

Diltiazem as an antispasmodic drug in radial artery

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Received: 20-08-2020 / Revised: 23-09-2020 / Accepted: 14-10-2020

Abstract

Background: Coronary catheterization is usually performed via the transfemoral approach. Transradial access offers advantages in comparison with transfemoral access, especially under conditions of aggressive anticoagulation and antiplatelet treatment in which bleeding complications at the femoral puncture site can result in increased morbidity and duration of hospitalization. **Aim:** This study was designed to compare the two different doses of IAD (Intra Arterial Diltiazem) during Trans Radial (TR) coronary procedure. **Materials and Methods:** This study is a prospective study, double blinded, randomised study comparing 5 mg (Group-I) versus 10 mg (Group-II) of IAD in patients undergoing coronary procedures. **Results:** Males were more than females in both the groups. The highest number of patients were in age group in both the groups was 50-60 years. Baseline characteristics were comparable between the two groups, There was no statistically significant difference between the two groups in the incidence of pain, spasm, need of additional drugs. In group I, patients needed more hemodynamic support. There was no statistically significant difference between the two groups in the sheath cannulation time. LOC to seath time was 4.2 ± 4.9 mins in group I and it was 3.7 ± 3.6 mins in group II, and the p value was 0.15. S to C time was 3.3 ± 2.5 mins in group I and it was 3.4 ± 3.3 mins in group II and the p value was 0.447 and procedure time was 28.5 ± 18.2 mins in group I and it was 32.4 ± 19.9 mins in group II and the p value was 0.008. **Conclusion:** IAD is an effective antispasmodic agent that can be used in transradial procedures. 5 mg of bolus of diltiazem is as effective as 10 mg.

Keywords: Acute coronary syndrome, Percutaneous coronary intervention, Intra-arterial Diltiazem.

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Introduction

The cornerstone of ischaemic heart disease management is percutaneous revascularization[1,2]. Through the common femoral artery, coronary angiography and intervention was predominantly performed previously. However, this procedure has an associated 1.5–9.0 % risk of complications, most of which are related to bleeding at the femoral access site[3,4]. These major complications remain important, despite a significant reduction in the incidence of major femoral bleeding complications during 1994 to 2005 from 8.4 % to 3.5 % respectively, related to technological advancement (including a reduction in size of interventional devices and, controversially, the introduction of vascular closure devices)[5]. Multiple large studies have shown a two- to eightfold increase in mortality rate in patients with acute

coronary syndrome (ACS) who experienced major bleeding following percutaneous coronary intervention (PCI). In cases of complex peripheral vascular disease and in some patients using anticoagulants, antiplatelets or fibrinolytic drugs, transradial access for percutaneous procedures, in the coronary artery was an alternative to femoral procedures. In decreasing radial artery spasms, the use of antispasmodic drugs has been proven more efficient. This study was designed to compare the two different doses of IAD (Intra Arterial Diltiazem) during Trans Radial (TR) coronary procedure.

Materials and Methods

This study is a prospective study, double blinded, randomised study comparing 5 mg (Group-I) versus 10 mg (Group-II) of IAD in patients undergoing coronary procedures. Total of 669 patients were selected in the study, out of which group I consisted of 320 patients, and group II consisted of 349 patients, All patients were administered with 5000 units of heparin and 100 mg NTG intra-arterially after sheath insertion. 1 cc of 1% xylocaine was used locally, with 1 µg/Kg of fentanyl

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intravenously. Pain, spasm, need for additional drugs, need for hemodynamic support and time between sheath insertion and coronary cannulation were compared in both the groups. Exclusion criteria was previous radial or brachial coronary angiography, continuous use of calcium channel blockers a history of myocardial revascularization, cardiac arrhythmia, ascending aorta aneurysm, valvular disease and congenital cardiomyopathy.

Results

Coronary catheterization is usually performed via the transfemoral approach. The rationale for the transradial approach is the intention to reduce access site bleeding complications, earlier ambulation, and improved patient comfort. Transradial procedures have been demonstrated to be an effective and safe alternative to transfemoral procedures.

Table 1: Sex distribution

Group I		Group II	
Male	Female	Male	Female
272	48	300	49
85%	15%	86%	14%

Table 1 shows that males were more than females in both the groups.

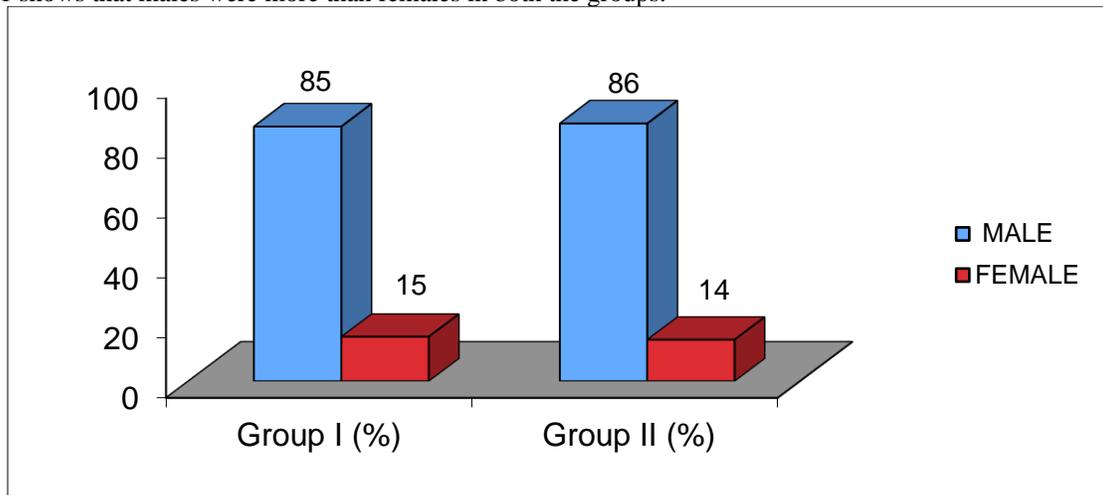


Figure 1: Sex Distribution

Table 2: Age distribution

Group I (%)		Group II n,(%)	
Below 50 years	(23.75%)	Below 50 Years	(24.36%)
50-60 years	(40.94%)	50-60 years	(40.11%)
Above 60 years	(34.38%)	Above 60 years	(34.96%)

The highest number of patients were in age group in both the groups was 50-60 years.

Table 3: Distribution between the groups related to baseline characteristics during treatment

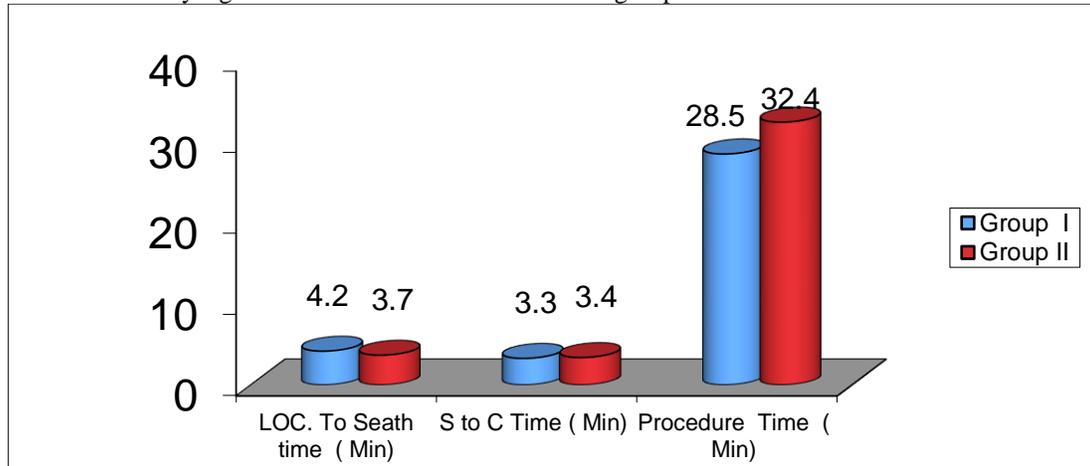
Variable	Groups I (no)	Group II (no)	OR	95% CI of OR
Spasm	16	22	0.782	0.782+0.3338
Pain	9	8	1.234	1.234+0.492
Additional Drugs	12	22	0.579	0.579+0.368
Supports	40	29	1.56	1.56+0.51

Baseline characteristics were comparable between the two groups, There was no statistically significant difference between the two groups in the incidence of pain, spasm, need of additional drugs. In group I, patients needed more hemodynamic support.

Table 4: Distribution between the groups related to variables during treatment

Variable	Group I	Group II	p Value
LOC. To Seath time	4.2 ± 4.9	3.7 ± 3.6	0.15
S to C Time	3.3 ± 2.5	3.4 ± 3.3	0.447
Procedure Time	28.5 ± 18.2	32.4 ± 19.9	0.008

There was no statistically significant difference between the two groups in the sheath cannulation time.

**Fig 2: LOC to seath time, S to C time, procedure time**

Discussion

In the present study, males were more than females in both the groups. The highest number of patients were in age group in both the groups was 50-60 years. Baseline characteristics were comparable between the two groups, There was no statistically significant difference between the two groups in the incidence of pain, spasm, need of additional drugs. In group I, patients needed more hemodynamic support. There was no statistically significant difference between the two groups in the sheath cannulation time. In **Pancholy SB[6]** study, they studied 500 consecutive patients randomly in which an intravenous group (n = 250), received 50 U/kg of unfractionated heparin (maximal dose 5,000 U) intravenously, and an intra-arterial group (n = 250) received the same dose intra-arterially. Intra-arterially, all patients received a vasodilator and underwent cardiac catheterization using a 5F introducer sheath and catheters. At the end of the procedure, the activated clotting time was measured. With a radial compression device (TR Band), all patients received hemostasis which was applied after sheath removal for 2 hours. 30 days after the procedure, a plethysmographic evaluation for RAO was performed at 24 hours. Early RAO occurred in 5.6% (n = 14) of the intravenous group and 6% (n = 15) of the intra-arterial group. The difference was not statistically significant (chi-square = 0.037, p >0.8). Chronic RAO occurred in 3.2%, (n = 8)

of the intravenous group compared to 4% (n = 10) of the intra-arterial group. The difference was not statistically significant (chi-square = 0.231, p >0.6). The activated clotting time was 211 +/- 16 seconds in the intravenous group and 213 +/- 17 seconds in the intra-arterial group, a statistically insignificant difference (t = -1.095, p >0.2).

Ozan Erdem et al; conducted a study in which 140 patients with a total of 361 grafts [205 (57%) arterial and 156 (43%) venous] were selected who underwent isolated coronary surgery[7]. Using transit time flow meter intra-operatively, all the grafts were measured. Group A (n=70) consisted of patients who received diltiazem infusion (dose of 2.5 microgram/kg/min), and Group B (n=70) didn't receive diltiazem infusion. In Group A, mean graft flow values of left internal mammary artery were 53 ml/min, and in group B, it was 40 ml/min (P<0.001). For Group A and Group B, pulsatility index (PI) values of left internal mammary artery were 2.6 and 3.0 respectively (P<0.001). Between venous graft parameters, no statistically significant difference was found. In a study done by **Mohammed Almansori et al[8]** they randomized 150 consecutive patients in which 75 patients received intra-venous heparin and in other group, 75 patients received intra-arterial heparin; the two groups were compared regarding different procedure related parameters. The success rate

was over 99% and rate of radial artery spasm was about 5%. There was no statistically significant difference between the two groups regarding the parameters tested. **Guo-Wei He et al**[9] conducted a study in which All calcium channel antagonists induced a full relaxation (97.8%-100%, n = 5-7 for each), with higher sensitivity ($P = .005$, analysis of variance [ANOVA] among the calcium channel antagonists for the effective concentration of the constrictor [or dilator] agent that caused 50% of maximal contraction [or relaxation]) to nifedipine ($-7.37 \pm 0.20 \log_{10} M$) than nicardipine ($-6.43 \pm 0.39 \log_{10} M$, $P = .1$), verapamil ($-6.08 \pm 0.13 \log_{10} M$, $P = .03$), and dil-tiazem ($-5.87 \pm 0.07 \log_{10} M$, $P = .01$). Pre-treatment with the plasma concentration of the calcium channel antagonists (60 nmol/L for diltiazem and 20 nmol/L for the others) inhibited the potassium-induced contraction (n = 6 for each) by nicardipine (from $138.6\% \pm 5.8\%$ to $101.4\% \pm 7.6\%$, $P = .001$) and nifedipine (to $87.7\% \pm 6.8\%$, $P = .0003$) but not by verapamil (to $140.3\% \pm 15.2\%$, $P = .9$) or diltiazem (to $132.8\% \pm 7.3\%$, $P = .8$), although at higher contractions ($-4.5 \log_{10} M$) all 4 Calcium channel antagonists abolished the contraction. **Jose Ronaldo Mont' Alverne Filho et al**[10] conducted a study in which The radial artery diameter of GI was 2.4 ± 0.5 mm before the procedure and 2.3 ± 0.5 mm after 30 minutes (NS), whereas in GII the diameter was 2.2 ± 0.3 mm before the examination and 2.5 ± 0.4 mm 30 minutes after it ($P < 0.001$). Radial artery output in group 1 was 7.3 ± 5.12 mL/min before the examination and 6.1 ± 3.5 mL/min 30 minutes after the examination (NS), and GII had an increase of 5.9 ± 2.5 mL/min before examination to 9.05 ± 7.78 mL/min after the examination ($P = 0.04$). Complications (spasm, occlusion, and partial obstruction) occurred in 4 patients (17.4%) in GI and did not occur in GII ($P = 0.04$).

Conclusion

IAD is an effective antispastic agent that can be used in transradial procedures. 5 mg of bolus of diltiazem is as effective as 10 mg.

Source of Support: Nil;
Conflict of Interest: Nil

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