Comparison of short- and long term compression after transradial coronary procedures

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Abstract

Background

Rates of transradial coronary procedures are increasing due to substantial benefits compared to the transfemoral approach. There is no standard in type or length of compression.

The aim of the study was to test two different decompression schemes using the TR - band with regard to bleeding complications, vessel occlusion and early patient discharge.

Methods

We compared two successive all - comer groups (n= 331 and n= 324) of patients after transradial coronary procedures between 1st October 2010 and 31st March 2011. The first group underwent compression of the puncture site for 1 hour before pressure was gradually released whereas pressure was maintained for 4 hours in the second group.

Results

No major access site complications occurred in each group.

Rate of minor bleeding was higher after short compression (34 (10.3 %) versus 16 (4.9 %), p = 0.015) after prolonged compression.

Short compression, female sex and use of Tirofiban where associated with bleeding complications.

Rates of vessel patency (98.8 % versus 99.4 %, p = 0.7) were high without any difference between the two groups.

Discharge of elective outpatients was postponed by 3 hours using the longer compression scheme.

Conclusion

Maintenance of high compression pressure over 4 hours leads to a lower frequency of bleedings without increasing rates of vessel occlusion. If no pressure augmentation was needed the discharge of elective outpatients was postponed by 3 hours using the longer compression scheme.

Abbreviations

PCI	Percutaneous Coronary Intervention
SO2	Oxygen Saturation
INR	International Normalized Ratio
LMWH	Low Molecular Weight Heparin
ACS	Acute Coronary Syndrome
STEMI	ST – Elevation Myocardial Infarction
FFR	Fractional Flow Reserve
GP IIb / IIIa	Glycoprotein IIb / IIIa

Introduction

Transradial coronary procedures show clear benefits in terms of bleeding risk, patient comfort and length of hospital stay. Register studies [1, 2] and a meta – analysis of small randomised trials [3] showed reduction in mortality by using the transradial approach compared to transfemoral approach. A large randomised multicenter trial showed mortality benefits for the radial approach in the subgroup of STEMI - patients and if the procedure was performed in a centre with high radial PCI volume [4]. Unpublished register data (Olivecrona G. Lower mortality with transradial PCI compared to transfemoral PCI in 14000 patients with acute myocardial infarction - Results from the SCAAR database. Presentation Euro PCR, Paris, May 20th, 2011) showed mortality benefits in patients with ACS using the transradial approach.

An increasing number of procedures are worldwide performed via radial approach. Hemostasis after radial artery puncture is more reliable compared to all efforts to achieve hemostasis after puncture of the femoral artery, even compared to modern closure devices [5].

Although a large number of procedures are performed via the radial artery it is still unclear how hemostasis can best be achieved. In terms of safety and to avoid bleeding a longer initial compression of the artery and thereafter gradual decompression seems reasonable. The longer and tighter compression is applied to the artery, the higher is the risk of occluding the vessel. Therefore compression - decompression is always a matter of bleeding versus vessel occlusion.

In terms of efficacy the shortest possible compression time is to be found, short enough to avoid bleeding, but long enough to assure safe hemostasis without provoking artery occlusion.

Vessel occlusion is documented in around 1 – 7 % of all cases [6]. In virtually all cases vessel occlusion is fully asymptomatic. Formerly it was and in most departments still is recommended that Allen`s test is to be performed before and in case that Allen`s tests shows assumed single - vessel blood supply to the hand it is considered as contraindicated to puncture the radial artery. In contrast to this, there is emerging evidence that Allen`s test is not needed before radial puncture [7]. There is a very well established collateral flow to the hand that may even be augmented in case of radial artery occlusion. Besides radial approach also ulnar approach is feasible and safe [8 - 10].

Rate of complications after radial approach is low but since numbers are increasing formerly unknown complications beside bleeding and vessel occlusion may more frequently occur like radial pseudoaneurysm [11], nervinjury and regional pain syndromes [12], compartment - syndrome [13],

carpal tunnel syndrome [14] or fistulas [15]. Most of them are rare events and do not hamper the overall benefits of the approach.

The aim of the present study was to find out which decompression scheme was favourable in terms of 1. bleeding complications, 2. rate of vessel occlusion and 3. early patient discharge after transradial procedure.

Results of this study should help to find shortest and best possible treatment after transradial approach.

Methods

In our cathlab right or left radial approach is the preferred access site in all clinical settings ranging from usual diagnostic procedures to PCI in cardiogenic shock.

In the 6 months study period from 1st October 2010 to 31st March 2011 763 procedures were registered, among those 655 via radial approach. PCI rate including pressure – wire measuring was 48 %. 367 (48 %) patients presented with ACS, 81 (11 %) with ST – elevation myocardial infarction (table 1)

We used two different decompression strategies while applying the TR - band® (Terumo Medical Corporation, Tokyo, Japan). The TR - band® is a transparent compression bandage that consists of two compression cushions in order to apply compression pressure precisely on the puncture site. Compression is increased by inflating air via a specially developed syringe into the cushion. A valve hinders air from coming out once syringe is unlocked from the bandage. Compression can easily and gradually been taken out by locking the syringe to the bandage.

After transradial angiography the bandage is wrapped around the wrist with a Velcro mechanism and applied precisely on the puncture site with help of a marker that is to lay 5 mm proximally from puncture site.

Introducer is drawn out of the vessel while simultaneously pressure in the band is increased using a specially suited syringe provided in the kit. Pressure is increased to maximal 18 ml air in the bandage. After sheath is removed pressure is decreased until it starts bleeding out of the puncture site, then another 3 ml of air are pushed back into the compression system. Pressure level is documented and patient leaves the cathlab.

All relevant demographic, interventional pre- and postinterventional data were collected with help of a standardform that accompanied every patient.

First decompression scheme (scheme I) was applied from 1st October 2010 until 31st December 2010 and consisted of high pressure level for 60 minutes, then a gradual decrease of pressure with 3 ml air drawn out every 60 minutes. If less than 6 ml remain then all air is released. If the bandage is fully evacuated it remains for another 60 minutes on puncture site (whole compression time varies from 5 to 7 hours). If bleeding occurs while decreasing pressure on one or more levels then pressure is again augmented and need of pressure increase is documented.

Scheme II was applied from 1st January 2011 to 31st March 2011. We kept high pressure now for 240 minutes. Pressure - release - scheme was then the same (whole compression time varies from 8 to 10 hours).

After bandage removal, the puncture site was inspected and bleeding was documented as follows: The occurrence of any bleeding was described and size of hematoma was measured. We classified hematoma size in three groups, those ≤ 5 cm, 6 - 10 cm and ≥ 10 cm.

We documented also if there was pulse and SO2 - signal, measured with a pulse oximeter (Model 2500, Nonin Medical Inc., Plymouth, MN USA) after sheath removal as signs of vessel patency.

Statistics

Differences between groups for categorical parameters were tested with Chi 2 - test or, if appropriate, Fishers exact test and for continuous parameters with Mann - Whitney's U test. Possible associations between bleeding and the various parameters were analysed using logistic regression. A significance level of $p < 0.05$ has been used despite the multiple comparisons, mostly for descriptive reasons. All statistical analyses were calculated with Statistica 10.0 (Statsoft Inc, Tulsa, Oklahoma, USA).

Results

The main results are depicted in table 2.

Demograhics

Both groups were comparable in terms of sex and age.

Anticoagulation

There was no statistically significant difference in the use of Aspirine, Clopidogrel, Prasugrel, Warfarin, Heparin or Fondaparinux.

We observed a significant difference in the use of Tirofiban (8.5 % vs 4.3 %, $p < 0.05$) which was more frequent in group I whereas use of Low Molecular Weight Heparin was more frequent in group II (0 vs. 2.2 %, $p< 0.01$).

Bleeding complications

There was no major bleeding in both groups.

Rate of overall minor bleedings differed with a significantly lower rate in group II (10.3 % vs. 4.9 %, $p < 0.05$) mostly due to a significant lower number of small hematoma ≤ 5 cm (6.9 % vs. 3.1 %, $p < 0.05$). Rate of hematoma > 10 cm was comparable in both groups.

Analysis could identify three independent risk factors among the overall patient group with hematoma which are a) short compression time, b) female sex and c) use of Tirofiban. These three factors show a strong relation towards bleeding as shown in table 3.

Among the small cohort of patients with hematoma – size larger than 10 cm (n = 12) subgroup analysis showed that the use of Tirofiban ($p < 0.01$), Warfarin ($p < 0.05$) and Fondaparinux ($p < 0.05$) was significantly more frequent than among all other patients.

Vessel occlusion

Rate of patency of radial artery measured according to S02 - signal (98.2 % vs. 98.5 %) and patent pulse (98.8 % vs. 99.4 %) was high in both groups. No difference could be found between the groups.

Pressure augmentation.

The need to again augment pressure after attempt to lower pressure in the bandage was significantly different between the two groups. 25.7 % of group I patients in contrast to 8.6 % of group II patients needed pressure augmentation because bleeding occurred while trying to lower pressure in the bandage ($p < 0.001$). If no pressure augmentation was needed the discharge of elective outpatients was postponed by 3 hours using the longer compression scheme.

Discussion

Since the use of the transradial approach is increasing there is need of proof which postprocedural care is best in order to achieve best hemostasis, lowest bleeding - risk, lowest possible risk of vessel occlusion but earliest possible patient discharge. The literature on this topic is scarce [16, 17].

Overall bleeding risk after transradial approach is very low. Minor bleedings occur in 0 – 2.9 % of all cases [4, 5], major bleedings in 0 – 0.5 % [4, 18], all in all much lower compared to femoral approach [2, 5].

Several bleeding classification schemes exist like TIMI [19], GUSTO [20], PRISM – PLUS [21] classifications or according to the definition in the RIVAl trial [4]. According to RIVAL and GUSTO classification, none of the bleedings in our study reached the definition criteria for minor bleeding in lack of requiring blood transfusions or need to modify antithrombotic therapy. According to TIMI all our bleedings would be classified as “minimal bleeding”, according to the classification of PRISM – PLUS as “minor”.

Surprisingly, no larger study, not even the so far largest randomized trial comparing radial and femoral approach [4] has specified the postprocedural care of patients especially in terms of length of compression on the puncture site, although it seems reasonable that this can affect the rate of bleeding.

Results after comparison of two groups with 331 resp. 324 patients in all clinical settings showed that transradial approach is safe with absence of major bleeding. Although nearly all patients were pretreated with platelet inhibition and almost all received Heparin under procedure, the rate of large hematomas is low and with 2.1% respectively 1.5% in the range of reported data in other studies [4].

We observed lower rates of bleedings in group II, mostly due to fewer rates of small hematomas ≤ 5 cm and a trend towards fewer bleedings with a medium - size ≤ 10 cm.

Analysis showed three main risk factors to develop bleeding which were shorter compression time, female sex and the use of Tirofiban. The influence of compression time on bleeding after transradial coronary procedures has never been examined before, whereas the influence of gender on bleeding risk is known [22] as is the increased bleeding risk of patients under GP IIb / IIIa blockers [22].

Overall groups were comparable in terms of anticoagulation. Looking more closely only at the cohort of patients that suffered from larger hematoma (larger than 10 cm), we could determine the presence of Tirofiban, Warafarin and Fondaparinux as risk factors. Even in this group women were more frequent as was the use of 10.000 units of Heparin, both without reaching clinically significance. The group was very small so that further conclusions can hardly be drawn.

Vessel occlusion is described in between 1 - 7 % of all cases [6] depending on several risk factors like French - size of introducer [23] and administration of Heparin [24]. Although we did not perform reverse Barbaeu`s test [17] or duplexultrasound examination after transradial procedure, palpable pulse and SO2 - signal are signs of patent radial artery although no definite proof because ulnar artery can take over palmar perfusion and may even retrograde fill radial artery that leads to a palpable pulse. Our number of vessel patency is very high though maybe somewhat overestimated by indirectly measuring patency of radial artery. No difference between the two groups was seen, so even prolonged compression with 4 hours maintenance of high pressure did not result in a higher number of vessel occlusion in contrast to the findings in another study [16]. No patient showed signs of ischemia.

Early discharge of elective outpatients is a clear advantage of transradial approach. According to scheme II with prolonged compression, patients could be discharged 7 – 9 hours after the procedure compared with those that were treated with shorter compression who could be discharged 3 hours earlier if there was no need of pressure augmentation. Augmenting pressure after attempt of lowering occurred in a quarter of patients in group I so that the profit of short compression in terms of early patient discharge was hereby lowered.

Summary

In summary, maintenance of high compression pressure over 4 hours leads to lower number of bleedings without increasing rates of vessel occlusion. If no pressure augmentation was needed the discharge of elective outpatients was postponed by 3 hours using the longer compression scheme.

Limitations

The study was retrospective with limitations inherent to this design. A prospective randomized trial is needed to further evaluate best treatment after transradial approach.

Declaration

The authors declare that they have no conflict of interest.

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Tables

Table 1 Characteristics of the overall patient population

	Number (%)
Number of procedures	763
Number of patients	692
Radial approach	655 (86 %)
Conversion from radial to femoral approach	22 (3 %)
Acute coronary syndrome (ACS)	367 (48 %)
ACS / STEMI	81 (11 %)
PCI including fractional flow reserve (FFR)	371 (48 %)
Diagnostic	392 (52 %)

Table 2 Demographic, pre- and postinterventional data

	Group 1 (n=331)	Group 2 (n=324)	p-value
Age, years			
mean (SD)	69 (10.5)	68 (11.1)	
range	31 - 94	30 - 94	0.164
Sex			
female	129 (39%)	123 (38%)	
male	202 (61%)	201 (62%)	0.853
French-size			
mean (SD)	5.9 (0.3)	6.0 (0.2)	
range	5.0 - 7.5	5.0 - 6.0	0.429
Anticogulation			
Aspirin	308 (93%)	303 (94%)	0.934
Clopidogrel	299 (90%)	289 (89%)	0.726
Warfarin	14 (4.2%)	20 (6.2%)	0.345
INR≥2	14 (4.2%)	20 (6.2%)	-
mean INR	2.4	2.3	0.625
Fondaparinux	104 (31%)	84 (26%)	0.142
Heparin	320 (97%)	314 (97%)	0.96
Mean units	6536	6315	
range	2500 - 12500	2500 - 10500	0.276
Tirofiban	28 (8.5%)	14 (4.3%)	0.045
LMWH	0 (0.0%)	7 (2.2%)	0.007
Prasugrel	1 (0.3%)	1 (0.3%)	1.000
Bloodpressure, mmHg			
systolic,mean (SD)	125 (24)	126 (22)	0.459
diastolic,mean (SD)	72 (14)	74 (13)	0.019
Bleeding			
Major bleeding	0	0	-
Minor bleeding	34 (10.3%)	16 (4.9%)	0.015
≤5cm	23 (6.9%)	10 (3.1%)	0.038
6–10cm	4 (1.2%)	1 (0.3%)	0.382
>10cm	7 (2.1%)	5 (1.5%)	0.8
SO2-signal after removal of bandage	325 (98.2%)	319 (98.5%)	0.972
Pulse after removal of bandage	327 (98.8%)	322 (99.4%)	0.701
Need of augmentation of bandage pressure	85 (25.7%)	28 (8.6%)	<0.001

Table 3 Risk factors for bleeding assessed using logistic regression analysis.

Parameter		Totalt	Bleeding n	Bleeding (%)	Multivariate logistic regression OR (95% conf int)	p
Arterial compression group						
	Long	324	16	4.9		
	Short	331	34	10.3	2.10 (1.12-3.95)	0.021
Sex						
	Male	403	16	4.0		
	Female	252	34	13.5	4.23 (2.22-8.04)	<0.001
Tirofiban						
	No	613	44	7.2		
	Yes	42	6	14.3	2.93 (1.09-7.88)	0.033