteoarthritis is a degenerative joint disease that involves the synovial joints such as the knees and the hips. It leads to inflammation, mechanical changes to the joints, and eventual functional decline. Total knee arthroplasty is a surgical procedure wherein the distal femur and proximal tibia are replaced with implants. The use of a tourniquet in total knee arthroplasty is a common practice amongst orthopedic surgeons. Exact guidelines as to how tourniquets are applied have not been established. This study seeks to compare: post-operative pain, blood loss, occurrence of nerve injury, and length of surgery among patients with knee osteoarthritis who undergo TKA with tourniquet use after limb elevation versus exsanguination with use of elastic bandage.

METHODOLOGY

A single-center, prospective, comparative, randomized controlled study was performed in Philippine Orthopedic Center, a specialty government hospital. Participants included all Filipino patients aged 50-80 years old with severe knee osteoarthritis that undergo any form of total knee arthroplasty. Patients were randomly added to two groups, one group had elevation method of tourniquet application, while the other group had manual exsanguination with elastic bandage use.

RESULTS

There was statistically no significant difference in post-op pain levels, blood loss, operative time, and occurrence of palsy between the two methods of tourniquet application.

DISCUSSION AND CONCLUSION

The method of tourniquet application for a total knee replacement does not significantly affect the post-operative pain of patients. It also does not significantly affect the operative time or blood loss. This study concludes that either method of tourniquet application is safe and has similar outcomes up to one-month post-surgery.

KEYWORDS

Total Knee Arthroplasty, Tourniquet, Knee Osteoarthritis

BACKGROUND OF THE STUDY

Osteoarthritis is a degenerative joint disease that involves the synovial joints such as the knees and the hips. It leads to inflammation, mechanical changes to the joints, and eventual functional decline. On radiographs, joint space narrowing, osteophytes, subchondral sclerosis, and bone contour changes can be appreciated. This condition presents as joint pain associated with activity. It is the most prevalent kind of arthritis, and most commonly affects the knee joint, which leads to functional limitations and disability in adults [1, 2, 3].

Treatment of osteoarthritis is essential and may be done with non-surgical intervention, surgery, or a combination of both. If non-operative treatment fails to relieve pain, total knee arthroplasty is indicated. This procedure, along with supplemented non-surgical treatment such as physical therapy, has been shown to be more effective in pain relief and functional outcomes as compared to non-surgical management alone [4]. The gold standard and most common surgical mode of treatment for osteoarthritis is Total Knee Arthroplasty, a surgical procedure involving replacing the distal femur, proximal tibia, with or without resurfacing the patella [3].

Total knee arthroplasty is a surgical procedure wherein the distal femur and proximal tibia are replaced with implants [5]. The use of a tourniquet in total knee arthroplasty is a common practice amongst orthopedic surgeons. The benefits of using tourniquet are

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improved visualization, shorter operative duration, and decreased blood loss. There has been literature that showed benefits of no tourniquet use include better postoperative pain, less wound complications, and better postoperative range of motion [6].

Exact guidelines as to how tourniquets are applied have not been established, however there are accepted rules for safe tourniquet use as stated by Bruner and modified by Barithwaite and Klenerman [7]. A common technique in applying a tourniquet is through elevating the limb and applying Esmarch bandage for exsanguination [8]. Another technique in tourniquet application is exsanguination through elevation of the limb alone [9]. One study comparing lower limb lifting and "squeeze exsanguination" has been done by Zhang et al, in which they compared the outcomes of lifting the lower limb at 45 degrees for 30 seconds with manual hand squeeze exsanguination immediately in patients undergoing total knee arthroplasty. This study noted that there was decreased incidence of skin tension blistering and less early postoperative pain reaction in the group with elevation done [10]. Other studies have been done comparing Esmarch bandage exsanguination and limb elevation in upper extremity surgeries. One study by Farbood et al claims that there is no significant difference in pain for either group, while another study by Tanpowpong notes that tourniquet tolerance was significantly lower in groups with manual exsanguination [11, 12]. A study by Blond and Madsen comparing the amount of reduction of blood volume in upper extremities exsanguinated through different methods concluded that exsanguination with external methods such as Esmarch bandage exsanguination and squeeze exsanguination, resulted in significantly greater reduction of blood volume than with elevation alone [13].

This study seeks to compare: post-operative pain, blood loss, occurrence of nerve injury, and length of surgery among patients with knee osteoarthritis who undergo TKA with tourniquet use after limb elevation versus exsanguination with use of elastic bandage.

RELEVANCE/RATIONALE

Osteoarthritis is the most common form of arthritis, commonly affecting the knees. Total knee arthroplasty is noted as the surgical gold standard of care. Post-Total knee arthroplasty pain is one of the most common and devastating complaints of patients 14. This may be affected by tourniquet use or the technique of tourniquet application. There is no widespread agreement as to whether exsanguination by elevation should be used over exsanguination with an external force. It is imperative to determine in the Filipino setting if there should be guidelines for tourniquet application for total knee arthroplasty. The results of this study would influence decision making as to which method of tourniquet application would be safer to apply. This is a local study intended to confirm the findings of other studies, to contribute to the foundation for a possible guideline for tourniquet use in knee arthroplasty.

RESEARCH PROBLEM

Population: Filipino patients aged 50-80 with severe knee osteoarthritis who underwent total knee arthroplasty with a medial parapatellar approach

Intervention: Tourniquet application after five minutes of elevation with the hip at 45 degrees flexion 9

Control: Tourniquet application after manual exsanguination with elastic bandage

Outcomes to compare

- Post-operative pain as measured through Visual Analog Scale (VAS) for pain at 12 hours post op, three days post op, two weeks post op, and one month post op
- Intraoperative blood loss
- Occurrence of palsy
- Length of surgery

HYPOTHESIS

Tourniquet application through exsanguination through elevation leads to less post-operative pain than using manual exsanguination with elastic bandage.

General and Specific Objectives of the Study

General

- To compare the outcomes of tourniquet application for TKA through exsanguination by elevation with manual elastic bandage exsanguination.

Specific

- To compare the following
    - VAS 12 hours, three days, two weeks, and one month post-operatively
    - Intraoperative blood loss
    - Length of surgery
    - Occurrence of palsy or neurologic injury

METHODOLOGY

A single-center, prospective, comparative, randomized controlled study was performed in a specialty government hospital.

Study Population and Sampling Methodology

Participants included all Filipino patients aged 50-80 years old with severe knee osteoarthritis that undergo any form of total knee arthroplasty. Block randomization was used to allocate patients into blocks of equal size to prevent imbalance in the number of cases. Patients were randomly added to two groups, one group had elevation method of tourniquet application, while the other group had manual exsanguination with elastic bandage use.

Inclusion Criteria

- Diagnosed cases of knee osteoarthritis indicated for surgery with Kellgren Lawrence Grade II to IV
- Patients for primary total knee arthroplasty under spinal anesthesia block
- Treated with Total Knee Arthroplasty with medial parapatellar approach, with use of pneumatic tourniquet
- Patients undergoing either unilateral or bilateral total knee replacement.

Exclusion Criteria

- Knee pain caused by different pathology such as referred pain from ipsilateral hip pathology, radicular pain from spine disease, peripheral vascular disease, rheumatoid arthritis, systemic lupus erythematosus, or other blood dyscrasias.
- Patients with deferred surgery due to cardiovascular conditions.
- Malaligned or non-acceptable implant position as screened by the senior surgeon
- Lower extremity palsy preoperatively

SAMPLE SIZE CONSIDERATIONS

A study by Danoff et al noted that the minimally clinically important difference (MCID) between two Visual Analog Scale (VAS) for pain scores to determine the minimal improvement a patient would perceive as significant is a 22 point difference with a standard deviation of 16.1. The study noted that a 22.6 mm difference on the VAS is enough for the patient to feel improvement in pain 15. With a sample size estimate for each group with alpha 0.05, with a power of 0.80 to detect a mean difference of 22.6 VAS points between two groups would require 18 participants per group or a total of 36 participants.

STUDY PROCEDURE

Admitted patients for total knee arthroplasty with the inclusion criteria were included in the study. Randomization through fishbowl method was done for assignment of patients to exsanguination or elevation groups. All surgeries were done by the hospital's senior joints surgeon and his joints surgery team. The method of surgery was a total knee arthroplasty done with a midline skin incision and medial parapatellar approach. Kinematic alignment without patellar component application and resurfacing was done for all cases. The patient was blinded as to which method of tourniquet application was used since tourniquet application was done after draping was done, with curtain covering the patient's view of the surgical team Informed consent was signed and secured from included patients upon admission at the specialty government hospital. This study is not in violation of the Declaration of Helsinki and was appraised by the institution's Ethics Review Board.

Tourniquet application by limb elevation was done with the leg held at 45 degrees for five minutes. This was based on the findings of Warren et al that holding the limb at such position leads to greater blood reduction in the limb as compared to shorter time held in position. Holding the limb as such more than five minutes will not lead to significant decrease in blood levels in the limb [9]. Tourniquet application by elastic bandage was done by holding the leg at 45 degrees, then immediately applying elastic bandage distally to proximally by encircling the limb. Pneumatic tourniquet was used in all patients with pressure ranging from 250 to no more than 350 mmHg depending on the systolic blood pressure of the patient 7. Tourniquet pressure used was calculated based on the estimated arterial occlusion pressure (AOP) of the lower extremity of the patient. This was done based on a method described by Tuncali et al. which follows the formula: (AOP = SBP + $10/K_{TP}$), wherein AOP is arterial occlusion pressure, SBP is systolic blood pressure, and K_{TP} is the tissue padding coefficient [17]. Tissue padding coefficient is to be based on the circumference of the thigh, which is measured 20 cm proximal to the superior pole of the patella with the knee in extension. Tourniquet cuffs were applied on the thigh with the distal edge approximately 15 cm proximal to the superior pole of the patella [18].

The method of tourniquet, operative time, and intraoperative blood loss as noted by anesthesia records and operative records, were the basis of data collection. Patients all had standardized pre-operative, peri-operative, and post-operative anesthesia medications. On the night before surgery, the patients were given one dose of Pregabalin 75 milligrams capsule or one dose of Gabapentin 300 milligrams tablet. Paracetamol 1 gram was given every eight hours intravenously on the night before surgery. Tranexamic acid 1 gram was given intravenously every 12 hours for three doses on the night before surgery. Intraoperatively, there was local infiltration analgesia (LIA) given. The local infiltration analgesia solution contains one ampule of Levobupivacaine/Bupivacaine Isobaric 100-150

milligrams per ampule, one ampule of Ketorolac 30 milligrams per ampule, one vial of Cefuroxime 750 milligrams per vial, and one ampule of Epinephrine 0.6 milligrams (1mg/ml/ampule), all of which were diluted in normal saline to a final volume of 90cc. This LIA was injected into the knee with a 50cc syringe with a gauge 16 needle. After surgery, the patients were given the following pain medications: Paracetamol 1 gram intravenously every eight hours for three doses, and Ketorolac 30 milligrams intravenously every six hours for four doses. For patients with intolerable pain despite being given the aforementioned medications, Etoricoxib 120 milligrams orally was given.

VAS was taken at 12 hours, three days, two weeks, and one month post-operatively. The patients had a standardized post-operative rehabilitation program which will include ankle plantarflexion and dorsiflexion, isometric knee extension, quadriceps strengthening, knee and hip flexion and extension, isometric buttock contraction, hip abduction and adduction, and straight leg raise exercises. Prior to discharge, the patients were referred to the rehab service of the hospital and given prescription for home therapy. Palsy was documented prior to discharge. Strict anonymity and confidentiality was enforced at all times, and patients were given the option to withdraw at any time during the course of the study.

The study design is a randomized, comparative prospective study. The value of the study lies in being able to closely monitor and periodically assess study subjects in a clinical setting, with a set of standardized parameters that would ensure comparability of results. A randomized controlled trial still remains the standard of treatment for measuring treatment effect in short and long term time frames, however, employing such a research design for surgical interventions remains difficult particularly in low-resource settings such as the Philippines, where patient accrual and standardization in surgical technique remain obstacles to achieving high validity. Blinding was applied for the patient and the outcome assessor. The surgeon was not blinded as to the method of tourniquet application used.

PRIMARY OUTCOMES ASSESSMENT

The primary outcome measure for this study is the Visual Analog Scale (VAS) for pain. This is a valid tool to assess pain that can be easily answered by the patient 16. Administering of the tool was done with the company of the doctor in charge or the attending nurse in order to guide the patient.

Blood loss was computed based on amount of blood in the suction machine as well as the number of soaked pieces of gauze. Operative time was based on the official operative record.

RESULTS

51 patients were initially enrolled, however only 44 subjects were included in the study due to the exclusion criteria. 18 cases were in the exsanguination group and 26 cases were in the elevation group. A Mann-Whitney U test was conducted in SPSS to compare the post-operative pain as measured by the Visual Analog Scale (VAS) for pain at 12 hours post op between two tourniquet applications, manual exsanguination with elastic bandage, and tourniquet application after five minutes of elevation with the hip at 45 degrees. Baseline characteristics of the procedure, including operative time and blood loss in addition to patient demographics, were first evaluated between the groups. Results show that there was no significant difference in patient ages between the Exsanguination group ($M = 65.94$, $SD = 7.97$) and the Elevation group ($M = 62.58$, $SD = 5.80$), $t(42) = 1.624$, $p = .112$). Meanwhile, there was no significant association between gender and tourniquet technique, $X^2(1, N = 44) = .702$, $p = .402$ (Table 2). No significant difference was also found in the operation times between the Exsanguination group ($M = 127.62$, $SD = 41.73$) and the Elevation group ($M = 136.33$, $SD = 39.72$), $t(42) = -.695$, $p = .492$. There was also no significant difference in the patient blood loss between the Exsanguination group ($M = 116.54$, $SD = 167.19$) and the Elevation group ($M = 108.89$, $SD = 121.41$), $t(42) = .166$, $p = .869$. Based on these analyses, the baseline characteristics of the patients in the Exsanguinate and Elevate groups were similar prior to the experiment (Table 1).

After comparing baseline characteristics of the operation procedure, the distributions were checked for normality to identify whether a parametric test is suitable for comparing the differences. It should be noted that the pain scale used is measured using lengths, and therefore, is not strictly ordinal. Histograms for the VAS scale (Fig. 2) show similarly right-skewed distributions. As such, the assumption of normality is violated, and since the sample sizes are small, then the non-parametric Mann-Whitney U test was used to compare the medians of the two groups. Results of the Mann-Whitney U test show that there was no significant difference in the VAS pain scores between the Exsanguinate and Elevate groups, $U = 207.5$, $z = -.711$, $p = .477$. Thus, there is insufficient evidence to conclude that post-op pain levels are different between the two techniques.

At three days after surgery, only one patient complained of pain at the operative site rated 2/10. Other patients did not complain of pain. All patients did not complain of pain at two weeks and one month post-operatively. There was only one adverse event in this study. One patient in the elevation group acquired post-operative foot drop after tight post-op bandage was applied to

the lower extremity for change of dressing. Otherwise, there were no adverse events for the patients in the study.

DISCUSSION

The method of tourniquet application for a total knee replacement does not significantly affect the post-operative pain of patients. It also does not significantly affect the operative time or blood loss. Peroneal nerve palsy, as evidenced by foot drop, occurred only in one case from the elevation group, while no patients from the exsanguination group developed any palsy, implying that exsanguination does not necessarily lead to nerve injury.

This study is similar to the pool of related literature gathered in that there is no significant difference in outcomes comparing the application of tourniquet. Two of the studies cited in the related literature with the same result however, were used to compare the tourniquet application in the upper extremity. The study by Zhang et al, noted that the elevation method of tourniquet application led to less immediate post operative pain compared to the exsanguination method. Zhang et al's study had a population of 236 patients, and measured occurrence of skin blistering, which was not a part of this study. However, the operative time and blood loss were also not significant in the study of Zhang et al[10].

It was noted in the study methodology that kinematic alignment total knee arthroplasty without patellar component placement and resurfacing was used with local infiltration analgesia. These may have affected the pain scores of the patients post-operatively, especially at 12 hours post-surgery due to possible effect of spinal and local anesthesia. It may be recommended to have a comparison of multiple factors such as patellar resurfacing, alignment in total knee arthroplasty used, use of local infiltration analgesia, and method of tourniquet application, based on their effect on pain, blood loss, and operative time. A standardized set of intravenous medications was also used for all patients, however the oral medications that the patients used when discharged was not kept track of, and may have affected the pain of the patients on subsequent follow up.

For clinical implementation, tourniquet application may be done safely with either method. The post-operative pain may also be affected by the pain medications given to the patient throughout the course of treatment. Other studies did not mention providing local infiltration analgesia for their patients. This could have affected the low pain outcome of the patients for this study.

CONCLUSION

For future research, larger sample sizes, and inclusion of outcomes such as skin blistering, infection, and longer term follow ups could be recommended. As for clinical practice guidelines in the Philippines, this study cannot recommend between use of exsanguination or elevation. The application can be up to surgeon preference since the outcomes are similar. This study concludes that either method of tourniquet application is safe and has similar outcomes up to one-month post-surgery.

DISCLOSURE

The authors of this study declare that they have not and will not receive benefits for personal or professional use from any commercial party related to the topics discussed in this paper.

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Outcomes to compare

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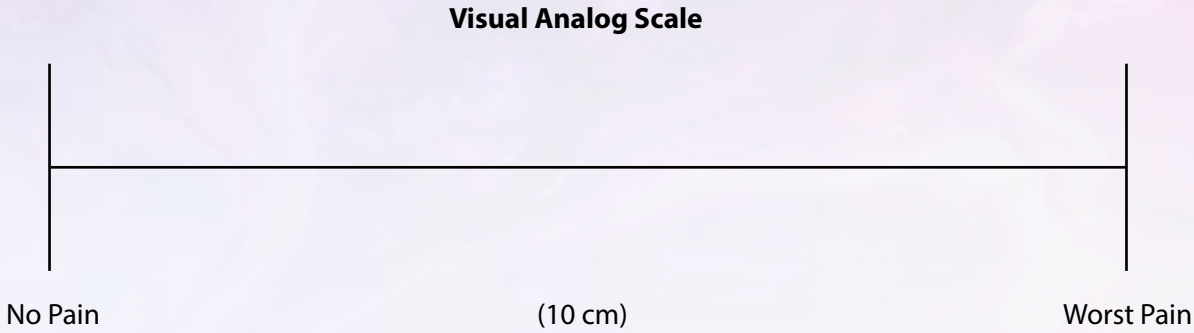
   a. Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, supervision, Visualization, Writing-original draft, Writing- review & editing

2. Joel Baron, MD, FPOA
   a. Conceptualization, Data Curation, Investigation, Methodology, Project administration, Supervision, Writing- review & editing

Appendix I: VAS



Appendix II: Philippine Orthopedic Center standardized medications for Arthroplasty

Appendix III: Tables and Figures

Table 1. Baseline Comparison of Patients

	Exsanguinate		Elevate		*t*	*p*	Cohen's *d*
	M	*SD*	*M*	*SD*			
Age	65.94	7.97	62.58	5.80	1.624	.112	.50
VAS Pain Levels	2.33	2.24	1.42	2.23	1.0351	.309	.33
Blood Loss	108.89	121.41	116.54	167.19	.166	.869	.05
Operation Time	136.33	39.72	127.62	41.73	-.695	.491	.21

[1]Welch *t*-test Procedure with d*f* = 28
[2]Equal variance assumed with d*f* = 42

Table 2. Contingency Table for Gender and Tourniquet Application Technique

		Gender		
		Male	Female	Total
Tourniquet	Elevate	19	7	26
	Exsanguinate	11	7	18
	Total	30	14	44

$X^2(1, N = 44) = .702, p = .402$

Figure 1. Distribution of Patients by Gender and Tourniquet Application Technique

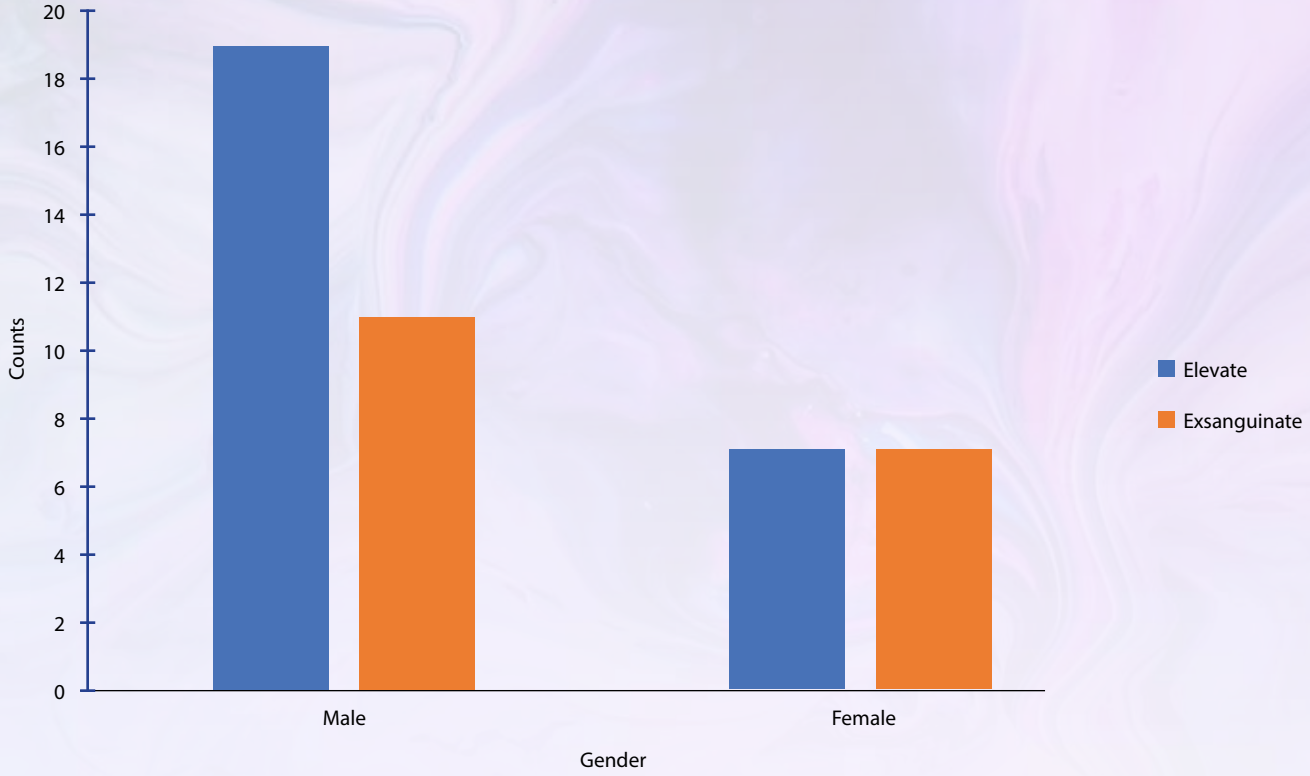
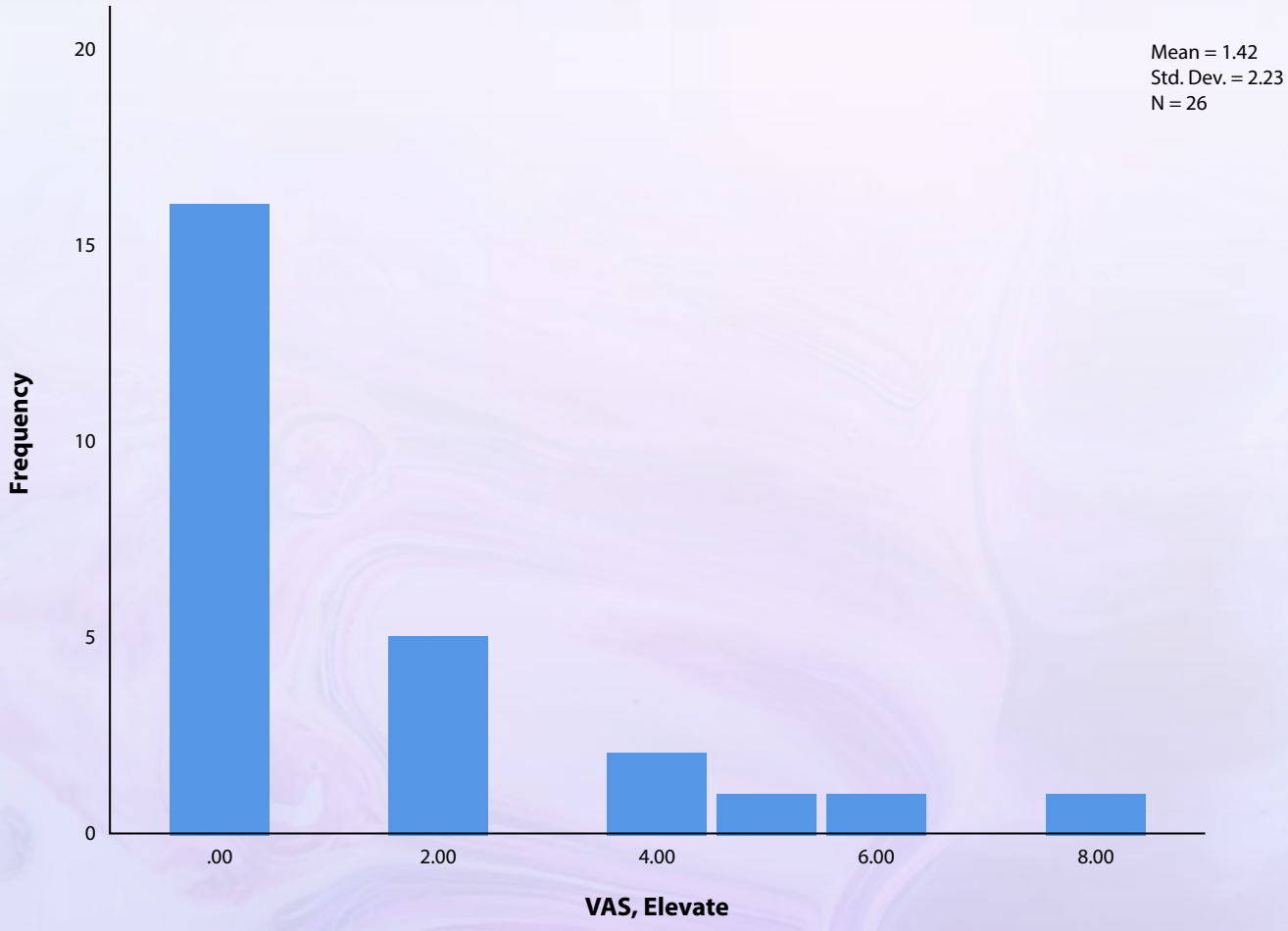
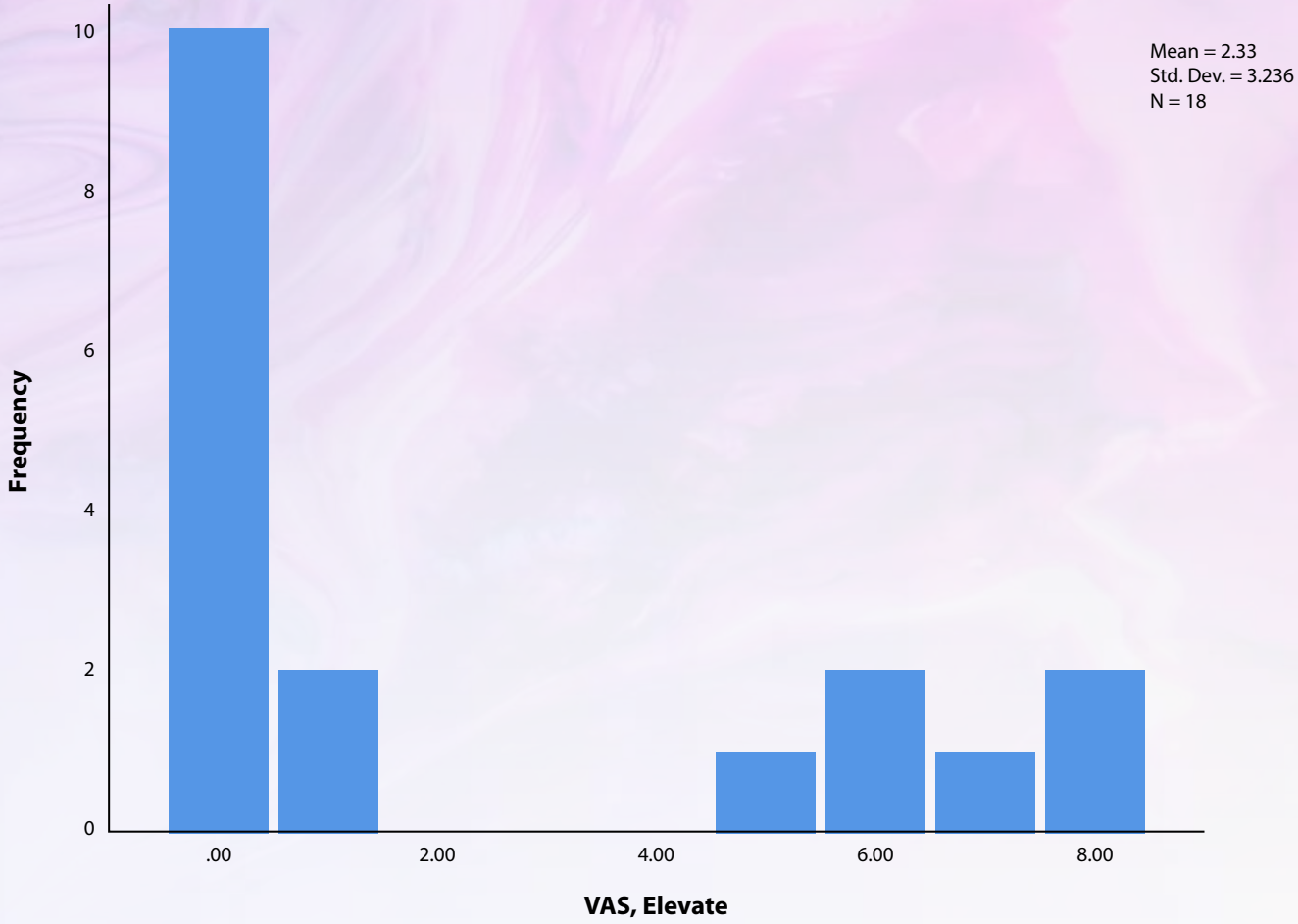


Figure 2. Histogram of Vas Pain Scores by Tourniquet Application Technique





Note: Figures show the distributions of the patients in the Elevate (top) and Exsanguinate (bottom) groups. Distributions are noted to be skewed right.