



Does the artery compression technique affect how much hematoma forms during a cardiac catheterization procedure? A systematic review of randomized controlled trials

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Abstract

It is standard practice to apply manual compression or mechanical devices to the puncture site after a cardiac catheterization to lessen the possibility of hematoma formation and bleeding. Hemostasis, or the cessation of bleeding, is the intended outcome. The purpose of this review is to ascertain whether using manual compression or other mechanical devices can lessen hematoma in patients following a cardiac catheterization procedure after removing the sheath. This systematic review was performed following PRISMA guidelines. A comprehensive search was carried out using multiple databases, including Science Direct, PubMed/MEDLINE, CINAHL, and Cochrane Library. A total of 52 studies were found in the selected databases. After eliminating 13 duplicates, 39 were screened for titles and abstracts. Twenty-two studies were selected for full-text screening, and 8 of them were eligible for the study criteria and included in the review. The studies that were chosen were all randomized controlled trials. After removing the catheter sheath, various interventions were attempted in the experiments to establish hemostasis. Patients who underwent radial catheterization were reported in three studies, while patients who underwent femoral catheterization to promote hemostasis and reduce possible complications. However, the decision between manual compression and mechanical devices is influenced by several variables, including the patient's health condition, the sheath's size, and the access site (femoral or radial). Mechanical closure, in addition to manual compression techniques, can be more consistent and controlled, which may shorten the time needed for hemostasis.

Keywords: Cardiac catheterization, chemical devices, hematoma, manual compression, mechanical devices, PRISMA, and vascular complications.

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1. Introduction

Cardiovascular diseases (CVDs) are the most significant health issue among the population, particularly in low- and middle-income countries, among the non-communicable diseases that are the main concern of public health [1]. Worldwide, it is estimated that 17.9 million people died due to heart disease in 2023, representing about 32% of global deaths [2]. Despite the high prevalence and mortality rates, limited counseling from healthcare providers, including doctors and nurses, further impedes awareness and lifestyle modifications, making prevention and management efforts more challenging [3]. Coronary vascular diseases encompass both the heart and blood vessels, including peripheral arterial disease, heart failure, acute coronary syndrome, and arrhythmias [4].

Several risk factors can play a major role in developing CVD, especially following unhealthy diet practices, a sedentary lifestyle that leads to a lack of physical activity, and other forces like globalization, the aging population, and rapid urbanization [5] which results in elevated blood pressure, increased blood sugar, obesity or overweight, or raised lipids level [6]. Alongside, CVD can be diagnosed using various tests, including blood tests, electrocardiograms (ECGs), Holter monitors, echocardiograms, stress tests, cardiac CT scans, cardiac MRIs, and cardiac catheterizations [7]. Cardiac catheterization is a minimally invasive procedure that can serve as both a diagnostic and therapeutic regimen for CVD [8].

Cardiac catheterization is considered the gold standard tool known as coronary angiography or cardiac cath, which involves inserting a catheter (a thin, flexible tube) into the blood vessels to access the heart and surrounding blood vessels [9]. Femoral (groin), trans-radial, and trans-brachial access are available procedures to perform the coronary angiogram or cardiac catheterization [10]. Right-sided (venous catheter) involves inserting the catheter from the vein to the right atrium, while left-sided (arterial catheterization) involves inserting the catheter from a systemic artery to the left atrium [8].

Femoral vascular complications are associated with high morbidity, mortality, high-cost implications, and other minor complications after sheath removal, ranging from hematoma, bleeding, retroperitoneal bleeding, and ecchymosis [11]. Hematoma is the main complication that occurs after sheath removal, which is manifested by swelling, pain, and discomfort [12].

Nurses play a key role in applying non-pharmacological interventions such as manual pressure application after removing the sheath, ice-backed gel application, digital pressure application, FEMOSTOP application, bedside clamp application, and vascular closure device [13]. Maintaining hemostasis at the time of removing the sheath device and minimizing the complications at the puncture site is a priority [14]. Furthermore, the most common complication that results from poorly controlled hemostasis is hematoma formation [15]. However, there is no clear evidence on the most effective and efficient method for maintaining hemostasis and reducing possible complications after sheath removal. Hence, this systematic review aims to ascertain whether using manual compression or other mechanical devices can lessen hematoma in patients following a cardiac catheterization operation after the removal of the sheath

2. Materials and Methods

2.1. Protocol and Registration

This systematic review was conducted and reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines [16]. The review was registered in the international prospective register of systematic reviews, "PROSPERO," and the registration is in process.

2.2. Eligibility Criteria

To answer the research question, the PICOT framework was used. Components include population (P), adult post-cardiac angiography, intervention (I), manual compression after sheath removal, comparison (c), compression using mechanical devices after sheath removal, and outcome (O), achieving hemostasis and preventing hematoma formation. So, the guiding question for the current review is "What is the best evidence-based practice to minimize hematoma after sheath removal post-cardiac catheterization?"

The retrieved articles will be included if they are: (1) research studies that use a quantitative approach; (2) involve adult patients post-cardiac catheterization; (3) report patients' outcomes after using manual compression or other mechanical devices; (4) are written in English; and (5) are published from 2010 to 2023.

2.3. Information Sources

Two researchers separately searched different electronic databases: PubMed through Medline, CINAHL, and Cochrane Library. The first search was conducted on April 16, 2023, and the last search was performed on May 26, 2023.

2.4. Search

The search was conducted using the Medical Subject Headings (MeSH) terms. Initially, broad categories of search terms were selected, including vascular complications, cardiac catheterization, hematoma, manual compression, and mechanical devices. Moreover, the reference lists of eligible articles were manually searched to identify publications that were not found by the electronic search.

2.5. Study Selection

Two researchers independently reviewed the titles and abstracts of the retrieved studies to identify those that met the inclusion criteria. Then, the full text of the potentially eligible studies was reviewed and examined for eligibility. A discussion with a third reviewer was conducted to resolve any disagreements over the eligibility of the studies.

2.6. Data Collection Process

An in-depth review of the selected studies was conducted by the researchers, these studies were presented in two tables. First, study characteristics include population, study design, countries in which the study was conducted, year of publication, and ICU specialty type. The second table studies the review matrix, with the following headings: research titles, purpose, design, procedure, settings, population, and results.

2.7. Risk of Bias in Individual Studies

The risk of bias in all studies was assessed by two researchers using the PROBAST tool, which evaluates the risk of bias and applicability of prediction model studies [17]. If the reviewers had given different scores, agreement was achieved by consulting a third researcher.

2.8. Synthesis of Results

The data were analyzed and synthesized, and the results were included in the review paper after achieving consensus among two reviewers. A narrative-descriptive synthesis of the main findings, along with tables, was presented. A combination of narrative and tables was used to enhance the presentation of the results.

3. Results

3.1. Study Selection

A total of 52 studies were found in the selected databases, after eliminating 13 duplicates, 39 were screened for titles and abstracts. Twenty-two studies were selected for full-text screening, of which eight were eligible for the study criteria and were included in the review. The PRISMA flowchart (Figure 1) showed the search strategy and selection process [18].



3.2. Study Characteristics

A total of 8 articles, published between 2010 and 2023, were included in the review. All of the selected studies were randomized controlled trials. The studies evaluated various interventions to achieve hemostasis following catheter sheath removal. Three studies reported findings from patients who underwent radial catheterization, while five studies reported findings from patients who underwent femoral catheterization. The characteristics of the selected articles are summarized in Table 1.

Table 1.

Characteristics of articles included in the review (N =8)	
Characteristics	Studies
Comparative mechanisms of compression	
Ice-bag + manual pressure vs manual	Baqal and Mahmood [8]
Manual pressure + sandbag vs manual pressure + air-filled close pad	Korkmaz and Morali [19]
vs manual pressure + cold pack pad + sandbag	
Manual + ChitoHem powder + sandbag vs	Rahmani, et al. [20]
manual + Zinc oxide scallop-shell powder + sand bags for 4-6 h vs	Moeinian, et al. [21]
manual + Zinc oxide scallop-shell powder + sandbag for 1 h	
Closure pad made of nonwoven proprietary polypropylene with a	Valikhani, et al. [22]
positive charge vs manual	
Ice with sandbag vs sandbag	Petroglou, et al. [23]
Inflatable air-filled wrist bracelet vs manual	Seto, et al. [24]
Potassium ferrate hemostatic patch + inflatable air-filled wrist	Kang, et al. [25]
bracelet vs inflatable air-filled wrist bracelet alone	
Compression devices and chitosan-based pads vs compression	Baqal and Mahmood [8]
devices alone	
Access site	
Femoral	Baqal and Mahmood [8]; Korkmaz and Morali
	[19]; Rahmani, et al. [20]; Moeinian, et al. [21]
	and Valikhani, et al. [22]
Radial	Petroglou, et al. [23]; Seto, et al. [24] and Kang,
	et al. [25]
Measurement of hematoma	
Two categories according to the hematoma size (cut point 10 cm^2)	Korkmaz and Morali [19]
Two categories according to the hematoma size (cut point 3 cm^2)	Moeinian, et al. [21]
EASY hematoma scale*	Petroglou, et al. [23] and Seto, et al. [24]
Four categories scale	Baqal and Mahmood [8]
Area of hematoma volume (cm ²)	Valikhani, et al. [22]
Not specified	Rahmani, et al. [20] and Kang, et al. [25]
Country	
Iran	Dehmoni at al [20], Maximian at al [21] and
11 (11)	Kannani, et al. [20]; Moennan, et al. [21] and
	Valikhani, et al. [22]
Iraq	Valikhani, et al. [22] Bagal and Mahmood [8]
Iraq Turkey	Valikhani, et al. [20]; Moennan, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19]
Iraq Turkey Greece	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23]
Iraq Turkey Greece USA	Rannah, et al. [20]; Moennah, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24]
Iraq Turkey Greece USA Republic of Korea	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24] Kang, et al. [25]
Iraq Turkey Greece USA Republic of Korea Publication year	Kanman, et al. [20]; Moennan, et al. [21] and Valikhani, et al. [22]Baqal and Mahmood [8]Korkmaz and Morali [19]Petroglou, et al. [23]Seto, et al. [24]Kang, et al. [25]
Iraq Turkey Greece USA Republic of Korea Publication year 2010-2019	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24] Kang, et al. [25]
Iraq Iraq Turkey Greece USA Republic of Korea Publication year 2010-2019	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24] Kang, et al. [25]
Iraq Turkey Greece USA Republic of Korea Publication year 2010-2019 2020-2023	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24] Kang, et al. [25] Petroglou, et al. [23]; Seto, et al. [24] and Kang, et al. [25] Bagal and Mahmood [8]: Korkmaz and Morali
Iraq Turkey Greece USA Republic of Korea Publication year 2010-2019 2020-2023	Ramman, et al. [20]; Moeman, et al. [21] and Valikhani, et al. [22] Baqal and Mahmood [8] Korkmaz and Morali [19] Petroglou, et al. [23] Seto, et al. [24] Kang, et al. [25] Petroglou, et al. [23]; Seto, et al. [24] and Kang, et al. [25] Baqal and Mahmood [8]; Korkmaz and Morali [19]; Rahmani, et al. [20]: Moeinian, et al. [21]

3.2. Risk of Bias within Studies

Generally, the Risk of bias in all studies was assessed by two reviewers using the. When reviewers assigned different scores, agreement was achieved by referring to the third reviewer. The risk of bias assessment for the selected studies is summarized in Table 2.

3.3. Results of the Studies

Two categories were created based on a thematic synthesis of the retrieved research studies: (1) mechanisms of achieving hemostasis and (2) hematoma formation. A detailed summary of the studies' review is presented in the matrix. Table 3.

Kisk of Dias within Studies (N – 6).									
		Bagal and	Korkmaz	Rahmani,					
		Mahmood	and Morali	et al. [20]	Moeinian,	Valikhani,	Petroglou,	Seto, et	Kang, et
Sections	Domains	[8]	[19]		et al. [21]	et al. [22]	et al. [23]	al. [24]	al. [25]
Is the basic study design	Did the study address a focused research question?	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν
valid for a randomized	Was the assignment of participants to interventions randomized?	CT	Y	Y	Y	Y	Y	Y	Y
controlled trial?	Were all participants who entered the study accounted for at its conclusion?	Y	Y	Y	Y	Y	Y	Y	Y
	Were the participants rendered 'blind' to the intervention they received?	Ν	Ν	Y	CT	Ν	Ν	Ν	Ν
	Were the researchers 'blind' to the treatment they were administering to subjects?	Ν	Ν	Y	CT	Ν	Ν	Ν	Ν
	Were the individuals evaluating or studying the outcome(s) "blinded"?	Ν	Ν	CT	CT	Ν	Ν	Ν	Ν
	At the commencement of the randomized controlled experiment, were the study								
Was the study	groups comparable?	Y	Y	Y	Y	Y	Y	Y	Y
methodologically	Did each research group receive the same standard of care (i.e., were they								
sound?	treated equally) aside from the experimental intervention?	Y	Y	Y	Y	Y	Y	Y	Y
	Were the intervention's effects thoroughly reported?	Y	Y	Y	Y	Y	Y	Y	Y
	Was the estimation of the intervention or treatment effect's precision reported?	Y	Y	Y	Y	Y	Y	Y	Y
	Are the advantages of the experimental intervention greater than the costs and								
What are the results?	negative effects?	Y	Y	Y	Y	Y	Y	Y	Y
	Can you apply the findings to your situation or to your local community?	Y	Y	Y	Y	Y	Y	Y	Y
Will the results help	Would the experimental intervention benefit the patients in your care more than								
locally?	any other current intervention?	Y	Y	Y	Y	Y	Y	Y	Y

Table 2. Risk of Bias within Studies (N =8).

Note: Y: Yes, N: No, CT: cannot tell.

Table 3.

Final retrieved articles in the review process.

No.	Author, Year, and Country	Title	Objective	Study design	Setting and Sample	Findings	Conclusion	Additional comments			
1	Baqal and Mahmood [8] Iraq.	Effect of Ice Bag with Direct Pressure in the Prevention of Local Vascular Complications After Femoral Sheath Removal Post-Cardiac Catheterization: A Randomized Clinical Trial	To determine the effect of applying an ice bag with direct pressure to prevent vascular complications (bleeding, hematoma, and ecchymosis) after femoral sheath removal of cardiac catheterization	RCT	A total of (n=60) patients who underwent cardiac catheterization at the "Karbala Centre for Cardiac Diseases and Surgery" between November 2021 and April 2022 participated in the study (n=30) in the control group and (n=30) in the experimental group.	The study's results showed a statistical significance difference between experimental and control groups in vascular complications such as bleeding severity, hematoma, and ecchymosis.	Instructed to perform the ice bag with direct pressure after removing the femoral sheath to decrease bleeding severity, hematoma, and ecchymosis.	The benefits of applying an ice bag with direct pressure to other invasive procedures such as arterial-venous fistula, central venous line, and arterial line should be investigated in another study			
2	Korkmaz and Morali [19]	Comparison of Sandbag, Close Pad, and Cold Application Combined with Sandbag in Proventing Pariphared	To compare the effectiveness of the sandbag method, close pad application, and cold application plus sandbag RCT		A total of (n=120) patients who underwent femoral catheterization were divided into 3 different methods. (n=40) patients in the	There were no significant differences in hematoma, hemorrhage, or ecchymosis among groups at 15 minutes, 4 hours, and one day after the coronary procedure.	It was concluded that all methods were effective in	-			
	(2022), Turkey	- Preventing Peripheral Vascular Complications After Cardiac Catheterization	in preventing peripheral vascular complications after the coronary procedure.	in preventing peripheral vascular complications after the coronary procedure.	in preventing peripheral vascular complications after the coronary procedure.	in preventing peripheral vascular complications after the coronary procedure.	al in preventing peripheral vascular complications after the coronary procedure.		sand group. $(n=40)$ patients with close pad and $(n=40)$ patients with cold application plus sandbag.	At day 2 evaluation, the ecchymosis was higher for the close pad group than the sandbag and sandbag plus cold application groups ($p = 0.047$).	complications.

3	Rahmani, et al. [20] Iran.	The Effect of Zinc Oxide Scallop-shell Powder and Complications After Coronary Angiography	To determine the effect of Zinc oxide scallop- shell powder as a topical hemostatic agent on complications after coronary angiography in comparison with conventional hemostasis procedures (manual compression and using sandbags)	Blind, parallel, RCT	A total of (n=150) patients underwent coronary angiography via the femoral artery. They were divided into three groups (group A Control), group B case 1) and (group C case 2).	The difference in time of hemostasis in the 3 groups was not statistically significant. Hematoma formation was observed in just 1 patient (2%) in the conventional treatment group (manual compression and using sandbags)	The Zinc oxide scallop-shell powder reduces catheter site bleeding after coronary angiography	Zinc oxide scallop-shell powder after angiography did not create vascular complications, such as hematoma, and bleeding, and enhanced patient comfort and back pain relief.
4	Moeinian, et al. [21] (2020), Iran	Comparison of the effect of manual compression and closure pad on post angiography complications: A randomized controlled trial	To compare the effect of manual compression and closure pad (CP) on vascular complications such as hematoma and bleeding.	RCT	A total of (n=238) patients who underwent femoral catheterization were randomly assigned to the MC and CP groups	After angiography, 7 and 5 patients had a hematoma in the manual compression MC and closure pad CP groups, respectively. Re-bleeding after hemostasis was observed in 2 patients in the MC group, but none of the subjects in the CP group had re-bleeding. There was no significant difference in bleeding volume between the two groups.	Same efficacy of MC and CP methods in the prevention of post-angiography vascular complications.	CP has the advantage of the possibility of changing the position in bed and increasing physical comfort in the patient, this method is recommended for angiography and catheterization.
5	Valikhani, et al. [22] Iran.	The Effect of Simultaneous Sand-Ice Bag Application on Haemorrhage and Hematoma after Percutaneous Coronary Intervention: A Randomized Clinical Trial	To determine the effect of using sand and ice bags on hematoma and hemorrhage after percutaneous coronary intervention (PCI).	RCT	The study was completed with the participation of (n=60) patients with femoral angioplasty candidates selected through convenience sampling method, The participants, lasted from November 22, 2017, to February 19, 2018, in Imam Reza Hospital in Mashhad.	There was no significant difference in the incidence, size, and dimensions of hematoma formation between groups. Although the incidence of hematoma in the intervention group was 6.7%, compared to 20% in the control group it was not statistically significant.	In the field of clinical management, the use of the proposed method, which is low-cost and available, can reduce the number of hospitalization days, reduce treatment costs, make up for a lack of financial and human resources, as well as increase patient satisfaction by reducing complications after angioplasty.	Given the evidence-based effectiveness and no complications for patients, this approach, if approved by experts, can be incorporated into the educational materials in this field.
6	Petroglou, et al. [23] Greece.	Manual Versus Mechanical Compression of the Radial Artery After Trans- radial Coronary Angiography	Comparing manual vs. mechanical compression (using an inflatable air- filled wrist bracelet) of the radial artery after coronary angiography via trans-radial access regarding radial artery occlusion access-site	RCT	Multicentre study. 595 patients were randomized	-At 24 h post-procedure, the incidence of radial artery occlusion was similar between manual (12%) and mechanical (8%) hemostasis. -No significant differences were found regarding hematoma or bleeding rates between the 2 groups.	Manual compression is an effective, safe, and less time- consuming hemostasis method compared with mechanical compression using devices that exert stable and continuous pressure on the	
			bleeding, and duration of hemostasis.		(304 in the manual compression group) and (285 in the mechanical group).	-Duration of Haemostasis was shorter in the manual compression group compared to the	radial artery.	

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						mechanical compression group.		
7	Seto, et al. [24]	Radial hemostasis is facilitated with a potassium ferrate	To determine whether a potassium ferrate hemostatic patch (PFHP) could serve as		A total of (n= 180) patients was designed to enable	Successful TRB deflation occurred at 43±14 minutes		. Further studies
	(2018),	hemostatic patch: the Stat seal with TR Band assessment	an adjunct to the air- bladder TR Band (TRB) to facilitate the implementation of a rapid deflation protocol	A prospective multicentre	four different sites to enroll patients, with a minimum contribution of	with PFHP and 160±43 minutes without PFHP (p< 0.001).	The PFHP hemostatic patch facilitated early deflation of the TRB with a non-significant increase in forearm hematomas. The use of the	will determine the optimal compression protocol to balance
	The USA.	trial (STAT)		RCT	(n=30) patients and a maximum of (n=60) from each site.	Minor hematomas occurred in nine (10.3%) of the TRB patients and 16 (17.2%) of the PFHP patients (p=0.20).	PFHP may improve patient throughput and allow earlier discharge following trans- radial procedures.	compression time and hematoma formation.
						Outpatients randomized to PFHP were discharged 51±83.5 minutes earlier than the control.		
8	Kang, et al. [25]	Hemostasis pad combined with compression	To test if the use of chitosan-based pads on top of the compression		Study participants (n=95) patients	Time to hemostasis, the primary endpoint, was significantly lower in the study group than in the control group (p<0.001).	This study suggests that the addition of chitosan-based pads on top of rotatory	Chitosan
	(2017),	device after trans-radial coronary procedures:	devices could improve hemostasis efficacy compared with compression devices alone after	A prospective, single-center RCT	were recruited from the cardiovascular center of Seoul National University Bundang Hospital	The hematomal formation did not differ statistically between groups.	CD may be an effective and safe strategy for puncture site hemostasis after radial artery	is produced by deacetylation of chitin, which is extracted from the shells of shrimps, lobsters,
	Republic of Korea.	A randomized controlled trial	trans-radial coronary angiography or interventions		between April and July 2016.	Both groups showed low rates	access.	and beetles. The positively charged chitosan molecules attract the negatively charged
						of vascular complications.		blood cells and platelets, thus promoting blood clotting.

3.3.1. Mechanisms of Achieving Hemostasis

The eight retrieved studies revealed different mechanisms of compression used to achieve hemostasis after sheath removals. Surprisingly, none of the studies tried to replicate a previous mechanism to test it. Generally, the used interventions can be summarized as follows: three studies tested the use of manual compression alone with a compression device, four studies tested the use of chemical hemostatic agents to achieve hemostasis, three studies tested the use of a sandbag, and three studies tested the use of the air-filled compressive device.

3.3.2. Manual Compression

Three studies compared manual compression alone with a compression device. In the first study, Baqal and Mahmood [8] compared manual compression alone with manual compression and ice bag application for 30 patients, and with manual pressure applied to the femoral artery for 20 minutes in another 30 patients. The second study compared manual compression alone applied on the femoral artery for 119 patients with a closure pad made of nonwoven proprietary polypropylene with a positive charge applied on the femoral artery for another 119 patients Moeinian, et al. [21]. The last study compared manual compression alone, applied to the radial artery, in 304 patients with an inflatable air-filled wrist bracelet applied to the radial artery in 285 patients [23].

3.3.3. Chemical Hemostatic Agents

Four studies tested the use of chemical hemostatic agents to achieve hemostasis. Rahmani, et al. [20] investigated the effect of Zinc oxide scallop-shell powder as a topical hemostatic agent on patients after femoral catheterization. They compared three groups. For the first group (n=50), they applied manual compression and ChitoHem powder and a sandbag for 4-6 hours. For the second group (n=50), they applied manual compression, zinc oxide scallop-shell powder, and sandbags for 4-6 hours. For the third group (n=50), they applied manual compression, zinc oxide scallop-shell powder, and sandbags for 4-6 hours. For the third group (n=50), they applied manual compression, zinc oxide scallop-shell powder, and sandbags for 1 hour.

The second study, explained in the previous section, examined the effect of a closure pad made of nonwoven proprietary polypropylene with a positive charge [21]. The third study, conducted by Seto, et al. [24] compared a Potassium ferrate hemostatic patch and an inflatable air-filled wrist bracelet for 93 patients and the use of an inflatable air-filled wrist bracelet alone for 87 patients following radial artery catheterization. Lastly, in the fourth study, Kang, et al. [25] compared chitosan-based pads and a rotatory compression device for 59 patients and a rotatory compression device alone for 36 patients following radial artery catheterization.

3.3.4. Sandbag Pressure

Three studies included sandbags in the protocol, in which Korkmaz and Morali [19] compared three groups; initially, they applied manual pressure for 15 minutes immediately after the catheter removal of all patients. Then for group one (n=40), they applied sandbag pressure for 4 hours, for group two (n=40), they placed a close pad with an inflated balloon pouch at the femoral region for 3 hours, and for the third group (n=40), they applied a cold pack pad for 15 minutes followed by sandbag for 4 hrs. The second study was conducted by Rahmani, et al. [20]. The third study was conducted by Valikhani, et al. [22], they compared the effect of placing a sandbag alone for 4 hours post femoral artery catheterization with placing a cloth ice bag and a sandbag for 15 minutes, followed by sandbag alone for 45 minutes (cycled over 4 hours) for another 30 patients post femoral artery catheterization.

3.3.5. Air-Filled Compressive Device

Three studies included the use of air-filled compressive devices: Korkmaz and Morali [19]; Petroglou, et al. [23] and Seto, et al. [24]. All studies' procedures are explained in previous sections.

3.3.6. Hematoma Formation

The formation of hematoma in the retrieved studies was evaluated and summarized; then we categorized the studies into two categories: the first one describes the studies that find no statistically significant differences in the hematoma formation. The second category describes the studies that reported a significant difference in hematoma formation.

3.3.7. No Significant Effect of the Intervention on Hematoma Formation

Seven out of eight studies revealed no statistically significant difference in hematoma formation between different compression mechanisms. We can conclude that hematoma formation post arterial sheath removal for cardiac catheterization patients was not reduced by a close pad with an inflated balloon pouch [19] Zinc oxide scallop-shell powder [20], Closure pad made of nonwoven proprietary polypropylene with a positive charge [21] ice with a sandbag [22] inflatable air filled wrist bracelet [23], Potassium ferrate hemostatic patch [24] or chitosan-based pads [25].

3.4. Significant Effect of the Intervention on Hematoma Formation

Only one study revealed a significant difference, concluding that adding an ice bag to manual compression significantly decreases the incidence of hematoma at 20 minutes, 2 hours, 4 hours, and 48 hours after femoral catheterization [8].

4. Discussion

4.1. Summary of Evidence

Apparently, this study provides a summary of studies that discuss the effect of applying different mechanisms to achieve hemostasis after sheath removal in patients post-cardiac catheterization, aiming to reduce hematoma formation as a potential complication of sheath removal. Different mechanical devices were used besides manual compression, such as sandbags, icebags, chitosan-based pads, and inflatable air-filled wrist bracelets. Also, chemical devices were used to achieve hemostasis, including ChitoHem powder, Zinc oxide scallop-shell powder, and Potassium ferrate hemostatic patch. Many studies have tested the effect of different chemical and mechanical devices to achieve hemostasis, but little evidence has been introduced to lessen the complications, such as hematoma formation, after sheath removal.

Manual compression involves applying direct pressure to the puncture site to promote clot formation, prevent bleeding, and achieve hemostasis to prevent complications [12]. All included studies using manual pressure showed significant differences in achieving hemostasis and reducing hematoma formation. Besides, included studies in the current review were using mechanical devices (n=6, 75%) that were designed to seal the pressure on the puncture site mechanically, for instances a study that was conducted by Baqal and Mahmood [8] used icebag with manual compression versus using the manual compression alone revealed that using both manual compression and icebag reduced vascular complications such as bleeding severity, hematoma, and ecchymosis significantly rather than using manual compression alone. These findings were consistent with a study result that was performed by Petroglou, et al. [23] who found that the duration of hemostasis was significantly shorter in the manual compared with the mechanical compression group.

In the same line, (n=2, 25%) of the included studies used chemical agents to reduce the risk of hematoma formation after sheath removal, such as Potassium ferrate hemostatic patch [24] and ChitoHem powder [20]. It was observed that using Zinc oxide scallop-shell powder reduces catheter site bleeding after coronary angiography. However, it was found that the difference in time of hemostasis in the three groups was not statistically significant. Besides, using the Potassium ferrate hemostatic patch found facilitated early deflation of the TR band with a non-significant increase in forearm haematomas.

Measuring hematoma formation includes assessing the size and characteristics to monitor the progression and determine the necessity of any intervention that could be initiated [26]. Visual inspection with different measurement devices can be utilized to measure the size of the hematoma [27]. Three studies (37.5%) used the hematoma size with different cut points [20, 21]. While there were two studies (25%) using the EASY hematoma scale, which is considered a quick and common way to measure the severity of hematoma (E-enlargement, A-Appearance, S-Symptom, Y-Yes or no), rapid expansion, severe pain, and neurological compromise must be noted. However, to accurately track hematoma growth, the measurement procedure must be kept consistent. Healthcare professionals should consider the hematoma's depth, shape, and any related symptoms, regardless of the method used. To ensure prompt action if necessary, regular monitoring of the hematoma's size and clinical condition is essential.

Finally, the included studies involve (n=5, 62.5%) femoral access catheterization, while (n=3, 37.5%) had a radial access involvement. Several factors specify the choice between radial and femoral access, such as the patient's condition, procedural requirements, and anatomical considerations. Using different access requires the healthcare providers to apply manual compression that could be aided by utilizing chemical substances such as potassium ferrate hemostatic patch in radial access, which was found to be an effective method to achieve hemostasis after sheath removal.

4.2. Limitations

This systematic review is limited by the number of included studies and the lack of replication of different compression devices to determine the most effective method of achieving hemostasis and reducing complications, such as hematoma formation. Furthermore, the heterogeneity of the studies' design during the search method restricts the included studies in this review.

5. Conclusion

Multidimensional techniques could be utilized after sheath removal following cardiac catheterization to promote hemostasis and reduce potential complications. However, the decision between manual compression and mechanical devices is influenced by several variables, including the patient's health condition, the size of the sheath, and the access site (femoral or radial). Mechanical closure, in addition to manual compression techniques, can be more consistent and controlled, which may shorten the time required for hemostasis and reduce the likelihood of complications such as hematoma formation. This is particularly beneficial under the supervision of skilled medical professionals, as mechanical closure can also be associated with its own set of hazards and considerations. Healthcare professionals, including nurses, must consider the specific circumstances of each patient to choose the best strategy for achieving hemostasis while minimizing consequences.

List of Abbreviations

CVD: Cardiovascular diseases ECG: Electrocardiogram PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis MeSH: Medical Subject Headings

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