The Effectiveness of "Siriraj Leg Lock" Brace on Back Pain after Percutaneous Coronary Intervention: PCI

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Background: The most common problem experienced by patients after Percutaneous Coronary Intervention (PCI) is back pain. After the procedure, patients are restricted to complete bed rest with no hip flexion for up to 10 hours, causing much discomfort, especially back pain. In some patients, anxiety arises due to limited movement, with the belief that movement might cause re-bleeding from the wound. To alleviate these problems, the "Siriraj Leg Lock" brace or SLL was initiated to confine the hip while allowing patients to freely move other parts of their body without complicating the wound. Hence, anxiety is relieved and mobility can lower the chance of getting back pain with more comfort.

Objective: The aims of this experimental study were to investigate the effect and satisfaction of SLL on back pain in post-PCI patients, and to compare bleeding and/or hematoma occurrences at the site of incision between experimental and control groups.

Material and Method: The randomized controlled trial (RCT) was conducted in 100 patients who underwent coronary angioplasty and/or stent placement interventions and received post procedural care at the intermediate cardiac care ward, Her Majesty Cardiac Center, from December 2006 to February 2007. The control group (49 patients) was to get standard care after the intervention, whereas the experimental group (51 patients) was fitted with the SLL device to allow free mobility right after the procedure.

Results: Lower maximum back pain scores and mean back pain scores in the experimental group than in the control group, with statistical significance (p < 0.001). Back pain score reduced from the day of admission in the experimental group after applying SLL, but increased in the control group. The occurrence of hematoma in both groups was not significantly different (p = 0.114). The experimental group with the SLL could freely change positions from upright to decubitus without any effects to the wound, feeling more comfortable and experiencing less back pain. Patients' satisfaction towards the SLL from 1 to 5 scale was 4.3. The satisfaction was evident especially in patients who had previous PCI experience, and desired to ask for SLL application if a future procedure to be needed.

Conclusion: Using SLL after sheath removal post PCI allows the patient to freely change position without any effects to the wound and reduces back pain with more patients' satisfaction.

Keywords: Percutaneous Coronary Intervention (PCI), Siriraj Leg Lock (SLL), Brace, Back pain

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At present, there are a higher number of patients presenting with coronary artery disease. Many advanced procedures and techniques, especially the so called Percutaneous Coronary Intervention (PCI), have been initiated for the management of coronary artery disease to these patients. The femoral artery is most commonly used as the access sites for therapeutic cardiac interventions. Post-PCI patients are restricted to complete bed rest with no hip flexion for up to 6-10 hours to prevent bleeding and/or hematoma occurrences at the site of incision⁽¹⁾ which could possibly be found in 0.43-4% of these patients^(2,3). Due to limited movement, most patients consequently experienced much discomfort, particularly back pain⁽⁴⁾ and lower extremities self-care deficits during post-PCI.

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has provided PCI service to more than 1,200 patients with coronary artery disease each year. After the intervention, these patients are moved to the Intermediate Cardiac Care Ward, for post-PCI care. The patients are restricted to complete bed rest with no hip flexion for up to 6-10 hours to prevent bleeding and/or hematoma occurrences at the site of incision, which as a result causes back pain and lower extremities self-care deficits to the majority of them.

There are several studies concerning the coping strategies for discomfort related to back pain. In the study, "Effect of Positioning on Back Pain after Coronary Angiography", the control group had to lie flat with the leg straight and received the standard care after the procedure, while the experimental group could change their positions with the nurse's help for right/ left side-lying or flat-lying. It was found that the control group reported higher levels of pain and much more discomfort than the experimental group, with statistical significance. However, there was no significant difference in terms of bleeding and hematoma between the two groups⁽⁵⁾.

In another study "Effect of modified positioning and limited mobilization on back pain after coronary angiography" the experimental group had their positioning modified with the head of bed elevated to a maximum of 45 degrees, and they could then start their mobilization 4 hours after the procedure, whereas, the control group had to lie flat for up to 6 hours. The results showed that the experimental group had less back pain than the control group, with statistical significance⁽⁶⁾.

In the study on "A randomized clinical trial of the effect of bed position after PCI" the control group remained flat in bed while the experimental group controlled and elevated their bed position. No significant difference in the amount of bleeding at the site of incision was found in either group. However, some patients in the control group reported ongoing back pain at dinner and bedtime⁽⁷⁾.

In addition, there was a study on "Positioning post-outpatient cardiac catheterization" aiming to determine the effects of 3 types of positioning on vascular complications and back pain after the procedure. The patients were randomized into three groups. Group 1 patients (control) remained flat in bed. Group 2 patients were side-lying, with the leg straight. Group 3 patients lay on their back, with the head of bed elevated at 15-30 degrees. The results revealed that Group 1 patients experienced higher degree of back pain than the other two groups (control = 16.7%, side-lying = 0%, head of bed elevated = 2.2%)⁽⁸⁾.

In the study on "Controlled trial of backrest elevation after coronary angiography", the control group had the head of bed elevated at 15 degrees or less for 5.5 hours after the procedure. The experimental group had the head of bed gradually elevated from 15 degrees to 30 degrees for the same period of 5.5 hours after the procedure. No statistically significant differences were noted between groups in term of vascular complications. The incidence of back pain at a level of more than 3 on a scale of 0 to 10 was less in the experimental group than in the control group, with statistical significance⁽⁹⁾.

In Thailand, a study on the safety of post-PCI care in outpatient groups showed that the average levels of anxiety were higher in patients in the observation ward than in patients ready to be discharged (p < 0.05). Also, no patients were found with internal or external bleeding of more than 100 cc at the site of incision and/or hematoma with the size exceeding 5 cm. The patients were allowed to have the head of bed elevated to a maximum of 45 degrees. A low degree of back pain was reported in most patients.

Many advanced procedures and techniques have been initiated for achieving the most efficacy and the least coronary complications in post-PCI patients. As in other countries, sheaths are pulled immediately after PCI and closure devices⁽¹¹⁾ are used in a bid to lower the time patients had to lie flat on their bed with leg straight to only 4-6 hours. In some patients either radial artery or brachial artery is used as vascular access to allow movement or self-care immediately after PCI, depending on each patient's vascular pathological conditions. However, the procedure of radial artery and brachial artery is more complicated than femoral artery, and should be done by specialized cardiologists.

Hence, the common post-PCI care is still that patients have to complete bed rest while flat-lying and with leg straight for a long period of time, causing unavoidable back pain, anxiety, and discomfort due to limited movement. To alleviate these problems, the "Siriraj Leg Lock" brace or SLL was initiated to provide knee, hip, and femoral support while allowing patients to freely move other parts of their body without complicating the wound while keeping it safe from bleeding and/or hematoma at the site of incision. As a result, anxiety is relieved and the greater mobility can lower the chance of getting back pain, resulting in more comfort.

Accordingly, the aims of this study were: (i)

to investigate back pain in patients with "Siriraj Leg Lock" device (experimental group) and patients without "Siriraj Leg Lock" device (control group); (ii) to compare vascular complications, especially bleeding and/or hematoma at the site of incision between experimental group and control group; and (iii) to evaluate patients' satisfaction on "Siriraj Leg Lock" device

Material and Method

Study Design

This experimental study was designed as a randomized controlled trial (RCT). The patients were assigned to one of 2 groups: the experimental group with standard care (the standard care group) or the control group with the support of SLL device (the intervention group).

Study Population

The study protocol was approved by the local Ethics Committee and all subjects gave written informed consent before study participation. The population in this study were the patients who received Percutaneous Coronary Intervention or PCI at Her Majesty Cardiac Center, Siriraj Hospital, and were also admitted at the Intermediate Cardiac Ward, Her Majesty Cardiac Center from December 2006 to February 2007.

Inclusion Criteria

- Patients under elective case with PCI and/or non-emergency catheterization, as well as sheath removal at ward, Her Majesty Cardiac Center

- Patients with femoral approach for the procedure

- Patients up to 18 years old or higher

- Patients who can communicate in Thai and cooperate well with the study

Exclusion Criteria

- Patients with known bleeding disorders

- Patients with active bleeding and hematoma at catheter insertion site before sheath removal

- Patients experiencing back pain before the procedure (considered from a medical history of spine surgery)

- Patients treated with drugs for back pain or physical therapy within a period of 6 months

- Patients developing any complications during the procedure

- Post-PCI Patients, with systolic blood pressure more than 190 mmHg, or diastolic blood pressure more than 110 mmHg.

Allocation of Study Population

In this randomized controlled trial (RCT), the patients were allocated into 2 groups through blocked randomization (block of 2, 4 and 8). The allocation sequence was put into a sealed opaque envelope. The blinded randomization was drawn by the principal investigator or the head nurse in case of the principal investigator's unavailability.

Intervention

After the procedure, patients diagnosed with coronary artery disease received post-PCI care at the intermediate cardiac care ward, Her Majesty Cardiac Center, Siriraj Hospital. The patients randomized as the sample group were applied with SLL device (Fig. 1) to support the straight leg and confine the hip while allowing patients to freely move other parts of their body without complicating the incision site. The SLL device was applied to the patients only by the specially trained nurses during their ward shifts. The patients received standard care and the degree of back pain was evaluated through numeric rating scale (range 0-10) during each period of time. The patients' satisfaction was also evaluated through numeric rating scale (range 1-5) before hospital discharge.

Definitions

Hematoma defined in this study was a collection of blood underneath the skin diameter ≥ 5 centimeters and active bleeding was defined by loss of blood more than 100 ml from the wound. The numeric rating scale of back pain ranges from 0 (minimum) to 10 (maximum) and the numeric rating scale of satisfaction ranges from 1(minimum) to 5 (maximum).

Data Analysis

The data were analyzed by SPSS 13 Version. The primary outcome was maximum back pain. Mann-Whitney U test was used to test the difference in statistical significance, p-value < 0.05. Fisher's Exact test was to test the difference in qualitative variable. The samples consisted of 50 patients per group with power of 80% to determine the clinical difference of 2 between the groups and the estimated standard deviation of 3.

Results

The personal data of sample groups and their diseases other than coronary artery disease (CAD) are shown in Table 1. The use of thrombotic drugs during the procedure and the activated clotting time (ACT) values before sheath removal were presented in Table 2. The degree of back pain score is indicated in Table 3. The patients' satisfaction scores and the need of SLL device are illustrated in Table 4-5.

The two sample groups were mostly male patients, with the age of 51-60 years in the experimental group and 61-70 years in the control group. The majority of the patients were housewives, followed by officers in the government or enterprise sectors. The similar number in both groups used to receive PCI (experimental group = 51%; control group = 46.9%).

Other than CAD, most patients had hyper-

Table 1.	The number and percentage of sample groups clas-
	sified by personal data and diseases other than
	coronary artery disease

tension (experimental group = 60.8%; control group = 63.3%), followed by diabetes (experimental group = 35.3%; control group = 36.7%).

Most sample groups received heparin (experimental group = 90.2%; control group = 93.9%), followed by the similar combination of heparin and eptifibatide (experimental group = 5.9%; control group = 6.1%). Meanwhile, the combination of heparin and abciximab was found only in the experimental group (3.9%).

Table 2.	The number and percentage of sample groups clas-
	sified by thrombotic drugs during the procedure
	and incidence of bleeding and hematoma at the site
	of incision

Sample Group	Experimental	Control	
	Group	Group	
	(n = 51)	(n = 49)	
	Number (%)	Number (%)	
Gender			
Male	36 (70.6)	33 (67.3)	
Female	15 (29.4)	16 (32.7)	
Age (year)			
40-50	6 (11.8)	6 (12.2)	
51-60	16 (31.4)	10 (20.4)	
61-70	10(19.6)	25 (51)	
71-80	14 (27.5)	8 (16.3)	
81-90	5 (9.8)	0 (0)	
Education			
Elementary	30 (58.8)	18 (36.7)	
Secondary	6 (11.8)	13 (26.5)	
Associate Degree	2 (3.9)	3 (6.1)	
Bachelor Degree	12 (23.5)	14 (28.6)	
Above Bachelor Degree	1 (2)	1 (2)	
Occupation			
Housewives	24 (47.1)	18 (36.7)	
Government Officer/	16 (31.4)	17 (34.7)	
State Enterprise			
Business Owner	4 (7.8)	6 (12.2)	
Employees	4 (7.8)	6 (12.2)	
Agriculturist	3 (5.9)	2 (4.1)	
PCI History			
Ever received PCI	26 (51)	23 (46.9)	
Never received PCI	25 (49)	2 (53.1)	
Diagnosis			
CAD	51 (100)	49 (100)	
DM	18 (35.3)	18 (36.7)	
HT	3 (60.8)	36 (63.3)	
GOUT	3 (5.9)	1 (2)	
Others	6 (11.8)	6 (12.2)	

Sample Group	Experimental Group (n = 51) Number (%)	Control Group (n = 49) Number (%)
Use of Thrombotic Drug (s)		
Heparin	46 (90.2)	46 (93.9)
Heparin and Eptifibatide	3 (5.9)	3 (6.1)
Heparin and Abciximab	2 (3.9)	0 (0)
First value of Activated		
Clotting Time (ACT) (sec)		
< 100	4 (7.8)	1 (2)
101-150	25 (49)	24 (49)
151-200	22 (43.1)	23 (46.9)
> 200	0 (0)	1 (2)

 Table 3. The comparison of the degree of back pain scores between the control group and the experimental group

Sample Group	Experimental Group (n = 51)	Control Group (n = 49)	p-value
Degree of Maximu	ım Back Pain		
Median	3	7	< 0.001
Mean (SD)	3.1 (2.1)	6.6 (2.4)	
Min, Max	0, 7	0, 10	
Differences between	en Degree of Bac	k Pain : end of	f study and
first admit			
Median	2	6	< 0.001
Mean (SD)	2.2 (2.6)	6.3 (2.4)	
Min, Max	-5, 6	0, 10	
Degree of Back Pa	in before discharg	ge	
Median	0	0	< 0.001
Mean (SD)	0.1 (0.7)	0.4 (1.1)	
Min, Max	0, 5	0, 5	

The first ACT values considered for sheath removal were similarly at the range of $101-150 \sec(\text{experimental group} = 49\%)$; control group = 49%).

The incidence of hematoma was not differently found in both groups (p = 0.114). Whereas, the



Fig 1. Siriraj leg lock (SLL) [Panel A: Hip support, Panel B: Knee support, Panel C: Siriraj leg lock]

 Table 4. The mean, SD, minimum and maximum values of patients' satisfaction on the use of SLL device

Degree of Patients' Satisfaction	Experimental Group (n = 51)
Mean	4.3
SD	0.7
Min, Max	3, 5

 Table 5. The number and percentage of sample groups classified by the degree of patients' satisfaction on the use of SLL device and the need of SLL device for future treatment with PCI

Aspect of Sample group $(n = 51)$	Number (%)
Degree of Patients' Satisfaction	
level 3 rd	10 (19.6)
level 4 th	14 (27.5)
level 5 th	27 (52.9)
Preference of using SLL device in the future	
Absolutely use	45 (88.2)
Never	0 (0)
Not sure	6 (11.8)

incidence of hematoma in the control group was 6.1%, this was not found in the experimental group. In addition, there was no active bleeding in either group.

The maximum back pain scores in the experimental group was less than the control group, with statistical significance (p < 0.001). The highest maximum back pain scores were 10 or an average of 6.6 in the control group, and 7 (mean = 3.1) in the experimental group.

In the experimental group, the degree of back pain scores was significantly lower after the application of SLL device. The differences between the degree of back pain scores at admission and after the study indicated the lowest of -5 and the highest of 6 (mean = 2.2). Whereas in the control group, the difference between the degree of back pain scores at admission and after the study indicated the lowest of 0 and the highest of 10 (mean = 6.3). However, the average degree of back pain scores before discharge was higher in the control group (0.4) than in the experimental group (0.1).

The experimental group did not receive analgesics, while there were 5 patients (10.2%) in the control group receiving analgesics. The control group received more pain drugs than the experimental group, with statistical significance (p = 0.025).

The degree of patients' satisfaction on the use of SLL device (range 1-5 points) was the lowest at 3 points and the highest at 5 points (mean = 4.3, SD = 0.7). About 52.9% of the experimental group indicated the highest degree of SLL device satisfaction (5 points), and 88.2% of the patients in this group preferred to use SLL device for their future treatment with PCI.

Discussion

Most of the patients in both the experimental group (70%) and the control group (67.3%) were males, with the mean age of 51-60 years in the experimental group and 61-70 years in the control group. According to the data from National Statistics Office Thailand regarding self-care behaviors among Thai population in 2003⁽¹²⁾, it was found that gender and age are factors that differentiated the incidence of coronary artery disease in each patient. Males (7.4%) are more likely to develop coronary artery disease than females (5.5%). In addition, the tendency towards acquiring coronary artery disease in these patients also relates to ages. Patients older than 60 years (14.8%) have the highest chance to get coronary artery disease, with no significant different in males and females, partly due to selfcare behaviors of the patients such as cigarette smoking or alcohol drinking and food consuming habits.

After the procedure, post-PCI patients are restricted to complete bed rest with leg straight for about 6-10 hours to prevent bleeding and hematoma at the site of incision, which can be found in 0.4-4% of the patients^(2,3). In this study, the incidence of bleeding and hematoma were not different, (p=0.114). Hematoma was found in 6.1% of the control group, but not in the experimental group. Also, no active bleeding was found in either group.

It is required that post-PCI patients lie flat with leg straight and endure limited movement for a long period of time⁽¹³⁾, causing muscle stress and back pain in most patients. With SLL device, the degree of back pain scores in the experimental group was less than in the control group, with statistical significance (p < 0.001). The highest back pain scores were 7 (mean = 3.1) in the experimental group and 10 (mean = 6.6) in the control group. The control group (10.2%) received pain drugs more often than the experimental group, with statistical significance (p = 0.025). However, no patients in the experimental group received pain drugs. With SLL device, patients in the experimental group could freely and more frequently move other parts of the body. Hence, anxiety concerning bleeding and hematoma at the site of incision was relieved resulting in less muscular stress and back pain. Moreover, limited movement can have some important effects on muscular and bony systems⁽¹⁴⁾. When patients are restricted to complete bed rest for about 3-4 hours, they will complain about back pain due to incorrect positions and muscular stress. Therefore, the patients should be able to change positions while having bed rest.

There were several studies concerning the coping strategies for discomfort related to back pain in post-PCI patients. In the study by Chair et al⁽⁵⁾ "Effect of Positioning on Back Pain after Coronary Angiography", the control group had to lie flat with the leg straight and received the standard care after the procedure, while the experimental group could change their positions with the nurse's help for right/left side-lying or flat-lying. In another study by Rein et al⁽⁸⁾ "Positioning post-outpatient cardiac catheterization", which aimed to determine the effects of 3 types of positioning on vascular complications and back pain after the procedure, the patients were randomized into three groups. Group 1 patients (control) remained flat in bed. Group 2 patients were side-lying, with the leg straight. Group 3 patients lay on their back, with the head of bed elevated at 15-30 degrees. Although the results of these studies were quite similar with regard to lowering back pain, the nurses' assistance was required in each process of patients' positioning or bed adjustment. With SLL device, patients could freely and more frequently move other parts of the body by themselves, thus requiring less assistance from nurses.

Regarding patients' satisfaction on SLL device, the experimental group (52.9%) showed highest satisfaction of 5 points (scale 0-5). In addition, about 88.2% of the patients in the experimental group preferred to use SLL device for their future PCI treatment.

The limitation of this study was that each patient knew to which group they would be assigned. However, the randomized samples were the patients with the application of SLL device. They were informed about the use of SLL device, without any clues concerning whether or not the device could lower back pain. They only perceived that the device would facilitate their free movement in bed, dependent only upon themselves.

Conclusion

Although the transradial approach technique was more frequently performed than in the past with improving technique and material, the transfemoral approach was still the main route for most operators. With this approach, patients' discomfort, especially back pain, always occurs.

Using SLL after sheath removal post PCI allows a free change of position without any effects to the wound and reduces back pain with more patients' satisfaction.

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ประสิทธิผลของอุปกรณ์ประคองต^{ุ้}นขา Siriraj Leg Lock ที่มีต[่]ออาการปวดหลังในผู้ป่วยภายหลังทำ หัตถการขยายหลอดเลือดหัวใจ

สุวัจชัย พรรัตนรังสี, สุดารัตน์ บุญเลิศ, อนุวัฒน์ ดวงประทีป, พิชชุดา วิรัชพินทุ, วิริยา วารี, ดำรัส ตรีสุโกศล, ประดิษฐ์ ปัญจวีณิน

ภูมิหลัง: การขยายหลอดเลือดหัวใจ (Percutaneous Coronary Intervention: PCI) ปัญหา สำคัญที่พบได้บ[่]อยๆ หลังทำหัตถการคือ อาการปวดหลัง เนื่องจากภายหลังทำหัตถการผู้ป่วยจะถูกจำกัดการ เคลื่อนไหว โดยต้องนอนราบห้ามงอขาเป็นเวลา 10 ชั่วโมงขึ้นไป ทำให้ผู้ป่วยเกิดความรู้สึกไม่สุขสบายเป็นอย่างมาก ผู้ป่วยบางรายมีความวิตกกังวลมาก ไม่กล้าขยับตัวเพราะกลัวว่า ขาจะงอและทำให้เกิดภาวะเลือดออกจากแผลที่ทำหัตถการ ซึ่งเป็นภาวะแทรกซ้อนที่สำคัญและอันตรายมาก จากปัญหาดังกล่าวนี้ผู้ศึกษาจึงคิดประดิษฐ์อุปกรณ์ประคองต้นขา 'Siriraj Leg Lock' (SLL) ขึ้นเพื่อช่วยให้ผู้ป่วย สามารถขยับตัวหรือพลิกตะแคงตัวได้สะดวกขึ้นโดยไม่มีผลกระทบต่อแผลที่ทำหัตถการ ผู้ป่วยจะรู้สึกสุขสบายขึ้น จากการไม่ต้องถูกจำกัดการ เคลื่อนไหวส่งผลให้อาการปวดหลังลดลง

วัตถุประสงค์: การวิจัยครั้งนี้เป็นการศึกษาวิจัยแบบทดลอง (Experimental Study) เพื่อศึกษาประสิทธิผล ของอุปกรณ์ประคองต[ื]้นขา SLL ที่มีต่ออาการปวดหลัง ในผู้ป่วยภายหลังทำการขยายหลอดเลือดหัวใจ ร่วมกับประเมินความพึงพอใจ ของผู้ป่วยต่อการใช้อุปกรณ์นี้ และเปรียบเทียบภาวะเลือดออกภายนอก (bleeding) หรือมีการเกิดลิ่มเลือดใต้ผิวหนัง (hematoma) บริเวณตำแหน่งที่แทงเข็มทำหัตถการระหว่างผู้ป่วยที่ใช้อุปกรณ์ประคองต[ื]้นขา SLL (กลุ่มทดลอง) กับผู้ป่วยที่ไม่ได้ใช้อุปกรณ์ ประคองต[ื]้นขา SLL (กลุ่มควบคุม)

วัสดุและวิธีการ: เป็นการศึกษาแบบสุ่มโดยใช้วิธี Randomized Controlled Trial (RCT) โดยกลุ่มควบคุมจะได้รับ การดูแลตามปกติที่หอผู้ป่วยปฏิบัติ (standard care group) ส่วนกลุ่มทดลองจะได้รับการใส่อุปกรณ์ประคองต้นขา SLL เพื่อช่วยให้ผู้ป่วยสามารถพลิกตะแคงตัวได้เองทันทีภายหลังทำหัตถการเสร็จ (Intervention group) กลุ่มตัวอย่าง เป็นผู้ป่วยภายหลังได้รับการขยายหลอดเลือดหัวใจด้วยบอลลูนและ/หรือขดลวดค้ำยัน (PCI) ที่มารับการรักษา ณ หอผู้ป่วยหลังทำหัตถการศูนย์โรคหัวใจฯ ชั้น 8 โรงพยาบาลศิริราช จำนวน 100 ราย (กลุ่มควบคุม 49 ราย และกลุ่มทดลอง 51 ราย) ตั้งแต่เดือนธันวาคม พ.ศ. 2549 ถึง เดือนกุมภาพันธ์ พ.ศ. 2550

ผลการศึกษา: พบว่าระดับคะแนนความปวดหลังสูงที่สุดและค่าเฉลี่ยระดับคะแนนปวดหลังในกลุ่มทดลองน้อยกว่า กลุ่มควบคุม อย่างมีนัยสำคัญทางสถิติ (p < 0.001) หลังจากกลุ่มทดลองได้ใช้อุปกรณ์ ประคองต้นขา SLL แล้วพบว่า ระดับคะแนน ความปวดหลังลดลง ในขณะที่กลุ่มควบคุมระดับคะแนนความปวดหลังเพิ่มจากเมื่อแรกรับ อุบัติการณ์เกิด hematoma ในกลุ่มควบคุมและกลุ่มทดลองไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ (p = 0.114) กลุ่มทดลองที่ใส่ อุปกรณ์ประคองต้นขา SLL สามารถพลิกตะแคงตัวได้สะดวกขึ้น ส่งผลให้อาการปวดหลังลดลง ผู้ป่วยรู้สึกสุขสบาย มากขึ้นโดยไม่มีผลกระทบต่อแผลที่ทำหัตถการ และความพึงพอใจของผู้ป่วยต่อการใช้อุปกรณ์ประคองต้นขา SLLที่ได้รับเฉลี่ย 4.3 (จากมาตรวัด 1-5) โดยเฉพาะอย่างยิ่ง ผู้ป่วยที่เคยมีประสบการณ์การรักษาแบบนี้มาก่อน เมื่อมาครั้งนี้และได้รับการใส่ SLL จะยิ่งแสดงความรู้สึกพึงพอใจมากพร้อมทั้ง แสดงความต้องการใส่หากต้องมารับการ รักษาอีก

สรุป: การใช้ SLL ในผู้ป่วยที่ได้รับการทำหัตถการขยายหลอดเลือดหัวใจทางขาหนีบและทำการกดแผลเพื่อระงับเลือดนั้นสามารถ ช่วยลดอาการปวดหลังและเพิ่มความพึงพอใจของผู้ป่วยโดยไม่มีผลกระทบต[่]ออัตราการเกิดผลแทรกซ้อน โดยเฉพาะเลือดออก หรือการเกิดลิ่มเลือดใต้ผิวหนัง (hematoma)