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PREVALENCE OF COMPLICATIONS RELATED WITH TRANSULNAR APPROACH IN PATIENTS UNDERGOING ELECTIVE PCI INTERVENTIONS

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Abstract

Introduction: This procedure has evolved to be a popular criterion in elective percutaneous coronary intervention (PCI) thus providing a reliable approach to managing stable coronary artery disease. However, it remains a concern to establish the frequency and the factors that determine complications that are linked with this strategy.

Objectives: To assess the rate of adverse outcomes evolving from the transulnar approach in this population of patients who underwent elective PCI and to determine the factors which affect it.

Materials and Methods: This work was conducted in the Fatima Jinnah Medical University/ Sir Ganga Ram Hospital, Lahore, Pakistan for the six month duration of this cross-sectional study. Patient records of three hundred patients admitted for elective PCI were used in the study. Both demographic and clinical data and procedural data were recorded and major clinical events were defined as bleeding, myocardial injury and vascular complications.

Results: Of 300 patients, 23% had complications, while 12% had bleeding and 8% had myocardial injury. Hemodynamic instability, advance age, raised inflammatory markers and increased clotting time were highly significant to adverse occasions.

Conclusion: The concept of transulnar approach in elective PCI is feasible but requires certain measures to be implemented for the optimization of procedural results.

Keywords: transulnar approach, percutaneous coronary intervention, complications, bleeding, myocardial injury, risk assessment.

INTRODUCTION

Nevertheless, despite promising percutaneous coronary intervention (PCI) results, the translunar approach has appeared as an essential technique in "classical" modern cardiology, including for patients with elective PCI. This conservative approach is familiar for the stabilization of chronic stable angina pectoris, the resolution of clinical consequences, and the enhancement of general patient experience and quality of life (1). However, the difficulties involved with the 'translunar approach," in terms of the number of procedure-based factors and risks involved, need to be better addressed to improve patients' clinical status and their early post-operative rehabilitation (2). One of these strategies includes the ability to carefully manage the risks of full anticoagulant agents and regimens, bleeding, myocardial injury, and technical complications with the benefits of the approach, thus requiring the development of customized risk management strategies for this approach (3). As demonstrated in previous works by Berkowitz et al. and Ramotowski et al., it is crucial to establish personalized innate anticoagulation strategies primarily due to the delicateness of treatment balancing during PCI (2, 3).

Left ventricular myocardial damage continues to be a concern in elective PCI, as it has been shown to be related to both short- and long-term endpoints. In another observational study, planned or unplanned PCI, Silvain et al. pooled patient-level data signifying a significant relationship between procedural myocardial injury infarction and mortality (3). Zhou et al. built upon this, delineating factors linked to periprocedural myocardial injury, including lesion complexity and inflammatory biomarkers, which inform clinical strategies to reduce risk (4). In addition, Mayer et al. investigated the use of novel therapeutic agents such as Revacept and showed that it had the potential to lower platelet activation whilst not worsening bleeding profiles, representing a potential progression in the care for patients undergoing PCI (5). Concerning outcomes in patients with heart failure, the effect of PCI has been extensively discussed. In this study, Parikh et al. showed that even with these procedural intricacies, PCI can result in clinically important improvements in function and quality of life when done on patients with stable ischemic heart disease (6). On the other hand, Waldo et al. also found that they found differences and even variations in the length of hospital stay depending on the prevailing healthcare setting and, more specifically, whether or not they were in a VA hospital or community care setting with regard to the complications (7). These observations assume special significance for the need to fine-tune procedural circumstances and sustain the cohesiveness and standardization of care processes.

Another issue in elective PCI was caused by COVID-19, the pandemic of which impacted various aspects of the (cardiac) surgeries. Keskin et al. investigated whether it was appropriate to delay effective interventions during the pandemic or not and said that timely interventions are vital to avoid the disease’s progression in chosen patients. But, at the same time, they pointed out that strong infection preventive standards have to be maintained to protect the patient as well as the healthcare professionals (8). This period also observed an enhancement in the patient-reported outcomes where Saxon et al. demonstrated differences between physician-estimated and patient-reported angina and pointed out the need for congruency (9). Overall, explanations regarding the generalisability of PCI have been offered by meta-analysis studies. To overcome this limitation, Chacko et al. post hoc divided the population based on stable and unstable CAD and observed that PCI has a favorable effect on mortality and myocardial infarction. But they reported that the degree of benefit was still different, which meant that individualised therapeutic approaches were required to be employed (10). Intensive antiplatelet therapy has become a cornerstone in this regard, with Galli et al. demonstrating the superiority of such an approach over standard therapy in terms of decreasing thrombotic events but with decreased bleeding risks (11).

Both patient characteristics and the indication for PCI are fundamental factors that define the PCI risk profile. There was a trend of providing the patient with better satisfaction and a lower complication rate found by Yang et al. while noting that there was an alignment of procedural indications with the

patient-reported outcome (12). Nichita-Brendea et al. also extended the knowledge about the timing of revascularization in multivessel coronary artery disease, reporting that full revascularization during the index hospitalization had better outcomes than staged revascularization (13). Other papers have also found inflammation biomarkers as predictive factors for complications. Zhao et al. noted that increased inflammatory biomarkers were found to be directly linked with periprocedural myocardial infarction, indicating that anti-inflammatory management of patients at high risk of this complication may enhance their prognosis (14). Last, Sun et al. compared the long-term results of PCI and CABG, stating that although the two methods have their advantages, the use of PCI was more effective for patients with severely reduced left ventricular ejection fraction as the less invasive method showed almost similar effect (15).

Finally, the role of the transulnar approach in elective PCI interventions is considered the most important area of discussion and investigation. Due to these complications the management of RE requires a multidisciplinary team in order to achieve the best results both in terms of safety and efficiency of the procedure. From the findings, in the current studies, more focus has been placed on patient-tailored approaches, rational evidential decision-making processes, and advances in medication and process methodologies. By consistent improvement of research studies and modification of the established best practices, the field can progress toward better and more efficient PCI interventions.

Objective: To evaluate the prevalence and predictors of complications associated with the transulnar approach in patients undergoing elective percutaneous coronary intervention (PCI), focusing on outcomes and risk mitigation strategies for improved patient care.

MATERIALS AND METHODS

Study Design: Cross sectional

Study setting: The study was conducted at Fatima Jinnah Medical University/ Sir Ganga Ram Hospital, Lahore, Pakistan, a tertiary care hospital specializing in cardiac procedures.

Duration of the study: The study spanned six months, from June 2023 to November 2023, allowing sufficient time for data collection, analysis, and interpretation.

Inclusion Criteria

This study only included patients, 18 years and older, who had elective PCI performed using the transulnar approach during the study period. Patients, 60 years or older, with stable coronary artery disease, clear indication for PCI, and complete chart information were considered for study. The use of data that is collected retrospectively has also had the consents given for its usage.

Exclusion Criteria

Patients who underwent urgent or emergency PCI, patients with missing clinical records or poor clinical status including newly diagnosis of active malignancy or other severe systemic diseases were excluded so as to maintain the accuracy and the comparative studies of these elective patients.

Methods

A descriptive research method was adopted in the study in a retrospective manner involving patients who underwent elective PCI through the transulnar approach at NICVD Karachi. Data of patients who met the inclusion criteria were retrieved from patients' records, which captured demographic, clinical, and procedural characteristics. Information on possible confounding factors, including age at onset, gender, other illnesses, and medication taken, were also recorded. The type of stent implanted and the use of anticoagulation in the procedure were also determined together with the time taken in the procedure. The bleeding diathesis, periprocedural myocardial injury, and vascular access site

complications were assessed based on the patient's charts and laboratory reports after the procedure. For correlation purposes, records on inflammatory markers and activated clotting times were also analyzed. The data analysis was done by SPSS computer software and the categorical data rate from frequency with a percentage while the continuous data rate from the mean then the standard deviation. Chi-square and t-tests are used to determine relations and the significance level used was 0.05. Permission to conduct the study was sought from the institutional review board.

RESULTS

A total of 300 patients who underwent elective PCI using the transulnar approach were included in this study. The mean age of the patients was 62.4 ± 10.2 years, with a male predominance (67%). Most patients had stable coronary artery disease (84%), while the remaining had angina refractory to medical management. Table 1 summarizes the baseline demographic and clinical characteristics of the study population.

Table 1: Baseline Characteristics of the Study Population

Characteristic	Value
Mean Age (years)	62.4 ± 10.2
Male (%)	67
Diabetes Mellitus (%)	38
Hypertension (%)	56
Smokers (%)	21

The prevalence of procedural complications was 23%, with bleeding complications (12%) being the most common. Periprocedural myocardial injury occurred in 8% of patients, while vascular access site complications were noted in 3%. The incidence of major adverse cardiac events (MACE) was 2%. Bleeding complications were primarily minor hematomas, while no cases of fatal bleeding were observed. Table 2 provides a breakdown of complications.

Table 2: Procedural Complications

Complication	Incidence (%)
Bleeding (minor)	12
Periprocedural Myocardial Injury	8
Vascular Access Site Issues	3
Major Adverse Cardiac Events	2

A subgroup analysis revealed that patients with elevated inflammatory biomarkers had a higher risk of periprocedural myocardial injury (p=0.03). Similarly, those with prolonged activated clotting times showed an increased likelihood of bleeding complications (p=0.01). Table 3 compares outcomes based on the presence of elevated inflammatory markers.

Table 3: Outcomes Based on Inflammatory Markers

Outcome	Elevated Markers (%)	Normal Markers (%)	p-value
Periprocedural Myocardial Injury	15	5	0.03
Bleeding Complications	20	8	0.01
MACE	3	1	0.20

The findings underscore the importance of personalized risk assessment, particularly in patients with elevated inflammatory markers or coagulopathy, to optimize procedural safety. Adjusting anticoagulation protocols based on real-time parameters and using imaging techniques for vascular access can significantly reduce complication rates. Lastly, while the transulnar approach in elective PCI is generally safe, a subset of patients remains at higher risk for complications. These results emphasize the need for proactive risk mitigation strategies, targeted therapeutic adjustments, and close post-procedural monitoring.

DISCUSSION

The transulnar approach in the management of stable coronary artery disease has made elective percutaneous coronary intervention (PCI) feasible. However, this technique is not without its disadvantages, more so in procedural square miles. To this end, the present study increases understanding of the complication rates related to the transulnar approach and enlightens aspects of its risk factors and possible solutions. Without a doubt, hemorrhagic side effects were identified to be the most prevalent adverse events in this study, whereby 12% of the patients presented bleeding complications. This finding is consistent with prior studies highlighting the bleeding concern with PCI because of anticoagulation therapy. Berkowitz et al. have shown that using fixed doses of heparin may decrease bleeding risks as much as using ACT-guided dosing yet retain similar efficacy in anticoagulation management; this underscores the need to standardize the practice of anticoagulation (1). In a similar vein, Ramotowski et al. observed that increased activated clotting time-definition of anticoagulation activity is associated with increased bleeding risk, so real-time monitoring is crucial for minimizing bleeding episodes (2).

Another acute periprocedural complication of elective PCI is periprocedural myocardial injury, which occurs in 8% of patients. This condition has been described in the literature, and Silvain et al., have highlighted Its relationship with long-term mortality and morbidity (3). Zhou et al. have pointed out factors that predispose to myocardial injury, such as lesion complexity, increased inflammatory response, and longer procedure time (4). Such results indicate that better stratification of high-risk patients prior to the procedure would allow clinicians to either avoid certain procedure time-consuming steps or use more detailed imaging of target vessels to improve stent positioning. Complication prevention has also been discussed concerning novel therapeutic agents. Mayer et al. studied the role of receipt, a platelet glycoprotein VI antagonist, in dampening platelet activity and periprocedural adverse effects. Based on these findings, they conclude that Revacept may replace traditional anti-platelet therapies, especially in high-risk bleeding patients (5). Implementation of such innovations to become part of a normal operation should enhance electoral patients' PCI process.

The differences in outcomes mean that the institutional practices and the resources available within respective healthcare facilities come into focus. Waldo et al. noted that complication rates differ between Veterans Affairs and community care institutions and indicate that better protocols and training are needed to improve procedural safety in dissimilar environments (7). Furthermore, Keskin et al. analyzed the effects of COVID-19 on elective PCI and concluded that delay in intervention might be associated with poor prognosis in patients with stable CAD. This emphasizes the need to keep elective surgery up to date, especially when blockages occur, such as public health concerns, and reducing up-to-date care whilst enforcing strict infection control standards (8).

Both the selection of patients and risk assessment of patients are very important in the determination of the success of PCI. Yang et al. highlighted the role of procedural concordance to patients' expectations and demonstrated that this model enhanced satisfaction and minimized complications (12). Such insights have suggested that PCI should ideally be centered around the patient where key management strategies would depend on patients' risk and volition. In addition, in patients with multivessel coronary artery disease, Nichita-Brendea et al. underlined the advantages of performing complete revascularization during the index hospital admission. Although this approach can be

expensive, the studies suggest that the risk of further interventions and enhanced adverse outcomes will be minimized in the future.

There is an interesting development of inflammatory biomarkers that act as significant markers of PCI complications. Zhao et al. showed that elevated markers were rather associated with periprocedentially occurring myocardial infarction and that addressing the underlying inflammation may reduce the consequences in high-risk patients (14). These results support the emerging literature on how the lack of mitigation of systemic inflammation leads to negative effects on cardiovascular health. Integrating biomarker assessment into routine pre-procedural risk evaluation could potentially improve utility and planning for therapeutic interventions. The long-term prognostic differences and benefits of PCI as an intervention compared with other interventions like CABG are still debatable. Similar to that in patients with moderately reduced LVEF, Sun et al. observed STE-ACS patients with severely reduced LVEF to have comparably equivalent long-term survival irrespective of the choice between PCI and CABG, while the less invasive nature of PCI was a particular advantage (15).

The study also discusses the importance of the therapeutic management of bleeding risk. Optimized anticoagulation regimens are imperative, especially when dealing with high bleed-risk patients. Galli et al. have shown how guided antiplatelet therapy is superior to conventional strategies in preventing thrombotic events with no significant additional risk of bleeding (11). Incorporating such individualized approaches effectively into common clinical practice could potentially decrease adverse event rates and increase patient outcomes. Last, the conclusion of this work supports the ongoing debate on strategies to address the lack of integrated cooperation between varied fields in PCI patients' care. This process can be safety optimized through a team-based approach that includes interventional cardiology physicians, anesthetists, and nurses who could make strong recommendations on methods of managing post-procedural patients. The potential of additional imaging and diagnosis equipment, including intravascular ultrasound and fractional flow reserve, can also improve stent placement and the rate of adverse outcomes.

Lastly, the transulnar approach in elective PCI is mostly safe and effective, but catastrophic risks, including bleeding or myocardial injury, are always a possibility. Findings from this study have implications for the need to develop individualized clinical management plans, specific mechanisms for anticoagulation, biomarker-based risk assessment, and utilization of novel compounds. The dissemination of institutional practices and guaranteeing the availability of protocols at the right time and under conditions that would supposedly make them difficult to access, such as during the COVID-19 outbreak, is especially important for enhancing results. Future studies and development in the field will only enhance the safety and clinical benefits of PCI patients with coronary artery disease.

CONCLUSION

In the elective PCI, the translunar approach provides a reasonable strategy for managing stable coronary artery disease, but it comes with some hurdles. In this work, data revealed a procedural complication rate of 23 percent, with bleeding emerging as the most frequent complication, myocardial injury, and vascular access site complications closely trailing behind. Increased blood levels of inflammation and visibility of markers for clotting were found to significantly increase the risk of adverse outcomes, and the role of individual risk assessment and management was further underlined. To enhance this probability, it is essential to conduct a proper preoperative assessment, appropriate individualized anticoagulation management, and real-time control of various parameters during percutaneous interventions. Additional improvements in imaging, as well as the development of new therapeutic compounds, could still reduce complications and enhance procedural safety. This work underlines the necessity of using the team approach, pinpointing the individual risks of each patient in case. Future investigations should aim to optimize the procedural approaches, evaluate novel management strategies regarding anticoagulation, and discover other prognostic indicators to provide further stratification. With these strategies, the PCI could further enhance the safety and

effectiveness of the treatment so that patients with coronary artery disease receive the best possible care.

References

1. Berkowitz, O., Halabi, M., Goldberg, A., Rosenfeld, I., Sharabi-Nov, A., Regev-Avraham, Z. and Israeli, Z., 2021. Routine fixed-dose heparin vs. ACT-guided heparin administration for elective PCI and its influence on patient in-hospital outcome: a retrospective study. Coronary Artery Disease, 32(6), pp.549-553.
2. Ramotowski, B., Lewandowski, P., Słomski, T., Maciejewski, P. and Budaj, A., 2024. Platelet reactivity and activated clotting time predict hemorrhagic site complications in patients with chronic coronary syndromes undergoing percutaneous coronary interventions. Coronary Artery Disease, 35(4), pp.292-298.
3. Silvain, J., Zeitouni, M., Paradies, V., Zheng, H.L., Ndrepepa, G., Cavallini, C., Feldman, D.N., Sharma, S.K., Mehilli, J., Gili, S. and Barbato, E., 2021. Cardiac procedural myocardial injury, infarction, and mortality in patients undergoing elective percutaneous coronary intervention: a pooled analysis of patient-level data. European heart journal, 42(4), pp.323-334.
4. Zhou, Y., Chen, Z., Ma, J., Chen, A., Lu, D., Wu, Y., Ren, D., Zhang, C., Dai, C., Zhang, Y. and Qian, J., 2020. Incidence, predictors and clinical significance of periprocedural myocardial injury in patients undergoing elective percutaneous coronary intervention. Journal of cardiology, 76(3), pp.309-316.
5. Mayer, K., Hein-Rothweiler, R., Schüpke, S., Janisch, M., Bernlochner, I., Ndrepepa, G., Sibbing, D., Gori, T., Borst, O., Holdenrieder, S. and Kupka, D., 2021. Efficacy and safety of revacept, a novel lesion-directed competitive antagonist to platelet glycoprotein VI, in patients undergoing elective percutaneous coronary intervention for stable ischemic heart disease: the randomized, double-blind, placebo-controlled ISAR-PLASTER phase 2 trial. Jama Cardiology, 6(7), pp.753-761.
6. Parikh, P.B., Bhatt, D.L., Bhasin, V., Anker, S.D., Skopicki, H.A., Claessen, B.E., Fonarow, G.C., Hernandez, A.F., Mehran, R., Petrie, M.C. and Butler, J., 2021. Impact of percutaneous coronary intervention on outcomes in patients with heart failure: JACC state-of-the-art review. Journal of the American College of Cardiology, 77(19), pp.2432-2447.
7. Waldo, S.W., Glorioso, T.J., Barón, A.E., Plomondon, M.E., Valle, J.A., Schofield, R. and Ho, P.M., 2020. Outcomes among patients undergoing elective percutaneous coronary intervention at Veterans Affairs and community care hospitals. Journal of the American College of Cardiology, 76(9), pp.1112-1116.
8. Keskin, G., Khalil, E. and Uysal, A., 2021, January. Should we postpone elective cardiovascular procedures and percutaneous coronary interventions during the COVID-19 pandemic?. In The Heart Surgery Forum (Vol. 24, No. 1, pp. E022-E030).
9. Saxon, J.T., Chan, P.S., Tran, A.T., Angraal, S., Jones, P.G., Grantham, J.A. and Spertus, J.A., 2020. Comparison of patient-reported vs physician-estimated angina in patients undergoing elective and urgent percutaneous coronary intervention. JAMA Network Open, 3(6), pp.e207406-e207406.
10. Chacko, L., P. Howard, J., Rajkumar, C., Nowbar, A.N., Kane, C., Mahdi, D., Foley, M., Shun-Shin, M., Cole, G., Sen, S. and Al-Lamee, R., 2020. Effects of percutaneous coronary intervention on death and myocardial infarction stratified by stable and unstable coronary artery disease: a meta-analysis of randomized controlled trials. Circulation: Cardiovascular Quality and Outcomes, 13(2), p.e006363.
11. Galli, M., Benenati, S., Capodanno, D., Franchi, F., Rollini, F., D'Amario, D., Porto, I. and Angiolillo, D.J., 2021. Guided versus standard antiplatelet therapy in patients undergoing percutaneous coronary intervention: a systematic review and meta-analysis. The Lancet, 397(10283), pp.1470-1483.

12. Yang, J.X., Stevenson, M.J., Valsdottir, L., Ho, K., Spertus, J.A., Yeh, R.W. and Strom, J.B., 2020. Association between procedure appropriateness and patient-reported outcomes after percutaneous coronary intervention. Heart, 106(6), pp.441-446.
13. Nichita-Brendea, M.T., Popescu, M.I., Popa, V. and Carmen, P.C.D., 2021. A clinical trial comparing complete revascularization at the time of primary percutaneous coronary intervention versus during the index hospital admission in patients with multi-vessel coronary artery disease and ST-elevation myocardial infarction uncomplicated by cardiogenic shock. Anatolian journal of cardiology, 25(11), p.781.
14. Zhao, L., Li, Y., Xu, T., Luan, Y., Lv, Q., Wang, Y., Lv, X., Fu, G. and Zhang, W., 2020. Impact of increased inflammation biomarkers on periprocedural myocardial infarction in patients undergoing elective percutaneous coronary intervention: a cohort study. Journal of Thoracic Disease, 12(10), p.5398.
15. Sun, L.Y., Gaudino, M., Chen, R.J., Eddeen, A.B. and Ruel, M., 2020. Long-term outcomes in patients with severely reduced left ventricular ejection fraction undergoing percutaneous coronary intervention vs coronary artery bypass grafting. JAMA cardiology, 5(6), pp.631-641.