Kardiologia Polska 2015; 73, 7: 511–519; DOI: 10.5603/KP.a2015.0038 ISSN 0022–9032

ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Periprocedural checklist in the catheterisation laboratory is associated with decreased rate of treatment complications

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Abstract

Background: Interventional cardiology and electrophysiology are disciplines with a growing number of complex procedures, which are exposed to the occurrence of many complications.

Aim: To assess efficacy and legitimacy of the periprocedural checklist in prevention of cardiovascular adverse events, in elective patients undergoing invasive diagnostic and treatment.

Methods: A total of 2064 patients directed to treatment in the catheterisation laboratory between May 2011 to August 2012 were analysed. Patients who were hospitalised without invasive diagnostics and treatment were not included in the study. Patients were divided into two groups: a control group — 1011 patients with invasive diagnostics and treatment before introduction of periprocedural checklist; and an intervention group — 1053 patients with invasive diagnostics and treatment after introduction of periprocedural checklist. We analysed the studied groups, assessing adverse events associated with hospitalisation and performed procedures. We also conducted subjective evaluation of checklists by medical staff on the basis of a questionnaire.

Results: Baseline characteristics between the studied groups were comparable except for a higher rate of stable coronary artery disease (50.7% vs. 39.6%, $p \leq 0.001$) and electrophysiology procedures in the control group. Implementation of a checklist was favourable in cases of decreased adverse events (6.8% vs. 3.9%, $p = 0.004$) especially bleedings (2.3% vs. 0.3%, $p < 0.001$). Multivariate analysis confirmed that lack of a periprocedural checklist during hospitalisation was an independent factor associated with a higher rate of adverse events (OR = 2.97, 95% CI 1.60–5.53, $p = 0.001$). Subjective evaluation of medical staff opinions showed that implementation of a checklist seems to be associated with improved communication skills, work organisation, prevention of the occurrence of medical errors, and reduced rate of complications associated with procedures.

Conclusions: Introduction of a periprocedural checklist was associated with significant reduction of adverse events among patients undergoing invasive procedures. It also showed a positive influence on team communication, and organisation and quality of treatment, according to the opinions of medical staff.

Key words: complications, percutaneous coronary intervention, coronary artery disease, electrophysiology, bleedings

Kardiol Pol 2015; 73, 7: 511–519

INTRODUCTION

Modern cardiology wards equipped with a Catheterisation Laboratory have to face rising requirements, which are associated with the rapid development of cardiology and electrophysiology in recent years. The wide spectrum of procedures inevitably increases the risk of unintended errors committed by physician and nurses. The estimated percentage of complications occurring during these procedures is around 3.36% for percutaneous coronary interventions (PCI) and 4% for electrophysiology procedures, and partially depends on whether the procedures are planned or urgent [1, 2]. Some of adverse events cannot be avoided; however, some of them could be caused by a lack of proper communication by medical staff or sufficient attention devoted to the patient during

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Received: 01.10.2014 **Accepted:** 22.01.2015 **Available as AoP:** 23.02.2015

particular stages of treatment. It seems that a solution that could be helpful in the optimisation of therapeutic process safety is the introduction of a periprocedural checklist. The whole concept was derived from airline pilot procedures, where it is used to minimise the risk of human-derived errors. The efficacy of the checklist in medicine was confirmed in surgery. A prospective multi-centre study showed that the introduction of a checklist was associated with a significant reduction in mortality (1.5% vs. 0.8%, $p = 0.003$) and complications (11% vs. 7.0%, $p < 0.001$) among patients undergoing surgical procedures [3].

Current European Society of Cardiology (ESC) and American Heart Organisation (AHA) guidelines do not contain recommendations suggesting the use of checklists on interventional cardiology wards; however, its construction for minimising human error and to prevent complications during interventional procedures was suggested in literature, but as yet no study has been conducted to asses its influence on treatment outcomes and complications [4, 5].

The aim of this study was to assess the efficacy and legitimacy of the periprocedural checklist in the prevention of adverse cardiovascular events in elective patients undergoing invasive cardiology and electrotherapy treatment before and after its introduction in a cardiology ward. Additionally, we evaluated subjective importance, and relevance in treatment process and work organisation of the checklist among medical staff.

METHODS

We conducted a retrospective analysis of consecutive patients admitted to the Department of Cardiovascular Diseases in the Silesian Centre for Heart Diseases before and after checklist introduction. We included only patients with stable coronary artery disease because our department does not have an emergency room for patients with acute myocardial infarction. The ward is equipped with 42 beds, including 12 intensive care units. The catheterisation laboratory is provided with access to the medical devices necessary to perform the whole spectrum of coronary, electrotherapeutic, and electrophysiology procedures. All patients who underwent invasive diagnostic and treatment were included in the analysis and were subsequently divided into two groups: a control group -— patients with invasive diagnostics and treatment before the introduction of the periprocedural checklist; and an intervention group — patients with invasive diagnostic and treatment after the introduction of the periprocedural checklist. Patients who were hospitalised in the ward without invasive procedures were not included in the study. Data regarding treatment process, performed procedures, and occurred complications were obtained from prospectively collected Central Database of Electronic Medical History and IT system of the Silesian Centre of Heart Diseases in Zabrze. Every adverse event observed in database was verified by inspection of medical history. All patients were pharmacologically treated according to current ESC guidelines.

Evaluation of the periprocedural checklist was performed on the basis of a questionnaire. The study included doctors, nurses, and medical technicians. It excluded persons who were employed after the introduction of the cardiology checklist to everyday practice and respondents whose answers were incomplete or imprecise. The method employed in this study was the diagnostic poll method; data were collected by means of a survey given to the participants, which contained a set of close-ended questions. All respondents were asked the same questions, concerning the periprocedural safety checklist and its influence on work organisation, communication, and the quality of care.

Intervention

The intervention involved implementation of the periprocedural checklist, which was prepared on the basis of the Cardiology and Cardiovascular Diseases Department's work characteristics. The checklist scheme represents following the steps of the patient's preparation for invasive diagnostics and treatment. A full version of the document is available in the Appendix 1. In brief, the checklist consists of four parts. The first part contains information about the type of planned procedure, conducted tests, current laboratory parameters and pharmacological treatment, patient allergies, preferred peripheral access, type of stent to be used, and consent to treatment signed by the patient. This part is authorised and signed by the physician. Subsequently, a periprocedural checklist is passed to the nurse on the ward, who fills in the section focused on the patient's preparation for the procedure. Afterwards the patient is transferred to the catheterisation/electrophysiological laboratory, where nurse and operator check his/her preparation, familiarise themselves with the information contained in the document, and confirm it with their signatures. The third part, complemented and signed by operator, includes data on the type and course of the procedure and also recommendations about further postprocedural care on the ward. The last part of the periprocedural checklist is designed to keep or in some cases modify the advice given by both the nurse and the physician on the ward. After patient discharge it is archived in the hospital database. This document refers to the whole course of the patient trough the diagnostic or treatment process including preparation, performing procedure/s, and the subsequent care. Immediately before the introduction of the periprocedural checklist, all personnel participating in the treatment process were carefully trained in fields complementing particular sections and interpretation of recommendations included in the document. Implementation of the mentioned instrument was preceded by a two-week probation period, during which the study team explained every concern and determined the final procedure of logistics. Optimisation of the treatment program was finally launched in November 2011.

Definition

For the purposes of the study, the endpoint was defined as the occurrence of major adverse cardiac and cardiovascular events (MACCE) during the treatment process, until discharge. The primary outcome measures consisted of: all bleedings, stroke/transient ischaemic attack (TIA), myocardial infarction, repeat PCI, and death. Moreover, we analysed separately any bleeding complications. Definitions were as follows: all bleedings — any bleeding which occurred during hospitalisation; stroke/TIA — neurological deficit of cerebrovascular cause that persisted beyond 24 h or was interrupted by death within 24 h, which is defined to last less than 24 h; repeat PCI — every subsequent revascularisation procedure; myocardial infarction — either new, abnormal Q waves and one ratio of peak creatine kinase-MB (CK-MB)/peak total CK > 10%, or new, abnormal Q-waves and one plasma level of CK-MB 5 × the upper limit for normal; death — death for any reason, all deaths were considered cardiac unless an unequivocal non-cardiac cause can be established.

Statistical analysis

Comparative analysis of the studied groups included: baseline clinical characteristics, types of performed procedures, and occurred complications. Distribution of quantitative variables was evaluated with Shapiro-Wilks test. Due to significant derogations from normal distribution, U-Mann-Whitney test was used. The results of quantitative analysis are listed as the arithmetic mean and standard deviation. Qualitative parameters were analysed using Pearson's χ^2 test. Analysis of factors influencing the occurrence of adverse events was conducted with logistic regression, and model reduction was conducted using stepwise regression. Results were listed as odds ratio (OR) and 95% confidence interval (CI). The level of statistical significance was $p < 0.05$ (two-tailed). STATISTICA 10 software (StatSoft, Inc., Tulsa, OK, USA).

RESULTS

A total of 2064 patients were enrolled in the study: the control group consist of 1011 patients, and intervention group consisted of 1053 patients. Baseline characteristics with regard to the leading medical diagnosis at admission and comorbidities are shown in Table 1. In the period before the introduction of the periprocedural checklist there was a significantly higher rate of patients with diagnosed stable coronary artery disease in the control group (50.7% vs. 39.6%, $p \leq 0.001$). Patients' ages were comparable in both studied groups (63.7 ± 10.4 vs. 63.3 ± 10.4, $p = 0.2$). Characteristics of performed invasive procedures are presented in Table 2. After introduction of the checklist we performed a significantly higher rate of cardioverter implantations, and fewer resynchronisation and right heart catheterisation procedures (respectively: 5.7% vs. 10.5%, $p = 0.001$; 5.7% vs. 3.7%, $p = 0.03$; 4.1% vs. 2.3%, $p = 0.03$). The number of ablations was relatively small in both study periods.

Table 1. Main diagnosis at admission and comorbidities

	Control (n = 1011)	Intervention (n = 1053)	P
Hypertension	70.2%	69.5%	0.8
Stable coronary artery disease	50.7%	39.6%	0.0001
Heart failure	28.4%	30.1%	0.4
Acquired heart defects	24.7%	21.0%	0.06
Atrial fibrillation	18.8%	16.9%	0.3
Complex ventricular arrhythmias	4.9%	3.4%	0.1
Atrial flutter	1.1%	1.1%	0.9
Congenital heart defect	1.3%	0.9%	0.4

Table 2. Type of performed procedure

	Control (n = 1011)	Intervention (n = 1053)	P
Coronary angiography	87.1%	87.2%	0.9
Percutaneous coronary intervention	32.0%	32.4%	0.8
Pacemaker implantation	4.7%	4.8%	0.9
Implantable cardioverter--defibrillator	5.7%	10.5%	0.0001
Resynchronisation therapy	5.7%	3.7%	0.03
Right heart catheterisation	4.1%	2.3%	0.03
Ablation	0.7%	0.3%	0.3

Study endpoint analysis showed a significantly smaller rate of combined adverse cardiac events in the intervention group (3.0% vs. 0.9%, $p = 0.001$). The results of adverse events rates in in-hospital observation are presented in Table 3. Multivariate analysis confirmed that the lack of a periprocedural checklist during hospitalisation was an independent factor associated with a higher rate of adverse events, together with diagnosis of stable coronary artery disease, valvular heart disease, atrial fibrillation at admission, and age of patients (Table 4).

Detailed data regarding the subjective importance of the survey were published elsewhere [6]. In brief, evaluation of the periprocedural checklist was performed by 85 persons: 31 doctors, 46 nurses, and 8 medical technicians. More than 80% of physicians and nurses found that implementation of the checklist was legitimate. Summarising, we could state that its implementation improved communication skills and work organisation in both the cardiology ward and the catheterisation laboratory, prevented the occurrence of medical errors, and reduced the rate of complications associated with the

Table 3. Results for primary outcome measurers

	Control (n = 1011)	Intervention (n = 1053)	P
Bleedings	2.3%	0.3%	0.0001
Access point	1.8%	0.3%	0.001
Gastrointestinal tract	0.4%	0%	NS
Retroperitoneal	0.1%	0%	NS
Stroke/transient ischaemic attack	0.5%	0.2%	NS
Acute myocardial infarction	0.2%	0.3%	NS
Repeat percutaneous coronary intervention	0%	0.2%	NS
Death	0%	0%	NS
Major adverse cardiac events — all	3.0%	0.9%	0.001

Table 4. Multivariate analysis of adverse events occurrence risk

	Odds ratio	95% confidence interval	P
Lack of periprocedural checklist	2.97	1.60–5.53	0.001
Stable coronary artery disease	2.04	1.33–3.12	0.001
Valvular heart disease	1.92	1.28–2.90	0.001
Atrial fibrillation	1.67	1.00–2.77	0.05
Age	1.08	1.02–1.13	0.004

procedure. Moreover, a significant proportion of personnel declared that it facilitated patient periprocedural care and also improved physicians' and nurses' quality care. The checklist precisely defines personnel tasks and specifies responsibilities. In the opinion of medical staff, implementation of the periprocedural checklist was legitimate.

DISCUSSION

Introduction of the periprocedural checklist decreased the rate of complications related to performed invasive cardiology and electrophysiology procedures. The positive effect observed after checklist implantation resulted principally from reduction of bleedings, especially from vascular access sites (relative risk reduction 83%). We did not observe significant differences in ischaemic complication rates. The positive impact of the periprocedural checklist on the occurrence of MACCE was confirmed in multivariate analysis.

The primary concept that encouraged the study team to introduce the periprocedural checklist was the assumption that a significant number of complications associated with invasive procedures could be caused by unintended mistakes and lack of proper team communication. The efficacy of the checklist was evaluated on a cardiology ward in which every type of interventional cardiology procedure is performed. Heterogeneity of the conducted procedures could cause unconscious omission of important aspects regarding periprocedural care by medical personnel. Considering the profile of the treated patients and the type of conducted interventions, during construction of the checklist we paid particular attention to aspects potentially connected with the occurrence of bleedings. It is known that bleeding complications determine patient prognosis to the same degree as ischaemic complications.

A number of studies have shown that bleeding complications after PCI are associated with adverse outcome [7–10]. Kinnaird et al. [10] observed that bleeding after PCI was associated with longer hospital stay (8.9 vs. 3.1 days, $p < 0.001$) and higher in-hospital and one-year mortality. In the multivariate regression analysis Thrombolysis in Myocardial Infarction, major bleeding after PCI was an independent predictor of in-hospital mortality [10]. These findings were confirmed in the large NHLBI Dynamic Registry, in which patients experiencing access-site haematomas requiring transfusions were nine times more likely to die during hospitalisation (1.2% vs. 9.9%; OR 9.32; 95% CI 4.93–17.63) [9]. In the REPLACE study assessing antithrombotic regiment with bivalirudin ± glycoprotein (GP) IIb/IIIa inhibitors, patients with major haemorrhage had significantly higher mortality rates at 30 days, and at 6 and 12 months. Major bleeding was found to be an independent predictor of one-year mortality [11].

The potential mechanisms underlying the association between bleedings and outcomes are multifactorial. Most obvious causes are: hypovolaemia, anaemia, hypotension, and diminished oxygen-carrying capacity from acute blood loss. The next factor is blood transfusion, which somehow increases the risk of adverse events among patients with major bleeding complications [10]. The reason for this correlation remains unclear [12].

Different strategies may be applied to diminish the risk of bleeding complications. The most important are optimisation of periprocedural pharmacology and procedural access site assessment. Unfractionated heparin (UFH) is the most common antithrombotic drug. There is a direct correlation between antithrombotic power assessed with activated clotting time and the risk of bleeding and ischaemic complications [13]. There were a lot of studies assessing different pharmacological strategies to reduce the risk of bleedings. In the STEEPLE trial low-molecular weight heparin (LMWH) was compered to UFH in 3528 patients undergoing elective PCI procedures. LMWH was given in two regimes: 0.5 mg/kg and 1.0 mg/kg. The rate of major bleedings was the lowest in the low-dose enoxaparin group (5.9% vs. 6.5% vs. 8.5% for 0.5 mg, 1.0 mg enoxaparin and UFH, respectively). However, the risk of ischaemic

complications was significantly higher in the low-dose enoxaparin group, which limited its widespread acceptance for PCI [14]. Another studied agent was bivalirudin. In the REPLACE-2 study 6010 patients undergoing elective and urgent PCI were assigned to UFH + GP IIb/IIIa inhibitors or bivalirudin with provisional GP IIb/IIIa. There was no difference in ischaemic adverse events frequency, but significant reductions in bleeding complications in the bivalirudin group were observed (2.4% vs. 4.1%, $p < 0.001$). The most common reason for major bleedings in this study was access site bleeding (2.5% vs. 0.8% for UFH and bivalirudin, respectively) [15]. The strategy without antithrombotic treatment during simple elective PCI procedure was assessed in the CIAO trial [16]. A total of 700 patients on dual antiplatelet therapy were randomly assigned to either a standard group (UFH dose 70–100 UI/kg) or a no-heparin group. Bleeding complications were significantly lower in the no-heparin group (1.7% vs. 0.0%, $p = 0.048$). There were no differences in ischaemic events. Surprisingly, in the no-heparin group there was a significantly lower incidence of postprocedural CK-MB elevation (1.7% vs. 3.1%, $p < 0.05$) [16].

Access site bleedings are the most common complication of the transfemoral approach [15]. Therefore, changing the access site to the radial artery may be the most effective single procedural method to reduce bleedings. In a large multicentre study conducted by Jolly et al. [17], which compared radial vs. femoral approach in patients directed to invasive diagnostics or treatment, there was a significant reduction in large haematoma at 30 days in patients who underwent procedures from radial approach compared to femoral (hazard ratio [HR] 0.40, 95% CI 0.28–0.57, $p < 0.0001$). However, there were no statistical differences in primary endpoint, which was composite of death, myocardial infarction, stroke, or non-coronary artery bypass graft-related major bleeding at 30 days (HR 0.92, 95% CI 0.72–1.17, $p = 0.50$) [17]. Almost all studies comparing transradial and transfemoral approach show benefits in terms of bleedings in the radial groups [18–20]. The transradial approach seems to be the most effective among patients with increased risk of bleeding complications like acute coronary syndromes treated with potent antithrombotic agents or atrial fibrillations requiring oral anticoagulation [17].

Bleeding complications, especially haematomas, occurred quite often after electrotherapy procedures, ranging from 2.9% to 9.5% of cases [21]. Similarly to coronary procedures, anticoagulation and antiplatelet therapies are the most important issue. Aspirin therapy carries a two-fold risk of bleeding, and dual antiplatelet therapy increases that risk by a factor of four [22]. Also, the use of heparin bridging to oral anticoagulation carries a substantial risk of bleeding; therefore, procedures with mild oral anticoagulation were proposed (international normalised ratio < 2.0) [23].

In the analysed population the primary effect of the introduction of the checklist was a reduction in periprocedural bleeding complications. This seems to be associated with effective and critical assessment of applied anticoagulant, antiplatelet treatment and the vascular access site used. When preparing the study, we were focused on the course of patient preparations to the procedure and communication within the medical staff. Therefore we did not analyse periprocedural preparation regimens and pharmacotherapy but concentrated on the systemic solution for the improvement of patient safety. The results of our study encourage use of the checklist for this purpose. However, it cannot be ruled out that the Hawthron effect was partially responsible for the achieved results, in which improved quality is associated with the fact that the evaluated team is being observed [24]. In the presented study there is no possibility to determine how it affected improvement of treatment quality.

Analysing subjective evaluation of periprocedural checklist by medical staff, it can be stated that every occupation group (physicians and nurses) favourably evaluated implementation of this procedure. The checklist is a simple tool for reduction of periprocedural complications, which helps medical personnel to provide proper patient care. Introduction of the checklist is legitimate and well understood by the therapeutic team.

Limitations of the study

The main limitation of presented study is fact that it was a retrospective analysis. Nevertheless, from the perspective of the reliability of the obtained data it could be an advantage, to some extent eliminating the impact of the Hawthrone effect. The therapeutic team was not aware that it would undergo quality assessment. Additionally, we did not collect data on pharmacology regimens, but in terms of the main principle of the study it was not an issue. Moreover, the results are derived from a single cardiology ward, which involves limitations typical for single-centre studies.

CONCLUSIONS

Introduction of the periprocedural checklist was associated with a significant reduction in adverse events among patients undergoing invasive procedures, especially bleedings. It also had a positive influence on team communication, organisation, and quality of treatment, in the opinion of medical staff

Conflict of interest: *none declared*

Appendix 1. Periprocedural checklist

First part

Preparation for the procedure on the ward			
Planned procedure	☐ Coronary angiography	☐ Pressure measurement	☐ Biopsy
	☐ PCI	☐ ICD implantation	☐ BIV-ICD implantation
	☐ EP test and ablation	☐ Stimulator implantation	☐ Other
Normal sinus rhythm	☐ Yes	☐ No	
ECHO test done	☐ Yes	☐ No	
Normal blood morphology	☐ Yes	☐ No	
Normal coagulation parameters	☐ Yes	☐ No	
Normal electrolytes level	☐ Yes	☐ No	
Normal renal parameters	☐ Yes	☐ No	
Signed consent to treatment	☐ Yes	☐ No	
Metformin discontinuation in patient directed to test with imaging contrast	☐ Yes	☐ No	
Pregnancy test	☐ Yes	☐ No	
Palpable pulse on artery:	Radial R ☐ L ☐	Femoral R ☐ L ☐	Tibial post. R ☐ L ☐
Murmur in the groin	Right ☐ yes ☐ no	Left ☐ yes ☐ no	
Current pharmacological treatment:			
Anticoagulant	☐ Yes	☐ No	
	☐ Unfractionated heparin	☐ Low molecular weight heparin	
	☐ Acenocoumarol/Warfarin	Last dose ……	
Antiplatelet	☐ Yes	☐ No	
	☐ ASA ☐ Clopidogrel		
Antibiotic allergies ……	☐ Yes	☐ No	
Suggested vascular access	☐ Femoral	☐ Radial	☐ Other
	☐ Right / ☐ Left	☐ Right / ☐ Left	
Suggested type of stent	☐ DES	☐ BMS	

Signature of physician on ward ……

→

Second part

Patient preparation for the procedure

Peripheral venous catheter	☐ Yes	☐ No
Shaving and pre-disinfection of procedural area	☐ Yes	☐ No
Complete documentation of patient before transfer to cath-lab	☐ Yes	☐ No
Patient fasting	☐ Yes	☐ No
Patient urinated before procedure	☐ Yes	☐ No
Antibiotics given	☐ Yes	☐ No

Nurse's signature on ward .....

Patient reception in catheterisation/electrophysiology laboratory

Nurse's signature ..... Operator's signature .....

Third part

Catheterisation/Electrophysiology laboratory

Procedure performed	☐ Coronary angiography	☐ Pressure measurement	☐ Biopsy
	☐ PCI	☐ ICD implantation	☐ BIV-ICD implantation
	☐ EP test and ablation	☐ Stimulator implantation	☐ Other

Vascular access used:	Left site	Right site
Femoral artery	☐ Yes	☐ Yes .....
Radial artery	☐ Yes	☐ Yes .....
Femoral vein	☐ Yes	☐ Yes .....
Jugular vein	☐ Yes	☐ Yes .....
Other	☐ Yes	☐ Yes .....
	☐ No complications	☐ Complications

Local complications in Laboratory .....

.....

General complications in Laboratory .....

.....

Sheath removed	☐ Yes	☐ No	
	☐ Manually	☐ Starclose	☐ Exoseal
Sheath to be removed after	☐ 6 h	☐ 12 h	☐ Other .....
Pressure dressing for	☐ 6 h from.....	☐ 12 h from.....	☐ Other ..... from .....

Comments .....

Operator's signature .....

→

Fourth part

Patient care on ward after procedure

Sheath removed at .....

Pressure dressing at .....

Complications	☐ Yes	☐ No
Murmur over access area	☐ Yes	☐ No

Nurse's signature on ward ..... Physician's signature .....

References

1. Stathopoulos I, Jimenez M, Panagopoulos G et al. The decline in PCI complication rate: 2003–2006 versus 1999–2002. Hellenic J Cardiol, 2009; 50: 379–387.
2. Poole JE, Gleva MJ, Mela T et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation, 2010; 122: 1553–1561. doi: 10.1161/CIRCULATIONAHA.110.976076.
3. Haynes AB, Weiser TG, Berry WR et al. Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med, 2009; 360: 491–499. doi: 10.1056/NEJMsa0810119.
4. Van de Walle S, Lerman A, Chevalier B et al. Constructing a checklist for the prevention of complications during percutaneous coronary intervention. EuroIntervention, 2008; 4: 189–192.
5. Naidu SS, Rao SV, Blankenship J et al. Clinical expert consensus statement on best practices in the cardiac catheterization laboratory: Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv, 2012; 80: 456–464. doi: 10.1002/ccd.24311.
6. Czapla K, Gąsior M, Hawranek M et al. Analysis of the subjective assessment of the 'Periprocedrual safety checklist for patients referred to the hemodynamic and electrotherapy laboratories' by employees of the cardiology department and the hemodynamic laboratory of the Silesian Center for Heart Diseases. Kardioch Torakoch Pol, 2013; 10: 87–90. doi: 10.5114/kitp.2013.34312.
7. Rao SV, O'Grady K, Pieper KS et al. Impact of bleeding severity on clinical outcomes among patients with acute coronary syndromes. Am J Cardiol, 2005; 96: 1200–1206.
8. Fuchs S, Kornowski R, Teplitsky I et al. Major bleeding complicating contemporary primary percutaneous coronary interventions-incidence, predictors, and prognostic implications. Cardiovasc Revasc Med, 2009; 10: 88–93. doi: 10.1016/j.carrev.2008.08.001.
9. Yatskar L, Selzer F, Feit F et al. Access site hematoma requiring blood transfusion predicts mortality in patients undergoing percutaneous coronary intervention: data from the National Heart, Lung, and Blood Institute Dynamic Registry. Catheter Cardiovasc Interv, 2007; 69: 961–966.
10. Kinnaird TD, Stabile E, Mintz GS et al. Incidence, predictors, and prognostic implications of bleeding and blood transfusion following percutaneous coronary interventions. Am J Cardiol, 2003; 92: 930–935.
11. Feit F, Voeltz MD, Attubato MJ et al. Predictors and impact of major hemorrhage on mortality following percutaneous coronary intervention from the REPLACE-2 Trial. Am J Cardiol, 2007; 100: 1364–1369.
12. Vavalle JP, Rao SV. Impact of bleeding complications on outcomes after percutaneous coronary interventions. Interv Cardiol, 2009; 1: 51–62.
13. Chew DP, Bhatt DL, Lincoff AM et al. Defining the optimal activated clotting time during percutaneous coronary intervention: aggregate results from 6 randomized, controlled trials. Circulation, 2001; 103: 961–966.
14. Ferguson JJ, Califf RM, Antman EM et al. SYNERGY Trial Investigators. Enoxaparin vs unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndromes managed with an intended early invasive strategy: primary results of the SYNERGY randomized trial. JAMA, 2004; 292: 45–54.
15. Yusuf S, Zhao F, Mehta SR et al. Effects of clopidogrel in addition to aspirin in patients with acute coronary syndromes without ST-segment elevation. N Engl J Med, 2001; 345: 494–502.
16. Stabile E, Nammas W, Salemme L et al. The CIAO (Coronary Interventions Antiplatelet-based Only) Study: a randomized study comparing standard anticoagulation regimen to absence of anticoagulation for elective percutaneous coronary intervention. J Am Coll Cardiol, 2008; 52: 1293–1298. doi: 10.1016/j.jacc.2008.07.026.
17. Jolly SS, Yusuf S, Cairns J et al. RIVAL trial group. Radial versus femoral access for coronary angiography and interventions in patients with acute coronary syndromes (RIVAL): a randomized, parallel group, multicenter trial. Lancet, 2011; 377: 1409–1420. doi: 10.1016/S0140-6736(11)60404-2.
18. Agostoni P, Biondi-Zoccai GG, de Benedictis ML et al. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures; Systematic overview and meta-analysis of randomized trials. J Am Coll Cardiol, 2004; 44: 349–356.
19. Chase AJ, Fretz EB, Warburton WP et al. Association of the arterial access site at angioplasty with transfusion and mortality: the M.O.R.T.A.L study (Mortality benefit Of Reduced Transfusion after percutaneous coronary intervention via the Arm or Leg). Heart, 2008; 94: 1019–1025. doi: 10.1136/hrt.2007.136390.
20. Kiemeneij F, Laarman GJ, Odekerken D et al. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. J Am Coll Cardiol, 1997; 29: 1269–1275.
21. Brignole M, Auricchio A, Baron-Esquivias G et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J, 2013; 34: 2281–2329. doi: 10.1093/eurheartj/eht150.
22. Tompkins C, Cheng A, Dalal D et al. Dual antiplatelet therapy and heparin "bridging" significantly increase the risk of bleeding complications after pacemaker or implantable cardioverter-defibrillator device implantation. J Am Coll Cardiol, 2010; 55: 2376–2382. doi: 10.1016/j.jacc.2009.12.056.
23. Ghanbari H, Feldman D, Schmidt M et al. Cardiac resynchronization therapy device implantation in patients with therapeutic international normalized ratios. Pacing Clin Electrophysiol, 2010; 33: 400–406. doi: 10.1111/j.1540-8159.2010.02703.x.
24. Mayo E. The human problems of an industrial civilization. Macmillan, New York 1933.

Związek wprowadzenia karty bezpieczeństwa w pracowni hemodynamicznej z redukcją liczby powikłań okołozabiegowych

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Streszczenie

Wstęp: Współczesne oddziały kardiologii wyposażone w pracownię hemodynamiki i elektroterapii muszą stawić czoła rosnącym wymaganiom związanym z dynamicznym rozwojem zarówno procedur przezskórnych, jak i elektrofizjologicznych, które wiążą się z ryzykiem wystąpienia wielu komplikacji.

Cel: Celem badania była ocena skuteczności i zasadności wprowadzenia karty bezpieczeństwa okołozabiegowego w prewencji niekorzystnych zdarzeń wśród pacjentów poddanych planowej inwazyjnej diagnostyce i leczeniu.

Metody: Przeanalizowano dane 2064 pacjentów skierowanych do leczenia w okresie od maja 2011 r. do sierpnia 2012 r. Chorzy, którzy byli hospitalizowani bez inwazyjnej diagnostyki lub leczenia, nie zostali włączeni do badania. Pacjentów podzielono na dwie grupy: grupę kontrolną — 1011 chorych poddanych inwazyjnej diagnostyce i terapii przed wprowadzeniem okołozabiegowej karty bezpieczeństwa; grupę badaną — 1053 chorych poddanych inwazyjnej diagnostyce i terapii po wprowadzeniu okołozabiegowej karty bezpieczeństwa. W badanych grupach przeanalizowano występowanie niekorzystnych zdarzeń związanych z hospitalizacją i wykonanymi procedurami. Przeprowadzono również subiektywną analizę karty bezpieczeństwa przez zespół medyczny na podstawie anonimowego kwestionariusza.

Wyniki: Wyjściowa charakterystyka między badanymi grupami była porównywalna, z wyjątkiem wyższego odsetka stabilnej choroby wieńcowej (50,7% *vs*. 39,6%; $p \leq 0{,}001$) oraz zabiegów elektrofizjologicznych w grupie kontrolnej. Wprowadzenie karty bezpieczeństwa miało korzystny wpływ na zredukowanie niekorzystnych zdarzeń sercowo-naczyniowych (6,8% *vs*. 3,9%; $p = 0{,}004$), zwłaszcza krwawień (2,3% *vs*. 0,3%; $p < 0{,}001$). W analizie wieloczynnikowej brak okołozabiegowej karty bezpieczeństwa był niezależnym czynnikiem wpływającym na wystąpienie niekorzystnych zdarzeń sercowo-naczyniowych (OR = 2,97; 95% CI 1,60–5,53; $p = 0{,}001$). Subiektywna ocena opinii personelu medycznego pokazała, że wprowadzenie karty bezpieczeństwa koreluje z poprawą zdolności komunikacyjnych, organizacją pracy, zapobieganiem występowania błędów medycznych i zredukowanej liczby kompilacji związanych z przeprowadzonymi zabiegami.

Wnioski: Wprowadzenie okołozabiegowej karty bezpieczeństwa wiązało się z istotną redukcją niekorzystnych zdarzeń sercowo-naczyniowych wśród pacjentów poddanych zabiegom inwazyjnym. Miała także pozytywny wpływ na komunikację w zespole, organizację i jakość leczenia w opinii personelu medycznego.

Słowa kluczowe: komplikacje, krwawienia, przezskórne interwencje wieńcowe

Kardiol Pol 2015; 73, 7: 511–519

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Praca wpłynęła: 01.10.2014 r. **Zaakceptowana do druku:** 22.01.2015 r. **Data publikacji AoP:** 23.02.2015 r.