# Manual versus Mechanical Compression for Femoral Artery Hemostasis after Coronary Catheterization

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Abstract: There are three methods are employed to achieve femoral artery hemostasis following sheath removal after cardiac catheterization, they are the manual compression, mechanical compression and vascular closure devices. Aim of the study: (1) Compare the effect of using manual compression and mechanical compression technique in achieving hemostasis after femoral sheath removal through: Assessment of time to hemostasis, assessment of time to ambulate from bed and assessment of patient comfort level. (2) Compare the effect of using manual and mechanical compression technique on patient vascular complications through: Assessment of hematoma formation, assessment of ecchymosis formation, assessment of oozing. Research design: A comparative study design was used to conduct this study. Setting: cardiac catheterization unit at Beni-Suef General Hospital and Beni-Suef University Hospital. Research subjects A purposive sample of 121 patients admitted to the previous mentioned settings. Tools for data collection: Patients Interview questionnaire tool, femoral artery hemostasis measuring scales and patients' vascular complications monitoring scales. Results: 77.0% of patients were achieved hemostasis within 5 to < 10 minutes when using the CRoC compressor, while 38.5% of patients were achieved hemostasis from 5 to 10 minutes when using the manual compression method and patients in the manual group had higher score of pain at time of sheath removal, while at the other three assessment times (5, 10, 20 minutes), the patients in the compressor group had the lower score of pain Conclusion: Combat Ready Clamp compression device is a safe, simple to use and effective alternative to the manual compression method for achieving hemostasis for the femoral artery after diagnostic coronary angiography and percutaneous coronary intervention. Recommendations: Provide an educational program for nursing stuff and health care providers about how to apply CRoC compression device and the most common post cardiac catheterization complications and how to manage them effectively especially in post catheterization unit.

Key words: manual, mechanical, compression, hemostasis, coronary cathterization.

Date of Submission: 06-07-2019 Date of acceptance: 22-07-2019

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# I. Introduction

Cardiovascular diseases are major causes of adult morbidity and mortality in Egypt<sup>1</sup> as ischemic heart disease is the leading cause of mortality and pre-mature deaths in Egypt<sup>2</sup>. Coronary artery disease (CAD) is a condition that is characterized by disruption of the integrity of the coronary arteries that supply blood to the heart muscle, usually due to a buildup of atherosclerotic plaque<sup>3</sup> and Cardiac Catheterization (CC) is considered the gold standard diagnostic test for CAD as it's performed to diagnose the extent and severity of coronary artery disease, valve disease, or disease of the aorta and it can also be used for interventional purposes such as angioplasty and stenting for stenotic or blocked artery<sup>4</sup>.

Vascular access site complications (VASCs) related to femoral artery remain an important source of increased morbidity, mortality, length of stay and cost. VASCs post diagnostic coronary angiography includes: hematoma, retroperitoneal hematoma, arterial venous fistula, pseudoaneurysms, acute limb ischemia/acute arterial thrombosis<sup>5</sup> and the incidence of complications increases with percutaneous coronary intervention, as it requires potent use of oral and intravenous antiplatelet and antithrombin medications which increase the effectiveness of PCI, but it is also accompanying with an increased risk of VASCs. The reported incidence of VASCs during PCI is from 5.4% to 20% <sup>6</sup>. There are three methods are employed to achieve femoral artery hemostasis following sheath removal after cardiac catheterization, those methods are the manual compression, mechanical compression and vascular closure devices. Manual compression has been the gold standard for

obtaining hemostasis at the vascular access site for years, but this standard has changed as new devices have come on the market<sup>7</sup>.

Manual compression for some practitioners is not an option because it requires strength and the ability to hold a good compression for 15 to 20 minutes and if hand and arm fatigue develops during the procedure, the amount of pressure applied to the femoral artery may vary causing vascular access site complications and it requires also long time for hemostasis and ambulation after achieving hemostasis<sup>8</sup>.

The second method is mechanical compression (MEC) which involves the application of constant pressure on the artery to obtain hemostasis for 10-20 minutes after sheath removal. MEC has many advantages such as allowing hands-free catheter removal so that nurses can monitor the patient and provide care as needed, safe and noninvasive technique, cost effective method as these devices are reusable and the technique itself is easy to learn. On the other hand, disadvantages include pain at arteriotomy site due to compression, prolonged mean time to achieve hemostasis (15 to 20 minutes) and prolonged mean time to safe ambulation (4 to 6 hours)<sup>9</sup>.

The device used in this study is a mechanical compressor called Combat ready clamp (CRoC) which was developed by the united states Army Medical Research (Combat Medical System, Fayetteville). CRoC was designed to exert mechanical pressure directly over the wound or indirectly over the groin area to occlude underlying blood vessels and stop hemorrhage, eliminating the need for manual pressure and provides hands free hemorrhage control and constant precise pressure as needed for hemostasis achievement<sup>10</sup>.

The interesting points about this device is that it is the first recommended device for seven-site junctional hemorrhage control, the CRoC has a vice-like compression disk that provides advantage of creating bi-directional pressure exactly where it is needed most, preassembled configuration deploys in 10-20 seconds, rust and corrosion resistant, aluminum construction<sup>11</sup>. The third method is vascular closure devices (VCDs) such as suturing and clip devices, and biodegradable devices which involve implanting a collagen seal into the arterial puncture site or a seaweed dressing device, but there are many disadvantages including that this is a difficult technique to learn as it has its own learning curve, it may take up to 20 cases to become proficient 12.

**1.1 Significance of the study:** Major advances in cardiac catheterization have included increasingly complex antiplatelet and antithrombotic regimens used in conjunction with PCI. Unfortunately, although these advances yield benefits, they also contribute to the occurrence of femoral vascular access site complications. VASCs remain an important source of increased morbidity, mortality, length of stay and cost. The economic ramifications of VASCs are significant. Interventions aimed at reducing the risk of adverse events are likely to improve both financial and clinical outcomes. Removing femoral sheaths and managing related complications after PCI are predominantly the responsibilities of nurses in many acute and critical care settings. Therefore, it is essential for nurses to understand the causes of and predisposing risk factors for VASCs and they should be instrumental in optimizing patients' outcomes.

**1.2 Aim of the study:** The present study was conducted to fulfill the following aims:

- 1- Compare the effect of using manual compression and mechanical compression technique in achieving hemostasis after femoral sheath removal through:
- a. Assessment of the time to hemostasis using manual and mechanical compression.
- b. Assessment of time to ambulate from bed after sheath removal.
- c. Assessment of patient comfort level using numeric rating pain scale (0-10) after using manual and mechanical compression methods.
- 2- Compare the effect of using manual and mechanical compression technique on patient vascular complications through:
- a. Assessment of hematoma formation.
- b. Assessment of ecchymosis formation.
- c. Assessment of oozing (bleeding).

**1.3 Research question:** What is the most effective method for achieving femoral artery hemostasis after coronary catheterization?

# II. Methods

2.1 Research design: A comparative study design was used to conduct this study.

**2.2 Research setting:** This study was conducted in the cardiac catheterization unit at Beni-Suef general hospital and Beni-Suef university hospital.

**2.3 Research subjects**: A purposive sample of 121 patients 69 patients underwent coronary angiography (CA) and 52 patients underwent percutaneous coronary intervention (PCI) admitted to the previous mentioned settings at the time of data collection were recruited in this study. The least sample size to be enrolled in this study was calculated using Epi- Info version 7 Stat Calc, (Center for Disease Control (CDC), WHO), based on the

# following criteria; rate of the problem, confidence level of 90%, margin of error of 5%.

**Inclusion Criteria:** Age (18-65) years old, INR < 1.4, Serum creatinine < 1.5 mg/dl, free from psychotic disorders, free from septic wound, free from blood disease (e.g. hemophilia, sickle cell anemia, hemolytic anemia, leukemia), free from other chronic diseases (e.g. liver cirrhosis, renal failure, cancer), free from another physical and psychological handicaps, undergo Coronary angiography and/or PCI (per cutaneous coronary intervention), post operation 12 hour to ensure that the patient able to ambulate and hemodynamically stable, gain access to femoral artery through one puncture trial.

# 2.4 Tools for data collection:

Three tools for data collection were used as follows:

# 2.4.1 Patients interview questionnaire tool:

This tool was developed by the researcher in English language. It was developed based on reviewing of related literatures<sup>13,14,15</sup>. It includes two parts:

**Part 1:** Patient's demographic characteristics: It aimed to assess the patients' socio-demographic characteristics such as age, gender, occupation, marital status, level of education, residence, and health insurance coverage.

**Part 2:** Patients clinical data: It was used to assess and collect data about patients' medical history such as weight, height, BMI, abdominal and pelvic girth, vital signs, laboratory investigations (INR, serum creatinine), presence of chronic diseases, current medications, past surgical history and presence of family history of cardiovascular disease.

# 2.4.2 Femoral artery hemostasis measuring scales that include:

**1-Hemostasis time using manual and mechanical compression:** It was constructed by the researcher to measure the time spent to achieve femoral artery hemostasis after sheath removal using one of the two methods of concern (manual compression or mechanical compression using CRoC device).

Scoring system classifies hemostasis time to:

- 3 to < 5 minutes.
- 5 to < 10 minutes.
- 10 to< 15 minutes.</li>
- More than 15 minutes.

**2-Time to ambulate from bed after sheath removal:** It was developed by the researcher to measure time spent by the patient in the supine position after sheath removal before starting to move from bed.

Scoring system classifies time to ambulate from bed after sheath removal to:

- 2 to <4 hours.
- 4 to <6 hours.
- 6 to <8 hours.
- More than 8 hours.
- **3- Patient comfort level scale:** It was used to assess pain site, frequency and the intensity of pain. This scale was adopted from Wong- baker face scale (2016)<sup>16</sup>.

The scale is a ten-point scale grading the intensity of pain. It ranges from grade 0-10. With grade (zero) represents no pain and grade (10) represents the worst pain. It was used immediately after sheath removal for patients underwent cardiac catheterization and after 5, 10, 15 and 20 minutes of compression over femoral artery puncture site.

#### Scoring system classifies patient's pain intensity to:

- No pain represent zero.
- Mild pain represent 1-3 grades.
- Moderate pain represent 4-6 grades.
- Severe pain represent 7-10 grades.

#### 2.4.3 Patients' vascular complications monitoring scales:

This tool includes 3 scales as follows:

- 1- Hematoma formation scale: Hematomas was defined as a collection of blood located in the soft tissue which occurs because of blood loss at the arterial and/or venous access site or perforation of an artery or vein. The scale was designed to assess and measure hematoma around femoral artery puncture site. This scale was adopted from Al Sadi et al (2010)<sup>17</sup>.
- Scoring system: it classified hematoma into four categories according to surface area:
- No hematoma ( $< 2 \text{ cm}^2$  in diameter).

- Small hematoma ( $2 \le 5 \text{ cm}^2$  in diameter).
- Medium hematoma ( $5 \le 10 \text{ cm}^2$  in diameter).
- Large hematoma (  $\geq 10 \text{ cm}^2$  in diameter).
- 2- Ecchymosis formation scale: Ecchymosis was defined as presence of any skin discoloration without a mass <sup>18</sup>. This scale was used to assess ecchymosis around femoral artery puncture site. It was adopted from Hamner et al (2010)<sup>19</sup>.

Scoring system: It classified ecchymosis into four categories according to surface area:

- No ecchymosis (< 2 cm<sup>2</sup> in diameter).
- Small ecchymosis ( $2 \le 5 \text{ cm}^2$  in diameter).
- Medium ecchymosis ( $5 \le 10 \text{ cm}^2$  in diameter).
- Large ecchymosis (  $\geq 10 \text{ cm} 2$  in diameter).
- 3- Oozing (bleeding) scale: This scale was used to measure any leakage of blood from the puncture site. It was adopted from Black (2008)<sup>20</sup>.

Scoring system: It classified oozing into four categories according to surface area soaked with blood:

- No oozing (dry dressing).
- Mild oozing ( $< 2 \text{ cm}^2$  in diameter dressing soaked with blood).
- Moderate oozing ( $2 \le 5 \text{ cm}^2$  in diameter dressing soaked with blood).
- Severe oozing  $(5 \le 10 \text{ cm}^2 \text{ in diameter dressing soaked with blood})$ .

**2.5 Tool Validity:** Validity of the proposed tools was tested using face and content validity by inspecting the items to determine whether the tools measure what supposed to measure. Validity was tested through a jury of seven experts from medical- surgical nursing department at the faculty of nursing, Ain Shams University. The experts reviewed the tools for format, simplicity, consistency, clarity, accuracy, understanding, comprehensiveness and relevance.

Minor modification was done such as scheduled frequency of assessments for patients underwent diagnostic coronary angiography changed from assessment at immediate, at 6 hours and 12 hours after sheath removal to perform assessment immediately, at 3 hours and at 6 hours after sheath removal, because the length of stay for patients underwent diagnostic coronary angiography in post catheterization unit according to hospital policy is 6 hours only, unless it is indicated to increase length of stay.

**2.6 Pilot study:** Before performing the actual study, a pilot study was carried out on 10% (12) of patients with post coronary catheterization to test clarity and applicability of tools used in this study. Some modifications were done based on the pilot study. The patients who included in the pilot study were excluded from the main study group

# 2.7 Ethical considerations:

The research approval was obtained from the ethical committee of the faculty of nursing of Ain Shams University before starting the study. The researcher clarified the objectives and aim of the study to patients included in the study before starting. The researcher assured maintaining anonymity and confidentiality of subjects' data included in the study. Subjects were informed that they were allowed to choose to participate or not in the study and they had the right to withdraw from the study at any time. Oral consent was obtained from the patient to participate in the study.

# 2.8 Procedures:

- Approval to carry out this study was issued from the faculty of nursing –Ain shams university to the
  medical and nursing director of Beni-Suef general hospital and Beni-Suef university hospital and nursing
  supervisor of cardiac catheterization unit in boths hospital and at which the study was conducted, explaining
  the purpose of the study and requesting the permission for data collection from the studied patients.
- Data collection took about 7 months started from June 2017 until December 2017. The data were collected by the researcher through 3 days/week from cardiac catheterization unit in Beni-suef general hospital and Beni-suef university hospital.
- Each patient was interviewed by the researcher for about 30 minutes before undergoing the procedure (preprocedure). First, demographic and clinical data were collected from the patient's medical records and from the patients themselves and sometimes from the patient's relatives. The interview questionnaire took about 10 minutes to be filled by the researcher.
- During the cardiac catheterization procedure, the patients were observed for number of femoral artery access puncture trials, dose of heparin received, and any other thrombolytic or anti-platelets medications given. The tool took about 30 minutes to be fulfilled.

- Post cardiac catheterization procedure, the patients were maintained in the supine position for 4 to 6 hours at least after sheath removal in the post catheterization unit.
- Groin area immediately assessed for oozing, hematoma and ecchymosis using vascular complications monitoring scales as mentioned before. It took about 10 minutes to be completed.
- Femoral artery sheath was removed by the researcher and nursing staff of post catheterization care unit, compression is applied using one of the two methods of concern in the study (manual compression or mechanical compression using combat ready clamp (CRoC device), and the time for hemostasis and pain degree were assessed after sheath removal, it took about 30 minutes to be completed and documented.
- For patients underwent coronary angiography, femoral artery sheath was removed immediately after arriving post catheterization unit. For patients underwent percutaneous coronary intervention, heparin must be off for at least four hours before sheath removal, to ensure returning of activated clotting time (ACT) to acceptable range.
- Vascular complications monitoring scales that include skin integrity scale, hematoma formation scale, ecchymosis and oozing scales were re-assessed at 3 and at 6 hours post hemostasis for patients underwent coronary angiography. For patients underwent percutaneous coronary intervention, the patients were re-assessed at 6 and at 12 hours post catheterization procedure and all data were collected by the researcher and documented. Documentation of all observed data took around 3 hours due to the frequent assessments performed by the researcher.

#### III. Results

Table (1): Percentage distribution of demographic characteristics of the studied patients (N=121).

Table 1 clarifies that; about 88.4% of the studied patients' age was ranging from 45 to 65 years, and the mean age of the studied patients was  $54.9 \pm 8$ . As regard to patient's gender, 76.0% of them were males. In relation to educational level, 37.2% were illiterate and 13.2% had higher education. Regarding occupation, 37.2% of patients are not working. Regarding residence, 65.3% of patients are living in rural areas. Moreover, 93.4% of the studied patients were married, and 67.8% of them didn't have health insurance. Lastly, 97.5% of patients are living with their families.

Demographic characteristics	Ν	%
Age		
• 18 – 44 years	14	11.6%
• 45 – 65 years	107	88.4%
$Mean + SD = 54.9 \pm 8$		·
Gender		
Male	92	76.0%
• Female	29	24.0%
Education level		
Illiterate	45	37.2%
Read and Write	34	28.1%
Secondary Education	26	21.5%
Higher Education	16	13.2%
Occupation		
<ul> <li>Does not work</li> </ul>	45	37.2%
• House wife	34	28.1%
Manual work	26	21.5%
Employee	16	13.2%
Residence		
Rural	79	65.3%
Urban	42	34.7%
Marital status		-
Married	113	93.4%
Separate	2	1.6%
Widow	6	5.0%
Health insurance		
• Yes	39	32.2%
No	82	67.8%
Living:		
Alone	3	2.5%
• With family	118	97.5%

 Table (2): percentage distribution of anthropometrics measurement data for patients undergoing cardiac catheterization (N=121).

Table 2 clarifies that 72.7% of the studied patients' weight was ranging from 75 to 100 Kg and 84.3% of them their height was more than 160 cm. Regarding body mass index (BMI) of patients undergoing coronary catheterization, 60.3% of patients their BMI was  $\geq$ 30.0 that are classified as obese. As regard to laboratory investigations of the studied patients, the INR of all patients was between 1 and 1.4 and for creatinine level, all patients have creatinine level ranged between 0.6 to 1.4 mg/dl. Regarding abdominal girth, 68.6% of the studied patients had abdominal circumference that classify them as very high risk for coronary artery disease as men circumference > 102 cm and women > 88 cm and for the pelvic circumference, 54.5% of the studied patients had pelvic circumference > 108 cm.

Items	Ν	%
Weight		
• < 75 Kg	21	17.3%
• 75-100 Kg	88	72.7%
• > 100 Kg	12	10%
Height		
• <160 cm	19	15.7%
• ≥160 cm	102	84.3%
Body mass index (BMI)		
• (<18.5) Underweight	0	0.0%
• (18.5 - 24.9) Normal range	6	5.0%
• (25.0-29.9) Pre-obese	42	34.7%
• (≥30.0) Obese	73	60.3%
Laboratory investigation:		
International normalization ratio (INF	R)	
• 1-1.4	121	100.%
Creatinine		
• 0.6-1.4 mg dl	121	100 %
Abdominal girth:		
<ul> <li>Low risk for coronary artery</li> </ul>		
disease	26	21.5%
• Men < 94 cm		
• Women $< 80 \text{ cm}$		
<ul> <li>High risk for coronary artery</li> </ul>		
disease		9.9%
• Men 94-102 cm	12	
• Women 80-88 cm		
<ul> <li>Very high risk for coronary</li> </ul>		
artery disease		68.6%
• Men >102 cm	83	
• Women > 88 cm		
Pelvic girth		
• 78 to < 90 cm	11	9.1%
• 90 to <108 cm	44	36.4%
• >108 cm	66	54.5%

Table (3): percentage distribution of vital signs data for patients undergoing cardiac catheterization (N=121).

Table 3 clarifies that 49.6% of the patients under study have stage 2 hypertension. Regarding the heart rate of the studied patients, 96% of them their heart rate ranged from 60 to 100 b/min and 78.5% of them their respiratory rate ranged from 14 to 20 t/m and 94.2% of them their body temperature ranged from 36.5 to  $37.5^{\circ}$ C.

Items	Ν	%
Blood pressure		•
< 120/80 (Normal)	20	16.5%
Systolic 120-129 or diastolic < 80	8	6.6%
Elevated)		
Systolic 130-139 or diastolic 80-89	33	27.3%
(Stage 1)		
Systolic $\geq 140$ or diastolic $\geq 90$	60	49.6%
mmHg (Stage 2)		
Heart rate		
< 60 b\ min	3	2.4%
60-100 b\ min	116	96%
> 100 b\min	2	1.6%
Respiratory rate		
$< 14 t \setminus min$	17	14.0%

DOI: 10.9790/1959-0804037793

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•	14-20 t\ min	95	78.5%
•	> 20 t\ min	9	7.5%
Bo	ody temperature		
•	< 36.5oC	0	0.0%
•	36.5-37.5oC	114	94.2%
•	> 37.5oC	7	5.8%

 Table (4): Clinical data of the studied patients undergoing coronary catheterization (N=121)

Table 4 shows that, 92.6% of the studied patients were taking medications for cardiac disease, but 56.2% of them aren't taking medications as prescribed, 92.6% of studied patients are taking acetylsalicylic acid 75 mg. Regarding the presence of chronic diseases, 63.6% of the studied patients suffered from cardiac disease and 48.8% of them had hypertension. Moreover, 54.5% of studied patients didn't undergo any surgical procedures and 3.3% only of them suffer from infection as post-operative complications. Also, 37.2% of the studied patients had family history of cardiovascular diseases.

Items	Ν	%
Taking medication for cardiac disease	:	
Yes	112	92.6%
• No	9	7.4%
Taking medication/s as prescribed		
• Yes	53	43.8%
• No	68	56.2%
Medications types taking by patients:		
Acetylsalicylic acid 75 mg	112	92.6%
Clopidogrel 75 mg	57	47.1%
Ticagrelor 90 mg	11	9.1%
Clexane	8	6.6%
Warfarin	1	0.8%
Presence of chronic disease:		
Diabetes mellitus	38	31.4%
Hypertension	59	48.8%
Cardiac diseases	77	63.6%
Thyroid disorder	1	0.8%
Instructed to discontinue any medicati	ons before the procedure:	
• Yes	0	0.0%
• No	121	100%
Underwent any surgical procedure bef	ore:	
Yes	55	45.5%
• No	66	54.5%
Complications types:		
Infection	4	3.3%
Family history of cardiovascular disea	ses:	
• Yes	45	37.2%
• No	76	62.8%
Types of inherited cardiovascular dise	ase:	
Coronary artery diseases	23	19.0%
Valvular heart disease	8	6.6%
Don't know	14	11.57%

 Table (5): Percentage distribution of the studied patients regarding type of coronary catheterization performed and methods of compression used (N=121).

Table 5 clarifies that 57.0% of the studied patients underwent coronary angiography and 43.0% underwent percutaneous coronary intervention. As regard to method of compression used, the manual compression was used with 49.6% of patients and mechanical compression used with 50.4% of patients. In relation to size of sheath used, all of patients used sheath size of 6 French.

Manual versus Mechanical compression for femoral artery hemostasis after Coronary ..

Items	Ν	%
Procedure performed		-
Coronary Angiography (CA)	69	57.0%
Percutaneous Coronary Intervention (PCI)	52	43.0%
Method of compression used		-
Manual compression.	60	49.6%
Mechanical compression (CRoC compressor)	61	50.4%
Size of sheath used in procedure		
6 F	121	100.0%

 Table (6): Percentage distribution of the studied patients regarding medication used before, during and after coronary catheterization (N=121).

Table 6 shows that 47.1% of the studied patients were taking antiplatelet medication before the procedure and 84.3% of them didn't receive thrombolytic medications before the procedure. Moreover 57.0% of the studied patients received 2500 IU of heparin during the procedure. Moreover 3.3% of them experienced vasovagal attack post procedure and all of patients didn't receive thrombolytic or heparin post procedure.

Items	Ν	%
Antiplatelet agents administer	ed before the procedure	1
Yes	57	47.1%
No	64	52.9%
Thrombolytic given before the	e procedure:	
Yes	19	15.7%
No	102	84.3%
Heparin administered in cathe	eterization lab:	
2500 IU	69	57.0%
10000 IU	52	43.0%
Thrombolytic infusion after th	ne procedure:	
Yes	0.0	0.0%
No	121	0.0%
Heparin administered post pro	ocedure	
Yes	0.0	0.0%
No	121	100%
Vasovagal attack exposure:		
Yes	4	3.3%
No	117	96.7%

 Table (7): Percentage distribution of patients underwent coronary angiography regarding hemostasis time using manual or compression methods (N=69).

Table 7 revealed that 17.6 % of patients were achieved hemostasis within 3 to < 5 minutes when using the manual compression method, while 5.7% of patients achieved hemostasis within 3 to < 5 minutes when using CRoC compressor method. The table also revealed that 65.7% of patients were achieved hemostasis within 5 to < 10 minutes when using the CRoC compressor compared with 41.3% in the manual compression group. The table shows that, there is no statistically significant difference in hemostasis time for patients undergoing coronary angiography when using manual or compression method as P > 0.05.

	emostasis Manual CRoC Compressor (N= 34) (N= 35)					
Time to hemostasis					X2	p -value
	Ν	%	Ν	%		
3  to < 5  minutes.	6	17.6%	2	5.7%		
5 to <10 minutes.	14	41.3%	23	65.7%		0.154880
10  to < 15  minutes.	8	23.5%	7	20.0%	5.24	P > 0.05 NS
$\geq$ 15 minutes.	6	17.6%	3	8.6%	5.24	Gri

 Table (8): Percentage distribution of patients underwent percutaneous coronary intervention regarding hemostasis time using manual or compression methods (N=52).

Table 8 revealed that 77.0% of patients were achieved hemostasis within 5 to < 10 minutes when using the CRoC compressor, while 38.5% of patients when using the manual compression method. Also, there is a statistically significant difference in hemostasis time for patients undergoing percutaneous coronary intervention when using manual or compression method as P < 0.05

Time to hemostasis	Manual (N= 26)		CRoC Compressor (N= 26)		X2	p -value
	N %		Ν	%		
3  to < 5  minutes.	0	0.0%	0	0.0%		
5 to $< 10$ minutes.	10	38.5%	20	77.0%		0.019362
10 to < 15 minutes.	13	50.0%	5	19.2%	7.89	P < 0.05
$\geq 15$ minutes.	3	11.5%	1	3.8%	7.89	r < 0.03 S

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

 Table (9): Percentage distribution of patients underwent coronary angiography regarding time to ambulate after sheath removal in both groups (N=69).

Table 9 shows that 37.1% of patients undergoing coronary angiography started to ambulate after sheath removal within 2 to < 4 hours when using the CRoC compressor, while 14.7% of patients started to ambulate within 2 to < 4 hours when using the manual compression. Also 82.4% of patients started to ambulate after sheath removal within 4 to < 6 hours when using the manual compression, while 62.9% of patients when using the CRoC compressor. The table revealed that there is no statistically significant difference in time of ambulation for patients undergoing coronary angiography when using manual or compression methods as P > 0.05.

		(	Group			
Time to ambulate after sheath removal	Manual (N=34)		CRoC Compressor (N=35)		X2	p –value
	Ν	%	N %		1	
2  to < 4  hrs.	5	14.7%	13	37.1%		
4 to < 6 hrs.	28	82.4%	22	62.9%		0.072000
6 to < 8 hrs.	1	2.9%	0	0.0%	5.26	P > 0.05
$\geq$ 8 hrs.	0	0.0%	0	0.0%		P > 0.03 NS

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

 Table (10): Percentage distribution of patients underwent percutaneous coronary intervention regarding time to ambulate after sheath removal in both groups (N=52).

Table 10 shows that 65.4 % of patients undergoing percutaneous coronary intervention started to ambulate after sheath removal within 4 to < 6 hours when using the CRoC compressor, while 53.8% of patients started to ambulate within 4 to < 6 hours when using the manual compression method. Also, the table shows that there is no statistically significant difference in time of ambulation for patients undergoing percutaneous coronary intervention when using manual or compression methods as P > 0.05.

Time to ambulate after sheath removal	Manual (N=26)			mpressor : 26)	X2	p –value
	N	%	N %			
2  to < 4  hrs.	2	7.7%	1	3.8%		
4 to < 6 hrs.	14	53.8%	17	65.4%	0.85	0.655119
6 to < 8 hrs.	10	38.5%	8	30.8%		P > 0.05 NS
$\geq$ 8 hrs.	0	0.0%	0	0.0%		115

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

 Table (11) Comparison of post cardiac catheterization pain level among patients under study in both groups (N=121).

Table 11 shows that patients in the manual group had higher level of pain at time of sheath removal, while at the other three assessment times (5, 10, 20 minutes), the patients in the compressor group had the lower score of pain. The table also shows that there is no statistically significant difference in pain level when using manual or compression method at time of sheath removal. But there is statistically significant difference in pain

		(	Froup			
Times of pain assessment	Manual (N=60)		CRoC compressor (N= 61)		t	P value
	Mean	SD	Mean	SD		
Pain level at the time of sheath removal	5.90	1.66	5.56	1.60	1.16	0.25018
Pain level after 5 minutes	4.67	1.46	3.97	1.34	2.75	0.00694*
Pain level after 10 minutes	3.07	1.96	2.20	1.40	2.81	0.00582*
Pain level after 15 minutes	1.03	1.63	0.43	1.10	2.41	0.01759*
Pain level after 20 minutes	0.33	1.17	0.00	0.00	2.22	0.02849*

level between two methods at the other three times of assessment (5, 10, 20 minutes) as P < 0.05.

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

 Table (12): Percentage distribution of patients underwent coronary angiography regarding hematoma formation in both groups (N=69).

Table 12 shows that 29.4% of patients who underwent coronary angiography experienced small hematoma formation immediately after sheath removal were in the manual compression group, while 14.3% of patients when using the CRoC compressor. Also in the reassessment after 3 hours, 53.0% of patients who experienced small hematoma formation were also in the manual compression group, while 28.6% of patients when using the CRoC compressor. Moreover, in the reassessment after 6 hours, 55.9% of patients experienced small hematoma formation were in the manual compression group and 31.4% of patients when using the CRoC compressor group. The table also shows that there is statistically significant difference in hematoma formation for patients undergoing coronary angiography when using manual or compressor methods at 3 and 6 hours post procedure as  $P \le 0.05$ .

		Group					
Hematoma categories		Manual (N= 34)		pressor (N=35)	X2	p –value	
	Ν	%	Ν	%			
Hematoma formation immediate:	-	-		-	-		
None ( $<2$ cm <sup>2</sup> )	24	70.6%	30	85.7%			
Small ( $2 \le 5 \text{cm}^2$ )	10	29.4%	5	14.3%		0.12778 P > 0.05 NS	
Medium $(5 \le 10 \text{ cm}^2)$	0	0.0%	0	0.0%	2.32		
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%			
Hematoma formation at 3 hours:							
None ( $<2$ cm <sup>2</sup> )	15	44.1%	25	71.4%		0.02158*	
Small ( $2 \le 5 \text{cm}^2$ )	18	53.0%	10	28.6%			
Medium $(5 \le 10 \text{ cm}^2)$	1	2.9%	0	0.0%	5.28	P < 0.05	
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		S	
Hematoma formation at 6 hours:							
None (<2cm <sup>2</sup> )	14	41.2%	24	68.6%			
Small ( $2 \le 5 \text{cm}^2$ )	19	55.9%	11	31.4%		0.02219*	
Medium $(5 \le 10 \text{ cm}^2)$	1	2.9%	0	0.0%	5.23	P < 0.05	
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		S	

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

 Table (13): Percentage distribution of patients underwent percutaneous coronary intervention regarding hematoma formation in both groups (N=52).

Table 13 revealed that 23.1% of patients underwent percutaneous coronary intervention experienced small hematoma formations immediately after sheath removal were in the manual compression group, while 7.7% of patients when using the CRoC compressor. Also, in the reassessment after 6 hours, 30.8% of patients experienced small hematoma formations were in the manual group, while 15.4% of patients when using the CRoC compressor. Moreover, in reassessment after 12 hours, 34.6% of patients experienced small hematoma formation were also in the manual compression group, while 15.4% of patients when using the CRoC compressor method. The table also revealed that there is no statistically significant difference in hematoma formation for patients undergoing percutaneous coronary intervention when using manual or compressor methods immediately, at 6 and 12 hours post procedure as P > 0.05.

Hematoma		Gi		p -value		
categories	Manual (n= 26)		CRoC Compressor (n= 26)		X2	
	Ν	%	Ν	%		
Hematoma formation immediate:		-	-	-		
None (<2cm <sup>2</sup> )	19	73.1%	24	92.3%		0.06683
Small $(2 \le 5 \text{cm}^2)$	6	23.1%	2	7.7%		P > 0.05
Medium $(5 \le 10 \text{ cm}^2)$	1	3.8%	0	0.0%	3.36	NS
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		
Hematoma formation at 6hours:		-				
None (<2cm <sup>2</sup> )	17	65.4%	22	84.6%		0.10931
Small $(2 \le 5 \text{cm}^2)$	8	30.8%	4	15.4%		P > 0.05
Medium $(5 \le 10 \text{ cm}^2)$	1	3.8%	0	0.0%	2.56	NS
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		
Hematoma formation at 12 hours:		-	-			
None (<2cm <sup>2</sup> )	16	61.6%	22	84.6%		0.06068
Small $(2 \le 5 \text{cm}^2)$	9	34.6%	4	15.4%		P > 0.05
Medium $(5 \le 10 \text{ cm}^2)$	1	3.8%	0	0.0%	3.52	NS
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

Table (14): Percentage distribution of patients underwent coronary angiography<br/>formation in both groups (N=69).

regarding ecchymosis

Table 14 shows that 41.2% of patients who underwent coronary angiography experienced small ecchymosis formation immediately after sheath removal were in the manual group, while 14.3% of them when using the CRoC compressor. Also, in reassessment after 3 hours, 41.2% of patients who experienced small ecchymosis formation were in the manual group, while 28.6% in the CRoC compressor method group. Moreover, in reassessment after 6 hours, 41.2% of patients who experienced small ecchymosis formation were in the manual group, while 28.6% in the CRoC compressor method group. Moreover, in reassessment after 6 hours, 41.2% of patients who experienced small ecchymosis formation were in the manual group, while 34.3% of them when using the CRoC compressor. The table also shows that there is highly statistically significant difference in ecchymosis formation for patients undergoing coronary angiography when using the CRoC compressor or manual compression methods immediately after sheath removal as P < 0.01, but there is no statistically significant difference in ecchymosis formation when using manual or compressor methods at 3 and 6 hours post procedure as P > 0.05.

		G							
Ecchymosis categories	Manual (N= 34)			ompressor = 35)	X2	p –value			
	Ν	%	Ν	%					
Ecchymosis formation immediately									
None (<2cm <sup>2</sup> )	19	55.9%	30	85.7%					
Small ( $2 \le 5 \text{cm}^2$ )	14	41.2%	5	14.3%		0.00632			
Medium $(5 \le 10 \text{ cm}^2)$	1	2.9%	0	0.0%		P < 0.01			
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%	7.46	HS			
Ecchymosis formation at 3 ho	urs								
None (<2cm <sup>2</sup> )	16	47.1%	25	71.4%					
Small ( $2 \le 5 \text{cm}^2$ )	14	41.2%	10	28.6%		0.13181			
Medium $(5 \le 10 \text{ cm}^2)$	4	11.7%	0	0.0%	2.27	P > 0.05			
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		NS			
Ecchymosis formation at 6 ho	Ecchymosis formation at 6 hours:								
None ( $<2$ cm <sup>2</sup> )	16	47.1%	23	65.7					
Small ( $2 \le 5 \text{cm}^2$ )	14	41.2%	12	34.3%		0.30975			
Medium (5≤10cm <sup>2</sup> )	4	11.7%	0	0.0%	1.03	P > 0.05			
Large ( $\geq 10$ cm <sup>2</sup> )	0	0.0%	0	0.0%		NS			

 Table (15): Percentage distribution of patients underwent percutaneous coronary intervention regarding ecchymosis formation in both groups (N=52).

Table 15 shows that 19.3% of patients in the manual compression group experienced small ecchymosis formation immediately after sheath removal while none of patients experienced any ecchymosis formation in the CRoC compressor group. Also, in the reassessment after 6 hours, 42.4% of patients in the manual group experienced small ecchymosis formation, compared to 15.4% of patients in the CRoC compressor group.

Moreover, in the reassessment after 12 hours, 46.2% of patients in the manual group experienced small ecchymosis formation compared to 15.4% of patients when using the CRoC compressor. The table also shows that there is high statistically significant difference in ecchymosis formation for patients undergoing percutaneous coronary intervention when using manual or compressor methods immediately, at 6 and 12 hours post procedure as P < 0.01.

	Group								
Ecchymosis categories	Manual		CRoC Compressor		X2	p -value			
	( <b>n</b> = 26)		( <b>n</b> = 26)						
	N %		Ν	%					
Ecchymosis formation imme	diate:								
None (<2cm <sup>2</sup> )	19	73.1%	26	100.0%					
Small ( $2 \le 5 \text{cm}^2$ )	5	19.3%	0	0.0%		0.00445			
Medium $(5 \le 10 \text{ cm}^2)$	1	3.8%	0	0.0%	8.09	P < 0.01			
Large ( $\geq 10$ cm <sup>2</sup> )	1	3.8%	0	0.0%		HS			
Ecchymosis formation at 6 h	Ecchymosis formation at 6 hours:								
None ( $<2$ cm <sup>2</sup> )	13	50.0%	22	84.6%					
Small ( $2 \le 5 \text{cm}^2$ )	11	42.4%	4	15.4%		0.00780			
Medium $(5 \le 10 \text{ cm}^2)$	1	3.8%	0	0.0%	7.08	P < 0.01			
Large ( $\geq 10$ cm <sup>2</sup> )	1	3.8%	0	0.0%		HS			
Ecchymosis formation at 12 hours:									
None (<2cm <sup>2</sup> )	12	46.2%	22	84.6%					
Small ( $2 \le 5 \text{cm}^2$ )	12	46.2%	4	15.4%	0.50	0.00356			
Medium (5≤10cm <sup>2</sup> )	1	3.8%	0	0.0%	8.50	P < 0.01 HS			
Large ( $\geq 10$ cm <sup>2</sup> )	1	3.8%	0	0.0%		115			

 Table (16): Percentage distribution of patients underwent coronary angiography regarding oozing formation in both groups (N=69).

Table 16 shows that 68.6% of patients who are in the CRoC compressor group experienced mild oozing immediately after sheath removal compared to 67.7% of patients were in the manual compression group. Moreover, in the reassessment after 3 and 6 hours 100% of patients in the CRoC compressor group didn't experience any oozing compared to 97.1% of patients in the manual compression group. The table also shows that there is no statistically significant difference in oozing formation for patients undergoing coronary angiography when using manual or compressor methods immediately, at 3 and 6 hours post procedure as P > 0.05.

		(	X2	p -value		
Oozing categories	Manual (n=34)				CRoC compressor (n= 35)	
	Ν	%	Ν	%		
Oozing formation immediate:	-	-	-	-	-	
None (Dry Dressing)	6	17.6%	10	28.6%		
Mild (<2cm2)	23	67.7%	24	68.6%		0.159277
Moderate ( $2 \le 5 \text{cm}^2$ )	5	14.7%	1	2.8%	3.67	P > 0.05
Severe (5≤10cm2)	0	0.0%	0	0.0%		NS
Oozing formation at 3 hours:						
None (Dry Dressing)	33	97.1%	35	100%		
Mild (<2cm2)	1	2.9%	0	0.0%		0.306766
Moderate ( $2 \le 5 \text{cm}2$ )	0	0.0%	0	0.0%	1.04	P > 0.05
Severe (5≤10cm2)	0	0.0%	0	0.0%		NS
Oozing formation at 6 hours:						
None (Dry Dressing)	33	97.1%	35	100%		
Mild (<2cm2)	1	2.9%	0	0.0%		0.306766
Moderate ( $2 \le 5 \text{cm}2$ )	0	0.0%	0	0.0%	1.04	P > 0.05
Severe (5≤10cm2)	0	0.0%	0	0.0%	]	NS

 Table (17): Percentage distribution of patients underwent percutaneous coronary intervention regarding oozing formation in both groups (N=52).

Table 17 shows that 80.8% of patients who underwent percutaneous coronary intervention and experienced mild oozing immediately after sheath removal were in the manual compression group, while 77.0% of patients when using the CRoC compressor. Also 3.8% of patients who experienced mild oozing in the reassessment at 6 and at 12 hours after sheath removal were in the manual compression group while no patients

in the CRoC compressor group at 6 and 12 hours post PCI procedure. The table also shows that there is no statistically significant difference in oozing formation for patients undergoing percutaneous coronary intervention when using manual or compressor methods immediately, at 6 and 12 hours post procedure as P > 0.05.

		(							
Oozing	Oozing Manual CRoC Compressor		X2	p -value					
	(n=	(n=26) $(n=26)$							
	Ν	%	Ν	%					
Oozing formation immediate:									
None (Dry Dressing)	3	11.5%	2	7.7%					
Mild (<2cm2)	21	80.8%	20	77.0%		0.640486			
Moderate ( $2 \le 5 \text{cm}2$ )	2	7.7%	4	15.4%	0.89	P > 0.05			
Severe (5≤10cm2)	0	0.0%	0	0.0%		NS			
Oozing formation at 6 hours:									
None (Dry Dressing)	25	96.2%	26	100%					
Mild (<2cm2)	1	3.8%	0	0.0%		0.312612			
Moderate ( $2 \le 5 \text{cm}^2$ )	0	0.0%	0	0.0%	1.02	P > 0.05			
Severe (5≤10cm2)	0	0.0%	0	0.0%		NS			
Oozing formation at 12 hours:									
None (Dry Dressing)	25	96.2%	26	100%					
Mild (<2cm2)	1	3.8%	0	0.0%		0.312612			
Moderate ( $2 \le 5 \text{cm}2$ )	0	0.0%	0	0.0%	1.02	P > 0.05			
Severe (5≤10cm2)	0	0.0%	0	0.0%		NS			

\* Significant P.-value at 0.05 HS P- value < 0.01 NS P- value  $\ge 0.05$ .

# IV. Discussion

Regarding the studied patients' demographic characteristics, the results of the present study revealed that about three quarters of studied patients were males and majority of them were above forty-five years old. This result is in accordance with Dressler  $(2014)^{22}$  and Kerut  $(2011)^{23}$  who confirmed that CAD and heart attacks are more common in males than females especially in middle-aged and older men than in any other group, also males over the age of 45 years and females over the age of 55 years are at increased risk for CAD and its complications.

Regarding to educational level, the study results revealed that more than one third of patients were illiterate and few of them have higher education. This finding is contradicted with Tillmann et al.  $(2017)^{24}$ , who revealed that increasing educational level is likely to lead to health benefits and decrease risk of CAD.

Concerning occupation, this study revealed that about two thirds of patients under study were not working (unemployed & housewives). This result is consistent with Bashore,  $(2015)^{25}$  and Dressler,  $(2014)^{22}$  who revealed that physical inactivity is associated with increased risk for CAD and increased levels of physical activity reduce risk for CAD.

Concerning body mass index (BMI), most of the patients under study were above normal range of the BMI and approximately two thirds of patients under study were obese (BMI  $\geq$ 30.0). These findings are in accordance with Mozaffarian et al. (2015)<sup>26</sup> who stated that increased body weight has been associated with an increased risk of morbidity and mortality from coronary heart disease (CHD) in several populations and agree with Alkhawam et al. (2016)<sup>27</sup> who stated that BMI  $\geq$ 30 is a risk factor for early development of CAD. This may be related to unhealthy eating pattern and cultural related food behaviors and sedentary life style including lack of physical mobility.

Regarding to taking medication for cardiac diseases, the study findings revealed that most of patients are taking medications for cardiac diseases, but more than half of them not taking medications as prescribed which result in worsening symptoms of coronary artery disease. This result is in consistent with Chase, Bogener, Ruppar & Conn, (2016)<sup>28</sup> who revealed that medication management is an important aspect of secondary prevention for CAD and nonadherence to prescribed medications for CAD has been linked with multiple poor outcomes on the patients and emphasizing on the role of the nurses as they are on the front lines of health behavior promotion among these patients and can be effective medication administration interventionists. This may be due to patients' knowledge deficit or poor health teaching or discharge instructions that should be performed by the nurses or may be due to increased cost of medication and in ability of patients to buy those medications as most of them not included in the health insurance coverage.

Regarding family history of cardiovascular diseases, this study revealed that more than one third of patients have positive family history of cardiovascular diseases. This result is consistent with Dai, Wiernek,

Evans and Runge,  $(2016)^{29}$  and Roger et al.,  $(2012)^{30}$ , who revealed that nearly 75% of patients with premature onset of CAD have a positive family history and positive family history confers a 1.5–2-fold increased risk of developing CAD. They also revealed that individuals with a family history of premature onset of AMI (e.g., father or brother before age 55, mother or sister before age 65) are at increased risk of developing CAD.

Regarding CRoC efficacy and its ability to obtain full hemostasis in patients underwent diagnostic CA, the current study showed that there is no statistical significance difference presented in time of hemostasis between manual compression group (MC) group and Combat ready clamp group. This result is in accordance with Hassan, Hasan & Ali,  $(2014)^{31}$  who demonstrated that time of hemostasis was  $13.9 \pm 3.5$  min for MC and  $14.5 \pm 4.5$  min for C-clamp. Also, Goswami  $(2016)^{32}$  demonstrated that mean time of hemostasis was 22 min for MC and 31 min for mechanical device compression. This is may be due to ease and speed of hemostasis process as most of challenges that might face the hemostasis process are absent, as the procedure is simple and there is no use of anticoagulant or antiplatelet therapy or wider sheath size.

For patients underwent interventional PCI, the current study revealed that CRoC compressor achieved femoral artery hemostasis for more than three quarters of patients under study within 5 to 10 minutes compared to more than one third of subjects in the manual compression group. These findings are in accordance with Chase, Bogener, Ruppar & Conn, (2016)<sup>28</sup> who showed that time of hemostasis was much shorter in the mechanical compression group (12.9 min) than the Femostop group (35.2 min). Moreover, the results are also in congruence with Mohammed, Said, & Salah, (2013)<sup>33</sup> who demonstrated that the time spent in manual compression of the artery was longer, compared to using the compressor (C-clamp). This may be due to the constant meticulously directed bi-directional compression applied over the femoral artery using CRoC compressor.

Regarding time of ambulation after sheath removal, the current study reveals that there is no statistical significance difference between the manual compression and CRoC compression methods. This finding is contradicted with Hassan, Hasan, Demetry, Refaat & Ali.  $(2015)^{34}$  who have demonstrated that patients with mechanical compression experienced early ambulation from bed with early discharge from the hospital than manual compression method. This is may be due to the strict instructions provided by the post catheterization nurses to the patient to stay in supine position at least 4 to 6 hours after sheath removal to avoid any incident of rebleeding of the arteriotomy site.

Concerning patient comfort, the pain level at the time of sheath removal did not differ significantly between CRoC group and the manual compression group. This result is in agreement with Hassan etal., (2014)<sup>31</sup> who reported that there is no statistical significance difference between manual and mechanical compression methods. This may be caused by that the exerted compression force in the Croc method similar to the exerted force in the MC.

Regarding hematoma formation as a vascular complication among patients underwent diagnostic coronary angiography in the two study groups, the current study has revealed that more than half of the patients in the manual compression group had small hematoma formation at 3 and 6 hours. This result was statistically significantly higher than the mechanical compression (CRoC) group. This result may be due to appropriateness of the compression disc which directs the compression force over the femoral artery preventing blood leakage or hematoma formation.

These results are in agreement with those of Merriweather & Sulzbach-Hoke, (2012)<sup>35</sup> who have reported that formation of hematomas occurred significantly more often in the manual compression group than in the group in which a mechanical device was used.

Also, in congruent with Smilowitz,  $(2012)^{36}$  who have reported that the incidence of hematoma formation using the manual compression method was higher than the mechanical compression method. Meanwhile, AlSadi et al.  $(2010)^{17}$  have claimed that both manual and mechanical compressions are equally effective for achieving hemostasis without hematoma formation.

On the other hand, these findings are contradicted with Sa'aleek et al.  $(1999)^{37}$  who reported that the rate of hematoma formation in mechanical compressor group was higher than the manual compression group. Also, the present study is disagreeing with the results of the study carried out by Benson et al.  $(2009)^{18}$ , where patients who underwent manual sheath removal had fewer hematoma formation compared with those who underwent sheath removal using the compressor or bandage pressure. On the same line, Hamel (2012) added that hematoma increased in mechanical compressor using C-clamp immediately after femoral sheath removal and decreased at 12-hour assessment period. These results are disagreeing with the present study findings.

Regarding ecchymosis, the present study has revealed that there is high statistical significance difference in ecchymosis formation between manual compression group and CRoC compression group in patients underwent interventional percutaneous coronary intervention (PCI) as about one fifth of the manual compression group experienced small ecchymosis immediately after sheath removal compared to none in the

CRoC compression group, also about two fifth of the manual compression group experienced small ecchymosis in the reassessment at 6 and 12 hours of sheath removal compared to only few of patients in the CRoC compression group. This result may be caused by high doses of anticoagulant and platelet therapy used before and during the PCI procedure which increases liability for blood leakage and bleeding from arteriotomy site and inability of the MC to completely block arteriotomy site leading to blood leakage subcutaneously and ecchymosis formation.

These finding are contradicted with Huang, Hassan, & Resnic (2018)<sup>39</sup> who showed that the frequency of ecchymosis formation was statistically similar between manual compression (38%) and mechanical compression (34% for C-clamp and 29% for Femostop). It also disagreed with Mohammed, Said & Salah (2013) who have highlighted increase in size of ecchymosis among the subjects who were given compression with "C-Clamp" or bandage compared to manual compression after 12 hours of sheath removal.

Regarding oozing and bleeding from the puncture site, the current study revealed that there is no significant difference between the two groups. This finding is agree with those of Su, Chang, Wu, and Liao  $(2018)^{40}$  & Jones  $(2012)^{41}$  who have reported that bleeding from the femoral puncture site after femoral sheath removal did not differ significantly when either a mechanical compression device or manual compression was used to attain hemostasis. This may be due to easiness ans ability of quick application of both methods immediately after femoral sheath removal which prevent blood leakage outside the body.

But the finding is contradicted with Chlan et al.  $(2010)^{42}$  who found a higher rate of bleeding in the compressor group (8%), compared to the manual compression group (3%), also Resnic et al.  $(2010)^{43}$  has reported that the incidence of oozing trended downwards after sheath removal across all groin compression methods. Furthermore, Benson et al.  $(2009)^{18}$  showed more significant re-bleeding 7/61 (11%) in mechanical compression compared to zero/30 in the manual compression group.

The current study results revealed that CRoC compression method usage following femoral sheath removal is accompanied with lower incidence of hemostasis time, hematoma, ecchymosis formation and impairment of skin integrity which strongly recommend using CRoC compression device as a simple, safe and effective alternative to the MC method following interventional percutaneous coronary angioplasty and diagnostic coronary angiography for achieving femoral artery hemostasis after sheath removal. This lower incidence of VASCs is accompanied with reducing hospitalization period and overall cost improving quality of care and client satisfaction.

The study results indicate the effectiveness of CRoC compression method and proof its advantages of being simple, easy to be applied, cost effective, provide hands free hemostasis permit the nurse to provide close monitoring, early detection and applying appropriate intervention to prevent any deterioration.

# V. Conclusion

Based on findings in the presented study, it can be concluded that:

- CRoC compression method is more effective than manual compression method in achieving hemostasis in the femoral artery after sheath removal as:
- CRoC compression method achieves femoral artery hemostasis in a shorter time than manual compression method.
- There is no difference in the time of ambulation after sheath removal when using CRoC compression method and manual compression method.
- CRoC compression method usage accompanied with better patients' comfort level than the manual compression method.
- Using CRoC compression method lower the incidence of hematoma formation than the incidence among patients in the manual compression.
- CRoC compression method is more effective than the manual compression method in preventing and decreasing the incidence of ecchymosis formation in the groin area after sheath removal.
- There is no difference between CRoC compression method and manual compression method in oozing (bleeding) incidence.
- Using CRoC compression method decrease skin integrity impairment in the groin area after sheath removal.

# VI. Recommendations

Based on the results of the current study, the following recommendations are suggested:

- Using Combat Ready Clamp (CRoC) compression device as an alternative to the traditional manual compression method as it allow the nurses and health care providers
- To provide close monitoring and hands free care to patients in case of any urgent situations during sheath removal and applying compression to achieve hemostasis in post catheterization unit.

- Provide an educational program for nursing stuff and health care providers about how to apply CRoC compression device and the most common post cardiac catheterization complications and how to manage them effectively especially in post catheterization unit.

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Fady Magdy Fathy. " Manual versus Mechanical Compression for Femoral Artery Hemostasis after Coronary Catheterization" .IOSR Journal of Nursing and Health Science (IOSR-JNHS), vol. 8, no.04, 2019, pp.77-93

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