FEMORAL ARTERY COLLAGEN PLUG APPLICATION IN INTERVENTIONAL CARDIOLOGY

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SUMMARY : *In the interventional cardiology practice, hemostasis of the femoral puncture site is a major problem, especially in the fully anticoagulated patients. Classical pressure dressing is a time consuming method with major complications.*

We compared the effectiveness and complications of the classical pressure dressing and a recently introduced method of collagen vascular plug (CVP) application, in 34 patients (group A) who had various therapeutic cardiac catheterization procedures (2 coronary stent, 1 directional atherectomy, 8 rotational atherectomy, 23 baloon angioplasty) after which CVP was used. The control group consisted of 30 patients (group B) who had percutaneous transluminal coronary angioplasty (PTCA). Classical pressure dressing was applied in this latter group. Both groups had full heparinization (1000 U/h i.v. infusion) during the procedure.

After CVP 12 patients (35 %) had immediate hemostasis, 14 (41 %) patients needed less than 20 minutes, 6 (18 %) patients needed more than 20 minutes, and 2 patients needed more than 30 minutes. Mean compression time was shorter in group A (9.3 ± 5.6) than in group B (45.1 ± 7.6) ($p<0.001$).

Major hematoma was seen in only one patient (3 %) in group A and in 5 patients (15 %) in group B ($p<0.005$). Regrettably, femoral artery stenosis with intermittent claudication developed in one patient in group A.

In conclusion, CVP was found to shorten the compression period after interventional cardiac catheterization procedures, especially in fully anticoagulated patients.

Key Words : *Femoral Collagen Plug, Hemostasis.*

INTRODUCTION

Even though not being in high numbers, invasive cardiovascular procedures sometimes end up with vascular complications. Although being non-fatal complications, they are bothersome for the patient and may require blood transfusions and even surgical intervention (3). Although getting lesser by the advancement of catheter and sheath technology, hemostatic vascular problem incidence continue to be reported as 4-12 % in various studies (6, 11). Besides post-thrombolytic interventional procedures; applications that need catheters with larger diameters, such as atherectomy and rotational ablation procedures increase vascular complication rates (7, 10).

Because of these consequences instead of the well known pressure dressing, more safe and effective techniques are tried to be developed just to eliminate the bothersome pressure dressing, decrease vascular complications and provide early mobilization.

In this study, we investigated the success rate of collagen vascular plug in providing hemostasis and its effects on the vascular complications.

MATERIALS AND METHODS

Collagen vascular plug was applied to 34 patients; 27 male, 7 female. Avarage age was 52. Distribution of the 34 patients according to the therapeutic procedure was as below :

Percutaneous Transluminal Coronary Angioplasty	(PTCA)	23 patients
Percutaneous Transluminal Rotational Angioplasty	(PTRA)	8 patients
Directional Coronary Atherectomy	(DCA)	1 patient
Intracoronary Stent		2 patients

PTCA was applied to 30 patients in the control group. Both groups received 24 h of heparin infusion at the dose of 1000 U/h, after the procedure. Heparin infusion was continued for 5 days in the stent case. 9 F sheath was used in 2 of the 34 patients and 8 F for the rest.

Collagen vascular plug (VasoSeal, Datascope) is made up of 3 pieces :

1. 11 F though edged dilatator
2. 11.5 F sheath
3. 180 mg collagen

The collagen was purified bovine collagen. Both by aggregating and activating the platelets, it provides hemostasis. This plug is a sterile, non-pyrogen and absorbable material (4).

The application of collagen vascular plug is shown below in the Figure 1.

RESULTS

The summary of the findings of 34 patients are shown in Table 1.

Complications of CVP application :

1. Major hematoma formation (diatemer > 6 cm)	1 patient (3 %)
2. Arterial occlusion*	1 patient (3 %)
	total : 2 patients

* arterial occlusion is shown in figure 2.

Major hematomas were seen in 5 patients in the control group and when compared with the study group, CVP application was shown to decrease the complication ratio significantly ($p<0.005$).

DISCUSSION

In PTCA procedures vascular complication ra-

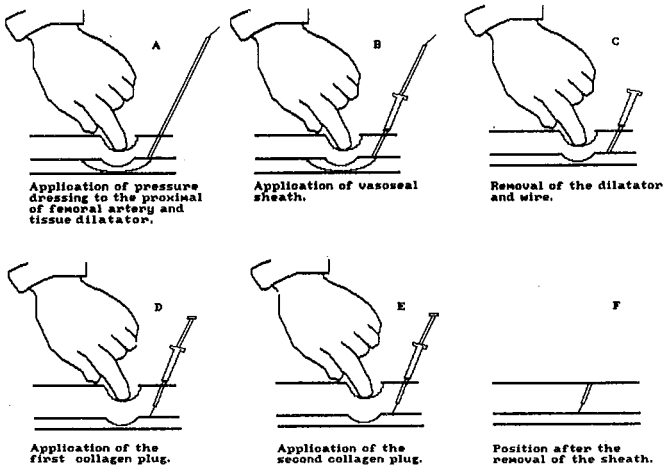

Fig - 1 : Collagen plug application.

Study group : $p < 0.001$

Patients	Duration (min)
12 (35 %)	0
14 (41 %)	7.1 ± 2.4
6 (18 %)	16.3 ± 4.7
2 (% 6)	37.0 ± 12.1
total 34 patients	**9.3 ± 7.6**

Control group :

Patients	Duration (min)
30	45 ± 7.6

Table I : Distribution of the compression dressing duration in both groups.

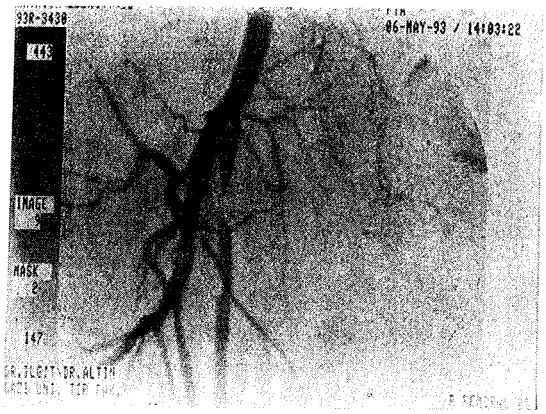

Fig - 2

tio is 3.4 %. In case of heparinization after the procedure, this ratio increases up to 10-17 % (5) . Femoral complication ratio in stent cases ranges between 8-20 %; usually requiring blood transfusions and femoral artery surgery (1). As femoral vascular complication ratio is too small (0.4 %) and not so significant in diagnostic cardiac catheterization, CVP application was thought to be unnecessary. In diagnostic cardiac catheterization CVP application did not alter the complication ratio but decreased the femoral compression time remarkably (8, 9).

In stent application (1), PTCA and in cases requiring long term anticoagulation after the procedure (2, 8, 9); CVP application decreased the local complication ratio and pressure dressing time significantly.

In our study, CVP application decreased the local complication ratio and pressure dressing period significantly in 34 patients, who received post-procedure heparin infusion. In two of the cases, pressure dressing time was rather long, such as the cases in the control group. This could be attributed to being in the very beginning of is procedure and being not very familiar with the application. In one case, CVP protruded towards the arterial lumen and led to femoral artery stenosis. The patient complained of claudication after the procedure but the long term prognosis could not be learned as the patient did not come back for the control examination 6 weeks later. As collagen is a biodegradable material and absorbed within 4-6 weeks, it should be evaluated after this period angiographically. The most important cause of the femoral artery occlusion in this patient is the application of 9 F sheath. Generally it is not advised to perform CVP after procedures using greater than 8.5 F sheath. Although the total complication ratio was significantly lower than the control group, we hope that the complications will be further decreased by a wider application of CVP.

As a conclusion, CVP, both by decreasing local complication ratio and pressure dressing time, eliminates the bothering effects of the invasive procedures and increases the patient comfort.

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