



Effect of Controlled Expiratory Pressures on Pain during Removal Femoral Arterial Sheath Post Percutaneous Coronary Intervention

Noor Al-Huda Alziyadi ¹, Mohammed Hakim Al-Hchaim ², Ahmed Nema Rjeeb ³.

¹ Adults Health Nursing Department, Faculty of Nursing, University of Kufa, AL-Najaf, Iraq.

² Adults Health Nursing Department, Faculty of Nursing, University of Kufa, AL-Najaf, Iraq.

³ Faculty of Medicine, University of Kufa, AL-Najaf, Iraq.

ABSTRACT

CORRESPONDING AUTHOR: Noor Al-Huda Alziyadi,
Adults Health Nursing Department, Faculty of Nursing,
University of Kufa, AL-Najaf, Iraq.
Email: nooralhudas.alziyadi@student.uokufa.edu.iq

Background: The removal of femoral arterial sheaths post-percutaneous coronary intervention (PCI) is often associated with pain, which can affect patient recovery. Multiple strategies have been suggested to mitigate these sensations, with controlled expiratory pressure (CEP) identified as a potential method for pain alleviation during procedural pain.

Objectives: To evaluate the effect of controlled expiratory pressure (CEP) on pain perception during the removal of femoral arterial sheaths following percutaneous coronary Intervention (PCI).

Methodology: A quasi-experimental design was performed at AL-Najaf Center for Cardiac Surgery and Cardiac Catheterization between (16th October to 1st December 2024). A purposive sample (non-probability) of (128) patients after PCI procedures. Pain was assessed using the Numeric Rating Scale (NRS).

Results: The current result indicated a significant reduction in pain intensity during the femoral sheath removal at a p-value of 0.05.

Conclusion: Controlled expiratory pressure is an effective, non-invasive technique for reducing pain post-PCI during femoral arterial sheath removal. This approach could offer an easy-to-implement adjunct to standard care, improving patient comfort.

Recommendations: According to the findings of the current study, the controlled expiratory pressure of valsalva maneuver should be for managing pain, and further studies are recommended to explore its clinical applicability and long-term benefits.

Keywords: Expiratory Pressure, Femoral Sheath, Pain, Percutaneous coronary Intervention.

INTRODUCTION

Coronary artery disease (CAD) is a complex condition that affects one or more of the arteries surrounding the myocardium, resulting in impaired or blocked blood flow (AL-ASHOUR et al., 2024). It is one of the most prevalent cardiovascular diseases in developed countries and continues to be a leading cause of morbidity and fatalities (M. H. S. Al-Hchaim, 2018).

CAD represents 32.7% of the global burden of cardiovascular disease, and it is a leading cause of death, with approximately 154 million cases reported worldwide in 2016 (Han et al., 2022). Additionally, the World Health Organization (WHO, 2024) estimates that (CAD) accounted for 13% of global deaths in 2021. Moreover, according to Global Burden of Disease, about 350,000 deaths are thought to occur annually (Noverike et al., 2024). Furthermore,

according to the Iraqi Ministry of Health (MOH), CHD is the most common disorder that can cause sudden cardiac death or hemodynamic instability (Abdul-Hussein & Hattab, 2022). The predominant form of heart disease is coronary artery disease, also known as ischemic heart disease (IHD) or atherosclerotic heart disease (Aljanabi & Hassan, 2020).

Percutaneous coronary intervention (PCI) is a standard therapy used to treat CAD (Rgeeb, 2013). It is a minimally invasive procedure that improves blood flow to the heart and preserves arterial patency by inserting a guide wire into the obstructed artery and then an inflated balloon. Furthermore, the stent is inserted at the time of the balloon to prevent other coronary stenosis (Mustafa et al., 2020). Millions of people have percutaneous coronary intervention every year, and the majority of them are treated with one or more drug-eluting stents (Yeh et al., 2024).

The most prevalent approach in the United States is femoral access, which involves introducing a catheter into the femoral artery in the thigh to reach the heart and arteries (Kaki et al., 2018). Trans-femoral access (TFA) was the preferred choice for percutaneous treatments because of the size of the femoral artery, which allows for more significant catheters and sheaths (Batra et al., 2020).

Patients conducting PCI procedures through the femoral artery access site experience life threatening complications in 2-6% (Al-Bayati & Al-Kassar, 2023). After PCI procedures, the arterial sheath is usually removed after (4–6) hours later. Furthermore, most patients suffer from pain while the sheath is removed (AL-Mussawi et al., 2024). Pain is an aversive sensory and emotional experience associated with potential or actual tissue injury (Bachi & Sadeq, 2022).

The assessment process is a critical step that nurses must undertake when dealing with patients with heart disease (M. H. Al-Hchaim et al., 2022). Through this process, nurses can implement targeted nursing strategies and interventions that align with their vital role in preventing vascular complications.

Consequently, this comprehensive approach significantly contributes to reducing complications associated with PCI (Ali et al., 2022).

Many pharmacological and non-pharmacological techniques have been used to relieve the intensity of pain, as controlled expiratory Pressure of valsalva maneuver is a non-pharmacological technique that can relieve pain by exhaling against a closed airway (Mohammed Mahmoud et al., 2021). The most appropriate controlled pressure is 40 mmHg. However, atypically ranging from 20 to 40 mmHg reduces potential adverse effects and facilitates the technique use (Jung et al., 2024).

AIMS OF THE STUDY

The present intended to evaluate the effect of controlled expiratory pressures on pain intensity during the removal of the femoral arterial Sheath post-PCI.

METHODOLOGY

Designs of the Study:

A quasi-experimental design was conducted in the CCU unit at Al-Najaf Cardiac Center for Cardiac Catheterization and Surgery.

Determination the Sample Size:

The participants in the current study are 128 patients undergoing elective percutaneous coronary intervention. The researcher uses G power analysis at an 80% power, effect size 0.5, and 95% confidence level.

Inclusion Criteria:

The criteria for the selection of the current study sample were:

1. A patient who underwent elective PCI with femoral intervention.
2. Patients who are 18 years old and older for both sexes; this is because the current study focused on adult patients to understand how to perform the maneuver.

3. Patient alert, conscious, and able to communicate verbally because this study used a numeric pain scale to determine pain level during femoral sheath removal.
4. Patients with no history of pain and use analgesic.
5. Sheath sizes 6 F and 7 are PCI's most common sizes.

Exclusion Criteria:

1. Patients with hemodynamic instability during or after PCI
2. Patients who suffer from diabetic neuropathy; this affects the sensation of the pain.
3. Patients who have glaucoma and have recent eye surgery; this is due to the intervention increased intraocular pressure.

Sample Technique:

The study sample selected through the non-probability technique (purposive sample) was allocated into two groups. Each group was (64) patients. The study group was implement controlled expiratory pressure under the pressure 20-40 mmHg to prevent possible complications during the femoral arterial sheath removal. However, the comparative group receive just routine care without any intervention.

Study Instrument:

The researcher adopted a study instrument based on previous scientific and academic literature to achieve study objective. The study instrument is divided into three parts as following:

Part I : Socio-Demographic Data:

The first part of the questionnaire collected the socio-demographic information obtained from the patients post-PCI using interviews. This part includes (5) items such as: (age, sex, marital status, level of education, and occupational status).

Part II : The Clinical Characteristics:

The second section of the assessment tool consists of (7) items, which include smoking, body mass index (BMI), past medical history, duration of present intra-cardiac catheterization (min), catheter size, duration of femoral sheath in site (min).

Part III: Assessment of patients Pain Using Numeric Rating Scale (NRS):

Including several degrees:

- 0 no pain.
- 1-3 mild pain.
- 4-6 moderate pain.
- 7-10 severe pain.

Ethical Considerations:

The ethical agreement sheet was implemented according to the National Research Ethics Committee's (NREC) guidelines for human study at the University of Kufa, College of Medicine; The reference number is 47, dated 30/9/2024 at Al-Najaf Cardiac Center for Cardiac Surgery and Cardiac Catheterization. Additionally, before starting the data collection process, the researcher introduced himself in the first interview with the participant, explaining the study's aims and benefits, confirming the patient's confidentiality and the freedom to withdraw from the current research without any changes in nursing care.

Methods of Data Collection:

The researcher conducted face-to-face interviews following percutaneous coronary intervention to gather sociodemographic characteristics and clinical data. Concerning the assessment of pain intensity, the researcher enquired of the patients regarding the severity of pain experienced during the femoral sheath removal. The data collection method commenced from 16th October to 1st December, 2024.

The Statistical Analysis:

The current study's data were analyzed using the Statistical Package of the Social Sciences (SPSS), version IBM 26, and Microsoft Excel (2016). The data is analyzed through the application of two statistical approaches, including descriptive and inferential data analysis methods, as follows:

1. Descriptive Statistical:

- Frequency and percentage tables
- Mean and standard deviation.
- Bar chart.

2. Inferential Statistical: Mann-Whitney U test: to test the difference between two groups.

RESULTS

Table (1) illustrates the distribution of the demographic characteristics in both study and comparative groups. Regarding the participant's age, the higher percentage (32.8% and 28.1%, respectively) in both study and comparative groups were 59–64. The mean age for the study group was (59.10) years old, while the comparative group was (58.96).

Concerning sex, most participants (53.1% and 48.4%, respectively) in both the study and comparative groups were female. The results showed that most participants (85.9% and 90%, respectively) were married in both study and comparative groups.

Regarding occupation, a higher percentage of PCI patients (43.8%) were housewives or jobless in the study group. In this regard, the majority of the sample in the comparative group (42.2%) were private or self-employed. Table (2) demonstrates the clinical data of both study and comparative groups. Regarding the smoking status, the majority of the participants (50.0% and 46.9%, respectively) for both the study and comparative groups were nonsmokers. Regarding past medical history, the majority of participants (57.8% and 45%, respectively) suffered from hypertension in both the study and comparative groups. Also, regarding sheath size, the majority (82.8% and 79.7%, respectively) of the study and comparative groups were 6F sheath. Table (3) demonstrates the levels of patients' pain in both study and comparative groups. The results show that a higher percentage (75.0 reported no pain during the femoral sheath removal in the study group.

Additionally, (18.8%) of the patients have moderate pain, and (6.2%) of the participants have mild pain. On the other hand, patients in the comparative group had mild, moderate, and severe levels of pain (9.4%, 54.7%, 35.9 %), respectively. Table (4) indicates that there is a highly significant

difference between the study and comparative groups regarding pain intensity after the intervention at a p-value (0.05).

DISCUSSION:

The current study aimed to assess the effect of controlled expiratory pressures on pain intensity during femoral arterial sheath removal following percutaneous coronary intervention (PCI). The study findings indicate a notable decrease in pain intensity in the study group relative to the comparative group. Regarding the pain levels during the removal of the arterial sheath, the study findings stated that most participants (54.7%) had moderate pain in the comparative group. In comparison, (75%) of the patients in the study group reported no pain. The study conducted by Sokhanvar et al., (2023) reported that the majority of participants (43.3%) had high pain tolerance in the control group, while (46.7%) had moderate pain in the intervention group.

Also, the findings of the present study corresponded with the Iranian study carried out by (Ghods et al., 2022), they reported that the pain and discomfort major complainant during femoral sheath removal, the majority of participants (40%) in the control group had moderate pain and (66.70%) in the intervention group had mild pain. Additionally, a significant reduction in pain intensity under the controlled expiratory pressure of the valsalva maneuver at ($p\text{-value} < 0.001$). Additionally, the study done by Saputra & Kasiman, (2020) reported that the results showed a significant reduction in the levels of pain before and after the intervention of the controlled expiratory pressure of the valsalva maneuver for insertion fistula pain in patients receiving hemodialysis at $P\text{-value} < 0.001$.

Also, the study conducted by Paulsamy et al., (2021) showed a significant reduction in pain levels among patients who implemented controlled expiratory pressure of the valsalva maneuver compared with the control group at $p\text{-value} < 0.01$. In addition, the findings of the current study are

concordant with a study performed by Alan & Khorshid, (2022) indicated a reduction in pain levels in the intervention group relative to the control group.

Study Limitation:

No limitations affected the generalizability of the study results, as the research utilized reliable instruments.

CONCLUSIONS:

The current study concluded the expiratory controlled pressure was very effective non pharmacological method on managing pain during the removal of femoral sheath post- percutaneous coronary Intervention.

RECOMMENDATIONS:

The current study recommends that controlled expiratory pressure of the valsalva maneuver should be utilized for pain management and during the removal of the femoral arterial sheath; further research is advised to investigate its clinical applicability and long-term advantages.

Funding Information:

The authors of this manuscript supported all research-related costs.

Conflicts of Interest:

Lack of any potential conflict of interest.

Acknowledgement:

The researcher expressed thanks to every patient who participated in the current study.

REFERENCES:

- Abdul-Hussein, H. N., & Hattab, W. A. A. (2022). Effectiveness of Pain Management Educational Program on Nurse's knowledge toward Chest Pain Management for Patients with Acute Myocardial Infarction. *Kufa Journal for Nursing Sciences*, 12(1).
- AL-ASHOUR, I. A., Al-Hchaim, M. H. S., & Abdullah, A. M. (2024). Impact of Coronary Artery Disease on Patient Functional Status in Al-Najaf City. *Latin American Journal of Pharmacy*, 43(Special Issue, Part 1), 264-270.
- Al-Bayati, H. M., & Al-Kassar, R. A. H. (2023). Effect of Direct Cold Compress for Femoral Arterial Sheath Removal on Reduction of Local Vascular Complications in Patients after Percutaneous Coronary Intervention: A Randomized Controlled Trial. *Kufa Journal for Nursing Sciences*, 13(2), 99–110.
- Al-Hchaim, M. H., Abdullah, A. M., & Abd Ali, D. K. (2022). Relationship Between Exercise Training and Quality of Life in Heart Failure Patients. *Al-Rafidain Journal of Medical Sciences* (ISSN 2789-3219), 2, 115–121.
- Al-Hchaim, M. H. S. (2018). IMPACT OF ISCHEMIC HEART DISEASE ON PATIENT FUNCTIONAL STATUS. *GSJ*, 6(7), 810.
- AL-Mussawi, G. A., Baqer, M. M., & Jubouri, A.-. (2024). Effect of Aromatherapy on Pain Intensity for Patients Undergoing Arterial Sheath Removal after Percutaneous Coronary Intervention: A Randomized Controlled Trial. *Pakistan Journal of Life and Social Sciences (PJLSS)*, 22(1), 1427–1436. <https://doi.org/10.57239/pjlss-2024-22.1.0096>.
- Alan, N., & Khorshid, L. (2022). Evaluation of efficacy of valsalva maneuver during peripheral intravenous cannulation on pain. *Pain Management Nursing*, 23(2), 220–224.
- Ali, B. R. M., Al-Ashour, I. A., Al-Hchaim, M. H. S., Aljanabi, M. A., & Kadum, J. F. (2022). Evaluation of Nurses' Performance Regarding Intravenous Cannulation. *Pakistan Journal of Medical & Health Sciences*, 16(08), 549.
- Aljanabi, M., & Hassan, H. (2020). Effectiveness of nursing intervention on physiological status for patients undergoing coronary catheterization. *Kufa Journal for Nursing Sciences*, 10(1), 1–11.
- Bachi, G. E., & Sadeq, A.-F. (2022). Association between Vital Signs Fluctuations and Pain Severity among Critically-ill Patients. *Kufa Journal for Nursing Sciences*, 12(2), 47–59.
- Batra, M. K., Rai, L., Khan, N. U., Mengal, M. N., Khawaja, S., Rizvi, S. N. H., Saghir, T., Qamar, N., Sial, J. A., & Karim, M. (2020). Radial or femoral

- access in primary percutaneous coronary intervention (PCI): Does the choice matters? *Indian Heart Journal*, 72(3), 166–171.
- Ghods, A. A., Roshani, A., Mirmohammadkhani, M., & Soleimani, M. (2022). Effects of valsalva maneuver on pain and vasovagal reaction during the removing of femoral arterial sheath after percutaneous coronary intervention: a randomized controlled trial. *Journal of PeriAnesthesia Nursing*, 37(6), 900–906.
- Han, K., Shi, D., Yang, L., Wang, Z., Li, Y., Gao, F., Liu, Y., Ma, X., & Zhou, Y. (2022). Prognostic value of systemic inflammatory response index in patients with acute coronary syndrome undergoing percutaneous coronary intervention. *Annals of Medicine*, 54(1), 1667–1677.
- Jung, J.-Y., Lee, Y.-B., & Kang, C.-K. (2024). Effect of Controlled Expiratory Pressures on Cerebrovascular Changes During Valsalva Maneuver. *Applied Sciences*, 14(22), 10132.
- Kaki, A., Blank, N., Alraies, M. C., Kaji, M., Grines, C. L., Hasan, R., Htun, W. W., Glazier, J., Mohamad, T., & Elder, M. (2018). Access and closure management of large bore femoral arterial access. *Journal of Interventional Cardiology*, 31(6), 969–977.
- Mohammed Mahmoud, H., Elsayed Mosaad, S., & Mohamed Elghareeb, S. (2021). Effectiveness of Valsalva maneuver on pain among patients undergoing peripheral intravenous cannulation. *Egyptian Journal of Health Care*, 12(4), 530–538.
- Mustafa, M. A., Jabbar, D. A., Mohammed, H. Q., Luaibi, S. I., & Al-Ghrebawi, R. H. (2020). Effect of Percutaneous Coronary Intervention (PCI) upon Lung Functions among Patients with Ischemic Heart Disease at Al-Najaf Cardiac Center: Correlation Study. *Indian Journal of Forensic Medicine & Toxicology*, 14(3), 1569–1575.
- Noverike, N., Rahimah, A. F., & Rohman, M. S. (2024). The Complexity of Premature Coronary Artery Disease. *Heart Science Journal*, 5(3), 4–9.
- Paulsamy, P., Alshahrani, S. H., Al-Asbi, G. M., Venkatesan, K., Sethuraj, P., & Chidambaram, K. (n.d.). Effect of Valsalva Maneuver on Pain Perception among Adult Patients Undergoing Spinal Procedures.
- Rgeeb, A. N. (2013). Percutaneous Coronary Intervention In octogerians compared with very young Patients. *Kufa Journal for Nursing Sciences*, 3(1), 118–123.
- Saputra, M., & Kasiman, S. (2020). Valsalva maneuver to decrease pain intensity during arteriovenous fistula insertion in hemodialysis patients. *Jurnal Keperawatan Indonesia*, 23 (2), 136–144.
- Sokhanvar, S., Tirgari, B., Forouzi, M. A., Salari, M., & Jahani, Y. (2023). Effect of Ice Bag Application to Femoral Region on Pain and Vital signs in Patients with Acute Myocardial Infarction Undergoing Percutaneous Coronary Intervention: A Randomized Controlled Trial. *The Open Nursing Journal*, 17(1).
- Yeh, R. W., Shlofmitz, R., Moses, J., Bachinsky, W., Dohad, S., Rudick, S., Stoler, R., Jefferson, B. K., Nicholson, W., & Altman, J. (2024). Paclitaxel-coated balloon vs uncoated balloon for coronary in-stent restenosis: the AGENT IDE randomized clinical trial. *JAMA*, 331(12), 1015–1024.

TABLES & Figures:

Table (1): Distribution of the Participants (Study and Comparative Groups) According to Demographic Characteristic:

| Demographic Data | Rating and Intervals | Statistics | Groups | |
|---------------------|--------------------------|------------|-------------|-------------------|
| | | | Study Group | Comparative Group |
| Age | 41 – 46 | Freq. | 2 | 3 |
| | | % | 3.1% | 4.7% |
| | 47 – 52 | Freq. | 9 | 11 |
| | | % | 14.1% | 17.2% |
| | 53 – 58 | Freq. | 19 | 16 |
| | | % | 29.7% | 25.0% |
| | 59 – 64 | Freq. | 21 | 18 |
| | | % | 32.8% | 28.1% |
| | 65+ | Freq. | 13 | 16 |
| | | % | 20.3% | 25.0% |
| | Mean \pm SD | | 59.10 | 58.96 |
| | | | 6.45 | 7.84 |
| Gender | Male | Freq. | 30 | 31 |
| | | % | 46.9% | 48.4% |
| | Female | Freq. | 34 | 33 |
| | | % | 53.1% | 51.5% |
| Marital Status | Single | Freq. | 1 | 0 |
| | | % | 1.6% | 0.0% |
| | Married | Freq. | 55 | 58 |
| | | % | 85.9% | 90.6% |
| | Divorced | Freq. | 5 | 2 |
| | | % | 7.8% | 3.1 |
| | Widowed/widow | Freq. | 3 | 4 |
| | | % | 4.7% | 6.3% |
| Occupational status | Governmental employee | Freq. | 15 | 10 |
| | | % | 23.4% | 15.6% |
| | Private or self-employed | Freq. | 17 | 27 |
| | | % | 26.6% | 42.2% |
| | Retired | Freq. | 4 | 7 |
| | | % | 6.3% | 10.9% |
| | Housewife\ Jobless | Freq. | 28 | 20 |
| | | % | 43.8% | 31.3% |
| | Total | Freq. | 64 | 64 |
| | | % | 100.0% | 100.0% |

* f.: Frequency, n.: number of sample, % : percentage , SD.: Standard deviation.

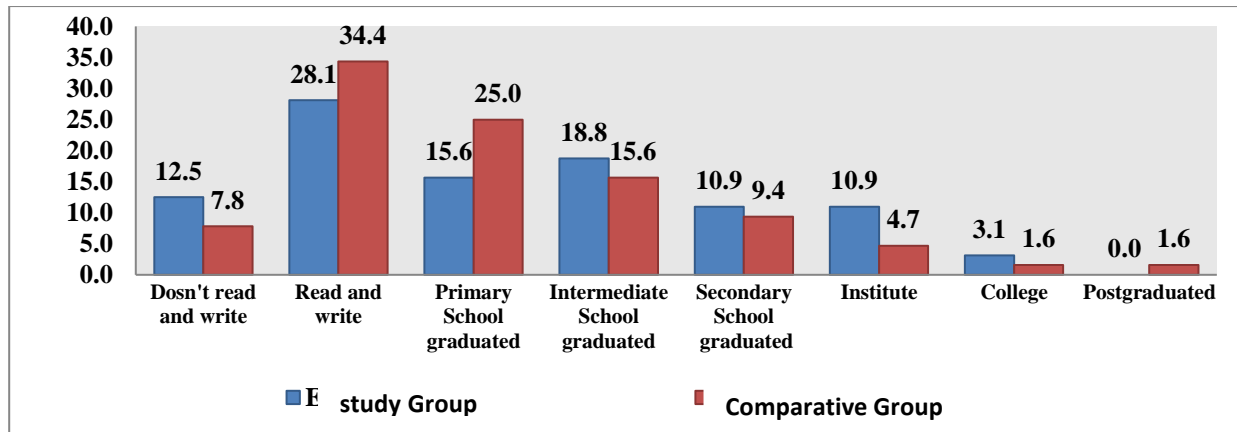


Figure (1): Shows Distribution of the Study Sample According to their Levels of Education

Table (2): The Distribution of the participants (Study and Comparative Groups) According to Clinical Data

| Clinical data | Rating and Intervals | Statistics | Groups | |
|-----------------------------|----------------------|------------|-------------------|-------------------------|
| | | | Study Group: n=64 | Comparative Group: n=64 |
| Smoking | Active | Freq. | 23 | 21 |
| | | % | 35.9% | 32.8% |
| | Passive | Freq. | 9 | 13 |
| | | % | 14.1% | 20.3% |
| | None | Freq. | 32 | 30 |
| | | % | 50.0% | 46.9% |
| Past Medical History | Not Present | Freq. | 12 | 11 |
| | | % | 18.8% | 17.2% |
| | Hypertension | Freq. | 37 | 29 |
| | | % | 57.8% | 45.3% |
| | DM | Freq. | 4 | 7 |
| | | % | 6.3% | 10.9 |
| | Hypertension and DM | Freq. | 11 | 17 |
| | | % | 17.2% | 26.6 |
| Sheath Size | 6F | Freq. | 53 | 51 |
| | | % | 82.8% | 79.7% |
| | 7F | Freq. | 11 | 13 |
| | | % | 17.2% | 20.3% |
| Duration of Sheath\ Minutes | 120 Min. | Freq. | 17 | 17 |
| | | % | 26.6% | 26.6% |
| | 135 Min. | Freq. | 13 | 11 |
| | | % | 20.3% | 17.2% |
| | 150 Min. | Freq. | 34 | 36 |
| | | % | 53.1% | 56.2% |
| Index Procedure | First time | Freq. | 34 | 25 |
| | | % | 53.1% | 39.1% |
| | Second time | Freq. | 19 | 15 |
| | | % | 29.7% | 23.4% |
| | Third time | Freq. | 8 | 12 |
| | | % | | |

| | | | | |
|-------|-----------------|-------|--------|--------|
| | | % | 12.5% | 18.8% |
| | More than third | Freq. | 3 | 12 |
| | | % | 4.7% | 18.8% |
| Total | | Freq. | 64 | 64 |
| | | % | 100.0% | 100.0% |

* f.: Frequency, n.: number of sample, % : percentage.

Table (3): Assessment of Pain Intensity during Removal of Femoral Sheath for Study and Comparative Groups

| Pain Intensity assessment | Statistics | Groups | |
|---------------------------|------------|--------------------|---------------|
| | | Experimental group | Control group |
| None | Freq. | 48 | 0 |
| | % | 75.0% | 0.0% |
| Mild | Freq. | 12 | 6 |
| | % | 18.8% | 9.4% |
| Moderate | Freq. | 4 | 35 |
| | % | 6.2% | 54.7% |
| Sever | Freq. | 0 | 23 |
| | % | 0.0% | 35.9% |
| Total | Freq. | 64 | 64 |
| | % | 100.0% | 100.0% |

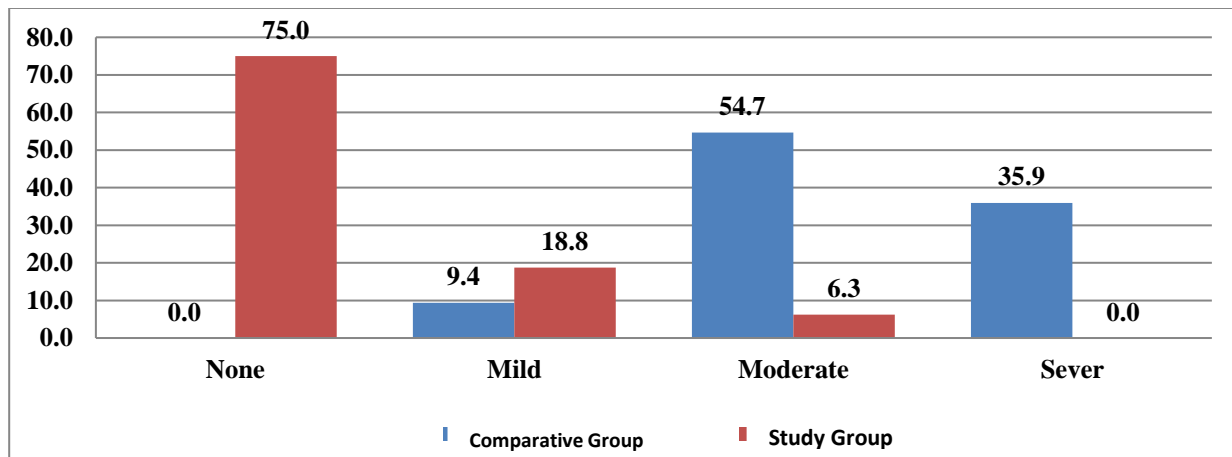


Figure (2): Assessment of Pain Intensity for both Study and Comparative Groups during Removal of Femoral Sheath

Table (4): Significant Difference between Study and Comparative Groups regarding Pain Intensity

| Pain Intensity | Groups | N | Mean Rank | Sum of Ranks | Mann-Whitney U | p-value |
|----------------|-------------------|-----|-----------|--------------|----------------|---------|
| | Study group | 64 | 45.0 | 2880 | 800.0 | 0.000 S |
| | Comparative group | 64 | 84.0 | 5376 | | |
| | Total | 128 | | | | |