Comparison of Different Methods for Achieving Hemostasis After Arterial Sheath Removal

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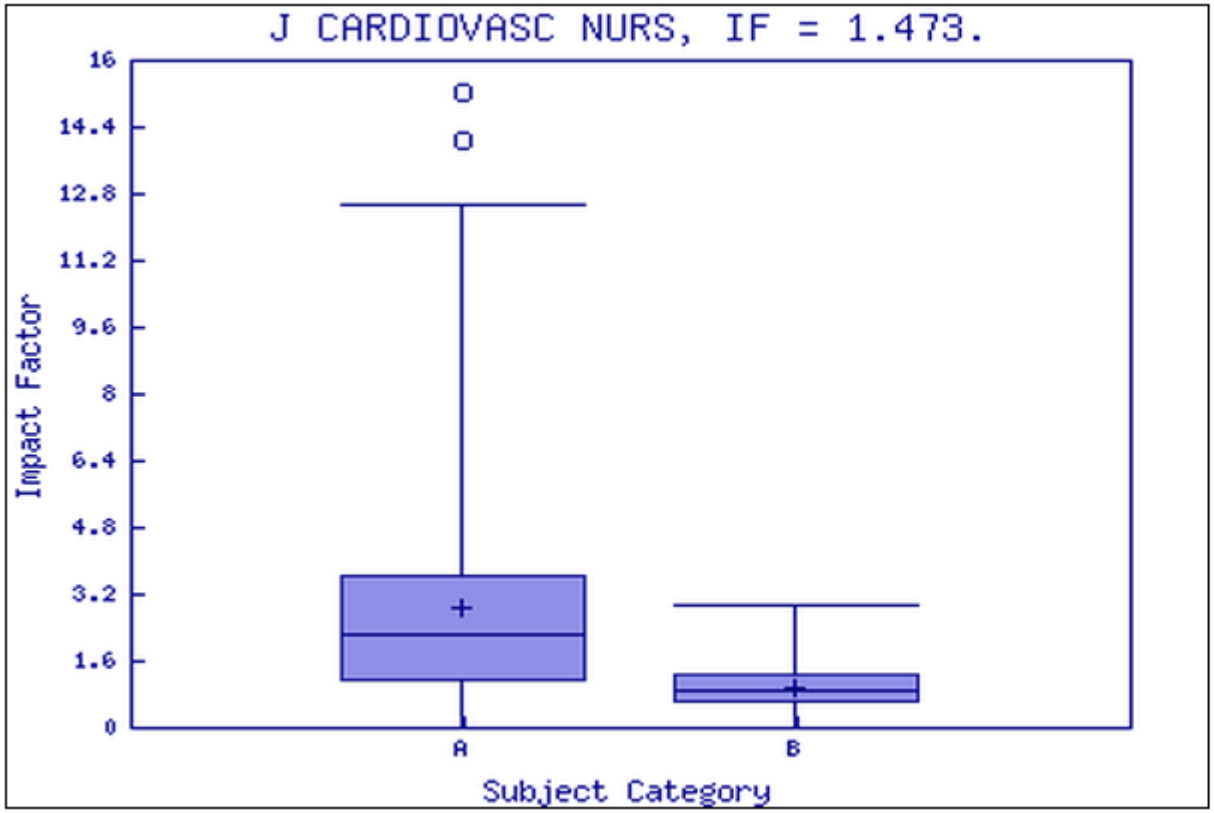
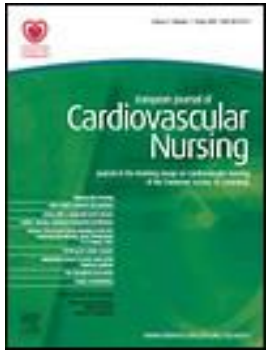
日期：2013.06.03.

Journal Club

JOURNAL OF CARDIOVASCULAR NURSING





Key

A - CARDIAC & CARDIOVASCULAR SYSTEMS

B - NURSING

步驟 1:研究探討的問題為何?

- **研究族群/問題 (Population/ Problem)**
  - Arterial Sheath Removal, arterial catheters
- **介入措施 (Intervention)**
  - Procoagulant pads
  - SyvekPatch NT及D-Stat Dry
- **比較 (Comparison):**
  - manual compression
- **結果 (Outcomes)**
  - Hemostasis (the time required to achieve hemostasis after arterial sheath removal)

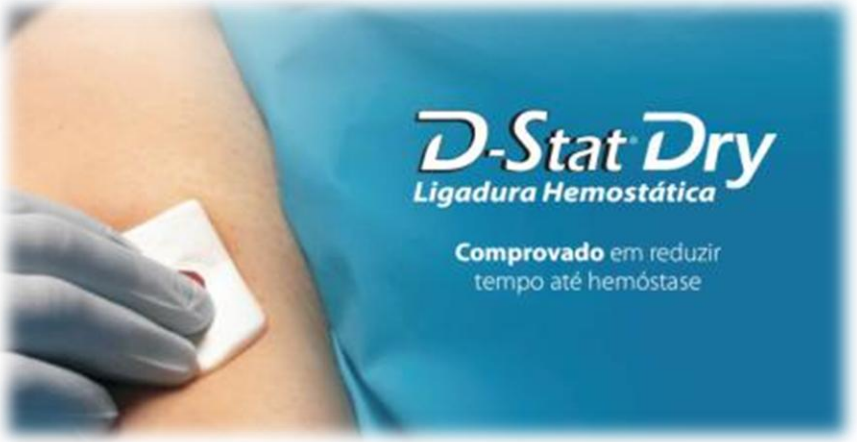
介入措施 (INTERVENTION)

1.SyvekPatch NT

http://syvek.com/syvek-nt.html

2.D-Stat Dry

https://www.youtube.com/watch?v=lpxCCY01VSU



步驟 2：研究的品質有多好(內在效度)？

招募(Recruitment) - 受試者是否具有代表性？我們是否知道病人族群為何(收案場所、納入 / 排除條件)？在理想情況下，納入本研究之受試者應具有連續性(有時為隨機取樣)，了解符合收案條件的對象且簽署同意書。

評讀結果：☑是　□否　□不清楚

Materials and Methods

病人族群：This study was conducted in a 394-bed community- based hospital in the Southeastern region of the United States. Approval was obtained from the institution’ s investigational review board before data collection.

隨機取樣：Randomization to treatment groups was performed by a computer- generated, random number sequence.

納入 / 排除條件：

Inclusion criteria included the presence of a 6-French femoral arterial catheter.

Exclusion criteria included emergent coronary artery bypass graft surery, medical management requiring hemodialysis, systolic blood pressure greater than 180 mm Hg and/or diastolic blood pressure greater than 95 mm Hg immediately before sheath removal, and/or allergy to latex(乳膠過敏).

分派(ALLOCATION) - 分派方式是否隨機且具隱匿性...？

最理想的方式是以中央電腦進行隨機分配，此方式常用於多中心試驗，而較小型的試驗可由獨立人員(如醫院藥師)「監督」隨機分配的過程。

評讀結果：☑是　　☐否　　☐不清楚

Consenting participants were randomly assigned by a computer-generated number sequencer to 1 of 3 methods for achieving hemostasis after sheath removal.

Investigators were blinded to group assignment until after study consent was obtained and just before arterial sheath removal.

(調查人員被蒙蔽組分配，直到後，得到研究同意和動脈鞘管拔除之前。)

每個組別，在研究開始時的情況是否相同？

若隨機分配順利，各組研究對象的條件應是相近、可互相比較的。每組研究對象的基本條件越相近越好。應有指標可確認各組研究對象之間的差異是否達到統計上顯著的差異(如 p值)。

評讀結果： □是　□否　☑不清楚

TABLE 1 Demographic Variables for 80 Patients Receiving 1 of 3 Methods for Hemostasis After Cardiac Catheterization

		Hemostasis Method		
	All Participants (N = 80)	Manual Pressure Alone (n = 26)	SyvekPatch NT + Manual Pressure (n = 26)	D-Stat Dry + Manual Pressure (n = 28)
Age[a]	65.2 ± 1.2	65.7 ± 2.1	63.4 ± 2.1	66.4 ± 2.2
BSA[a]	1.99 ± 0.02	1.94 ± 0.04	2.0 ± 0.04	2.0 ± 0.05
Gender				
Male	58	16	19	23
Female	22	10	7	5
Antiplatelet treatment				
Angiomax	51	15	17	19
Epitifibatide	24	11	5	8
Activated coagulation time, s[a]	156.9 ± 2.1	155.8 ± 3.0	158.6 ± 3.1	156.7 ± 4.8

Abbreviation: BSA, body surface area.
[a]Mean ± SE.

維持(MAINTENANCE) - 各組是否給予相同的治療？

各研究組別之間，除了對病人的介入之外，其餘的治療應完全相同(即為了執行本研究所增加的治療、檢驗或評估應相同)。

評讀結果：☑是　　☐否　　☐不清楚

1. The manual compression alone group had manual pressure applied immediately after the removal of the arterial sheath with direct occlusive pressure. (有一致的使用說明書)
2. In all 3 groups, the site was observed for 5 minutes after the initial release of manual pressure. Pressure was reapplied for 10 minutes at the site if there was any evidence of oozing of blood at the puncture site.
3. arterial sheath with direct occlusive pressure (absence of distal pulse for 1 minute.
4. Nonocclusive pressure for a total of 13 minutes for SyvekPatch NT and 10 minutes for the D-Stat Dry pads.

是否有足夠的追蹤(FOLLOW UP)？

研究中流失(無法繼續追蹤)的病人，最好少於 20%。病人應依照隨機分配的組別進行統計分析(即「治療意向分析法」ITT analysis)

評讀結果：☑是　□否　□不清楚

Results

A total of 80 patients (manual, n = 26; SyvekPatch NT, n = 26; D-Stat Dry, n = 28) were enrolled and completed study participation from April 2008 to June 2010. Participant characteristics and demographic data are summarized in Table 1, with no significant differences found between groups for any of these variables.

TABLE 2 Outcome Variables for 80 Patients Receiving 1 of 3 Methods for Hemostasis After an Interventional Cardiac Catheterization

		Hemostasis Method		
	All Participants (N = 80)	Manual Pressure Alone (n = 26)	SyvekPatch NT + Manual Pressure (n = 26)	D-Stat Dry + Manual Pressure (n = 28)
Required additional pressure application after initial release				
Second pressure application	21	3	9	9
Third pressure application	5	0	2	3
Use of Femostop if hemostasis is not achieved with third pressure application	6	3	1	2
Total manual pressure time, min[a,b]	19.16 ± 0.8	22.3 ± 1.2	17.8 ± 1.3	17.5 ± 1.4
Hematoma formation	2	2	0	0
Retroperitoneal bleeding	0			
Pseudoaneurysm	0			
Vasovagal reaction	0			

評估(MEASUREMENT) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(BLIND)？

在客觀結果(如：死亡)方面，盲法的重要性較低，但在主觀結果(如：症狀或功能)方面，評估者維持盲法非常重要。

評讀結果：☑是　　☐否　　☐不清楚

1.Investigators were blinded to group assignment until after study consent was obtained and just before arterial sheath removal.

2.Limitations in the design of this study include thelack of investigator and participant blinding to inter-vention groups.

3. Whether similar results would occur with compression applied with a mechan-ical device is not known

步驟 3：研究結果的意義為何？

使用何種評估方式，療效有多大？這個研究結果是否可能隨機(巧合)發生？

評讀結果：☑是　　☐否　　☐不清楚

In PCI patients, time to hemostasis averaged almost 5 minutes shorter for patients receiving procoagulant pads combined with manual pressure than for patients receiving manual pressure alone.

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DISCUSSION

What's New and Important

- Significant differences were found among 3 methods for time to arterial sheath removal in interventional cardiology patients.
- Procoagulant pads significantly reduced the manual compression time to achievement of hemostasis.

- A third of patients with procoagulant pads had oozing at the site at the end of the manufacturer's recommended initial period of pressure, requiring a second or third application of pressure to achieve hemostasis.
- Clinicians should not assume that the 10- or 13-minute manufacturers' recommended compression times for the procoagulant pads will be adequate in all PCI patients.

LIMITATION

- Limitations in the design of this study include the lack of investigator and participant blinding to intervention groups, as well as the evaluation of a manual compression technique only.
- Whether similar results would occur with compression applied with a mechanical device is not known, and future studies should evaluate this compression technique as well.
- Another limitation is that this study evaluated only 1 manu facturer’ s product for 2 different types (poly-n-acetyl glucosamine and thrombin) of procoagulant pads.

討論

是否建議病人在移除股動脈導管後，自費使用止血棉加壓止血？

- 同意 1
- 懷疑 14
- 不同意 10

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