The risk factors associated with complications of coronary angiogram: A cross-sectional observational study

Shanila B Rani, Lakshmi R1, Ajith Anantha Krishna Pillai2, Arul Nisha S1

College of Nursing, AIIMS, Rishikesh, Uttarakhand, Departments of 1Medical Surgical Nursing, College of Nursing, 2Cardiology, JIPMER, Puducherry, India

ABSTRACT

Background: Over the years, coronary angiogram (CAG) has evolved to become indispensable diagnostic and therapeutic procedure for coronary artery disease (CAD). The procedure even though minimally invasive with shorter length of hospital stay and low cost has some risk for morbidity and even mortality. Large extents of the risks are dependent on the clinical status of the patient at the time of the study and comorbid illness. Aims: The present study was planned to assess the complications and to identify the risk factors associated with complications among patients undergoing CAG for CAD. Methods: A cross-sectional observational design was used in 250 patients who underwent diagnostic or interventional procedure of CAG through either transradial or femoral route. The convenience sampling technique was used to select the study sample. Results: Majority (32.8%) of the patients were in the age group of 50-59 years, followed by 28.0% of the patients in the age group of 60-69 years. Male preponderance was noted (87.6%). About 6.8% of the participants had developed complications, among them 4.4% had hematoma, 1.2% had vasovagal reactions, and 1.2% had periprocedural myocardial infarction. History of current smoking was identified as risk factor for complications ($P < 0.05$). The risk of complications was higher in percutaneous coronary intervention (PCI) patients, (odds ratio 6.21 [1.96-19.68] at 95% confidence interval) and who had femoral access site ($P < 0.05$). Conclusion: Even as the improved patient outcome is seen with cardiac catheterization, it is not totally free from risk. Newer strategies such as radial approach have managed to reduce the risks considerably. History of smoking, femoral access, and PCI were identified as risk factor for complications following CAG.

Key words: Angiogram, complications of angiogram, hematoma, risk factors, vasovagal effect

INTRODUCTION

Across the globe, cardiovascular disease is responsible for high morbidity and mortality. By 2020, coronary heart disease will become the most common cause of death in India and worldwide. The gold standard for the most accurate diagnosis of cardiac disease is cardiac catheterization, which is quite a safe procedure but it has some risk for morbidity and even death. This study is undertaken to identify the complications and its risk factors so that strategies can be developed to minimize complications after catheterization such
as documenting the types of medicines administered (anticoagulants), maintaining adequate compression at the access site, monitoring access site, providing patient education, and ensuring high-quality patient care. This will ultimately help in improving the patient safety and care.\[4,6\]

**METHODS**

A cross-sectional observational design was used to assess the complications of cardiac catheterization and to identify the risk factors associated with complications among patients undergoing coronary angiogram (CAG). The study was conducted in Coronary Critical Care Unit, Cardiology Wards, Cath Lab and Postcath Recovery Room of a Tertiary Care Centre of South India under Ministry of Health and Family Welfare and an institution of national importance. The study included 250 patients who underwent elective diagnostic or interventional cardiac catheterization and fulfilled inclusion criteria. Sample size was estimated with an expected percentage of patients developing complications as 20%[7] at 5% level of significance and 5% absolute precision. Inclusion criteria were age above 18 years and patients undergoing cardiac catheterization. Exclusion criteria included patients with a history of coagulation and bleeding diseases, impaired skin integrity at the access site, recent history of cardiac catheterization (within a month). The convenience sampling technique was used to select the study sample. Data were collected using participant data sheet for 6 months period (between August 2013 and January 2014). It included items about nonmodifiable risk factors and modifiable risk factors. Checklist was used to assess the complications of cardiac catheterization and also from the written records. Case sheet was used to countercheck the complication and its further management of complication during hospitalization. It included bleeding/hematoma formation, peripheral arterial occlusion, cardiac perforation, allergic reaction, vasovagal reaction, arteriovenous fistula formation, cardiac tamponade, and peri-procedural myocardial infarction (MI). Some of the late complications such as retroperitoneal hematoma, pseudoaneurysm also observed at the time of discharge of the patient from hospital; however, follow-up of this complications was not done.

The clinical data proforma and checklist were developed by the investigator based on the review of the literature. The devised checklist was evaluated by experts from the field of cardiology and nursing. Reliability of the checklist was established through interobserver reliability. The observations on complications and its risk factor for 20 subjects were observed by the investigator and clinical expert. Pearson correlation was established ($r = 0.8$).

Ethical Committee permission was obtained from the Institutional Review Board (Number JIP/IEC/SC/2/335/2013). A written informed consent was taken from all participants. The data regarding risk factors and associated complications was collected through participant data sheet, checklist, and written records. Data were collected from the patients until their discharge after cardiac catheterization. The data analysis was performed using both descriptive and inferential statistics. The distribution of data was expressed as frequencies and percentages. Chi-square test was used to find the association between the risk factors and complications. Data analysis was performed in IBM-SPSS version 19. All statistical analysis was carried at 5% level of significance.

**RESULTS**

Out of 250 patients who underwent cardiac catheterization for coronary artery disease, 32.8% of the patients were in the age group of 50-59 years, followed by 28.0% of the patients in the age group of 60-69 years. Mean age of the participants was $52 \pm 7$ years. Majority of the study participants were males (87.6%) [Table 1].

In case of modifiable risk factors, 4% had body mass index (BMI) ($kg/m^2$) $>30$, 12.8% had stage 2 hypertension, and 39.6% had diabetes. The low-density lipoprotein level was elevated in 9.6% of the patients, 8% had elevated total cholesterol levels, and low levels of high-density lipoprotein levels were noted in 76.4% of the patients. Regarding the smoking status, 15.6% were current smokers and 20.8% ever smokers. 93.6% had acute coronary syndrome, 79.2% had prior percutaneous coronary intervention (PCI), 0.2% had prior coronary artery bypass graft, 55.6% had prior MI, 0.4% had prior stroke, 23.2% had normal coronary vessels, 44.4% had single vessel disease, 6.8% of them had triple vessel disease, and 98% of the patients had left ventricular ejection fraction within 30-50%. In majority of the patients (96.4%) prior thrombolysis was not done, 10.4% of the patients had femoral vascular access, all patients received heparin $>2000$ U, use of mechanical/manual compression was found to be $<1$ h (femoral access) in 99.2% of the patients [Table 1].

Seventeen (6.8%) participants had developed complications. Out of these, 11 (4.4%) had hematoma, 3 (1.2%) had vasovagal reactions, and 3 (1.2%) had periprocedural MI [Figure 1]. No other complications such as retroperitoneal hematoma, arteriovenous fistula, pseudoaneurysm, peripheral arterial occlusion, cardiac tamponade, cardiac perforation, or allergic reaction were reported among the patients who underwent cardiac
Table 1: Distribution of demographic and clinical variables (n = 250)

| Risk factors                              | Frequency (n = 250) | Percentage |
|-------------------------------------------|---------------------|------------|
| Age (in years)                            |                     |            |
| 30-39                                     | 18                  | 7.2        |
| 40-49                                     | 62                  | 24.8       |
| 50-59                                     | 82                  | 32.8       |
| 60-69                                     | 70                  | 28.0       |
| 70-79                                     | 18                  | 7.2        |
| Gender                                    |                     |            |
| Male                                      | 219                 | 87.6       |
| Female                                    | 31                  | 12.4       |
| Body mass index (kg/m²)                   |                     |            |
| <18.5                                     | 6                   | 2.4        |
| 18.5-23                                   | 168                 | 67.2       |
| ≥23                                       | 76                  | 30.4       |
| Random blood sugar (mg/dl)                |                     |            |
| <140                                      | 151                 | 60.4       |
| ≥140                                      | 99                  | 39.6       |
| Serum lipids (mg/dl)                      |                     |            |
| Low density lipoprotein                   |                     |            |
| <100                                      | 226                 | 90.4       |
| ≥100                                      | 24                  | 9.6        |
| Total cholesterol                         |                     |            |
| <200                                      | 230                 | 92         |
| ≥200                                      | 20                  | 8          |
| High density lipoprotein                  |                     |            |
| ≥40                                       | 59                  | 23.6       |
| <40                                       | 191                 | 76.4       |
| Current smoking                           |                     |            |
| Yes                                       | 39                  | 15.6       |
| Ever smoker                               |                     |            |
| Yes                                       | 52                  | 20.8       |
| Number of diseased vessels                |                     |            |
| Nil                                       | 58                  | 23.2       |
| Single vessel                             | 111                 | 44.4       |
| Double vessel                             | 64                  | 25.6       |
| Triple vessel                             | 17                  | 6.8        |
| Left ventricle ejection fraction (%)      |                     |            |
| <30                                       | 4                   | 1.6        |
| 30-50                                     | 245                 | 98         |
| >50                                       | 1                   | 0.4        |
| Prior thrombolysis                        |                     |            |
| Yes                                       | 9                   | 3.6        |
| Use of heparin >2000 U                    |                     |            |
| Yes                                       | 250                 | 100        |
| Femoral vascular access site              |                     |            |
| Yes                                       | 26                  | 10.4       |
| Use of mechanical/manual compression <1 h (femoral access) |                 |            |
| Yes                                       | 248                 | 99.2       |

Figure 1: Coronary angiogram complications

Among 39 patients with the history of current smoking, 7 of them had complications which are significant at the $P < 0.05$ when compared to nonsmokers. Furthermore, among 52 patients who were ever smokers, 8 of them developed complications which are significant at $P < 0.05$ [Table 3].

Out of 93 patients who underwent PCI, 13 patients had developed complications. Compared with CAG patients, the risk of complications was higher in PCI patients (odds ratio [OR] 6.21 [1.96-19.68] at 95% confidence interval [CI]) [Table 4].

Majority of the complications were reported in patients who had femoral access site for undergoing cardiac catheterization. It was found to be statistically significant ($P < 0.05$). History of thrombolysis and external compression <1 h was not found to be related with the development of hematoma. Age was not associated with complications [Table 5].

DISCUSSION

This study was intended to identify the complications and its risk factors following CAG. Common complications reported in this study were hematoma, vasovagal reactions, and periprocedural MI. History of current smoking was identified as risk factor for complications $P < 0.05$. The risk of complications was higher in PCI patients, (OR 6.21 [1.96-19.68] at 95% CI) and who had femoral access site ($P < 0.05$).

Although studies show that elderly patients have a higher risk for getting CAG complications, the same was not reported in this study as the age factor was not associated with complications.[8] 7.2% of young
Complications of coronary angiogram

Table 2: Complications of coronary angiogram (n = 250)

| Complications                  | Frequency (n = 250) | Percentage |
|-------------------------------|---------------------|------------|
| Absent                        | 233                 | 93.2       |
| Present                       | 17                  | 6.8        |
| Hematoma                      | 11                  | 4.4        |
| CAG                           | 3                   | 1.2        |
| PTCA                          | 8                   | 3.2        |
| Vasovagal reaction            | 3                   | 1.2        |
| CAG                           | —                   | —          |
| PTCA                          | 3                   | 1.2        |
| Peri-procedural myocardial infarction | 3               | 1.2        |
| CAG                           | 1                   | 0.4        |
| PTCA                          | 2                   | 0.8        |

CAG = Coronary angiogram, PTCA = Percutaneous transluminal coronary angioplasty

Table 3: Comparison of smoking in relation to the complications of coronary angiogram

| Smoking status | Total Complications | Statistical significance (P) |
|----------------|---------------------|------------------------------|
|                | No (n = 233)        | Yes (n = 17)                 |                              |
| Current smoking|                     |                              |                              |
| Yes            | 39                  | 32                           | <0.05*                       |
| No             | 211                 | 201                          | 0.086                        |
| Ever smoker    |                     |                              |                              |
| Yes            | 52                  | 44                           | <0.05*                       |
| No             | 198                 | 189                          | 0.338                        |

*Fisher exact test

Table 4: Risk for complication in relation to type of procedure (n = 250)

| Type of procedure | Complications | Total | Statistical significance |
|-------------------|---------------|-------|--------------------------|
|                   | No (n = 233)  | Yes (n = 17) | OR: 6.21 (1.96-19.68) at 95% CI |
| CAG               | 153           | 4      | 157                      |
| PTCA              | 80            | 1      | 93                       |

CAG = Coronary angiogram, PTCA = Percutaneous transluminal coronary angioplasty; OR = Odds ratio, CI = Confidence interval

Table 5: Comparison of prior thrombolysis, external compression <1 h, femoral access, in relation to hematoma as a complication of coronary angiogram (n = 250)

| Risk factor                  | No (%) | Yes (%) | Statistical significance (P) |
|------------------------------|--------|---------|-------------------------------|
| Prior thrombolysis           |        |         |                               |
| Yes                          | 8 (88.9)| 1 (11.1)| Fisher exact-0.338 (>0.05)     |
| No                           | 231 (95.9)| 10 (4.1)| 241                          |
| External compression <1 h    |        |         |                               |
| Yes                          | 238 (96.0)| 10 (4.0)| 248                          |
| No                           | 1 (50.0)| 1 (50.0)| 2                             |
| Femoral access               |        |         |                               |
| Yes                          | 22 (84.6)| 4 (15.4)| 26                            |
| No                           | 217 (96.9)| 7 (3.7)| 224                          |

Note: *P value significant

In this study, 6.8% of them had complications. Out of these, 4.4% had hematoma, 1.2% had vasovagal reactions, and 1.2% had periprocedural MI. In a similar study by Alconero Camarero et al. in 153 patients who were subjected to primary angioplasty complications appeared in 39% of the patients (hematoma 28%). Increased BMI, high blood pressure, diabetes mellitus, and elevated cholesterol levels were not found to be significant with respect to complications in the current study; however, studies support the effect of these factors in complications. Smoking status was found to be significant. Patients with history of current smoking (15.6%) and with history of ever smoking (20.8%) developed complications and was found to be significant in this study, the same has been supported in other studies also.

Complications of femoral access following coronary angiography or PCI have been studied extensively. Hematoma formation at the femoral access site was reported in nearly 21% of CAG studies and in nearly 40% of PCIs, respectively. In this study, 15.4% of patients had femoral access which was found to be statistically significant (P < 0.05). Majority of the complications were reported in patients who had femoral access site for undergoing cardiac catheterization. It was found to be statistically significant (P < 0.05). However, the catheter size and operators experience also influence the complications, but in this study, the uniform catheter size, i.e., 5F, 6F catheter were used for radial approach in diagnostic and therapeutic CAGs, respectively. 6F catheter was used for femoral approach in diagnostic and therapeutic CAGs.

The chance of getting complications is 2 times more in PCI patients than in patients who underwent CAG. OR calculated as 6.21 (1.96-19.68). These findings are similar to those conducted by Berry et al. in which he compared femoral site bleeding following diagnostic angiography to coronary interventional procedures. However, this study did not assess the long-term complication following CAG.
CONCLUSION

Even though improved patient outcome is seen with CAG, it is not totally free from risk. Newer strategies have managed to reduce the risks considerably. It was found that patients who had a history of smoking was significant. The study also suggested that compared with CAG patients, the risk of complications was higher in PTCA and patient with femoral access site, hence these patients to be monitored well during, and after the procedure for early recognition of complications.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. World Health Organization. The Global Burden of Disease: 2004 Update. Geneva: World Health Organization; 2008.
2. Subban V, Lakshmanan A, Victor SM, Pakshirajan B, Udayakumaran K, Gnanaraj A, et al. Outcome of primary PCI : An Indian tertiary care center experience. Indian Heart J 2014;66:25-30.
3. Honda T, Fujimoto K, Miyao Y, Koga H, Hirata Y. Access site-related complications after transradial catheterization can be reduced with smaller sheath size and statins. Cardiovasc Interv Ther 2012;27:174-89.
4. Scanlon PJ, Faxon DP, Audet AM, Carabello B, Dehmer GJ, Eagle KA, et al. ACC/AHA guidelines for coronary angiography. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on Coronary Angiography). Developed in collaboration with the Society for Cardiac Angiography and Interventions. J Am Coll Cardiol 1999;33:1756-824.
5. Steffenino G, Dutto S, Conte L, Dutto M, Lice G, Tomatis M, et al. Vascular access complications after cardiac catheterisation: A nurse-led quality assurance program. Eur J Cardiovasc Nurs 2006;5:31-6.
6. Liew R, Liddler S, Gorman E, Gray M, Deaneer A, Knight C. Very low complication rates with a manual, nurse-led protocol for femoral sheath removal following coronary angiography. Eur J Cardiovasc Nurs 2007;6:303-7.
7. Sulzbach-Hoke LM, Ratcliffe SJ, Kimmel SE, Kolansky DM, Polomano R. Predictors of complications following sheath removal with percutaneous coronary intervention. J Cardiovasc Nurs 2010;25:E1-8.
8. Bauer T, Möllmann H, Weidinger F, Zeymer U, Seabra-Gomes R, Eberli F, et al. Predictors of hospital mortality in the elderly undergoing percutaneous coronary intervention for acute coronary syndromes and stable angina. Int J Cardiol 2011;151:164-9.
9. Rao SV, Ou FS, Wang TY, Roe MT, Brindis R, Rumsfeld JS, et al. Trends in the prevalence and outcomes of radial and femoral approaches to percutaneous coronary intervention: A report from the National Cardiovascular Data Registry. JACC Cardiovasc Interv 2008;1:379-86.
10. Al Sadi AK, Omeish AF, Al-Zaru IM. Timing and predictors of femoral haematoma development after manual compression of femoral access sites. J Pak Med Assoc 2010;60:629-5.
11. Kinnaird TD, Stabile E, Mintz GS, Lee CW, Canos DA, Gevorkian N, et al. Incidence, predictors, and prognostic implications of bleeding and blood transfusion following percutaneous coronary interventions. Am J Cardiol 2003;92:930-5.
12. Ammann P, Brunner-La Rocca HP, Angehrn W, Roelli H, Sagmeister M, Rickli H. Procedural complications following diagnostic coronary angiography are related to the operator's experience and the catheter size. Catheter Cardiovasc Interv 2003;59:13-8.
13. Hamon M, Coutance G. Transradial intervention for minimizing bleeding complications in percutaneous coronary intervention. Am J Cardiol 2009;104 5 Suppl:55C-9C.
14. Alconero Camarero AR, Casás Pérez M, Mirones Valdeolivas LE, García Zarrabeitia MJ, García Campo ME, Pérez Bolado C. Descriptive study of vascular complications secondary to antithrombotic agents and percutaneous cardiovascular interventionism in a coronary unit. Enferm Intensiva 2006;17: 96-103.
15. Berry C, Kelly J, Cobbe SM, Eteiba H. Comparison of femoral bleeding complications after coronary angiography versus percutaneous coronary intervention. Am J Cardiol 2004;94:361-3.