A relevant Byrd dilator sheath damage during transvenous lead extraction – the rare phenomenon with potentially serious consequences

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Introduction

Mechanical tools, still commonly used in transvenous lead extraction (TLE), invented in the late 1980s in the United States, revolutionized electrotherapy [1-4]. After 20 years, telescopic dilator sheaths cutting fibrotic tissue around the leads are still used without major modifications, which is an extraordinary phenomenon in medical technology. Each instrument that fits the lead route shape in the vascular space is exposed to tension forces and an excessive deflection angle (forced by anatomical conditions), which may sometimes lead to damage of sheaths orientated coaxially. In such cases a broken tool is replaced with a new one. A problem arises if this incident is not recognized on time, and further rotation of a damaged sheath may lead to serious consequences. To our knowledge, in the 1990s[1-4] and since[5-8] there have been no studies concerning this phenomenon, including any problems for experienced operators. The number of extraction procedures is constantly growing, new centers are being established, and more and more young doctors are engaged in TLE. In our opinion, they should be aware of the possible negative effects of Byrd dilator sheath damage (BDD).

Aim of study

Analysis of the frequency, conditions of appearance and possible risk factors of BDD and influence of BDD on safety and effectiveness of TLE. We found it particularly important to present this phenomenon which is not a complication per se, but in the case of inappropriate handling might become one.

Materials and Methods

A retrospective analysis of an 8-year-old database of transvenous lead extraction procedures comprising 1728 patients with 2901 extracted leads was carried out. The main criterion for including the procedure was the dwelling time of leads in the cardiovascular system. For pacemaker (PM) leads it was >12 months and for implantable cardioverter defibrillator (ICD) leads >6 months; another inclusion criterion for procedures with a shorter dwelling time was the necessity of using other tools due to ineffective simple traction (not attached to a lead by the factory). The database of TLE procedures contains patients' demographic data, indications for TLE and information about the implanted leads: lead number, age, model, implantation site and data concerning the procedure: duration, technique used, technical problems and complications. TLE in which BDD occurred were compared with the remaining TLE procedures. The following parameters were compared: 1. Patient demographic and clinical information. 2. System and abandoned lead information 3. TLE technical procedure information, procedural efficiency, technical problems, assessed on the basis of the procedure duration, the need for changing technique during the procedure due to defragmentation of the extracted lead. Procedure effectiveness was defined according to the Heart Rhythm Society (HRS) guidelines (major complications, clinical success, procedural success, radiological success, procedure-related death)[9].

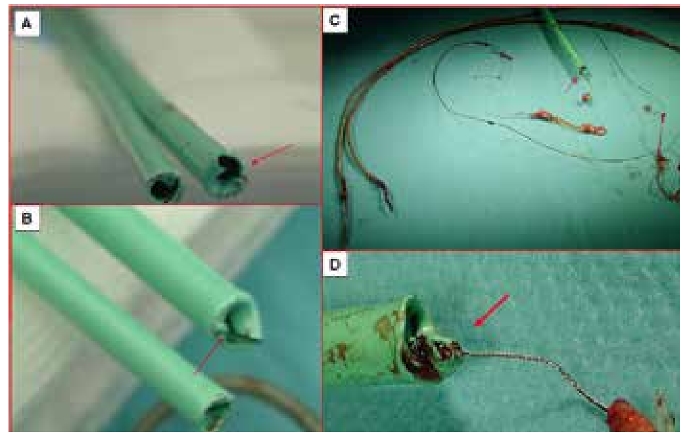

Figure 1 Cutting ending damage, which is not a fracture - not included in our study; may lead toprocedure prolongation.

Patients and procedures

We have extracted 2901 ingrown (PM >12, ICD >6 months) leads in 1728 patients (60.5% males), mean age 64.6 years. 72.7% of leads were (PM) bipolar, 10.1% (PM) unipolar, 15.3% ICD and 1.9% were VDD leads; 65.4% passive fixation and 34.6% active fixation. 35.3% of leads were in the right atrium (RA), 5.9% in the coronary sinus (CS), 54.9% in the right ventricle (RV), 3.6% in the heart vein branch and 0.2% in the left atrium or left ventricle (erroneous placement). Mean dwelling time was 84.7 months. The most common (59.2%) were non-infective indications for TLE; local pocket infection (PI) and lead-related endocarditis (LRIE) were less frequent (12.4% and 28.4%).

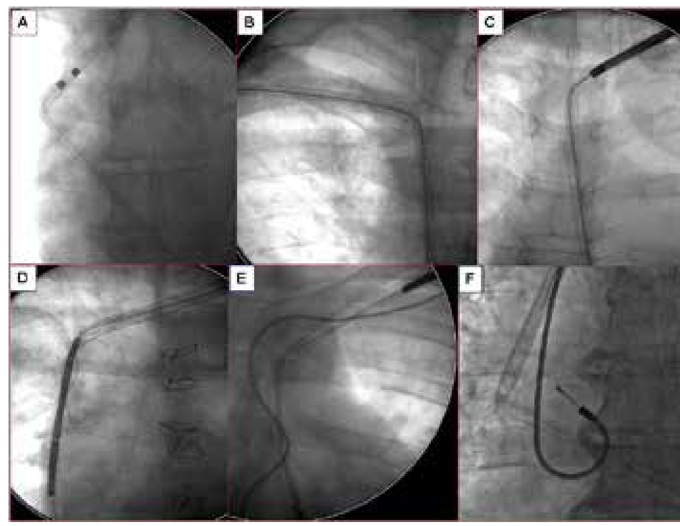

Figure 2 Several examples of radiograms showing typical Byrd dilator damage.

Description of lead removal methods

Leads accessible from the pacemaker (PM) pocket were extracted using mechanical devices during TLE procedures. Dilators were produced by Cook company (polypropylene Byrd dilators). No laser or high radiofrequency energy support was used. Standard stylet or, less frequently, locking stylets with anchoring function were used. Polypropylene telescopic Byrd dilators of all sizes (blue, yellow, green, white and orange) were used in two available lengths; steel sheaths were utilized sporadically. In case of significant resistance in the cardiovascular system (CVS) a pair of polypropylene sheaths was replaced with another one of a larger diameter. Broken leads with an unavailable proximal ending in the pacemaker pocket were extracted using various techniques described by us in other reports[10,11].

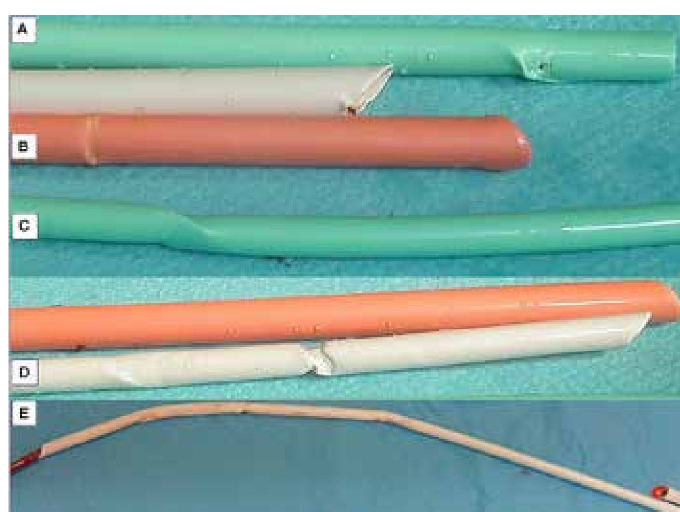

Figure 3 Examples of BDD in which after partial tube straightening, the sheath was removed (thelead not affected by sheath's pulling forces).

Damage degrees

There are two main types of sheath damage: blunting of the cutting ending (not a fracture, not evaluated in this study) and damage of a tube in its middle segment. The first situation (Figure 1) causes loss of effectiveness of fibrotic tissue separation only; the second, however, may lead to serious consequences (Figure 2).

Three main damage types:

1. A high deflection angle causes the damage, a broken sheath is blocked and cannot be moved relative to the lead (Figure 3) – type A.
2. Late BDD recognition – tube torsion is blocking the lead. The sheath may be easily broken into two pieces if pulled or moved forward (Figure 4,5) – type B.

Figure 4 An example of Byrd dilator sheath damage and torsion blocking both the lead and the tube.Removal possible only with use of a sheath with a bigger diameter.

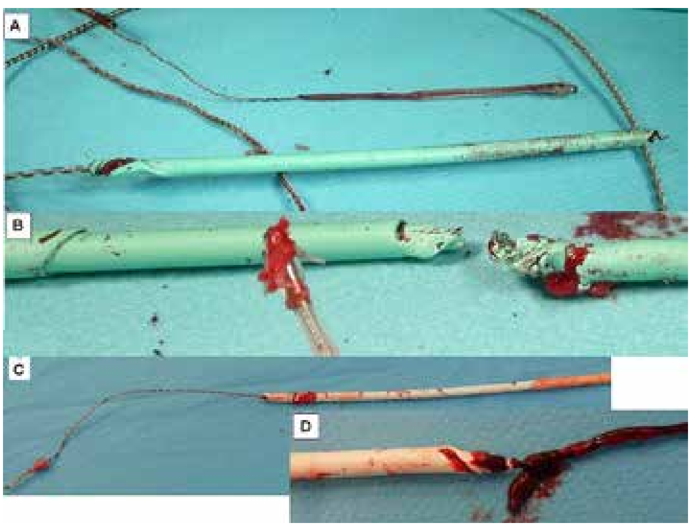

Figure 5 Other examples of BDD removed with wider sheaths. B: the torsed tube with the extractedlead "outside" the patient.

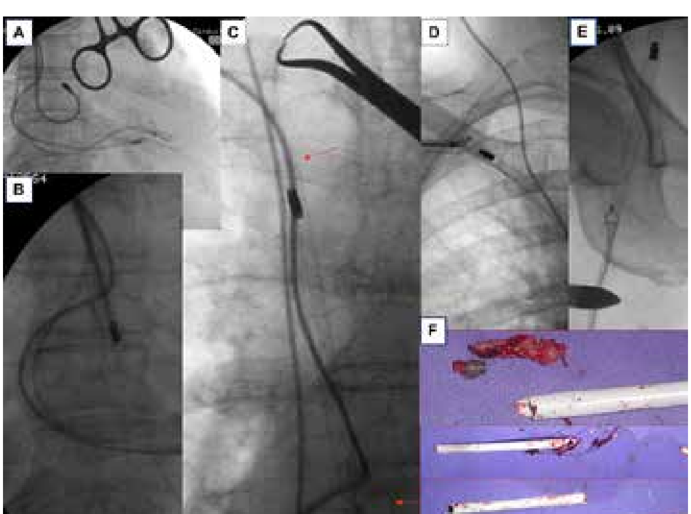

Figure 6 BDD with fragmentation of both the sheath and the lead. A problematic situation. Anineffective removal attempt via subclavian approach and a successful extraction via femoral access.

3. A sheath fracture with subsequent fragmentation (Figure 6) – type C.

Statistical analysis

Statistical analysis comprised: descriptive statistics – average values, standard deviation (SD) for all parameters; comparison of average measurable parameters using the chi2 test. P<0.05 was assumed as statistically significant.

Results

Byrd dilator damage was observed in 39 patients out of 1728 (2.25%) extraction procedures of 2901 (1.34%) leads. Detailed analysis of cases is presented in Table 1. There were 59 procedures from the right or both side subclavian approach; 10 (25.6%) incidents of BDD occurred in this group. In 15 (38.5%) cases of damage, ICD leads were involved. Eleven (28.2%) incidents were noted in cases of particularly strong adherence between the leads. BDD was identified in: the superior vena cava (SVC) 17 (43.6%), right atrium 8 (20.5%), right brachiocephalic vein 8 (20.5%), left subclavian vein 5 (12.8%) and right ventricle 1 (2.6%). It is interesting that practically in all 26 cases of BDD in the SVC, RA and RV location the lead was extracted via the left subclavian approach (2 of them were noted in the right venous angle). Green sheaths (10F) used in pacemaker lead extraction were most often damaged (20 – 51.3%); white (11.5F) frequently needed for ICD lead removal were second (12 – 30.8%); orange (13F), used as an option if procedural difficulties arose, were broken rarely (6 – 15.4%). Only one yellow (8.5F) sheath was damaged (2.5%). In 8 (20.5%) procedures damage of another sheath occurred in the same location. In 3 (7.7%) cases complete sheath rupture was observed, and there was 1 (2.5%) incident of sheath torsion (without fragmentation). Thirty-one (79.5%) cases of damage were eliminated by covering the broken inner sheath with the outer sheath followed by their common removal. In 4 (10.2%) cases a wider tube was introduced over the damaged one and extracted at the end of the procedure with the lead. In 3 (7.7%) cases during attempts of sheath straightening the distal ending of the lead was spontaneously liberated, and the procedures ended without complications. Only in 1 (2.5%) case could the fragment of the sheath not be removed via the same access – it was shifted to the inferior vena cava and extracted by the femoral approach. A following surgical procedure was not necessary.

BDD risk factors and influence of the phenomenon on TLE effectiveness

Procedures in which BDD was observed concerned relatively young patients (mean age 56±18.9 vs 64.8±15.8 p=0.0006) with more extracted leads (1.9±1.2 vs 1.7±0.8 lead per patient, p=0.05), with longer lead body dwelling time (120±63.6 months vs 83.9±63.2 p=0.0004), with more unnecessary lead loops (17.9% vs 6.2% p=0.003) and with leads on both sides of the chest (17.9% vs 4.3% p=0.001). In general, this phenomenon occurs mostly in complex procedures. In Table 2 characteristics

Table 1. Cases analysis

Nr	Gender	Approach	Lead detailed information	Lead to lead adhesions	Fracture location	Colour	Single / Multiple	Break Yes/No	Management
1	F	L	PM BP A	Yes	SVC	G-W-O	S	No	Replacement
2	M	L	PM BP P	No	SVC	W-O	S	No	Replacement
3	M	L	ICD C2 P	Yes	SVC	W-O	S	No	Replacement
4	M	R	ICD C2 P	No	SVC	G-W-O	S	Yes	Over-the technique
5	M	L	PM BP P	Yes	LSV	G-O	M	Yes	Over-the technique
6	M	R	ICD C2 A	No	RBC	W	M	No	Over-the technique
7	F	L	ICD C2 P	No	SVC	W-O	S	No	Replacement
8	M	R	PM UP P	No	RBC	Y-M	S	No	Replacement
9	M	L	ICD C2 A	No	LSV	O	S	No	Replacement
10	M	L	PM VDD P	No	SVC	O	S	No	Replacement
11	M	R	PM BP P	Yes	RV	W	S	No	Traction
12	M	L	ICD C2 A	No	SVC	O-O-O	M	No	Replacement
13	M	L	ICD C2 A	No	SVC	O-O-O	M	No	Replacement
14	M	L	ICD C2 A	Yes	SVC	O-O-O	M	No	Replacement
15	M	L	PM BP P	Yes	SVC	G-G	S	No	Replacement
16	F	L	ICD C2 P	No	SVC	O-O-O	S	No	Traction
17	F	L	PM BP P	Yes	RA	G-G-W	S	No	Replacement
18	F	R	PM BP P	Yes	RBC	G-W-O-	M	No	Replacement
19	F	L	PM BP A	No	RA	G-G	S	No	Replacement
20	M	L	PM BP P	No	RA	G-G	S	No	Over-the technique
21	M	L	ICD C2 A	No	SVC	G-W-O	S	No	Replacement
22	M	L	PM BP P	No	RA	G-W-O	S	No	Replacement
23	F	L	PM UP P	No	LSV	G-W-O	S	No	Replacement
24	F	L	PM BP P	No	RA	G-W-O	S	No	Replacement
25	F	L	PM VDD P	No	LSV	W-W	S	No	Replacement
26	F	R	PM BP P	No	RBC	G-W-O	M	No	Replacement
27	F	L	PM BP A	No	SVC	G-G	S	No	Replacement
28	M	L	ICD C2 A	No	SVC	W-O-O	S	No	Replacement
29	M	L	ICD C2 A	No	SVC	W-O-O	S	No	Replacement
30	M	R	PM BP P	No	RBC	G-G	S	No	Replacement
31	M	L	PM BP P	Yes	RA	G-G	S	No	Traction
32	M	L	PM BP P	No	RA	G-W	S	No	Replacement
33	F	L	PM BP P	No	LSV	G-G	S	No	Replacement
34	M	R	PM BP P	No	RBC	G-G	S	No	Replacement
35	M	L	ICD C2 P	No	SVC	W-O-O	S	No	Replacement
36	F	R,F	PM BP P	No	RBC	W-O	S	Yes	Femoral
37	M	L	PM BP P	Yes	SVC	G-W-O-O	S	No	Replacement
38	F	L	ICD C2 P	No	RA	W-O-O	S	No	Replacement
39	F	R	ICD C2 P	Yes	RBC	W-O-O-O	M	No	Replacement

Gender: F-female, M-male; **Approach:** L-left subclavian, R-right subclavian, F-femoral; **Lead:** PM/ICD, BP - bipolar, UP - unipolar, A-active fixation, P-passive fixation, C - coil number; **Fracture location:** SVC - superior vena cava, LSV - left subclavian vein, RBC - right brachiocephalic vein, RV - right ventricle, RA - right atrium; Colour: G- green, W - white, O- orange, Y - yellow, M - metal,

Table 2. Byrd dilator sheath damage during TLE – patient characteristics

Patient / system / procedure information	Without BDD	BDD	t / X2	P**	All procedures
Number of patients	1689	39	-	-	1728
Patient's age (SD)	**64,8** ±15,8	**56,0** ±18,9	**3,44**	**0,0006**	**64,6 ±15,9**
Sex (% of male patients)	1021 60,4%	25 64,1%	0,21	0,63	1046 60,5%
General infection (LRIE)	480 28,4%	10 25,6%	0,14	0,68	490 28,3%
Local pocket infection	209 12,4%	6 15,4%	0,32	0,58	215 12,4%
Non-infective indications	1000 59,2%	23 58,9%	0,001	0,98	1023 59,2%
Number of extracted leads in one patient (SD)	**1,7** ±0,8	**1,9** ±1,2	**2,00**	**0,05**	**1,68 ±0,79**
Number of leads in the system	1,80 ±0,64	1,74 ±0,59	0,58	0,56	1,80 ±0,64
Number of abandoned leads	0,2 ±0,6	0,3 ±0,6	1,10	0,27	0,21 ±0,56
CS (LA, LV) lead extraction	246 **14,6%**	1 **2,6%**	**4,48**	**0,04**	**247 14,29%**
VH therapy (ICD) lead extraction	426 25,2%	15 38,5%	3,52	0,06	441 25,52%
Too long loops or long loop in right atrium or ventricle	104 **6,2%**	7 **17,9%**	**8,82**	**0,003**	**107 6,42%**
Number of procedures before lead extraction	**1,9** ±1,1	**2,3** ±1,2	**2,30**	**0,02**	**1,89 ±1,16**
Mean leads body dwelling time	**83,9** ±63,2	**120,0** ±63,6	**3,53**	**0,0004**	84,75 ±63,45
Both (R&L) chest side lead venous entry	73 **4,3%**	7 **17,9%**	**16,03**	**<0,001**	**80 4,63%**

of patients who underwent TLE procedures with/without a BDD incident are compared.

BDD (compared with the no-BDD group) was associated with the phenomenon of lead-to-lead adherence (28.2% vs 4.7% p<0.001) and TLE from a right or even both side subclavian approach (2.6% vs 1.7% p=0.007). Although BDD concerned more complex procedures, the complication rate in these cases was not significantly higher. The full procedural success rate was slightly lower (84.6% vs 95.4% p=0.002), but the full clinical success rate was comparable in both groups (97.4% vs 98.1%, p=NS). The influence of BDD on TLE difficulty and effectiveness is presented in Table 3.

Discussion

Byrd dilator sheath damage is well known to cardiologists involved in TLE. BDD is not a complication unless a serious clinical state threatening the patient's health occurs. In our opinion it should be regarded as a technical complication, which prolongs the procedure and makes it even more difficult. However, BDD occurrence may require sheath movements (tube removal or shift inside the cardiovascular system into a straight section of the vein), also pulling the lead blocked by the broken sheath fragment, with no counter-traction forces – which may lead to a major procedural complication. The first reports regarding lead extraction do not mention incidents of BDD [1-4], probably because at that time thick Teflon sheaths were used. In the next years the authors still did not analyze separately technical complications (which prolong the procedure), focusing on major and minor procedural complications [5-8]. Recently, in two major studies such issues were also not presented[12,13]. On the other hand, nowadays laser or radiofrequency powered sheaths are commonly used. These tools may resist strong deflection forces. However conventional mechanical sheaths are still frequently used (for economical reasons as first line equipment); therefore the BDD phenomenon remains interesting.

In our previous studies technical (apart from major and minor) complications were assessed[10,11,14,15]. BDD is an example of such difficulty, but there are also strong lead-to-lead adherence, accidental lead rupture, dislocation of a functional

Table 3. Comparison of TLE effectiveness, safety and procedural factors in BDD and no-BDD group.

Patient / system / procedure information	Without BDD	BDD	t / X2	P**	All procedures
Extracted lead to another lead strong adherence	79 4,7%	11 28,2%	19,99	<0,001	90 5,2%
Right side extracted lead venous entry	55 3,3%	9 23,1%	8,26	0,001	64 3,7%
Both (R&L) chest side lead extraction	28 1,7%	1 2,6%	7,88	0,007	29 1,7 %
Major complications	25 1,5%	1 2,6%	0,30	0,58	26 1,5%
Other technical problems during TLE	229 13,6%	18 46,1%	33,06	<0,001	247 14,3%
Full radiological success	1612 95,4%	33 84,6%	9,77	0,002	1645 95,2%
Full Clinical success	1657 98,1%	38 97,4%	0,09	0,75	1695 98,1%
Full procedural success	1611 95,4%	33 84,6%	9,55	0,002	1644 95,1%
Procedure related death	5 0,3%	0 0,0%	0,12	0,71	5 0,3%
Indication related death	4 0,2%	0 0,0%	0,09	0,75	4 0,2%
Operating room stay-in time (whole procedure duration) (minutes)	107,7 ±44,3	155,3 ±61,2	6,57	<0,0001	108,7 ±45,3

lead, complete extraction after lead fragmentation, and the necessity of approach site change.

Fracture mechanisms:

Byrd dilator sheaths, like other tools used for separation of a lead from fibrotic tissue, function most efficiently if the lead course is rather straight. A high deflection angle is potentially the main reason for fractures. Therefore the extraction of the leads implanted on the right side of the chest and a specific anatomy (broad, short thorax and dilated heart volume) may cause technical complications (Figure 7).

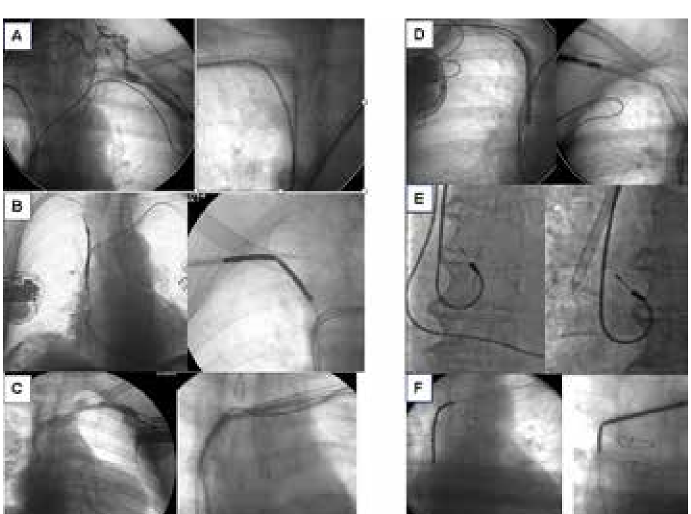

Figure 7 Examples of procedures, in which the operator would expect fractures - right subclavianapporach (A,B,D) proximal defibrillating coil ingrown in right (B,D) or left (F) brachiocephalic vein,broad chest and dilated heart (C), the lead firmly adhering RA wall (E).

Damage was observed from the very beginning of TLE; therefore the conception of a pair of tubes called the telescopic system which reduced not only rolling resistance, but also the probability of fractures on mild curves, appeared to be revolutionary. A pair of sheaths used simultaneously increases stiffness of the system, which in turn may lead to vessel wall damage on the sharp bend – a single sheath is used in these regions, which implies higher risk of fractures (Figure 8).

Appropriate lead tension plays a very important role during extraction (Figure 9). Accidental decrease of the traction (pulling) forces, when the distal ending is firmly fixed, may lead to fracture (even of the system of two sheaths).

A fracture may occur during the process of moving the outer sheath forward (over the inner sheath) after crossing

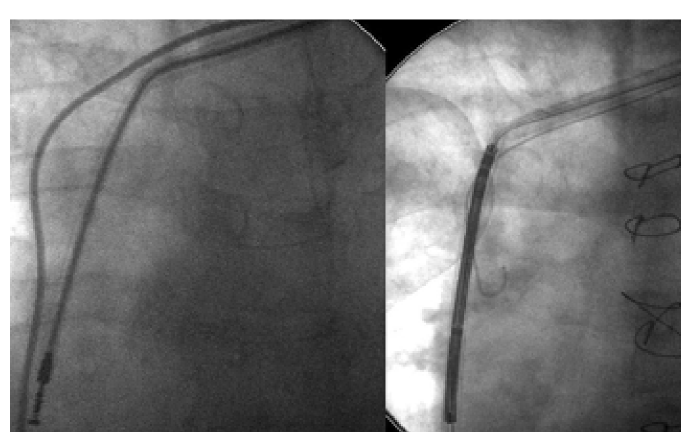

Figure 8 "Sharp bend" - the inner (more flexible) sheath is coming out of the outer sheath. The distalending of the outer sheath might be a location of a fracture.

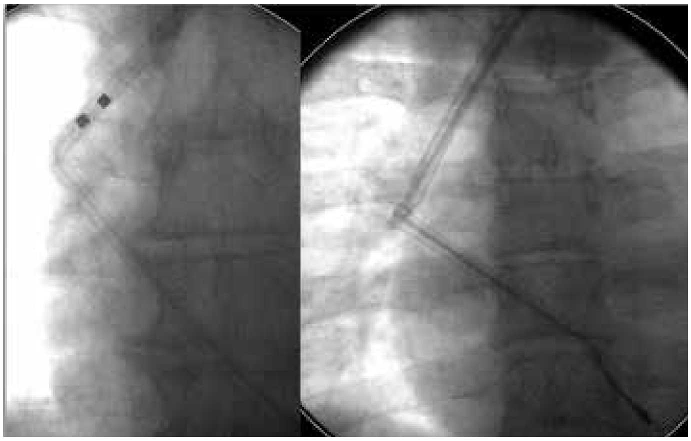

Figure 9 A sudden lead tension decrease- results in taking the arc form of the telescopic system. Themoment of a sheath replacement is particularly dangerous.

a sharp curve to prevent vessel wall damage. Difference of stiffness (between the inner sheath and the two sheaths) may lead to a fracture. The last mechanism is very similar to the previous one. Once the cutting edge of the inner sheath becomes blunt and the sheath is removed without withdrawal of the whole telescopic system, the difference in stiffness at the curves might cause a fracture.

Effects of Byrd dilator sheath damage and solutions of the arising problems

1. The damage itself, if identified on time, does not imply any negative consequences; a damaged sheath should be replaced. The X-ray image is characteristic; the operator may experience a new, elastic resistance during the moves of rotation. Early detection (if a broken sheath still has a lumen) enables gentle withdrawal of the damaged tube.
2. If the elastic resistance mentioned in the first point is slightly overcome by the operator (BDD is not identified early), the lumen of the sheath might be nearly closed. Removal of such a tube might become difficult. Pulling out this sheath results in simple traction of the extracted lead without countertraction forces, which may cause lead rupture or vessel wall damage. In such situations, the broken fragment should be moved out of the region of the curve – forwards or backwards. Then a new, wider sheath ought to be introduced over the damaged one, so that the procedure can be continued (Figure 10).
3. Sometimes many rotations are performed by the operator until he realizes that the sheath is severely damaged. In this case, the situation is more complex – both the tube and the extracted lead might be broken. "Emergency techniques" are the same as above.
4. Complete sheath rupture – in the X-ray image, the distal ending of the sheath was not moving despite the action of rotation forces. The course of action is similar as above, but the proximal (broken) ending needs to be recaptured. A thinner tube should be introduced (as a guide wire) over the lead; afterwards, the widest possible sheath may cover the broken fragment (Figure 11.).
5. Complete sheath and lead rupture – the worse variant. The course of action in such cases depends on the operator's creativity and technical skills. All efforts should be made to avoid serious thoracic surgery. (Figure 6)

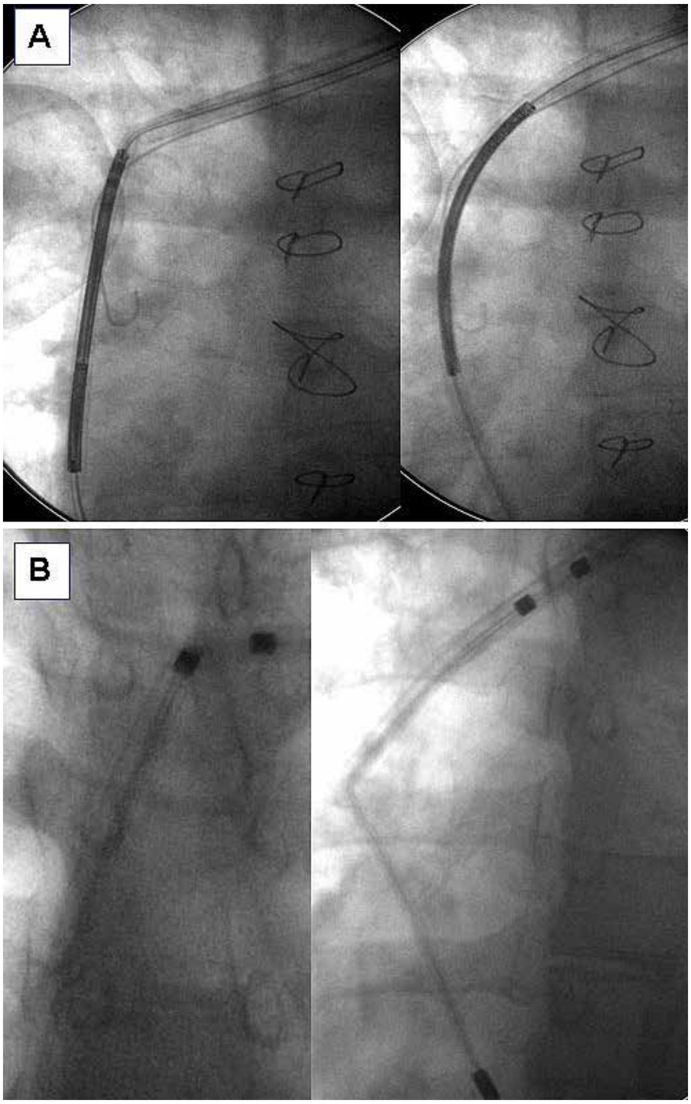

Figure 10 Covering the broken sheath with a new wider tube. In this option, the tension of the leadshould be reduced (potentially dangerous) resulting in lower degree of deflection of the broken sheath,so that a wider tube could be introduced.

Conclusions

1. Byrd dilator sheath damage (excluding blunting of the sheath edge) occurs in about 2% of transvenous lead extraction procedures. Only damage followed by sheath lumen closure, or rupture, which are the results of the late identification of the phenomenon, remains problematic.
2. Byrd dilator sheath damage occurs in patients with numerous procedural risk factors – more extracted leads, unnecessary lead loops, longer lead dwelling time.

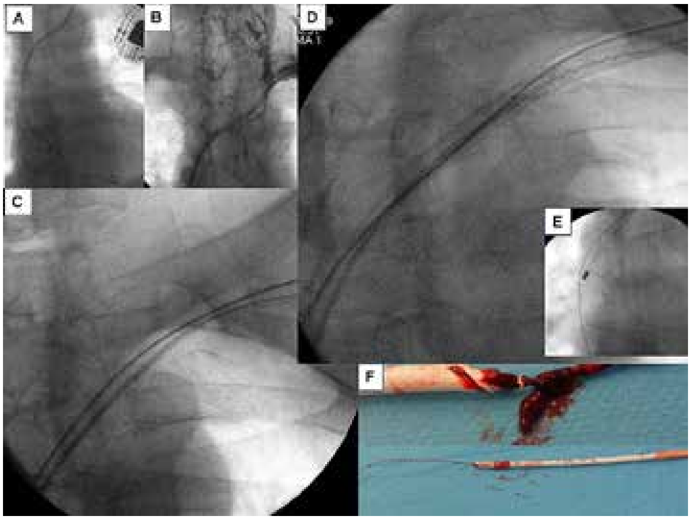

Figure 11 The example of handling a complete sheath rupture (without a lead fracture). Wider sheathintroduction plays a key role.

3. Byrd dilator sheath damage does not have an influence on transvenous lead extraction effectiveness but results in procedure prolongation.
4. Because serious Byrd dilator sheath damage concerns the mid part of the sheath, one should observe the total course of the sheath all the time.

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