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The effect of evidence-based care guidelines on outcomes after removal of arterial sheath in patients undergoing angioplasty

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Original Article

Abstract

BACKGROUND: Evidence-based clinical care guidelines effectively assists medical teams to increase the quality of clinical practice, and improve outcomes in patients. This study aimed to design and implement evidence-based care guidelines for removing arterial sheath in patients undergoing angioplasty of coronary artery.

METHODS: This clinical trial study was performed on 200 patients (two groups of 100 patients) with mean age of 62.5 ± 10.8 years, from July 2014 to February 2014 in Baqiyatallah University of Medical Sciences (BUMS), Tehran, Iran. First, we designed a five-step guideline for removing arterial sheath. Then, the designed guideline (based on five-step Stetler model, i.e. preparation, validation, comparative study, implementation, and execution) in the current study, and the routine guideline were used for removing arterial sheath in patients in the intervention and the control groups, respectively. In both groups, the relevant outcomes including bleeding, vasovagal reactions, urinary retention, and pain were evaluated.

RESULTS: There were significant differences between the two groups in terms of bleeding, hematoma, vasovagal reactions (n = 11 versus n = 24), urinary retention (n = 8 versus n = 31), and back pain after removing arterial sheath (P < 0.050 for all).

CONCLUSION: Based on the results of this study, the use of evidence-based care guidelines after removal of atrial sheath in patients undergoing angioplasty is recommended.

Keywords: Evidence-Based Practice, Guideline, Peripheral Catheterization, Transluminal Coronary Balloon Dilation, Outcomes Assessment

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Introduction

Currently, cardiovascular diseases are considered as the most common serious diseases in developed and developing countries. The coronary heart disease ranks first among all cardiovascular diseasesin terms of prevalence. The coronary heart disease is the most important cause of death in the developed countries, and also in the developing countries, such as Iran.[1,2]

In Addition to coronary artery bypass graft surgery (CABG), percutaneous trans luminal coronary angioplasty (PTCA) is also one of the preferred treatments for coronary artery disease.[3,4] Performing PTCA in eligible patients reduces the cost and recovery time, significantly as compared to the coronary artery bypass graft surgery. The rate of death caused by the PTCA, approximately 1%-4%, is similar to that caused by the coronary artery bypass surgery.[3,5,6] After angioplasty procedure, arterial sheath is remove,d and patients are monitored for 24-48 hours for clinical outcomes in stay in the cardiac care unit (CCU).

In recent years, the use of evidence-based guidelines has been highlighted in improving the outcomes of the disease, and improving the quality of care. Evidence-based practice is an attempt to use data from scientific methods in various clinical aspects, especially in the assessment of advantages and disadvantages of a treatment.[7,8] Therefore, the process of evidence-based is an effort to enhance the quality of information based on which an efficient decision can be achieved. In fact, an evidence-based practice can improve the clinical outcomes in terms of patient's safety, recovery time, and cost;[9,10] evidence-based guideline reduces the gap between scientific evidence and clinical practice,

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and guides the clinical care.[11]

There is no established and standard clinical guideline for removing arterial sheath in health centers and hospitals in Iran. In addition, the use of different methods results to adverse events in patients undergoing angioplasty. Therefore, an efficient guideline can result in high quality care, prevent improper clinical procedures, assist in correct clinical decision, improve patients' safety and outcomes of clinical care, and reduce significantly the cost and time of removing arterial sheath. This study aimed to design and implement an evidence-based care guideline for removing arterial sheath in patients undergoing angioplasty of coronary artery.

Materials and Methods

This study was conducted in two phases. First, we designed a guideline according to the Stetler model for removing arterial sheath.[12] Then, in a clinical trial study on patients undergoing PTCA, outcomes of removing arterial sheath were investigated in 100 patients in intervention group and also in 100 age- and sex-matched patients in control group. This study was carried out in Baqiyatallah University of Medical Sciences (BUMS), Tehran, Iran, from July 2014 to February 2015.

Patients under hemodialysis and patients with emergency PTCA were excluded. Additional exclusion criteria was as patients who, for any reason, had a sudden increase in serum creatine leading to hemodialysis, and patients who developed severe hemorrhage in the arterial sheath place, and returned to cath lab.

Data entry forms were initially designed based on a literature review, and then finalized on the basis of suggestions and comments from eleven cardiologists and nurses. In this form, the demographic information, and also the outcome measures such as bleeding, vasovagal reactions, urinary retention, and back pain were recorded. To monitor blood pressure and heart rate, we used a cardiac monitoring device (LX110, SAIRAN Electronics Inc., Iran). We also used Hemochron-JR for measuring activated clotting time (ACT). Gauze (10 × 10 cm) was used to calculate blood volume as well. Each piece of gauze has a maximum absorption of 35 and a minimum absorption of 21.5 grams of blood. Mean absorption of gauze was assumed to be 30 grams in this study.

In routine care, the arterial sheath was removed 4 to 6 hours after angioplasty, and then the manual compression was used for hemostasis. Two 8-kg sandbags compressed the dressing position. The first and second sandbags were removed two hours and 4-6 hours after removing the arterial sheath, respectively. Patients were out of bed 6 hours after removing the arterial sheath.

To design an evidence-based guideline, we used a five-step Stetler model, i.e. preparation, validation, comparative study, implementation, and execution.[12]

- Preparation: We investigated problems of removing arterial sheath in patients undergoing angioplasty of coronary artery. An extensive review of the literature was performed in order to address these problems.

- Validation: We designed an initial guideline after reading and discussing the related articles thoroughly. This initial guideline was validated and completed by considering the comments and instructions from several cardiologists and cardiac nurses in CCU.

- Comparative study: A panel of nurses and residents were consulted to determine practicality of the designed guideline.

- Implementation and execution: After designing the guideline, nurses and residents were trained to execute procedures, and remove arterial sheath.

Patients were studied in intervention and control groups. In control patients, arterial sheath was removed routinely, as mentioned before. Finally, outcomes of removing arterial sheath, during this procedure and up to one day after that, were logged in data record form.

In the intervention group, removal of the arterial sheath and clinical care were based on the following protocol.

1. Control ACT in the third hour after angioplasty.
2. If ACT was less than or equal to 175 seconds, arterial sheath would be removed by manual compression.
3. Put direct pressure on the arterial sheath insertion site for two to three minutes; so that the dorsalis Pedi's pulse disappears. Then, lower the pressure to feel the dorsalis pedis pulse. Continue pressuring until hemostasis (10 to 20 minutes).
4. Put pressure dressing on arterial sheath area by a trained physician or nurse.
5. Put two sandbags (4 kg of weight per bag) on the dressing by nurse.
6. Remove the first and the second sandbags two and three hours after removing the arterial sheath, respectively.
7. Patients can be out of bed three hours after removal of arterial sheath in case of no complication.
8. Record outcomes of removal of arterial sheath in the data record form (all outcomes during the removal and up to one day after that were recorded).

Table 1. Disease history and other information of the control and intervention groups of patients (n = 100 for each one)

Variables	Group	Intervention	Control	P
Sex [n (%)]	Women	37 (37)	37 (37)	> 0.999
	Men	63 (63)	63(63)	
HTN (n)	Yes	59	66	0.307
PVD (n)	Yes	4	1	0.176
Arterial length (n)	11 cm	100	98	0.155
	23 cm	0	2	
Operator (n)	Nurse	36	29	0.293
	Physician	64	71	
Age (year) [Mean ± SD]		63.01 ± 11.03	61.90 ± 10.50	0.410
BMI [Mean ± SD]		26.50 ± 2.01	27.01 ± 2.55	0.160

Chi-square test was applied for arterial length and operator, independent-samples t test was applied for age and BMI, and Fisher's exact test was applied for others variables.
HTN: Hypertension; PVD: Previous vascular disease; SD: Standard deviation; BMI: Body mass index

This study was approved by the Ethics Committee of the BUMS (number 5904 approved at 07/02/2014). Objectives of the study were explained to the patients and informed consent was obtained from them.

We used SPSS software (version 20. IBM Corporation, Armonk, NY, USA) for the descriptive [mean and standard deviations (SD)] and inferential (e.g. chi-square, Fisher's exact, and independent-samples t tests) statistics in this study.

Primarily, the normality of the study variables was assessed by performing the Kolmogorov-Smirnov test. This test showed that the distribution of all study variables was normal. Consequently, we used the Fisher's exact test for examining the correlation between groups in terms of variables such as sex, blood pressure, previous vascular disease, tacking aspirin, vasovagal reactions, urinary retention, and used gauzes, chi-square test for back ache, operator, and arterial length, and independent-samples t test for between-groups comparisons of group in terms of variables such as age, body mass index (BMI), prothrombin time (PT), partial thromboplastin time (PTT), international normalized ratio (INR), hemoglobin (HB), and hematocrit (HCT).

Results

Content of evidence-based care guidelines included 8 steps as described in methods.

Based on our findings, using our designed guideline for removing arterial sheath (based on the Settler model) prevented effectively misconduct in treating patients, and assisted in obtaining appropriate clinical decisions. If there were any complication, evidence-based measures for clinical management in our guideline would be considered.

The chi-square and Fisher's exact tests showed that control and intervention groups were homogeneous in terms of demographic and other variables. The results of the independent-samples t test revealed that age and BMI in two groups were also homogenous (P > 0.050 for both) (Table 1).

The results of independent-samples t test showed that there was no significant difference in mean ± SD of PT, PTT, HB, and HCT between control and intervention Group (Table 2).

Table 2. Compassion of results in two study groups (n = 100 for each one)

Group Consequence	Intervention Mean ± SD	Control Mean ± SD	P
PTT (s)	28.9 ± 6.30	29.10 ± 7.79	0.870
INR	1.07 ± 1.11	1.07 ± 0.13	0.110
HB (g/dl)	13.80 ± 1.69	13.70 ± 1.85	0.820
HCT (g/dl)	40.80 ± 4.46	40.90 ± 5.16	0.880

The results are from using independent-samples t test.
SD: Standard deviation; PTT: Partial thrombin time; INR: International normalization ratio; HB: Hemoglobin; HCT: Hematocrit

However, the results of chi-square and fisher's exact tests revealed that the patients in intervention group had urinary retention, back pain, and vasovagal reactions lower than control group (P < 0.050 for all) (Table 3).

Discussion

Findings of this study show that the proposed evidence-based guideline for removing arterial sheath in patients undergoing angioplasty can reduce bleeding, vasovagal reactions, urinary retention, and back pain during and after removing the sheath.

Table 3. Comparison of the relative prevalence of bleeding, vasovagal, urinary retention, and back pain in two study groups (n= 100 for each one)

Consequence	Group	Intervention (%)	Control (%)	P
Vasovagal		11	24	0.010
Urinary retention		8	31	0.001
Back pain	Severe	0	16	0.001
	Moderate	3	19	
	Light	11	33	
	Does not have	86	32	
Used gauzes	10-15	0	1	0.020
	5-10	0	6	

Chi-square test was applied for back pain and Fisher's exact test was applied for others variables.

Study conducted by the American Association of Critical Care Nurses (AACN) showed that bleeding was an important side effect of the coronary angioplasty, and appropriate protocol for removing arterial sheath could reduce bleeding from location of the sheath.[13] In agreement with findings of the AACN study, our results demonstrated importance of an effective guideline for removing arterial sheath. Although guideline plays an important role in outcome of removing arterial sheath and also in patients' comfort, it is interesting that this guideline is not standardized across different hospitals.[13-15]

In another clinical trial study, arterial sheath was removed immediately after angioplasty, and vascular complications, including hematoma greater than 10 cm, pseudoaneurysm, and arterial bleeding, were reported.[16] We had less bleeding compared to this study, since we removed arterial sheath three hours after angioplasty by checking ACT (ACT ≤ 175 s).

Juergens et al. reported that vasovagal reactions during removal of arterial sheath caused stent thrombosis and adverse cardiac events (myocardial infarction).[17] To address this issue, the arterial sheath removed according to care instructions in our study, and we found a significant reduction in vasovagal reaction in intervention group that decreased the risk of stent thrombosis. Capasso et al. reported that the most effective method for hemostasis after removal of arterial sheath was to use manual compression.[18] Consistent with their study in terms of bleeding, we also used the manual compression for hemostasis in the current study.

In a clinical trial study, Augustin et al. investigated the effects and outcomes of early removal of arterial sheath in two groups of patients.[16] Arterial sheath in the first group (172 patients) was removed immediately after angioplasty, and the patients were allowed to come down from the bed three hours later. Complications such as hematoma greater than 10 cm, pseudoaneurysm, and arterial bleeding during or after walking in these patients were reported. Arterial sheath was removed 4-6 hours after angioplasty in the second group (175 patients), and then the patients were allowed to come down from the bed 4-6 hours after removal of the sheath. Although hematoma was less than 10 cm in patients in the second group, they had more back pain and urinary retention compared to the patients in the first group.[16] We removed arterial sheath three hours after angioplasty if ACT was less than 175 s, and then patients were allowed to come down of bed three hours after removal of the sheath. Using our guideline, we found that urinary retention and back pain significantly reduced in these patients.

Conclusion

Implementation of an evidence-based guideline for removing arterial sheath in patients undergoing angioplasty can have an effective role in reducing bleeding, hematoma, vasovagal reactions, urinary retention, and back pain. Using a guideline in clinical practice prevents misconduct, assists appropriate clinical decision, improves patient's safety and outcomes, and saves treatment time and cost.

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Conflict of Interests

Authors have no conflict of interests.

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