The Comparative Study of the Efficacy between the Reinforced PTFE and the Non-Reinforced PTFE in the Forearm Arteriovenous Access for Hemodialysis

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Background: *Common problems with arteriovenous hemodialysis access were early graft thrombosis, prolong hemostasis time resulted from improper technique in compression. Reinforced PTFE graft offered stable, visualized contour which might decreased these problems.*
Objective: *This objective of this study was to evaluated the efficacy between the reinforced Polytetrafluoroethylene (PTFE) and the non-reinforced PTFE as the prosthetic graft in the forearm arteriovenous access in the aspects of 6-month primary patency, numbers of cannulation attempts, time to successful cannulation, hemostatic compression time and satisfaction level of dialysis nurses.*
Material and Method: *Sixty patients with end-stage renal disease suitable for forearm arteriovenous graft creation at Ramathibodi hospital were randomized to Non-reinforced and Reinforced PTFE graft access group. Demographic data were collected. Questionnaires were sent to dialysis nurses whom in-charge for access cannulation. The informations included date of cannulation, numbers of cannulation attempts on each hemodialysis session, experience of dialysis nurse, hemostatic compression time and satisfaction scores for the access in the first month of hemodialysis. Post-operative follow-up scheduled for the assessment of the patency, the forearm circumference at 2nd week and 4th week. The complications were recorded.*
Results: *The Reinforced PTFE group demonstrated comparable 6-month primary patency to non-reinforced PTFE group (100% vs. 100%), shorter time to successful cannulation (22 vs. 31.5, $p<0.05$), lower numbers of cannulation attempts (1 vs. 1.1, $p<0.05$), shorter compression time (5.64 vs. 7.61, $p<0.05$). Experience didn't affect numbers of cannulation attempts on Reinforced PTFE group. There were no significant differences in the increased in Forearm circumference at postoperative period (2nd week and 4th week) compared with preoperative period between the two groups.*
Conclusion: *Reinforced PTFE graft had a comparable 6-month primary patency and complication rate with shorter duration of successful cannulation.*

Keywords: *Reinforce PTFE, Time to first cannulation, Patency rate, Hemodialysis*

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Arteriovenous graft (AVG) for hemodialysis were utilized in cases where no appropriated vasculature for creation of Arteriovenous fistula (AVF). Traditionally, a Polytetrafluoroethylene (PTFE) graft was a graft of choice[6]. It came with a non-reinforced tubular structure which in turn led to disfigured in many situations. A reinforced PTFE graft was introduced to market with aimed to enhanced maintaining graft contour. It was used mainly in surgical bypass when conduit was inevitably crossing joint area.

After creation of AVG for hemodialysis, The AVG could be cannulated at least 2 weeks later in the fear of introducing infection to the serum-filled space in the tunnel the AVG situated. Forearm swelling might persisted up to 4 weeks after the creation and caused difficulty in cannulation at that time[6].

In obese patients, the cannulation could be difficult due to thick subcutaneous fat. In addition to the difficulty in cannulation, ones might encounter slow hemostasis due to misidentified the graft or sometimes put excess pressure on the non-reinforced graft led to graft thrombosis.

Tassanavipas et al reported a comparable primary and secondary patency of reinforced PTFE

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graft for hemodialysis utilized inflow and outflow from above elbow joint with acceptable complications[3].

We further evaluated the properties of the reinforced PTFE in terms of numbers of cannulation attempts, time to successful cannulation, compression for hemostasis and satisfaction of dialysis nurses on using the graft.

Material and Method

This was a prospective, randomized study designed to test the hypothesis that reinforced PTFE graft would provided a comparable short-term patency to standard non-reinforced PTFE graft. According to its stiff contour feature further evaluations were then to tested its properties in terms of duration until successful cannulation since the time of AVG creation, numbers of cannulation attempts and compression time for hemostasis.

Sixty patients were included. Demographic data (sex, age, side, arterial and vein sizes, etc) were collected and analyzed. Other informations such as date of the first cannulation, duration from AVG creation to successful cannulation, complications of AVG, date on which complications occured, patency, forearm circumference (measured at proximal and distal 1/3) at preoperative period, 2nd and 4th week postoperative period.

After AVG creation, questionnaire were sent to dialysis nurses about numbers of cannulation attempts, satisfaction on using the AVG, experience of dialysis nurse in charge of cannulation at a given session (experience ≤5-year or >5-year), compression time for hemostasis (manual compression for a cycle of 2.30 min). The above informations were gather at a period of 1-month after first cannulation.

Graft

Both reinforced and non-reinforced PTFE grafts were 6mm in diameter supplied by same company (LeMaitre).

Vessel sizes

When Radiocephalic fistula were ineligible the patients were evaluated for forearm AVG creation according to Ramathibodi hospital policy (Brachial artery size of ≥3 mm and/or Cephalic vein size of ≥3 mm).

Randomization

Patients were randomized using block-4 randomization. The surgeon would knew which procedures were chosen between using reinforced or non-reinforced graft after label opening. The surgeon would not told the patient of which graft was used on the patient. Surgeons were 2nd year vascular surgery fellows at Ramathibodi hospital.

Forearm circumference

Forearm circumference was measured on proximal and distal 1/3 of the forearm length preoperative, 2- and 4-week after operation.

Follow-up

Patients were scheduled for follow-up at 2-, 4-week, 2-, 3- and 6-month.

Complications

Any complications related to the procedure were collected as the patients were scheduled for follow-up.

Satisfaction

Dialysis nurse's experience on each session which categorized into experience of ≤5-year and >5-year and how did the dialysis nurse feel for the given AVG on cannulation rated as 1 to 5. 1 was strongly dissatisfied, 2 was somewhat dissatisfied, 3 was neither satisfied nor dissatisfied, 4 was somewhat satisfied and 5 was strongly satisfied.

End points

Primary end-point was a primary patency at 6-month period. Secondary end-points were duration since AVG creation to first cannulation. Average numbers of attempts on cannulation at each hemodialysis session. Average time of compression for hemostasis.

Statistical methods

We used Stata V.14 statistical software for data and statistical analysis. To test an independent of result, we used Pearson's χ^2 test as a statistical method and used t-test in comparing mean data between groups.

Results

Demographic data were comparable between the 2 groups. Mean ages were 64.773 and 64.067 (*p*-value = 0.829) for reinforced and non-reinforced group, respectively. Mean arterial sizes were 3.75 mm and 3.8 mm (*p*-value = 0.473) for reinforced and non-reinforced group, respectively. Mean venous sizes were 4.03 mm

and 3.98 mm (p-value = 0.4469) for reinforced and non-reinforced, respectively (Table 1).

Forearm circumferences were measured at proximal and distal 1/3. The preoperative proximal 1/3 circumference were 23.5 cm and 23.93 cm (p-value = 0.4578) for reinforced and non-reinforced group, respectively. At 2nd week, the proximal 1/3 circumference were 26.23 cm and 25.71 cm (p-value = 0.4106) for reinforced and non-reinforced group, respectively. At 4th week, the proximal 1/3 circumference were 24.39 cm and 24.47 cm (p-value = 0.9005) for reinforced and non-reinforced group, respectively. The measurements were comparable between the 2 groups at preoperative, 2nd and 4th week (Table 2). The preoperative distal 1/3 forearm circumferences were 18.77 cm and 18.63 (p-value = 0.7719) for reinforced and non-reinforced group, respectively. At 2nd week, the distal 1/3 circumference were 19.93 cm and 20.13 cm (p-value = 0.7002) for reinforced and non-reinforced group, respectively. At 4th week, the distal 1/3 circumference were 19.25 cm and 19.33 cm (p-value = 0.8665) for reinforced and non-reinforced group, respectively. The measurements were comparable between the 2 groups at preoperative, 2nd and 4th week (Table 2).

Table 1. Demographic data

	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)	*p*-value
Age (years)			
Range	43-80	40-78	
Mean	64.733	64.067	0.829
Sex			
Male	17	14	
Female	13	16	
Side			
Right	11	8	0.580
Left	19	22	
Artery (mm)			
Range	3-4	3.5-4	
Mean	3.75	3.8	0.473
Vein (mm)			
Range	3.5-5	3.5-4.5	
Mean	4.03	3.98	0.4469
Nurse's experience (%)			
≤5-year	161 (47.92)	183 (50.83)	
>5-year	175 (52.08)	177 (49.17)	

Table 2. Forearm circumferential

Time at measurement	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)	*p*-value
Proximal 1/3			
Preoperative (cm)	23.5	23.93	0.4578
2-week (cm)	26.23[a]	25.71	0.4106
4-week (cm)	24.39[a]	24.47	0.9005
Distal 1/3			
Preoperative (cm)	18.77	18.63	0.7719
2-week (cm)	19.93[a]	20.13	0.7002
4-week (cm)	19.25[a]	19.33	0.8665

[a], n = 28 due to 2 AVGs were terminated as a result from grade 3 steal syndrome

There were no graft occlusion in the study period of 6-month in both groups (Table 3).

The reinforced group showed shorter duration of successful cannulation at 22.04 days compared with 31.53 days for the duration of non-reinforced group (p-value <0.05) (Table 3).

Seven patients had dialysis associated-steal syndrome (DASS). In reinforced group, 1 had grade 1 DASS, 1 had grade 2 DASS whereas other 2 had grade 3 DASS whom presentation were severe rest pain which led to graft termination. In non-reinforced group, 2 had grade 1 DASS and another 1 had grade 2 DASS. All of non-grade 3 DASS were treated successfully medically. There were no statistical difference between the 2 groups in term of complications (p-value = 0.657) (Table 4) and all of non-grade 3 DASS were treated medically successful within few weeks.

Overall, reinforced group showed lower numbers of cannulation attempts for each hemodialysis session at 1 attempt compared to 1.106 attempt for non-reinforced group (p-value <0.05) (Table 3). Nurse's experience had no effects on cannulation attempts in reinforced group appeared as only 1 attempt for all hemodialysis sessions. In non-reinforced group, nurse's experience of ≤5-year showed statistically higher cannulation attempts on each hemodialysis sessions compared with reinforced group, (1.197 vs. 1.011, p-value <0.05) (Table 6).

In reinforced group, the compression time for hemostasis was statistically shorter than in non-reinforced group, (5.64 vs. 7.61, p-value <0.05) (Table 3).

Overall dialysis nurses favored non-reinforced group with satisfaction rate of 4.75 compared with 4.24 in reinforced group, p-value <0.05 (Table 5). In subgroup analysis, Nurses with experience of ≤5-year favored the reinforced group at satisfaction rate of 4.49 compared to 4.01 for nurses with experience of >5-year, p-value <0.05. But there were no statistical difference in satisfaction rate between the 2 groups of nurse's experience in non-reinforced group, 4.72 for nurse's experience of ≤5-year vs. 4.77 for nurse's experience of >5-year (p-value = 0.302) (Table 6).

Discussion

Schuman et al were the first to conducted a study to compared efficacy of reinforced and non-reinforced PTFE graft in terms of hemodialysis access and found a diversion in primary patency at 3-month between the groups[4].

There were comparable primary and secondary patency(78.6% and 98.2%) according to a study from Tassanavipas et al which utilized inflow and outflow from above elbow vessels[3].

Reinforced PTFE graft was created with an ability to resisted external compression force and kinking. Its primary used was in cross-joint bypass such as Popliteal bypass. We evaluated the graft in terms of primary patency, their influences on time to successful first cannulation, numbers of cannulation

Table 3. Results

	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)	p-value
6-month primary patency	100%	100%	-
Duration (days)	22.04[a]	31.53	<0.05
Attempts	1	1.106	<0.05
Compression time (minutes)	5.64	7.61	<0.05

[a], n = 28 due to 2 AVGs were terminated as a result from grade 3 steal syndrome

Table 4. Complications

	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)	p-value
Grade 1 steal syndrome	1	2	0.554
Grade 2 steal syndrome	1	1	1
Grade 3 steal syndrome	2	0	0.15

attempts and compression time on hemostasis. And further evaluated some potential factors that might associated with numbers of cannulation attempts such as dialysis nurse experiences. Satisfaction of the grafts by dialysis nurses were also evaluated.

After AVG formation, there were no difference in forearm circumference between the 2 groups. The reasons behind successful earlier cannulation in reinforced PTFE group might be from its stiffness and non-compressible properties that led to an easier identification of the graft. In turns, gave an easy-to-palpate graft configuration to dialysis nurses and patients. These properties also helped in shorter compression time for hemostasis. Another advantages of the reinforced PTFE graft was that it helped lower experience dialysis nurses in cannulation.

There were many early-cannulation grafts for hemodialysis available in the market and showed as early as 72 hours of cannulation after AVG creation[7]. As the stiffness of reinforced graft, we further evaluated if its easy-to-palpated property affected identification and compression of the graft. The results showed lower time consumption for hemostasis which we also believed a consequence of the easy-to-palpated property of the graft. These reinforced graft might not showed as early as the commercial early-cannulation grafts in cannulation but still earlier than a conventional graft. And because of the nature of the reinforced graft, it might had an advantages on obese and/or some bleeding tendency patients.

The only complications we found in the present study was DASS. The overall rate of DASS was around 5 to 10% when Brachial artery was used. There was 11% DASS in our study which was comparable in overall prevalence[8]. We treated non-grade 3 DASS conservatively. With the used of Gabapentin and Beraprost sodium, the symptoms resolved completely within few weeks. In contrast, all grade 3 DASS patients presented with intense rest pain which led to graft termination. There were no digital gangrene or tissue loss in all grade 3 DASS patients.

Most dialysis nurses favoured the non-reinforced PTFE graft over the reinforced one. The main reason was that they felt uncomfortable while cannulating the hardening reinforced graft. Although, they made a successful cannulation.

The drawbacks of the present study were that we did not evaluated the cost-effective impact of the graft on each patient and neither provided an intermediate or long-term data.

The results of the present study might shed light on AVG creation in area where there were not so much choices of PTFE graft available and may had some benefit on obese and/or bleeding tendency patients.

Conclusion

The reinforced PTFE graft for hemodialysis

Table 5. Satisfaction

	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)	*p*-value
Overall	4.24	4.75	<0.05

[a], n = 28 due to 2 AVGs were terminated as a result from grade 3 steal syndrome

Table 6. Impact of Nurse's experiences

	Reinforced PTFE graft (30)	Non-reinforced PTFE graft (30)
Satisfaction		
Experience ≤5-year	4.49	4.72
Experience >5-year	4.01	4.77
p-value	<0.05	0.302
Cannulation attempts		
Experience ≤5-year	1	1.197
Experience >5-year	1	1.011
p-value	-	<0.05

had a comparable short-term primary patency to conventional graft and had advantages in helping lower experience dialysis nurse in cannulation and also its easy-to-palpated nature aided in earlier cannulation and compression for hemostasis.

What is already known on this topic?

KDOQI guideline recommends not to cannulate arteriovenous graft for at least 2 weeks or swelling subside after creation due to the fear of infection into the serum-filled space around the graft.

Generally, it takes around 4 weeks after creation of the graft until first cannulation for hemodialysis due to forearm swelling.

Sometimes pseudoaneurysm developed due to inappropriate hemostatic compression (In obese patients, the thick subcutaneous fat leads to mobility of the graft which leads to difficulty in cannulation and hemostatic compression).

6-month primary patency rate of non-reinforced arteriovenous graft is 78% from our previous study.

What this study adds?

After 2 weeks period of creation, reinforced arteriovenous graft can be cannulated earlier than non-reinforced arteriovenous graft due to its non-conformable contour.

The lesser time it takes for the reinforced arteriovenous graft to be compressed for hemostasis.

Nurse's experience in hemodialysis department doesn't affect cannulation attempts in a given hemodialysis session in contrast to non-reinforced arteriovenous graft which cannulation attempts are higher in lower experience nurse.

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Potential conflicts of interest

None.

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หลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยัน: การเปรียบเทียบประสิทธิภาพของเส้นฟอกไตเทียม

หลักชัย วิชชาวุธ, สุทัศน์ ฮ้อศิริมานนท์, วิวัฒน์ ถิระพานิช, โสภณ จิรสิริธรรม, สุรศักดิ์ ลีลาอุดมลิปี, ปิยนุช พูตระกูล, ณัฐสิริ กิตติถิระพงษ์, ศักดา อาจองค์วัลลิภากร

ภูมิหลัง: *ปัญหาที่พบบ่อยในผู้ป่วยฟอกไตเทียมตันก่อนเวลาอันควร พบว่าหลายครั้งเกิดจากการกดผิดตำแหน่งหรือกดแรงเกินไป เส้นฟอกไตเทียมแบบมีวงแหวนค้ำยันอาจให้ประโยชน์ในการป้องกันปัญหาดังกล่าวจากคุณสมบัติความคงตัวของเส้นฟอกไตเทียมดังกล่าว*

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิภาพของหลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยันกับชนิดไม่มีวงแหวนค้ำยันในด้าน 6-month primary patency rate, จำนวนความพยายามในการแทงเข็มเพื่อฟอกไต, ระยะเวลาหลังจากผ่าตัดทำเส้นฟอกไตเทียมจนถึงวันที่ใช้เส้นฟอกไตครั้งแรก, ระยะเวลาในการกดห้ามเลือด, คะแนนความพึงพอใจต่อเส้นฟอกไตของพยาบาลผู้แทงเส้นฟอกไต*

วัสดุและวิธีการ: *ผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นโรคไตวายเรื้อรังจำนวน 60 ราย ในโรงพยาบาลรามาธิบดีที่เส้นเลือดแดงและดำที่แขนระดับต่ำกว่าข้อศอกเหมาะสมต่อการผ่าตัดทำเส้นเลือดฟอกไตเทียมรับการสุ่มเพื่อแบ่งเป็นกลุ่มที่ได้รับการผ่าตัดทำเส้นฟอกไตเทียมชนิดมีและไม่มีวงแหวนค้ำยัน ข้อมูลประชากรถูกรวบรวมแบบสอบถามเรื่องวันที่ได้ใช้เส้นฟอกไตเทียมครั้งแรก จำนวนความพยายามในการแทงเข็มเพื่อฟอกไต ประสบการณ์ในห้องไตของพยาบาลที่แทงเข็มฟอกไต ระยะเวลาในการกดห้ามเลือดและคะแนนความพึงพอใจต่อเส้นฟอกไตของพยาบาลผู้แทงเส้นฟอกไตถูกส่งให้กับพยาบาลที่แทงเส้นฟอกไตในครั้งนั้นๆ โดยมีการนัดผู้ป่วยเพื่อตรวจประเมินการทำงานของเส้นฟอกไตโดยการคลำ และภาวะแทรกซ้อนจากเส้นฟอกไตที่ 2 และ 4 สัปดาห์ จากนั้นที่ 2, 3 และ 6 เดือน โดยตรวจวัดเส้นรอบวงของแขนที่ 2 และ 4 สัปดาห์*

ผลการศึกษา: *ไม่พบความแตกต่างของเส้นรอบวงของแขนข้างที่ทำผ่าตัดทั้งก่อนผ่าตัดและที่ 2 และ 4 สัปดาห์ หลังผ่าตัดไม่พบความแตกต่างของ 6-month primary patency rate ระหว่างเส้นฟอกไตทั้งสองชนิด (100% vs. 100%) ระยะเวลาหลังจากผ่าตัดทำเส้นฟอกไตเทียมจนถึงวันที่ใช้เส้นฟอกไตครั้งแรกของกลุ่มหลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยันสั้นกว่ากลุ่มหลอดเลือดฟอกไตเทียมชนิดไม่มีวงแหวนค้ำยัน (22 วัน vs. 31.5 วัน, p-value <0.05) จำนวนครั้งของความพยายามในการแทงเข็มเพื่อฟอกไตในกลุ่มหลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยันน้อยกว่าในกลุ่มหลอดเลือดฟอกไตเทียมชนิดไม่มีวงแหวนค้ำยัน (1 ครั้ง vs. 1.1 ครั้ง, p-value <0.05) ระยะเวลาในการกดห้ามเลือดในกลุ่มหลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยันสั้นกว่ากลุ่มหลอดเลือดฟอกไตเทียมชนิดไม่มีวงแหวนค้ำยัน (5.64 นาที vs. 7.61 นาที, p-value <0.05) ประสบการณ์การทำงานในห้องไตของพยาบาลไม่มีผลต่อจำนวนครั้งของความพยายามในการแทงเข็มเพื่อฟอกไตในกลุ่มหลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยัน*

สรุป: *หลอดเลือดฟอกไตเทียมชนิดมีวงแหวนค้ำยันช่วยลดระยะเวลาหลังจากผ่าตัดทำเส้นฟอกไตเทียมจนถึงวันที่ใช้เส้นฟอกไตครั้งแรก สามารถใช้เพื่อแทงเส้นฟอกไตได้ง่าย ช่วยลดระยะเวลาในการกดห้ามเลือดโดยมี 6-month primary patency rate และภาวะแทรกซ้อนเทียบเท่ากับหลอดเลือดฟอกไตเทียมชนิดไม่มีวงแหวนค้ำยัน*