

Totally implantable port management: impact of positive pressure during needle withdrawal on catheter tip occlusion (an experimental study)

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ABSTRACT: Background: Totally implanted ports (TIP) have become a standard part of patient care, providing long-term central venous access for treatment administration and other procedures. Despite overall the safety and effectiveness of TIP, complications still occur. Negative pressure created during needle withdrawal induces blood reflux and subsequent catheter occlusion. Application of positive pressure during needle withdrawal is thought to largely prevent such reflux, but supporting data are limited.

Purpose of research: To quantify the role of positive pressure, using a test model designed to simulate physiological conditions.

Methods: Reflux associated with needle withdrawal with and without applied positive pressure was tested using various TIP models from different manufacturers mounted on a specially designed test bench. In addition to the presence or absence of positive pressure during needle withdrawal, study variables comprised of needle type (safety and standard), needle gauge and port septum diameter.

Results: Application of positive pressure during needle withdrawal reduced the incidence of reflux during needle withdrawal by nearly 80% (22% vs. 99%, $p < 0.001$). When reflux did occur, the mean residual volume was half that observed without positive pressure. In the absence of positive pressure, mean reflux increased with septum diameter and needle gauge to a statistically significant extent. None of these variables significantly affected reflux in the context of needle withdrawal under positive pressure.

Conclusion: The results of this study support the use of positive pressure during needle withdrawal to prevent blood reflux potentially leading to catheter tip occlusion. (J Vasc Access 2010; 11: 46-51)

Key words: Totally implanted ports, Safety Huber needle, Positive pressure, Catheter thrombosis, Catheter occlusion

INTRODUCTION

Totally implanted ports (TIP) have become an integral part of patient care, particularly in oncology departments where patients require repeated venous access for the implementation and monitoring of therapy. TIP consists of a plastic or titanium chamber with a compressed silicon septum designed for puncture by a non-coring needle (1, 2). TIP have proven to be a valuable alternative to external systems owing to lower complication rates from infection and greater ease of use.

Despite their safety and effectiveness, TIP are still associated with various complications: infection (3), venous thrombosis (4), and catheter occlusion (5). Catheter tip occlusion has variously been reported to occur in 1-8% of cases (6) or as many as 28% of patients with TIP (5). Thrombi may develop at the catheter tip when the tensile pressure exerted on the port septum by needle withdrawal, analogous to a suction effect, results in upward distension of the septum, creating a nega-

tive pressure at the distal end of the attached catheter leading to blood reflux (7). These thrombi may hamper blood withdrawal or therapy delivery and also lead to other complications, such as infection of the intravascular device (3, 8). All these complications are likely to result in increased nursing time, the need for chest x-rays, thrombolytic medications, and even device replacement (2-6, 8, 9).

Various measures are employed to prevent thrombus formation and tip occlusion, including the use of anti-thrombotic flush solutions, pressure activated safety valves and positive pressure applied during needle withdrawal (2, 5, 8, 9). The application of positive pressure operates on the principle that reflux can be prevented by exerting a countervailing force to balance the negative pressure leading to blood reflux and thrombosis (5). In its December 2000 recommendations, the French *Agence Nationale d'Accr  ditation et d'  valuation en Sant  * (ANAES) called for positive pressure to be applied during needle withdrawal (10). However, specific data supporting this rec-

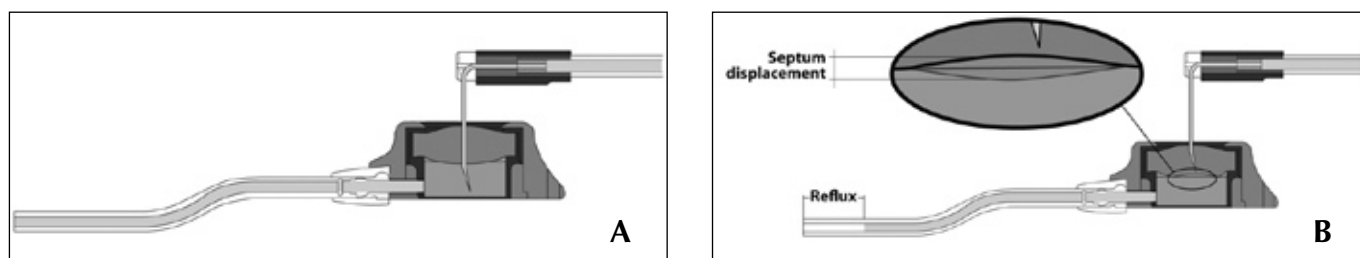


Fig. 1 - Reflux at the distal end of the catheter resulting from displacement of the TIP septum on needle withdrawal.
 Panel A: Insertion of a Huber needle into the TIP chamber.
 Panel B: Withdrawal of the Huber needle, resulting in septum displacement and reflux at the distal end of the catheter.

ommendation remain limited.

Using non-implanted TIP linked to a pressure monitor, Millet et al measured the pressure change in the port chambers resulting from withdrawal of a Huber needle from the TIP according to routine clinical practice (11). The mean (\pm SD) maximum change in pressure was -21.6 mmHg \pm 4.1 mmHg ($n=60$ withdrawals), confirming the value of counteracting this pressure nadir by maintaining a positive pressure during needle withdrawal as recommended by the ANAES (10, 11). Laboratory analysis showed that reflux can cause a static column of blood up to 5 mm in length from the catheter tip (5). While these studies confirm that reflux occurs, they do not provide more detailed specifics.

It seemed worthwhile to confirm the results of the above studies while exploring this further. The aim of this study was to quantify the role of positive pressure by developing an experimental model and examining its role in reducing reflux across a range of variables.

MATERIALS AND METHODS

All experiments were performed using a test bench designed to simulate the conditions of injecting into TIP in routine clinical practice and to allow precise measurement of reflux at the distal end of the catheter on needle withdrawal. The test bench comprised a horizontal support for the TIP and attached catheter, with a layer of artificial skin (3 mm thickness of soft PVC) through which the needle was inserted into the TIP septum. After insertion of the needle into the TIP, the chamber was rinsed and the catheter filled with colored isotonic saline. The needle was then withdrawn with or without the application of positive pressure, achieved by the injection of additional solution. A scale graduated in millimeters, integrated in the section of the test bench supporting the catheter, permitted the measurement of reflux at the distal end of the catheter on needle withdrawal (Fig. 1).

Safety (Polyperf[®] Safe) and standard (Polyperf[®]) 20 mm

long, beveled 19, 20 and 22 gauge Huber needles (with diameters of 1.1, 0.9 and 0.7 mm, respectively) were supplied by Laboratoires Perouse (Ivry le Temple, France). In contrast to standard Polyperf[®] needles, Polyperf[®] Safe needles have a protective housing totally shielding the needle after withdrawal and thereby preventing accidental needle stick injuries. Importantly, they permit one-handed withdrawal of the needle, freeing the other hand to simultaneously inject isotonic saline into the chamber, thereby ensuring a positive pressure in this as the needle is withdrawn. Both types of needle have the same curved angle and beveling.

Thirty different TIP from various suppliers were tested. Septum diameters ranged from 7.5 mm to 12.93 mm and internal catheter diameters from 0.67 mm to 1.6 mm. Catheter length was uniformly 35 cm. Each TIP and needle was randomized (computer-generated list) so that the operator was blinded to the model used in each test. A screen prevented the operator from identifying the needle tested and observing the reflux on needle withdrawal. Needle withdrawals were performed by one operator and results measured and recorded by a second, both operators remaining the same throughout the duration of the study.

For each TIP, 30 withdrawals were performed, 15 with positive pressure and 15 without (five withdrawals with 19, 20 and 22 gauge needles, respectively). Both needle withdrawal and reflux were filmed. The examination of individual frames allowed the precise measurement of needle movement and accompanying liquid displacement during reflux. The linear displacement of the liquid at the catheter's distal end at peak aspiration (D_{max}) was recorded, as was the residual linear displacement at the end of extraction (D_{res}). Maximum and residual volumes (V_{max} and V_{res} , respectively, expressed in microliters) were calculated from D_{max} and D_{res} by multiplying the liquid displacement by the area of the internal catheter lumen.

Following analysis of the initial results obtained, a second, complementary study was performed using only one type of TIP (Polysite[®] 4008; Laboratoires Perouse, Ivry le Temple, France) specifically to investigate further the effect of needle gauge (22, 20, 19 gauge) on reflux at the distal end of the catheter.

Statistical analysis

The primary end point of the study was reflux into the catheter with the application of positive pressure in comparison to reflux without the application of positive pressure. The effects on reflux of needle type (safety or standard), needle gauge and TIP septum diameter were secondary end points.

The statistical significance of the difference in observed reflux at the catheter's distal end was determined by analysis of V_{max} and V_{res} using a paired Student's t-test. All statistical analyses were performed using SPSS software, version 15.0 (SPSS Inc., Chicago, USA), with an α -risk of 5%. A probability of $p < 0.05$ was defined as statistically significant.

The effects of septum diameter and needle gauge were further investigated by post-hoc pairwise analyses, using the Games-Howell test to determine the statistical significance of differences between pairs. This test is designed particularly for comparing groups with unequal variances and of unequal size, including small groups, as was the case in this study.

RESULTS

The total number of withdrawals was 870 (435 with the application of positive pressure and 435 without the application of positive pressure).

The mean values of D_{res} and V_{res} with and without the application of positive pressure were compared taking into account all needle withdrawals performed (Tab. I) and then, only the withdrawals resulting in reflux (Tab. II). In both cases, the magnitudes of D_{res} and V_{res} were significantly smaller when needle withdrawal was accompanied by the application of positive pressure ($p < 0.001$).

Analysis of the primary end point demonstrated a 99.1% (431/435) rate of reflux in the absence of positive pressure during needle withdrawal, compared to only 21.6% (94/435) when positive pressure was applied (Tab. I). This difference was highly significant ($p < 0.0001$; chi-square test), the application of positive pressure led to a nearly 80% reduction in the rate of reflux. Furthermore, in the few cases where reflux did occur under positive pressure, its magnitude was only half that observed on needle withdrawal without positive pressure (Tab. II): mean V_{res} $1.77 \mu\text{L} \pm 1.66$ (95% CI = 1.43-2.11) vs. $3.53 \mu\text{L} \pm 1.63$ (95% CI = 3.37-3.68).

With regard to the secondary end points, the type of Huber needle used (safety or standard) did not affect V_{res} or V_{max} when the needle was withdrawn without the application of positive pressure (data not shown).

In contrast, the reflux associated with needle withdrawal in the absence of positive pressure increased markedly with increasing needle diameter (22, 20 and 19

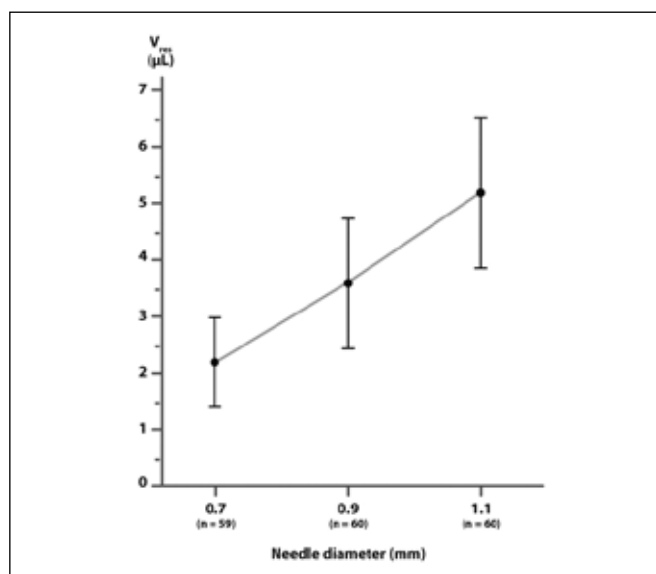


Fig. 2 - Effect of needle diameter on distal catheter reflux in the absence of positive pressure using a single TIP model (Polysite® 4008). V_{res} : residual volume of reflux at the end of needle withdrawal. The total number of needle withdrawals was 180 (60 per group). The analysis was based solely on withdrawals in which reflux was observed: 179/180 (99.4%). Both V_{res} and V_{max} (data not shown) differed significantly according to needle diameter: $p < 0.001$ (ANOVA).

TABLE I - EFFECT OF NEEDLE WITHDRAWAL WITH AND WITHOUT POSITIVE PRESSURE ON RESIDUAL DISTANCE (D_{res}) AND RESIDUAL VOLUME (V_{res}) OF DISTAL CATHETER REFLUX AT THE END OF NEEDLE WITHDRAWAL

Parameter mean \pm SD	Without positive pressure* (n=435)	With positive pressure** (n=435)	P value (ANOVA)
D_{res} (mm)	3.69 ± 2.04	0.35 ± 0.93	<0.001
V_{res} (μL)	3.49 ± 1.65	0.38 ± 1.06	<0.001

* Reflux observed in 431/435 withdrawals (99.1%); ** reflux observed in 94/435 withdrawals (21.6%)

TABLE II - EFFECT OF NEEDLE WITHDRAWAL, WITH AND WITHOUT APPLICATION OF POSITIVE PRESSURE, ON RESIDUAL DISTANCE (D_{res}) AND RESIDUAL VOLUME (V_{res}) DISTAL CATHETER REFLUX AT THE END OF NEEDLE WITHDRAWALS ACCOMPANIED BY REFLUX

Parameter mean \pm SD	Without positive pressure (n=431)	With positive pressure (n=94)	P value (ANOVA)
D_{res} (mm)	3.72 ± 2.01	1.62 ± 1.40	<0.001
V_{res} (μL)	3.53 ± 1.63	1.77 ± 1.66	<0.001

The total number of withdrawals was 870 (435 without the application of positive pressure and 435 with the application of positive pressure). The analysis was based solely on withdrawals in which reflux was observed: 431/435 (99.1%) without the application of positive pressure and 94/435 (21.6%) with the application of positive pressure

gauge). Differences were statistically significant between the needle sizes ($p < 0.001$; ANOVA) (Tab. III). Post-hoc pairwise comparisons also showed statistically significant differences in mean V_{res} and V_{max} values between the three needle groups in this study ($p < 0.001$; Games-Howell test). The statistically significant effect of needle diameter on reflux, in the absence of positive pressure, was confirmed by

TABLE III - EFFECT OF NEEDLE DIAMETER ON DISTAL CATHETER REFLUX IN THE ABSENCE OF POSITIVE PRESSURE DURING NEEDLE WITHDRAWAL, USING 29 DIFFERENT TYPES OF TIP

Needle gauge (diameter, mm)	V_{res} , μL Mean \pm SD	V_{max} , μL Mean \pm SD
22 G (0.7)	2.52 \pm 1.20 n=143	7.22 \pm 5.65 n=145
20 G (0.9)	3.72 \pm 1.49 n=143	10.05 \pm 7.02 n=144
19 G (1.1)	4.33 \pm 1.61 n=145	11.63 \pm 7.67 n=145

V_{res} : residual volume of reflux at the end of needle withdrawal; V_{max} : maximum volume of reflux during needle withdrawal. The total number of withdrawals was 435 (145 per group). The analysis was based solely on withdrawals in which reflux was observed: 431/435 (99.1%) for V_{res} and 434/435 (99.8%) for V_{max} . Both V_{res} and V_{max} differed significantly according to needle diameter: $p < 0.001$ (ANOVA)

TABLE IV - EFFECT OF NEEDLE GAUGE ON THE FREQUENCY AND MAGNITUDE OF DISTAL CATHETER REFLUX DURING NEEDLE WITHDRAWAL WITH APPLICATION OF POSITIVE PRESSURE

Needle gauge	Total withdrawals		Withdrawals in which reflux was observed		
	N		n	n/N, %	V_{res} , μL mean \pm SD
19	145		31	21.4	1.54 \pm 0.84
20	145		32	22.1	1.86 \pm 2.04
22	145		31	21.4	1.91 \pm 1.86
Total	235		94	21.6	1.77 \pm 1.66

The residual volume of reflux at the end of needle withdrawal (V_{res}) did not differ significantly between the three groups (ANOVA)

TABLE V - EFFECT OF SEPTUM DIAMETER ON THE MAGNITUDE OF DISTAL CATHETER REFLUX WITHOUT APPLICATION OF POSITIVE PRESSURE

Septum diameter, mm	7.5; 8.7	>8.7; 9.9	>9.9;11.1	>11.1;12.3	>12.3;13.5
V_{res} , μL ; mean \pm SD [95% CI]	2.35 \pm 0.56 [2.23 - 2.47] n=90	2.89 \pm 1.17 [2.53 - 3.25] n=43	3.34 \pm 1.34 [3.06 - 3.62] n=90	3.87 \pm 1.36 [3.58 - 4.15] n=90	4.54 \pm 1.96 [4.18 - 4.90] n=118
V_{max} , μL ; mean \pm SD	4.59 \pm 1.30 n=90	5.89 \pm 2.20 n=44	7.99 \pm 3.22 n=90	10.12 \pm 4.67 n=90	15.65 \pm 9.55 n=120

V_{res} : residual volume of reflux at the end of needle withdrawal; V_{max} : maximum volume of reflux during needle withdrawal. The total number of withdrawals was 435. The analysis was based solely on withdrawals in which reflux was observed: 431/435 for V_{res} and 434/435 (99.8%) for V_{max} . Both V_{res} and V_{max} differed significantly according to needle diameter: $p < 0.001$ (ANOVA). The post-hoc pairwise comparisons of V_{res} according to septum diameter class, show statistically significant differences between the class [0.75-8.7 mm] and the four other classes ($p = 0.046$ for the comparison with the class [8.7-9.9 mm] $p < 0.001$ for the other three comparisons; ANOVA) and between the class [12.3-13.5 mm] and the four other classes ($p = 0.034$ for the comparison with the class [11.1-12.3 mm]; $p < 0.001$ for the other three comparisons; ANOVA)

a second, complementary study using a single TIP model (Fig. 2). For this complementary study 180 withdrawals were performed (60 for each size of needle tested).

In contrast, when positive pressure was applied during needle withdrawal, the magnitude of reflux (V_{res}) no longer differed significantly according to needle diameter and this variable had no impact on the incidence of reflux (Tab. IV).

The analysis of V_{res} and V_{max} on withdrawals performed in the absence of positive pressure also showed a statistically significant increase in reflux volume with increasing septum diameter (range: 7.5 to >13.5 mm; Table V). Pairwise comparisons of mean values of V_{max} similarly showed statistically significant differences between the five septum diameter classes (data not shown). In contrast, when positive pressure was applied during needle withdrawal, no statistically significant effect of septum diameter on V_{res} was observed (analysis of needle withdrawals accompanied by reflux; data not shown).

DISCUSSION

Positive pressure has long been suspected to play a role in the reduction of distal catheter reflux; its application during needle withdrawal from TIP is now recommended in clinical practice (10). Few studies, however, have directly examined the phenomenon and its underlying

ing influences (5, 11). This study demonstrates that blood reflux, frequently leading to catheter tip occlusion, could be easily prevented in most cases by applying positive pressure during needle withdrawal.

Critique of the model

Although the results of this study clearly demonstrate the value of positive pressure in reducing distal catheter reflux, some aspects of its methodology could have affected the results obtained. For example, the study was not performed *in vivo*, under physiological conditions. Although every effort was made to simulate physiological and clinical conditions, the isotonic saline displaced in the catheter on needle withdrawal clearly did not fully replicate blood in terms of characteristics, such as viscosity, likely to affect specific reflux outcomes. Furthermore, the intra-thoracic pressure fluctuations normally occurring *in vivo* (5), which could potentially modify reflux magnitude, were not present in this study.

Nonetheless, while the volume and distance of displacement might have been altered by *in vivo* conditions, it is unlikely that the overall study outcome with regard to the beneficial effect of applying positive pressure during needle withdrawal, and the fundamental relationships between study variables, would have been significantly affected.

A further methodological issue concerns the needles used in the study. Two different types of Huber needle were used: safety and standard. This choice was made to reflect clinical conditions accurately where safety Huber needles, permitting one-handed needle withdrawal, are used to inject isotonic saline into the port chamber as the needle is withdrawn and thereby create a positive pressure in it. It is conceivable that these different needle designs may have altered pressure dynamics, thereby modifying reflux outcomes between the two groups. To address this issue, the mean reflux volumes associated with the use of both types of needle were compared without positive pressure application. The results of this analysis revealed that the type of needle (safety or standard) had no significant effect on reflux.

Although TIP type was blinded, the operator recording the displacements did know whether or not positive pressure was being applied. It is doubtful, however, that this led to any meaningful bias; the results with or without positive pressure stand in stark contrast to one another, and it is not clear how observer bias could have affected that outcome given the study design.

One could also argue that the application of positive pressure was highly manipulator-dependent, and that different results might have been achieved by different needle operators. Though it remains unclear the extent to which a particular needle operator would impact the results, it is unlikely that the overall outcome would have been significantly affected.

Impact of positive pressure application

When positive pressure was not applied, a 99% frequency of reflux into the distal end of the catheter was observed, contrasting sharply with the 22% only rate of reflux observed with positive pressure. The application of positive pressure, accomplished by flushing the TIP with isotonic saline throughout the process of needle withdrawal, consequently led to a nearly 80% reduction in the rate of reflux. Furthermore, on the relatively few occasions when reflux was observed under positive pressure, the mean reflux volume recorded was only half that determined in the absence of positive pressure during needle withdrawal. These findings are consistent with the lower rate of catheter occlusion, manifested in the difficulty in withdrawing blood, reported by Carlo et al with the use of valved TIP resisting reflux (5).

Whereas the magnitude of reflux at the distal end of the catheter appeared to be independent of both needle gauge and septum diameter when needle withdrawal was performed under positive pressure, these parameters significantly affected reflux in the absence of positive pressure. The residual volume of reflux at the end of needle withdrawal increased to a statistically significant extent both with increasing needle diameter and with increasing septum diameter. The results of the second study performed without the application of positive pressure during needle withdrawal, using only one type of TIP to reduce the number of variables, confirmed the increased incidence of distal catheter reflux with the use of larger diameter needles. In the light of these findings, we recommend the avoidance of large TIP and large diameter needles if positive pressure cannot be applied during needle withdrawal.

It is important to bear in mind that positive pressure must be applied via active flushing with isotonic saline throughout the process of needle withdrawal in order to be fully effective. Furthermore, although the incidence and magnitude of reflux under positive pressure were shown to be minor in this study, these variables might be operator-dependent. Therefore, the ideal solution would be to develop a system allowing nearly automatic application of positive pressure upon needle withdrawal. This would eliminate any potential complications introduced by incorrect technique or operator variability.

With regard to the potential impact of positive pressure application during needle withdrawal from TIP in routine clinical practice, our experience relating to the use of TIP in the oncology department of a large teaching hospital is worth mentioning. Introduction of the systematic application of positive pressure was cost effective as it resulted in a two-fold reduction in the expenditure of fibrinolytic agents to clear catheter obstruction over a 2-yr period, in comparison to the previous 2-yr period, corresponding to a saving of 20,000 euros (results reported in

an oral presentation by J. Lapalu at the 5^{ème} Congrès des Dispositifs Intraveineux de Longue Durée, Paris, France, March 2009).

CONCLUSION

This study provides the first experimental evidence demonstrating the value of positive pressure in reducing reflux at the catheter's distal end upon needle withdrawal, a potential cause of catheter tip occlusion. Moreover, the application of positive pressure attenuated or eliminated the effect of variables such as needle gauge and septum diameter on the magnitude of reflux observed in the absence of positive pressure during needle withdrawal. Specific clinical techniques, however, may require further refinement. The application of positive pressure has yet to be universally defined in a clinical setting.

Furthermore, it appears that the positive pressure will reduce the global cost during management of TIP, but this needs to be confirmed by a clinical multicentric study.

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Conflict of interest statement: None.

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