



The Effect Of Suture-Mediated Closure Device On Hemostasis In Patients After Transfemoral Cardiac Procedures - An Evidence-Based Practice

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ABSTRACT

Patients who used manual compression after transfemoral cardiac procedures could suffer from several problems. The suture-mediated closure device may be proven as an effective alternative, offering earlier sheath removal, and potentially a reduction in vascular complications. The aim of this study was to discover empirical bases and clinical application of suture-mediated closure devices on hemostasis in patients after transfemoral cardiac procedures. This study was applied on evidence-based practice in the clinical setting. The search process for evidence-based practices used 3 databases such as MEDLINE, PubMed, and Web of Science, obtaining 14 studies published between 2000 and 2016. The studies selected were assessed by two reviewers for their methodological quality and level of evidence prior to inclusion in the review. Research subjects were patients at the age of ≥ 20 years old who suffered from coronary artery disease and required transfemoral cardiac procedures. This study was implemented in a Medical Intensive Care Unit, Changhua Christian Hospital. The hemostasis status was evaluated based on two categories of, bleeding or not bleeding. Six patients were included in this study. Most of the patients were male with average age of 69.33 ± 11.70 years old. Hypertension, diabetes mellitus, and hyperlipidemia were their common history of diseases. Based on the evaluation outcome, five patients showed hemostasis status and only one patient had bleeding after the compression procedures. This study concludes that the suture-mediated closure device is effective for patients after transfemoral cardiac procedures to reach hemostasis status quickly based on clinical evaluation.

Keywords: cardiac procedures; closure device; hemostasis

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INTRODUCTION

Coronary Artery Disease (CAD) is defined as a heart disease in which substance called plaque accumulates in the arteries of the heart. These arteries supply rich oxygen-blood into the heart muscle (Thompson, D & Webster, R, 2004). CAD is the most leading cause of death and the most common heart disease in the United States and other developed countries (Mozaffarian et al., 2016; Ohira & Iso, 2013). An estimated 15.5 million Americans have CAD with total prevalence of 6.2% including 7.6% men and 5% women every year. The prevalence of CAD is predicted to increase to 18 % in 2030 (Mozaffarian et al., 2016). In another country such as Taiwan, its department of health (2014) data showed that heart disease ranked as the second

leading cause of all deaths with 19.399 death and 82.9 crude death rates. The heart diseases included myocardial infarction, heart failure, and others.

When some of the plaques rupture because the function of vascular walls decreases, the clots are formed. The clots then follow the bloodstream into smaller arteries downstream and completely block the blood flow. This process is called atherosclerosis. If the arteries which rich of oxygen supply remains blocked, the muscle cells in the heart will begin to die and leads to coronary attack or myocardial infarction (MI). American Heart Association (AHA) statistics reported in 2016 that there are 660 thousand Americans newly suffered from coronary attack (defined as the first hospitalized coronary attack and myocardial infarction (MI) death) every year and 305 thousand have a recurrent attack. Additionally, there are 160 thousand patients suffer from myocardial infarctions (MI) every year which means than one American dies every minute (Mozaffarian et al., 2016). Typically, the disease will start to occur in productive ages or earlier and it will become worse quietly for decades. Patients who have CAD need immediate treatment to prevent this conditions.

Coronary Procedure is a treatment for patients suffer from CAD. The Coronary Procedure has two kinds of procedures such as Coronary Angiography (CA) and Percutaneous Coronary Intervention (PCI). These procedures were used to make an assessment, diagnosis, and intervention for patients who may have CAD. A catheter will be installed into a peripheral artery or vein in radial or femoral under x-ray guidance. During the procedure, the contrast agents are injected to look for detail contrast image of the heart and coronary arteries (Thompson, D & Webster, R, 2004). The Coronary Procedures involve a balloon catheter installation into the stenosis (narrowing of the artery) to opening the blood flow in the artery which is affected by the coronary artery. To prevent abrupt artery closure, a small mesh tubular (stent) is permanently placed within the stenosis. The most common approach for performing the procedure is femoral approach (Moscucci, 2013; Thompson, D & Webster, R, 2004). After this procedure, a closure device of arteriotomy site is usually achieved through standard manual compression (Schulz-Schüpke et al., 2014).

Patients with standard manual compression need at least 6 until 8 hours bed rest after the procedures in order to stop their bleeding (Schwartz, B et al., 2010). Standard manual compression on femoral puncture site, hip and leg mobility becomes restricted causing common complaints such as back soreness and related problems if it is used for a long time. Standard manual compressions are performed on patients with severe back, groin, and leg pain used for hemostasis after coronary procedures (Pollard et al., 2003). Incidences of vascular-related complications using the standard manual compression are most commonly associated with hemostasis after coronary procedures by approximately 2–10% including hematoma, bleeding, pseudoaneurysm, arteriovenous fistula, peripheral arterial thrombosis or embolism, and infections (Hamel, W, 2009; Merriweather & Sulzbach-Hoke, L, 2012).

Suture-mediated closure devices have been introduced in 1994 into clinical practice with the aim of improving efficacy and safety of percutaneous procedures. Different types of Suture-Mediated closure devices have been developed by Perclose Inc. (Redwood City, CA, USA) (Dauerman, H, Applegate, R, & Cohen, D, 2007; Schulz-Schüpke et al., 2014). There are three types of suture-mediated devices such as Perclose ProGlide, Techstar, and Prostar. The advantages of suture-mediated closure device require only 1 until 2 hours bed rest. Suture-Mediated closure device also possibly improves patients comfort, less nursing time for post-procedure monitoring, faster hemostasis, and early hospital discharge (Vinayakumar et al., 2017). Compared with standard manual compression, Suture-Mediated closure devices

can increase efficacy such as reduced time to hemostasis, bleeding control, allowing immediate sheath removal and early ambulation (Arora, Matheny, M, Sepke, & Resnic, 20017). Previous study randomly compared percutaneous suture device with manual compression for femoral artery hemostasis, showing that the percutaneous closure of femoral artery allows immediate sheath after percutaneous coronary angioplasty in fully anticoagulated patients without increasing the incidence of vascular complications (Tron et al., 2003). The aim of this study was to discover empirical bases and clinical application effect of suture-mediated closure device on patients' hemostasis after transfemoral cardiac procedures.

METHOD

This study was a part of advanced clinical program during practice in Medical Intensive Care Unit (MICU) of Changhua Christian Hospital, Taichung, Taiwan on July 2016. This study was applied on evidence-based practice in clinical setting regarding the effect of suture-mediated closure devices on patients' hemostasis after transfemoral cardiac procedures. After selecting and summarizing evidence-based studies on literature review, the author planned to evaluate the compression procedures of suture-mediated closure devices in the clinical setting. This study was performed by following evidence-based practice approach guidelines (Holly, Salmond, S, & Saimbert, 2011).

Review Articles

Inclusion Criteria

A Meta-analysis (MA) and Randomized controlled trials (RCTs) were considered as the primary focuses. The articles were all studies that involved patients suffering from coronary artery disease and required cardiac procedures (i.e. diagnostic or interventional angioplasty or stent placement). The intervention of article selection was a suture-mediated closure device which also called Perclose (Techstar, Prostar, and ProGlide). The following outcome measure was hemostasis.

Search Strategy

The search was limited to English language papers published until 2016. An initial limited search of MEDLINE, PubMed, and Web of Science, was undertaken followed by an analysis of the text words contained in the title and abstract, and the terms used to describe the article. The search used keywords of "Transfemoral cardiac procedure", "Angiography", "Femoral angiography", "Percutaneous coronary intervention (PCI)", "Balloon procedures", "interventional angioplasty", "stent placement", "Suture-Mediated Closure devices", "Vascular closure device", "Closure Device", "Manual compression", "Manual Compression Device", "Manual Compression Method", "Manual Compression Technique", "Hemostasis", "Blood Coagulation", and "Fibrinolysis".

Evaluation of Methodological Quality

The articles selected for retrieval were assessed by two independent reviewers for their methodological validity prior to inclusion in the review. Any disagreements that arise between the reviewers were resolved through discussion or with a third reviewer. The reviewers used standardized critical appraisal instruments from AMSTAR Tool (Seo, H & Kim, K, 2012; Shea, B et al., 2007), and Jadad scale (Jadad, A et al., 1996).

Participants and Outcomes

The patients who were at the age of ≥ 20 years old, suffering from coronary artery disease which required transfemoral cardiac procedures (i. e. Angiography, PCI balloon only, and PCI balloon + stenting) with 6-Fr until 8-Fr (French) catheter size were involved in this study.

There were two categories outcomes of Hemostasis evaluation on puncture site after the compression procedures such as still-bleeding and stop-bleeding status. Score "0" was given to the patients who were still bleeding even after the procedures, while score "1" was for patients who stopped bleeding after the compression procedures. The author also invited cardiologist and clinical nurse preceptor for validating this outcome.

RESULTS

Selection of the Studies

There were three databases used to search for the articles including MEDLINE (n= 74), PubMed (n= 43), and Web of science (n= 160) obtaining total of 277 published studies. After removing duplicates (n= 148) and performing the screening of studies by reading the title and abstracts (n= 32), 24 articles were retrieved. From 24 articles, we excluded 10 articles because they did not meet the specified inclusion criteria and their methodologies were not suitable (retrospective study and non-randomization design) Finally, 14 articles were selected for assessment quality of evidence (Figure.1)(Liberati et al., 2009).

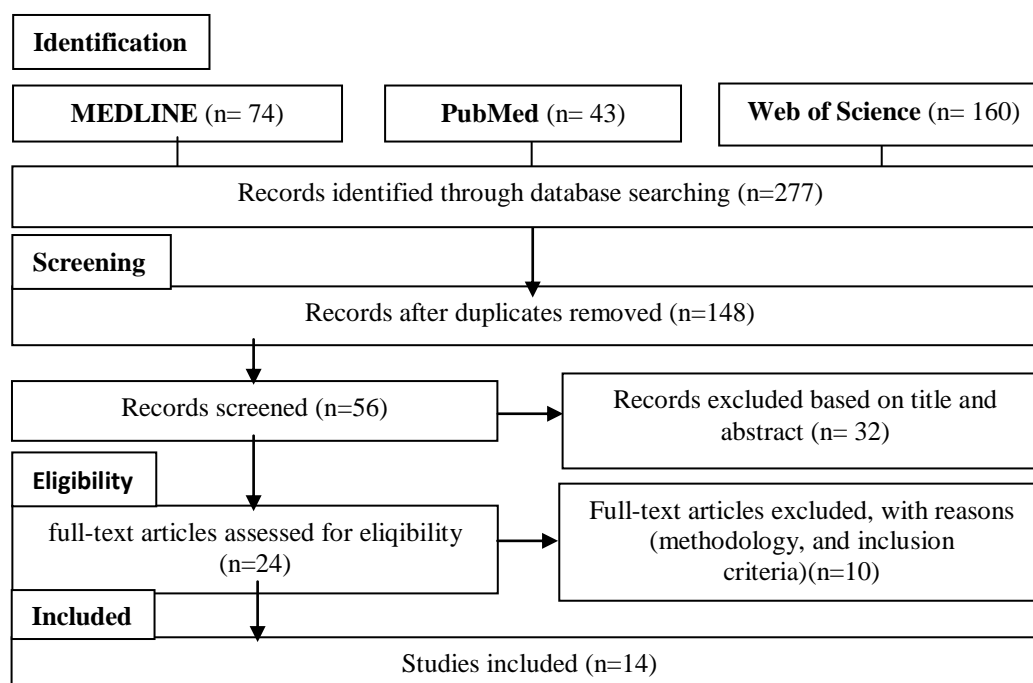


Figure 1. Flow diagram for the selection of 14 studies involved

Review of the Study

The 14 articles involved were published between 2000 and 2016. They were conducted in various countries such as United State of America (USA), United Kingdom (UK), Italy, Sweden, Austria, Germany, France, Switzerland, and China. All studies measured the effect of suture-mediated closure devices in patients after transfemoral cardiac procedures, which provided information for the topic. This study summarized the articles published based on the authors (years), country, design, study and participants, intervention, and results (see Table.1)

Characteristics of the Study

In terms of study design, nine articles (64.29 %) were conducted through Randomized Controlled Trial (RCT), while five articles (35.71 %) were conducted through Meta-Analysis. According to the location where the research was performed, five articles (33.33 %) were conducted in USA, two articles (13.33 %) were conducted in UK, two articles (13.33 %) were

conducted in Switzerland, one article (6.67 %) was conducted in Italy, one article (6.67 %) was conducted in Sweden, one article (6.67 %) was conducted in Austria, one article (6.67 %) was conducted in Germany, one article (6.67 %) was conducted in France, and one article (6.67 %) was conducted in China. Furthermore, regarding the participants involved in the studies, total participants from 14 studies were 73.368 participants. Regarding type of devices used, eight articles (22.22 %) used Angioseal, 14 articles (38.89 %) used Perclose, four articles (11.11 %) used VasoSeal, and 10 articles (27.78 %) used another Service. The characteristics of the selected studies were presented in table.2.

Analysis of Evidence

This study found that the range of critical appraisal score for Meta-Analysis study based on AMSTAR Tool was between 7 and 11. There are 4 articles indicated a good evidence quality and just 1 article had moderate quality. Most of Meta-Analysis articles showed design and method clearly but did not explain the quality of the included studies and conflict of interest. In randomized controlled trials design, the range of critical appraisal score based on Jadad score was between 2 and 3. There are 5 articles indicated good evidence quality, while 4 articles had poor quality. Most of the articles described the randomized design, but lack of information on double-blind method, withdrawals, and dropouts of participants. The category of evidence level in this study used a standard category level of evidence (Masita, Musdi, & Subhan, 2012). The category of evidence level in 14 studies was level I for five Meta-Analysis articles (35.71 %) and level II for nine randomized controlled trials articles (64.29 %) (See Table.2).

Table 2.
Characteristic of 14 selected studies

	Characteristics	Number (%)
Study Design	Randomized Controlled Trial (RCT)	9 (64.29 %)
	Meta-Analysis	5 (35.71 %)
Study Location	USA	5 (33.33 %)
	UK	2 (13.33 %)
	Italy	1 (6.67 %)
	Sweden	1 (6.67 %)
	Austria	1 (6.67 %)
	Germany	1 (6.67 %)
	France	1 (6.67 %)
	Switzerland	2 (13.33 %)
	China	1 (6.67 %)
Quality of Evidence	Good quality	4 (28.57 %)
	Moderate quality	6 (42.86 %)
	Poor quality	4 (28.57 %)
Level of evidence	Level I	5 (35.71 %)
	Level II	9 (64.29 %)
Participants of 14 studies	Total	73.368
Type of devices	Angioseal	8 (22.22 %)
	Perclose	14 (38.89 %)
	VasoSeal	4 (11.11 %)
	Other devices	10 (27.78 %)

Summary of Evidence

Based on the result of this literature review, most articles indicated a good quality and high level of evidence. The review shows that Suture-mediated closure devices had significantly shorter time to hemostasis compared with manual compression in patients after transfemoral cardiac procedures. Although some articles did not explain their methodology completely, this study used the best available evidence in illustrating the effect of suture-mediated closure devices on hemostasis outcome.

Clinical Evaluation

Overall, six patients, who were involved in this study, used suture-mediated closure devices. There were five males (83.35%) and one female (16.67%) aged 69.33 ± 11.70 years old. The mean number of BMI patients was 23.71 ± 2.58 . Hypertension (n=5), Diabetes Mellitus (n=4), and Hyperlipidemia (n=4) were the common history of diseases in patients. A family member of positive heart disease history also presented in 33.34 % of patients (n=2). The patients underwent transfemoral cardiac procedures for STEMI in two cases (33.34 %), NSTEMI in three cases (50.01 %), and another heart disease in one cases (16.67 %).

Most of the patients used diagnostic test (Angiography) first before obtained percutaneous coronary intervention procedure (n=6). Five patients (83.35 %) of transfemoral cardiac procedures received balloon and stenting. Aspirin was used as the anticoagulation strategy in all Patients (n= 6) during and after transfemoral cardiac procedures. Based on hemostasis assessment, five patients (83.35 %) showed hemostasis status after the compression procedures and just one patient has still-bleeding status after the procedures.

DISCUSSION

Gender

The research results showed that most of the respondents are female by 56 respondents (62.2%). This research is in accordance with the research conducted by Affandi (2017) entitled the Effect of Deep Breath and 5-Finger Technique on Students' Stress, which stated that women are more prone to experience stress than men. Gender also determines the occurrence of stress. According to Brizendin (2007), there are differences in responses between men and women when experiencing problems/conflicts. The structure of the female brain has a negative alertness to conflict and stress. When women experience conflict, negative hormones will be triggered higher than usual, causing stress, anxiety, and fear. Women will feel more stressed when they experience conflict. Women feel that they need more protection. Meanwhile, men generally enjoy the existence of conflict and competition, and even think that conflict can provide a positive boost.

Age

Most of the research respondents were 18 years old with a total of 50 respondents (55.6%). This age belongs to adolescence group which is the age of transition or change from the childhood stage to the adult stage, starting from 12 years old to 20 years old (Budiargo, 2015). Many changes occur during adolescence, including physical, biological, psychological, attitudes, behavior and thought patterns changes. Teenagers want to appear and be the same as other people or role models that they are proud of.

The desire to be like other people and the same as other people, makes teenagers do many things to make it happen. When they cannot make it happen, stress will occur. Stress occurs because of an imbalance between needs, hopes and desires with accepted reality. The

immature age of adolescents greatly determines adolescents in their attitude toward their condition. This is also what causes stress.

Class

The results of the study obtained that most of the respondents were at class X by 54 respondents (60%). Respondents who were involved in this study were only class X and class XI, while class XII was not included because they were preparing for the final school exams. Class XII students experience more stress due to exam preparation. So that if included there will be bias in the results of the study.

Class X and XI students are transitioning from junior high school to high school, they still have to adapt to different assignments and learning from the previous class. Moreover, the current learning system (COVID-19 pandemic) was carried out from each home (study from home). This is one of the causes of the stress they experience.

Stress before and after Therapy

The stress level of the majority of respondents before participating in the 5-finger technique was moderate stress (50%), while after participating in the 5-finger technique, the majority still experienced moderate stress (55.6%). There was an increase in the number of respondents who experienced moderate stress. Likewise, the level of normal and light stress before therapy, from the initial number of 10 respondents (11.1%) and 15 respondents (16.7%), to 15 respondents (16.7%) and 25 respondents (27.7%) on the measurement after giving 5-finger technique therapy. However, there was a significant decrease in respondents who experienced severe and very severe stress before the therapy, namely 12 respondents (13.3%) and 8 respondents (8.9%) who were not experienced at all by respondents in the post-therapy measurement.

The effect of therapy on stress

The analysis conducted by using Mann-Whitney test obtained a p-value of 0.000, meaning that there was a significant difference between the average stress level before and after the 5-finger technique therapy. Thus, it can be concluded that there was a significant effect of 5-finger technique therapy on reducing stress levels.

In accordance with Affandi's research (2017), 5-finger hypnosis was proven as a very effective method to reduce stress levels. Anxiety and stress can be overcome with relaxation techniques, distraction, spiritual activities and hypnotherapy (Keliat, 2015). There are several types of hypnosis that can be done, one of which is hypnosis using the 5-finger technique. Individuals or clients are helped to change their perceptions of anxiety, stress, tension and fear by accepting suggestions on the threshold of unconsciousness or in a relaxed state by moving their fingers according to orders (Long, 2010).

By entering the client's subconscious mind with the media of fingers, negative patterns that have been done by the client can be corrected and reprogrammed by providing new insights that can provide long-term comfort and calm for the client. The 5-finger technique is a therapy that uses fingers as a medium for distraction (Axelrad, 2009). Five-finger hypnosis is a technique of distracting someone's thoughts by touching the fingers while imagining things that are fun or like (Keliat, 2015).

The stress conditions experienced by students could not be identified, because there was no complete interview session with all respondents. However, from the opportunities that exist, the researchers had time to interact online with respondents through whatsapp conversations.

The results showed that the stress experienced was caused by many factors, including the condition of Covid-19 pandemic which could not be ascertained when it would end, the online learning process which sometimes caused delays in following and uncertainty about the future due to conditions. This is experienced by some respondents, researchers cannot confirm that all respondents experience the same thing. Many internal and external factors cause stress which may be experienced by respondents.

However, stress is a condition that requires special handling. Non-pharmacological management is highly recommended because it does not affect the body's organs and can be done independently anywhere and anytime in a comfortable place such as by giving therapy as has been done. The results of this study proved that there was a decrease in stress level after giving the 5-finger technique. This therapy provides a feeling of relaxation or comfort so that students feel better about themselves than before.

CONCLUSION

The study shows that the suture-mediated closure device is effective and efficient to be used on patient after transfemoral cardiac procedures based on the evidence and clinical practice evaluation. Nurses could update knowledge on caring for patients undergoing transfemoral cardiac intervention by knowing the safety and faster wound healing through suture-mediated closure device. Further longitudinal studies are needed to recruit more patients and to obtain a good quality on this type of studies.

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