Interventional Cardiology Journal
ISSN: 2471-8157

Open Access Research Article

Prevalence of Pain and Access Complications Following Percutaneous Coronary Intervention *via* Radial Artery Access

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ABSTRACT

Background: Post procedural pain is underestimated problem that usually is overlooked. In this study the focus is on prevalence of access-site pain and complications after Percutaneous Coronary Intervention (PCI) *via* radial artery access.

Material and methods: The data (demographic and periprocedural) of selected patients (n=161) 60.9% males and 39.1% females, who underwent elective PCI were collected prospectively and analysed in 2019. Verbal analogue scales were used to evaluate pain intensity after 2, 12, 24, 48 hours, 1 and 3 months after PCI.

Results: Access-site pain during the PCI procedure occurred in 29.8%. In 17.4% of cases moderate pain was persisting immediately after the procedure ($p<0.05$).

After 2, 12, 24, 48 hours pain was felt accordingly in 54%, 38.5%, 16.8%, 10.6% cases and it was moderate ($p<0.05$). 1 week and 1 month after the PCI procedure 7.5% of patients felt strong site pain. Chronic pain developed in 3.7% of patient and it was moderate. Compilations were arterial bleeding (9.3%), hematoma (26.7%), hand swelling (66.5%) and neuropathy (6.32%).

Conclusion: During 3-month period of time after PCI most patients experienced moderate pain. Despite that the access-site pain intensity was decreasing, post-procedural acute pain developed. Chronic pain developed in 3.7% of patients after PCI. Most common site complications were hematoma, arterial bleeding and hand swelling.

Keywords: Percutaneous coronary intervention; Acute pain; Chronic pain; Radial artery

INTRODUCTION

The most common method used to diagnose and treat diseases caused by coronary arteries pathology is Percutaneous Coronary Intervention (PCI), because of it's relatively easy and fast performance, short patient's recovery time, immediate treatment effect and early patient's mobilization after procedure. Today, the method of first

Received:	06-December-2019	**Manuscript No:**	IPIC-24-3032
Editor assigned:	11-December-2019	**PreQC No:**	IPIC-24-3032 (PQ)
Reviewed:	25-December-2019	**QC No:**	IPIC-24-3032
Revised:	21-June-2024	**Manuscript No:**	IPIC-24-3032 (R)
Published:	19-July-2024	**DOI**	10.21767/2471-8157.10.06.51

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Citation: Brogiene L, Baksyte G, Klimaite A, Paliokas M, Macas A (2024) Prevalence of Pain and Access Complications Following Percutaneous Coronary Intervention via Radial Artery Access. Interv Cardiol J. 10:51.

choice for PCI is Trans-Radial (TR) approach, because of lower risk of complications related to puncture site comparing with Trans-Femoral (TF) approach. In spite of PCI benefit to the patient and it's conducting security this procedure can also cause negative outcomes, which are rare but can cause debilitating conditions. The present studies describing these possible complications: Acute artery spasm, thrombosis, occlusion, difficult to controlled arterial bleeding (this can cause formation of hematoma, it's spreading, also compartment syndrome), pseudoaneurysm, arteriovenous fistula, nerve damage or infection, which rate of manifestation, according to literature sources, varies.

There is still lack of information about other conditions after this procedure. One of them is access-site pain syndrome after PCI. Post-procedural pain can occur after any procedure that causes actual or potential tissue damage and individuals who undergo potentially painful procedures must have optimal pain management before, during and after the procedure.

However, recently presents a growing number of clinical cases describing precisely debilitating pain syndromes as complex regional syndrome and some studies that describes prevalence of acute pain after PCI at intervention site. Acute post-procedural arm pain occurs approximately in 1 out of 20 patients after PCI *via* trans-radial approach. Several studies reported severe peri-procedural pain with prevalence of 4.49%-9.57%.

Chronic pain development after the procedure in literature described as rare condition and its prevalence is low. Important thing is that this rare state is very disturbing patient's everyday life with restriction of ability to work and it is hard to treat.

Post procedural pain and its management is underestimated problem that usually overlooked. Our aim is to focus on prevalence of access-site pain and complications after PCI *via* radial artery access [1].

MATERIALS AND METHODS

This is a prospective observational longitudinal study. The data collected of patients, who underwent elective PCI procedure using trans-radial access in hospital of Lithuanian university of health sciences department of cardiology and analysed in 2019. All patients were informed properly and gave their written consent to participate in our study, which protocol was approved by the local institutional bioethics committee (protocol number BEC-MF-328). Primer outcome is to identify acute and chronic pain prevalence and complications and second outcome observe assessment and management of the pain (pain relieve medication given/not given) after PCI procedure *via* radial artery access.

Patients (n=161) who underwent scheduled PCI procedure were included and followed up them for 3 months. The demographic (patients age, gender, body mass index >25, anxiety (yes/no) before procedure, smoking, arterial hypertension, diabetes mellitus, dyslipidaemia, depression, rheumatoid arthritis, carpal tunnel syndrome and other comorbidities) and peri-procedural (intervention duration, changing location of intervention during procedure, arterial bleeding from puncture site, hand swelling, intervention wound pressure time after PCI, hematoma in puncture site, pseudoaneurysm, arterial thrombosis, arteriovenous fistula, neuropathy, intervention site infection, pain before, during and after the procedure) data were collected prospectively. Patients with limitation of self-expression or having emergency PCI procedure, a severe psychiatric illness or <18 years old patients were excluded.

Pain Assessment

Patients were asked about paint appearance at the intervention site after PCI. For each patient who presented with pain evaluation questions were assessed (pain location, spreading, nature, intensity, occurrence circumstances, reducing/increasing factors, accompanying signs) [2]. Patients evaluated their pain nature by choosing one of these provided options: Dull, burning, prickling, tight, uncomfortable. Pain manifestation and duration time was divided in three groups: Acute post-procedural pain (pain occurred during first 48 hours after PCI), acute prolonged pain (patients felt pain more than 48 hours, but less than 3 months after PCI), chronic pain (pain lasted more than 3 months after PCI). Pain intensity was evaluated according to Verbal Rating Scale (VRS): No pain-0, mild-1, moderate-2, severe-3, very severe-4 and worst possible pain-5 after 2, 12, 24 and 48 hours in hospital settings and they were interviewed after 1 week, 1 and 3 months after PCI when they were discharged (**Figure 1**). Patients were followed for other manifested complications (bleeding from puncture site, hematoma, etc.). We contacted with each patient personally by telephone after 1 week, 1 and 3 months after PCI. Pain management was recorded from the medical notes and during the interview after discharge from the hospital.

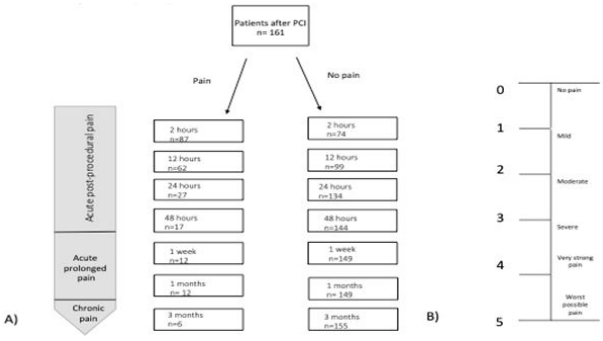

Figure 1: Pain assesment and pain intensity. A) Distribution of patients in the follow up sample, B) Intensity according to Verbal Rating Scale (VRS).

PCI Procedure and Haemostasis

Access method, sheath size, shape of guiding catheter, medical therapy, other materials are left to the discretion of the operator. During our research PCI was provided by performing catheterization through radial artery of the right or left hand. When TR method was used, the first step before

puncture was to find the needed artery by anatomical orientations and palpation. Before providing PCI, local aesthetic medicament is being injected underneath the skin (lidocaine solution 0.5 ml-1 ml, 1%) the operator would puncture the radial artery with the introducer needle through the Seldinger technique [3]. Haemostasis was provided by applying pressing bandage on the wrist on the puncture site and it was keeping tight after intervention for 17.98 (± 6.16) hours. It should be noted that the bandage was started to release after 4 hours and continuous releasing, until it was safe to remove it completely.

Pain Management

Pain medication was given as needed by the ward medical staff and was recorded in drug chart.

Statistical analysis: Data analysis was performed with SPSS statistical software (v. 20.0 IBM). Normally distributed continuous variables were presented as mean ± SD and univariately compared using student t test. When the distribution is not normal, median along with first (Q25) and third quartiles (Q75) were presented and the groups were compared using a Wilcoxon rank sum test. Categorical data was presented as frequency and percentage and were statistically tested using the *chi-square* test or the Fisher's test, Mann-Whitney where appropriate. Missing data points were not imputed. All differences were considered statistically significant at a p less than 0.05.

RESULTS

In the study 60.9% males (n=98) and 39.1% females (n=62) were enrolled. Patients mean age was 66.23 (± 10.59) years and there was significant difference found between males 63.13 (± 10.24 yrs.) and females 71.05 (± 9.32 yrs.), p<0.001. In age groups <55 and 60-64 years PCI was performed more in males than females and in ≥ 75 years group more in females than males (**Figure 2**).

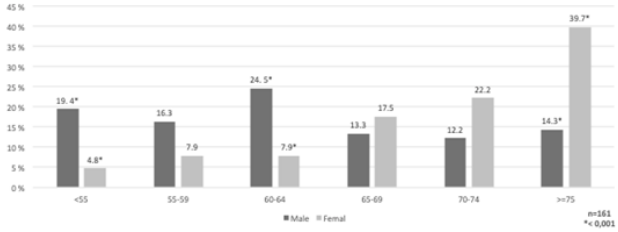

Figure 2: Distribution of patients (%) by gender in age groups.

Patient's demographic and clinical data is showed in the **Table 1**. There was found no difference between gender and age groups according to comorbidities, body mass index [4]. All patients had history of ischemic heart disease and the median was 7 (2-15) years.

Table 1: Patient demographics and clinical data.

Variable	No. (%) of patients (n=161)
Gender (female/male)	63 (39.1)/98 (60.9)
Mean (range) age (years)	66.23 (± 10.59)
Diabetes mellitus	27 (16.8)
Smoking (female/male)	4 (6.3)/46 (46,9)✣
Dyslipidemia	92 (57.1)
Arterial hypertension	127 (78,9)
Tunnel carpal syndrome before procedure	5 (3.1)
Median of IHD (years)	7 (2-15)
Depression	2(1.2)
Rheumatoid arthritis	4(2.5)
Body mass index (kg)	28.62 (± 4.77)
Median duration of the procedure (minutes)	25 (20-40)
Mean time of the bandage removal (hours)	17.98 (± 6.16)
First time preformed PCI	96 (59.6)
Anxiety before the procedure (female/male)	19 (11.8)/16 (9.9)✣
Pain before the procedure in puncture site	5 (3.1)

Note: *Except otherwise indicated ✣ p<0,001

Access-site complication after PCI established in 28.6% (n=46) of patients (Table 2). Hematoma occurred in 26.7% (n=43) of cases and statistically more in females then males accordingly 14.9% (n=24) *vs.* 11.8% (n=19).

Table 2: Access-site complications after procedure.

Variable	No.(%) of patients (n=161)
Arterial bleeding	15 (9.3)
Hematoma	43 (26.7)
Neuropathy (objective findings)	10 (6.2)
Hand swelling	107 (66.5)
Changing location of intervention during procedure	5 (3.1)

According to medical records, post-procedural pain management (pain relieve) was performed only, when patients were self-referring about the pain to ward medical staff. There is no post-procedural pain assessment and management protocol on the ward. In all cases pain management started with non-steroidal drugs (ketoprofen intravenous or intramuscular) [5]. If it was not helping to reduce the pain, strong opioids as morphine were chosen.

Access-site pain during the PCI procedure occurred in 29.8% (n=48) of patients. For 2.5% (n=3) pain medication (strong opioid) were given (p<0.01). Immediately after the procedure 28.6% (n=46) of patients felt moderate pain (median 2 (2-3)) which was dull (35%), burning (10%) and prickly (28%). 12.4% (n=20) patients who felt pain during the procedure had no pain immediately after the procedure, but in 17.4% (n=28) of cases continuous moderate pain was found (p<0,001).

After 2 hours moderate pain (median 2 (2-4)) was felt in 54% (n=87) of patients which was mostly encroaching (41%), dull (25%) and prickly (23%) by nature (Figure 3). For 5.7% (n=8) of patients' pain medication (non steroids, anti-inflammatory) were given and in 62.5% (n=5) of cases they relieved the access-site pain.

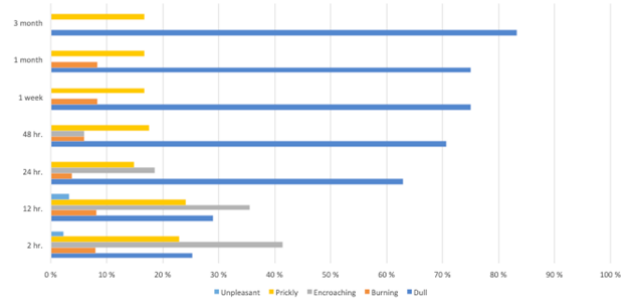

Figure 3: Distribution (%) of the nature of pain in time after PCI.

After 12 hours moderate pain (median 2 (1-2)) was felt in 38.5% (n=62) of patients. To 11.2% (n=7) patients were given pain medication and in 85.7% (n=6) of cases pain was relieved. Pain by nature was mostly encroaching (35.5%), dull (29%) and prickly (24.2%).

After 24 hours pain was felt in 16.8% (n=27) of patients and intensity was moderate (median 2 (1-3)). Four patients (14.8%) get pain medication (anti-inflammatory, strong opoids) and in 50% (n=2) it helped to relieve the pain. 48h after 10.6% (n=17) patients was in pain, intensity was moderate (median 2 (1-4)); 23% (n=4) received pain medication (anti-inflammatory) and in 75% of cases it was effective. 1 week after the PCI pain occurred in 7.5% (n=12) of cases and intensity was strong site (median 3 (1-4)). For 41% (n=5) pain medication was given and in 80% (n=4) of cases it helped. 1 month after the PCI procedure 7.5% (n=12) of patients felt pain and it was moderate intensity pain (median 2 (1-2)). For 16.6% (n=2) pain medication was given and in 50% (n=1) of cases it was effective.

During the 1-month period access-site pain intensity (Figure 4) statistically significantly was decreasing, despite that, chronic pain developed in 3.7% (n=6) of patients and it was mild-moderate by intensity (median 1.5 (1-3)) and dull (83.3%) or prickly (16.7%) by nature [6]. Only one patient reported, that he was prescribed pain medication (anti-inflammatory) and it was effective.

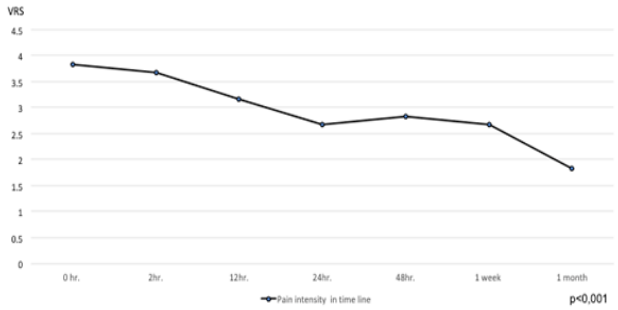

Figure 4: Pain intensity during 1 month period. 0 hr-pain immediately after PCI; VRS-Verbal Rating Scale.

DISCUSSION

Ischemic Heart Disease (IHD) is widespread life-threatening condition and in women develops 10 years later compare with men. In our study we have more males than females, but distribution in age group is different. In age group >65 years, we have more female than males who undergo PCI procedure. We observed that first time PCI procedure was performed in 59.6% patients and statistically more in females than males. In literature we can find gender differences regards IHD and that more attention is given to male patients. Recent studies summarized, that risk factors of IHD in women is underestimated. Women are less likely to be referred for functional testing for IHD, there are lower rate of diagnostic PCI performed.

Radial access highly reduced vascular complications compare with femoral access. However, radial access can be associated with complications such as hematoma, pseudoaneurysm, artery occlusion or spasm [7]. In the same time, we have studies coming up, that describing upper extremity disfunction with prevalence up to 9.6%.

Cheng, et al., reported that female gender associated with higher presence of bleeding during haemostasis and ecchymosis. Complications in our study was arterial bleeding, hematoma, neuropathy and swelling. We found no difference between females and males in hand swelling onset, but significantly more women developed hematomas after PCI compared with men. These results show that medical staff should pay more attention to female gender in order to avoid access-site complications.

In literature, higher pain sensitivity observed in females than males and population-based studies show bigger pain prevalence among women relative to men either. These findings are explained by the biological and psychosocial mechanisms. However, results from post-procedural or post-surgical pain studies in gender differences varies and they are contradictory. Some studies indicate a higher pain intensity among men's, other among women's population. In our study there was no differences among gender according to pain intensity or pain prevalence, while male percentage was higher compare to female [8]. Notable, that females in our study felt more anxiety compare to males. In most literature anxiety is identified as a risk factor for acute pain development after surgery.

Acute pain is caused by injury, surgery, illness, trauma or medical procedures lasting for short period of time and disappears when the underlying cause is healed. Access-site pain after PCI mostly can be caused by vascular complications (ischemia, thrombosis, spasm), direct or indirect nerve damage, post-procedural site pain care (haemostasis). Prolonged or inappropriate compression at the puncture site of radial artery may result in damage or injury of radial sensory nerve, causing the pain or hand dysfunction. Radial compression may result in blood flow reduction into the surrounding tissues such as muscles. Studies shows how lactate released from ischemic muscle may cause ischemic pain by acting sensory neurons that innervates muscles [9].

Dharma, et al., in the retrospective study concluded that the prevalence of site pain is 4.5%. Pain was evaluated 1 day after procedure and authors highlighted, that initial data collection was not set to collect all the data that might interact with forearm pain.

In other study from Cheng Ka Yen, et al., post procedure pain was evaluated after 3 and 24 hours. They found that pain intensity after 3 hours was 0-71 (range 0-100) and the median was 9. After 24 hours pain intensity was decreasing 0-40 (range 0-100), but more than 50% of patients were in pain [10].

We find that acute pain prevalence during the time period was changing, highest point was during 12 hours after that it was decreasing, but the intensity remained moderate according to VRS. The nature of pain was dull, prickly, burning and encroaching and only 3.2% during 12 hours after procedure felt discomfort or unpleasant feeling rather than pain [11].

In 24-48 hours, patient still had pain and the prevalence was up to 16%. The pain intensity was moderate and by nature dull, encroaching or prickly. The nature of pain showing that nociceptive and neuropathic mechanisms can be involved in the pain process. But more detailed studies are needed [12].

In several clinical cases was reported complex regional syndrome, debilitating condition, which can lead to chronic pain state. Chronic pain is defined as continuous, long-term pain lasting more than 12 weeks or after the time that healing would have been expected. In literature chronic pain after PCI it is very rare condition, but exceptionally disturbing patient's daily life and restricting patient's ability to work.

Our study shows 3.7% prevalence of chronic pain after PCI procedure. The most important is to prevent this debilitating condition that can be hard to treat. We know from chronic post-surgical pain studies, that one of the main clinical factors, which is important in prediction of persisted pain development are intensity of acute postoperative pain and percentage of time spent in severe pain [13].

The recognition and good management of acute pain state after PCI procedure is essential. Our study showed, acute postprocedural pain has high prevalence and stay up to one month. Pain medication was given only if patient had complained about pain (self-reported). There is no post-procedural pain management protocol. It can be associated with doctors believes about pain after this particular procedure and cultural issues. Most Lithuanians tend to withhold anxiety, depression or pain. There is spread thinking that after procedure or surgery there should be pain and, in most cases, they will refer pain only if it would be severe. There is a lack of literature and randomized studies assessment and management in topic of post-procedural pain after PCI, especially in complex patients, who has comorbidities and pain management strategy in acute or chronic pain state in patients with IHD or heart failure can be difficult [14].

Different studies report different risk factors for post-procedural pain and most of them are for acute pain after PCI. Those risk factors are low BMI, small wrist, female gender, haemostasis, radial artery occlusion, hematoma, number of access attempts.

Main focus should be on identification of risk factors, which would help to prevent acute and chronic pain after PCI manifestation in the future and will help to create post-procedural pain management protocol or guideline. Limitation is that this study is observational, performed in single centre with small size sample, specific compression devices and were individually applied and not regulated by the researchers [15].

However, it is important to have wider knowledge about acute and chronic post-procedural pain development and management after PCI and further research on assessment, management, risk factors identification is needed.

CONCLUSION

Our study is demonstrating that most of the patients experienced acute post-procedural and acute prolonged pain with moderate intensity after PCI. Despite that the access-site pain intensity was decreasing during 3-month period, post-procedural chronic pain developed in 3.7% of cases. Most common site complications were hematoma, arterial bleeding and hand swelling.

ACKNOWLEDGEMENT

We would like to thank Lithuanian University of Health Science, Department of Cardiology for allowing research data collection.

AUTHORS CONTRIBUTIONS

L. Brogiene designed the research; M. Paliokas and A. Klimaite performed the research; L. Brogiene, M. Paliokas, A. Klimaite analysed the data and wrote the manuscript; G. Baksyte and A. Macas revised the research and made the final approval.

DISCLOSURE

There were no conflicts of interest in this work.

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