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ORIGINAL ARTICLE

Groin hematoma after electrophysiological procedures—incidence and predisposing factors

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Abstract

Objectives. We evaluated the incidence and predisposing factors of groin hematomas after electrophysiological (EP) procedures. *Design.* Prospective, observational study, enrolling consecutive patients after EP procedures (Atrial fibrillation: $n = 151$; Supraventricular tachycardia/Diagnostic EP: $n = 82$; Ventricular tachycardia: $n = 18$). Patients underwent manual compression for 10 min and 3 h post procedural bed rest. AF ablations were performed with INR 2–3, ACT > 300, and no protamine sulfate. Adhesive pressure dressings (APDs) were used if sheath size ≥ 10F; procedural time > 120 min; and BMI > 30. Patient-reported hematomas were recorded by a telephone follow-up after 2 weeks. *Results.* Hematoma developed immediately in 26 patients (10%) and after 14 days significant hematoma was reported in 68 patients (27%). Regression analysis on sex, age, BMI 25, ACT 300, use of APD, sheath size and number, and complicated venous access was not associated with hematoma, either immediately after the procedure or after 14 days. Any hematoma presenting immediately after procedures was associated with patient-reported hematomas after 14 days, odds ratio 18.7 (CI 95%: 5.00–69.8; $P < 0.001$). *Conclusions.* Any hematoma immediately after EP procedures was the sole predictor of patient-reported hematoma after 2 weeks. Initiatives to prevent groin hematoma should focus on the procedure itself as well as post-procedural care.

Key words: *ablation, femoral, groin, hematoma, predisposing factors*

Introduction

Groin hematomas are the most common complication of electrophysiological (EP) procedures with femoral access (1), and patients who develop a hematoma may be seriously hindered in normal physical activities.

While often a cause of anxiety and discomfort, hematomas may also pose a risk for the patient. Several case reports have described serious complications related to groin hematoma, for example, pseudoaneurysms, hypovolemic shock, neuropathy, and retroperitoneal hematoma (2–4).

Thus, groin hematomas may lead to incremental health costs due to complications and extended length of stay in hospital.

Predisposing factors are not well described, and preventive measures are often based on local tradition rather than evidence-based knowledge. Further, an increasing number of patients undergo invasive electrophysiological procedures, and health care personnel should therefore be able to inform of common complications and their prevention.

We investigated the incidence of groin hematomas from a patient perspective after EP procedures.

Materials and methods

Study design and setting

The study was conducted at Aalborg University Hospital (AUH), Denmark as a prospective, observational study, enrolling consecutive patients undergoing different types of invasive EP procedures. The current study cohort included patients who underwent invasive EP procedures, either for diagnostic purposes, supraventricular tachycardia (SVT), atrial fibrillation (AF), or ventricular tachycardia (VT).

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The AUH provides EP services to 700.000 inhabitants in the North Denmark Region and is currently performing approximately 400 EP procedures per year. Consecutive patients were included in the study, if they were >18 years of age, were able to understand oral patient information on the study, and accepted a telephone interview by a study nurse (ABD) two weeks after the procedure.

Enrolment began in December 2010 and ended in December 2011 with the last follow-up in January 2012.

Clinical practice

Physicians and nurses informed the patients prior to and after the EP procedure, and specifically addressed the risk of hematoma development. Patients were instructed to adhere to 3 h of post procedural bed rest.

Vascular access was performed by the use of an 18 G puncture needle during local anesthesia. Vascular access was classified as "complicated" at the physician's discretion. The relevant sheaths were introduced over guidewires. For ablation of SVT and VT as well as diagnostic procedures, only the right groin was used for vascular access (5F, 6F, and 7F venous sheaths). For ablation of AF, both groins were used (Right: 12F and 8F venous sheaths; Left: 5F and 6F venous sheaths). After the procedure, sheaths were removed by the physician with subsequent manual compression for at least 10 min or until any bleeding had subsided. Any arterial access for accessory pathway and VT ablation was performed with 7F or 8F sheaths and subsequently closed with a vascular closing device (Femoseal™, St Jude Medical, St Paul, MN, USA).

Patients treated with vitamin K antagonists (VKA) (including AF ablations) underwent procedures during continued treatment with INR 2–3. In patients with INR >3, small doses of vitamin K was administered until INR was 2–3.

Patients undergoing AF ablation were heparinized and ACT was maintained >300 with measurements taken every 30 min. No protamine sulfate was administered after the procedure. Adhesive pressure dressings (APDs) were used if sheath size ≥ 10F; procedural time >120 min; and BMI >30.

Ethical considerations

The development of hematoma after EP procedures often leads to significant distress and discomfort among patients. Therefore, a deeper understanding of predictors is important in order to develop preventive nursing procedures. The study was evaluated by the regional Ethics Committee and found not to require formal approval by the committee. Further, informed consent was not required, as the study constituted an integral part of quality improvement in the Danish health care system.

Data collection and follow-up

Demographic data as well as procedural and postprocedural data were recorded during the hospital stay. Hematoma was defined as follows: minimum 5 cm in diameter and palpable at skin level (5). Prior to the study, the nursing staff in the EP laboratory and the bed unit received information and training regarding hematoma development, scoring, and follow-up. Two EP nurses attending the patient during the procedure scored the presence and size of any periprocedural hematoma. In case of disagreement, the treating physician determined whether hematoma was present or not. Two weeks after the EP procedure, a structured telephone interview was performed by a study nurse (ABD), focusing on whether the patient had a hematoma present at 14 days after the procedure that met the pre-definition of a hematoma (see above). During the hospital stay, the patient was informed by a study nurse (ABD) on how to define a hematoma and how self-examination of the groin should be performed. The telephone interview was performed as follows:

Information/data about the patient and the EP procedure performed was confirmed. The following questions were asked:

- "Did you or did you not develop a groin hematoma (translated to Danish layman's terms) postprocedural that is present after 14 days?"

If Yes:

- "Does the hematoma appear in the left or the right groin, or bilateral?"
- "Does the hematoma appear well-defined and palpable at skin level?"
- "What is the hematoma diameter?"
- Additional comments from the patient.

Statistics

Continuous data are reported as medians with indication of ranges.

A focus group interview including physicians and nurses from the EP lab and bed ward identified independent variables that, from clinical experience, were presumed to be predictors of hematomas (sex, age, BMI $<$ or >25, ACT $<$ or >300, the use of APDs,

number and size of sheaths, and complicated venous access). A multiple regression analysis was performed using STATA version 11.2 (StataCorp. 2009. Stata: Release 11. Statistical Software. College Station, TX: Stata Corp LP). Statistical tests were two-tailed, and $P < 0.05$ was considered significant.

Results

In total, 321 patients undergoing EP procedures were included in the study. Sixty-eight patients were excluded due to missing values in the data collection sheet, and thus, 253 patients entered the final analysis. The reason for incompleteness of data was in the large majority of cases missing values regarding the procedure itself and/or the post-procedural stay in the bed unit. Baseline and procedural characteristics of patients who were excluded due to missing values did not differ significantly from the patients who were included in the final analysis. Nor was there any indication that patients undergoing a specific procedure type, for example, AF ablation, had to be excluded due to missing data.

Of 144 patients who received APDs, 20 cases were due to hematoma identified immediately after the EP procedure. Thus, 124 patients received APDs for prophylactic purposes, for example, long procedure time and ACT > 300. Three patients with APD due to post-procedural hematoma and 30 patients with prophylactic APDs reported significant hematoma after 14 days ($p = 0.57$).

Twenty-six patients (10%) developed hematoma immediately following the procedure. In total, 68 patients (27%) reported significant hematoma after 14 days. Baseline characteristics of patients with and without hematoma after the EP procedure as well as after14 days are shown in Table I.

Although 68 patients reported significant hematoma, only 43 patients experienced adverse events: One patient (0.4%) had a prolonged hospitalization due to serious complications (hematoma and pseudoaneurysm) and underwent vascular surgery and blood transfusion. A further 6 patients (2.4%) underwent ultrasound scan to rule out pseudoaneurysm in the department´s outpatient clinic, whereas 9 patients (3.6%) saw their general practitioner (GP) due to hematoma. One of the latter patients received antibiotics due to clinical suspicion of cutaneous infection.

Twenty patients (7.9%) reported pain due to hematoma but did not require medical attention by hospital or GP. 7 patients (2.8%) reported significant pain and walking impairment but had not sought medical attention by hospital or GP.

Table II shows the results of the regression analysis of possible predictors of late hematoma (after 14 days) for patients without any periprocedural hematoma. The variables sex, age, BMI < or > 25, ACT < or > 300, the use of APDs, number and size of sheaths, as well as complicated venous access were not statistically significant predictors of hematomas, either immediately after the EP procedure or after 14 days.

Table III shows the results of the regression analysis of possible predictors of hematomas at the end of the EP procedure as well as after 14 days. The aforementioned variables were not statistically significant predictors of hematomas, either immediately after the EP procedure or after 14 days. However, a hematoma that had been identified and received relevant interventions at the end of the EP procedure

Table I. Demographics of patients with and without hematomas immediately after the EP procedure and after 14 days.

	No hematoma after EP procedure	With hematoma after EP procedure	No hematoma after 14 days	With hematoma after 14 days
Female, *n* (%)	63 (91)	6 (9)	52 (75)	17 (25)
Male, *n* (%)	170 (92)	14 (8)	133 (72)	51 (28)
Age, median y (range)	62 (26/76)	60 (39/79)	62 (28/76)	60 (24/75)
BMI, median (range)	27.2 (20.9/36.7)	27.6 (23.6/42.6)	27.2 (21.3/36.7)	27.3 (20.9/37.1)
Difficult venous access, *n* (%)	26 (61)	17 (39)	26 (61)	17 (39)
Closure device (arterial), *n* (%)	247 (100)	0 (0)	246 (99.6)	1 (0.4)
ACT > 300, *n* (%)	73 (86)	12 (14)	54 (64)	31 (36)
Procedure, *n* (%)	185 (73)	68 (27)	185 (73)	68 (27)
SVT/Diagnostic	80 (95)	4 (5)	63 (77)	19 (23)
Atrial Flutter/A-Fib	136 (90)	15 (19)	104 (69)	47 (31)
VT/VES	17 (95)	1 (5)	16 (89)	2 (11)
Oral anticoagulation*	138 (89)	17 (11)	107 (69)	48 (31)
Platelet inhibitors**	70 (88)	10 (12)	55 (69)	25 (31)
GFR, mL/min, median (range)	76 (6/109)	81 (45/105)	76 (6/109)	74 (19/105)

*Vitamin K antagonists.
**Dipyridamole, Aspirin, GPIIb/IIIa antagonists.

Table II. Regression analysis of possible predictors of hematomas after 14 days without periprocedural hematoma.

	Predictors of late hematoma (14 days) without periprocedural hematoma		
Variable	Odds ratio	CI 95%	*P* value
Sex			
Male	Ref	–	–
Female	0.87	(0.44;1.83)	0.78
Age			
<50 years	Ref	–	–
≥50 years	0.91	(0.46;2.33)	0.94
BMI			
<25	Ref	–	–
≥25	0.74	(0.39;1.39)	0.35
Activated Clotting Time (ACT)			
<300	Ref	–	–
≥300	1.75	(0.91;3.33)	0.09
APD			
No	Ref	–	–
Yes	1.34	(0.71;2.51)	0.84
Difficult venous access			
No	Ref	–	–
Yes	1.93	(0.89;4.18)	0.10
Periprocedural hematoma			
No	–	–	–
Yes	–	–	–

Table III. Regression analysis of possible predictors of hematomas immediately after the EP procedure and after 14 days.

	Predictors of periprocedural and late hematoma (14 days)		
Variable	Odds ratio	CI 95%	*P* value
Sex			
Male	Ref	–	–
Female	0.74	(0.35;1.54)	0.42
Age			
<50 years	Ref	–	–
≥50 years	0.83	(0.35;1.94)	0.68
BMI			
<25	Ref	–	–
≥25	0.75	(0.39;1.44)	0.40
ACT			
<300	Ref	–	–
≥300	1.86	(0.83;4.14)	0.13
APD			
No	Ref	–	–
Yes	0.92	(0.41;2.04)	0.84
Difficult venous access			
No	Ref	–	–
Yes	1.84	(0.85;3.95)	0.12
Periprocedural hematoma			
No	Ref	–	–
Yes	18.72	(5.02;69.86)	<0.001

was associated with patient-reported hematoma after 14 days with odds ratio of 18.7 (CI 95%: 5.00–69.8; $P<0.001$).

Discussion

The primary findings of the present study are that 27% of patients reported significant hematoma after 14 days and that the only predictor of a significant patient-reported hematoma after 14 days was a hematoma present immediately after the EP procedure [odds ratio 18.7 (CI 95%: 5.00–69.8; $P<0.001$)]. Despite a wide confidence interval, reflecting the limited number of study subjects, an odds ratio of this magnitude is highly significant, and the significance of sizeable hematomas should not be discounted. Hematoma developed immediately after the procedure in 10% of patients, and this was also not predicted by our pre-specified variables. When a hematoma is detected in its early phase, it is often thought that prolonged manual compression may minimize its development. However, in the current study, the early detection and interventions, that is, manual compression and APDs, did not prevent patient-reported hematoma at 14 days.

Due to advances in ablation techniques of both AF and VT, an increasing number of EP procedures are performed on the left side of the heart requiring concomitant administration of intravenous unfractionated heparin (UFH) (6). Furthermore, a large proportion of these patients are treated by anticoagulants, either vitamin K antagonists (VKA), platelet inhibitors, or in some instances both. The effects of large hematoma may range from a mere nuisance over pseudoaneurysms, arterio-venous fistula, to life-threatening complications (2–4,7). In the health care system incremental costs due to large hematomas are considerable and can be attributed to prolonged hospital stays, the need for interventions—sometimes by surgery—and the risk of subsequent infection. Health care economic evaluations in patients who develop vascular complications after percutaneous coronary interventions have shown that incremental hospital costs are approximately 4,300 USD per patient (8). Also, patients and society may experience economic consequences due to prolonged sick leave and the need for rehabilitation. Previous research indicates that the incidence of significant hematoma is in the range of 1.5–10% after AF ablation (9–11). In the follow-up interviews in this study, 27% of patients reported that they experienced significant hematoma after 14 days. One must, therefore, suspect that hematomas are grossly underreported, especially regarding the late effects, for example, concerning mobilization and prolonged sick leave.

Initiatives to prevent hematomas can broadly be aimed at the following:

1. Optimizing venous and arterial access.
2. Decreasing leakage of blood from puncture sites during the procedure.
3. Post-procedural care including manual compression and APDs.

For optimization of arterial and venous access, puncture skills may be trained in a skills laboratory, but the number of EP procedures for the individual operator remains very important. Venous access may also be assisted by ultrasound imaging, making a precise puncture of the femoral vein and artery possible (12).

Occasionally, the puncture needle will accidentally perforate both the femoral vein and artery leading to immediate development of hematoma or a graduate leakage during the procedure.

The present study did not find that a difficult venous access, sheath size, and UFH therapy with ACT $>$ 300 were significant predictors of hematomas. Nevertheless, the risk of hematoma seemed to be highly dependent on hematomas developing during the procedure, that is, before sheath removal. We believe that these results indicate that initiatives to prevent hematomas should be aimed at the first two of the above-mentioned categories rather than post-procedural care. The use of APDs may not have a positive effect, possibly due to concealment of the groin, thus hindering adequate inspection and timely manual compression. Ideally, a prospective, randomized trial should be performed by randomizing patients to different post-procedural regimens.

Particularly for catheter procedures on the left side of the heart, considerations on additional heparinization are essential due to the risk of thrombus formation. Current guidelines recommend that UFH should be administered when performing transseptal puncture to achieve an ACT of $\geq$300–400 s (13). However, this goal may be achieved by different anticoagulation regimens, often depending on local tradition. Some use an intravenous bolus dose of UFH 5,000 U with ACT measurements at regular intervals and supplementary UFH administrations if ACT $<$300 s. Others use a more aggressive approach with a UFH bolus of 100 or even 200 U/kg to rapidly achieve the desired ACT level (14). In both regimens, protamine sulfate may be used for neutralizing heparin after leaving the left side of the heart (13). In this study, UFH 5,000 IE was administered with regular ACT measurements without the use of protamine sulfate. However, the optimal strategy for anticoagulation remains undetermined and calls for randomized trials. Recent techniques for the prevention of hematoma may include the use of compression pads impregnated with agents that causes the blood to clot quickly (15). Also, vascular closing devices designed for the femoral artery may be used on the venous side (16).

In patients undergoing AF ablation, it was previously customary to interrupt VKA treatment before and during the ablation procedure with concomitant bridging with either UFH or low molecular weight heparins. However, recent research has shown that patients may safely continue warfarin therapy during the ablation procedure with a resulting decreased risk of bleeding complications (11,17).

Limitations

First, the current study was observational and took place in a non-randomized setting. Moreover, the study is based on telephone interviews rather than a visual inspection of hematomas. Ultrasound measurement of volumes may be the gold standard in hematoma assessment. However, due to large geographical distances in our region, this was not an option. Therefore, we chose a path of "patient centered care" rather than assessment by health care professionals. This may provide valuable information on patients' perception of the hematoma and its consequences.

There is a potential risk that the patients who had a hematoma at the end of procedure would claim having a hematoma also 2 weeks after the procedure, at the time of the interview. We attempted to reduce this risk by guiding the patients to describe the possible hematoma as thoroughly as possible.

Second, data from 68 patients (21%) had to be excluded due to missing data. The baseline and procedural characteristics of these patients do not suggest that this was a particular subset of patients, for example, patients with particular dispositions or complications.

Third, a larger study cohort would probably lead to narrowing of confidence intervals and possibly show statistical significance for more variables. Thus, the results from the study should primarily be considered as hypothesis generating and serve as the basis for future studies.

Conclusions

A high proportion of patients (27%) reported hematomas at 14 days after an EP procedure. Patients with a hematoma detected at the end of an EP procedure had a significantly increased 18-fold risk of developing a patient-reported hematoma after 14 days. All other recorded variables were not associated with the presence of hematomas after 14 days. The results

suggest that initiatives to prevent groin hematomas should be aimed at both the procedure itself as well as post-procedural care.

Implications for practice

- Significant hematomas may develop *during* EP procedures.
- APDs do not decrease the risk of hematoma after 14 days.
- Focus on per- *and* post-procedural care may improve outcomes.

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