

SP563

New Low Pressure Technique (LPT) to Improve Patency Period

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【Introduction】

At this conference two years ago we presented our findings on low pressure VAIVT. Although our findings using low pressure were very encouraging, when using high pressure for full expansion the time of stenosis for intimal hypertrophy and intimal injury occurring shortened significantly.

【Aims】

Determining the placement of the end point depends on whether your aim is VAIVT for full expansion or dialysis blood flow rate. This study presents our findings on data collected over a 39 month period on our low pressure methods, the balloon specifications, and how they effected the patency period.

【Methods and Objects】

Data : From September 2010 to November 2013.

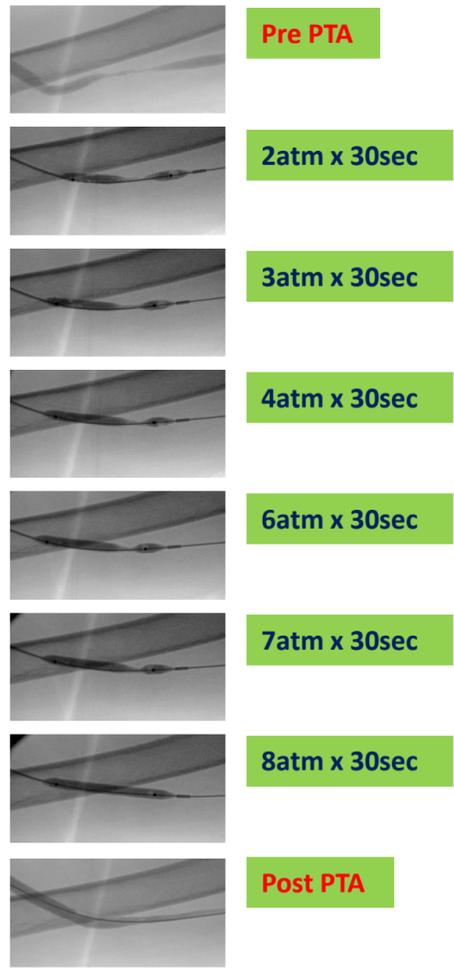
Cases : 798 VAIVT Cases.

Ratio: AV-f : AV-g, 505 : 293

Considered views : Balloon size, Balloon specifications, Average atmosphere, Patency Period. Number of stenosis points

Analysis : the Kaplan Meier Method and Log-rank Test.

New Low Pressure Technique (LPT)



- ① New Low Pressure Technique (LPT) is an attempt to maximize blood flow rate when using maximum pressure is not an option.
- ② In this example of LPT we take a balloon rated to 15atm but only using it up to its nominal pressure of 6atm. Beginning at 1atm and expanding and contracting the balloon 20 to 25 times a minute while increasing the pressure by 1 atm every minute up to the nominal pressure of 6atm. Total time is 6 minutes and in some cases slight more time.
- ③ Balloon expansion is gradually increased during the first 5 minutes to full vein size in the final minute.
- ④ This method applies to all balloon pressures and is used accordingly based on the balloon's rated pressure and nominal pressure.

One of the goals of this technique is to achieve full expansion at low pressure.

※Super-non-compliant balloon (CONQUEST®, Yoroi®)

【Results】

《Fig. 1 : Super-Non-compliant Balloon VS Other Balloons Over 6ATM》

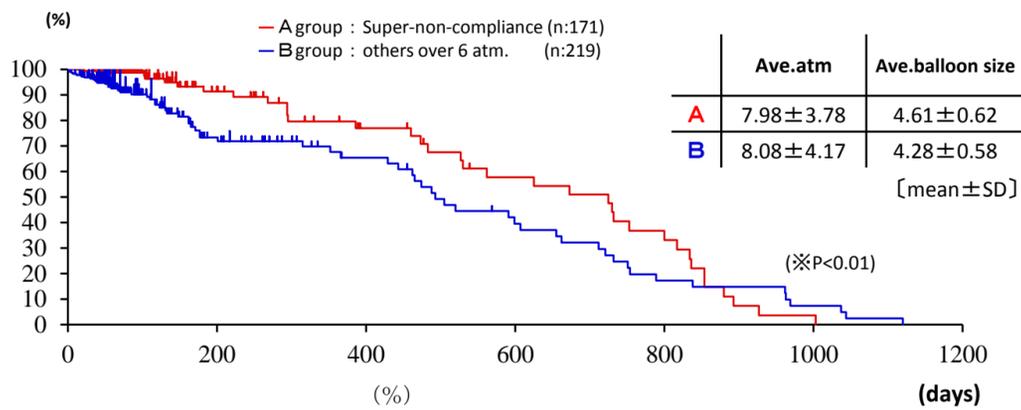
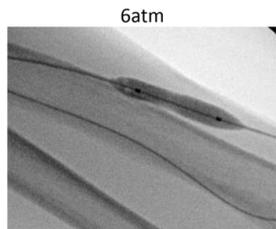


Fig. 1 Compares group A using super-non-compliance balloon to group B using other balloons at over 6 ATM with no significant difference in balloon size and pressure. There was a significant difference in the Patency period of group A which was longer than group B. Therefore, showing the advantages of using super non-compliant balloons.

Super-non-compliant balloon vs Others

Dog-bone phenomenon

As shown in the figure, group B, when using a semi-compliant balloon that looks like it is being bitten by a dog, causes intimal injury and the main objective is not achieved due to the fact that the balloon expands beyond the optimal size.



Super-non-compliant Balloon

As shown in the figure, group A, using a super non-compliant balloon eliminates the occurrence of dog bone phenomenon. Vein damage is also avoided because the balloon is limited in its expansion.



《Fig. 2 Incomplete Dilation of Super-Non-Compliant Balloons Compared With Other Balloons Over 6ATM》

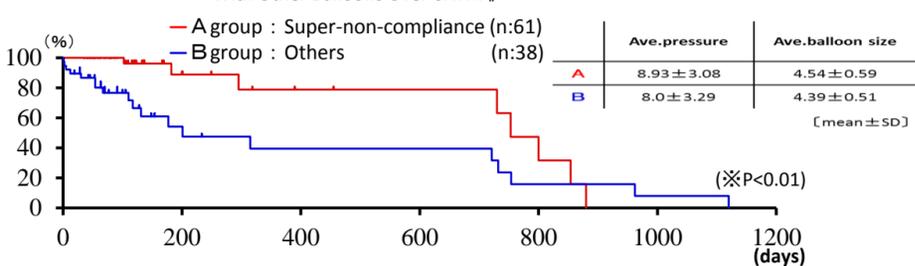


Fig. 2 In the following chart there is no significant difference in the ATM or balloon size used between group A and B. However, in B, cases of Dog Bone Phenomenon, intimal damage was observed at balloon points. In group A there was a significant difference in the Patency period compared to group B.

《Fig.3.4.5 Differences Between Super-Non-Compliant Balloons and Other Balloons With Single Stenosis Points and Multiple Stenosis Points》

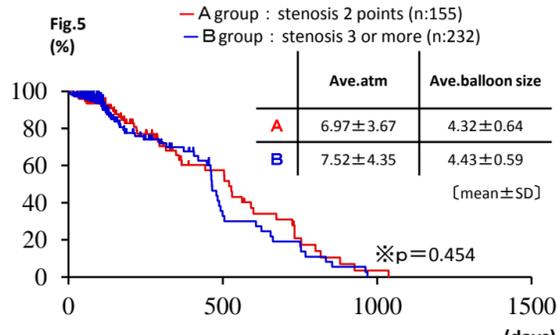
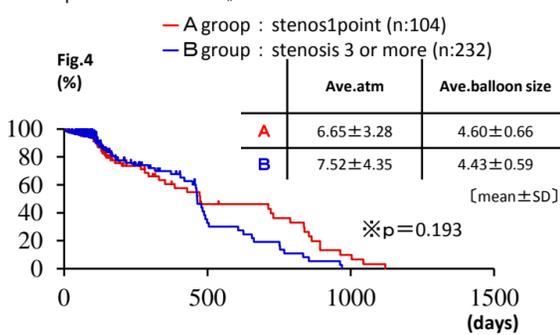
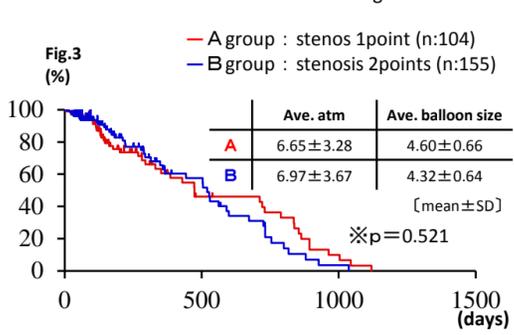


Fig. 3 compares group A one stenosis point to group B two points, Fig. 4 compares group A one point to group B three or more points. Fig. 5 compares group A two points to group B three or more. There is no significant difference in balloon size or pressure between groups A and B. There was also no significant difference in the Patency period. Therefore, it is evident that there is no benefit in using multiple stenosis points.

【Consideration】

Period of Study was 39 months. AV-f using balloon specification and LPT produced significant results. LPT using Super-non-compliant balloons prevented the occurrence of Dog Bone Phenomenon. Through this technique Intimal Damage was reduced or prevented. Lengthening of the Patency period was also achieved. No significant difference in Patency between single or multiple stenosis points was also evidenced.

【Conclusions】

- 1) Dog-bone phenomenon can be avoided by using a super-non-compliant balloon.
- 2) LPT, using nominal pressure, resulted in very good patency period.
- 3) LPT prevents intimal injury and vein damage.

COI Disclosure

This presentation is not related to any company with a conflict of interest that should be disclosed