Does Sludge/Debris Exist in Today's Vascular Access Ports?

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Abstract

Sludge is defined as a slushy mass, deposit, or sediment. In vascular access ports (VAPs), it appears to be the buildup of clotted blood, blood components, drug and mineral precipitates or residues, and lipids that adhere to or reside in the internal path of the reservoir. Several studies note the presence of sludge as a risk factor for increased incidence of VAP-related bloodstream infections as well as higher occlusion rates. Overall, the occurrence of sludge in implanted vascular ports may increase patient-associated risks and costs to health care providers by as much as $40,000 per incident. Understanding the significance of these associated risks and costs may lead to solutions that save health care facilities money; better serve health care providers; and ultimately, improve patient outcomes.

Keywords: *cost savings, CVAD, occlusion, spherical chamber, sludge, thrombosis, VAP, VAP-BSI*

Introduction

Sludge is defined as a slushy mass, deposit, or sediment. In vascular access ports (VAPs), it appears to be the buildup of clotted blood, blood components, drug and mineral precipitates or residues, and lipids adhering to or residing in the internal path of the reservoir. It is believed that when blood is aspirated from a port, small amounts of residual blood can adhere to the catheter and/or portal reservoir causing fibrin buildup that can lead to infection. Additionally, sludge that accumulates within the reservoir can obstruct the entrance to the internal catheter.[1]

During the mid-1990s, the issue of sludge in totally implanted VAPs was a topical issue. Investigation at that time demonstrated that sludge existed (M.D., unpublished data, 1992-1994). The literature suggests that such sludge is related to the incidence of infections and total or partial withdrawal occlusions.[1-5] However, whereas port reservoir design has remained nearly unchanged since that initial study, the sludge discussion has gone relatively quiet. Is this because sludge has disappeared from VAPs? To investigate, Norfolk Medical Products, Inc, commissioned a study to determine if sludge, often located underneath the septum in VAPs, still exists in today's ports.

For more than 30 years, the septum has remained a flat, circular silicone rubber disk. Aside from the Vortex (Angiodynamics, Latham, NY), which offers a toroidal chamber, and the SportPort (Norfolk Medical Products, Inc, Skokie, IL), which offers a spherical chamber, the chamber has remained a cylindrical space with a flat bottom and straight walls with corners. This design creates a cylindrical chamber with a flat top and bottom. Because these technologies have remained largely unchanged, the problems associated with this configuration have been documented and have been compensated for through various medical interventions such as the use of thrombolytics, lysing agents, and pulsatile flushing of ports. The cylindrical chamber design of such ports promotes the formation of sludge in the corners and in the dead spaces. In addition, the conventional perpendicular outlet produces chaotic chamber flow and inadequate clearance, thereby contributing to sludge buildup.

The major issues encountered with this design are the presence of sludge and sludge-related patient risks such as occlusion, VAP-related bloodstream infections (VAP-BSIs), increased costs for health care providers to remedy such complications, and a lack of awareness by the medical community of specific chamber flushing volumes for different ports.

Several studies note the presence of sludge as a risk factor for increased incidence of VAP-BSIs. A study by Douard

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et al[2] analyzed the relationship between accumulation of infected clots under the silicone septum of the reservoir and the occurrence of VAP-BSIs, finding that the "infected deposits that accumulate under the VAP septum are the source of VAP-BSI." Similarly, a study by Longuet et al[3] found that "the reservoir is the key piece of the catheter-involved bateremia." Whitman et al[4] found that "the most predictive culture specimen in a potentially infected port is the thrombotic material inside the reservoir."

Furthermore, the presence of sludge is directly correlated to higher occlusion rates. A study by Athale et al[5] demonstrated "rates of partial occlusion of up to 33%, and total occlusion up to 28% in VAPs." Of all VAP-related complications, occlusion is the most frequent. Overall, the occurrence of sludge in implanted vascular ports may increase patient-associated risks as well as costs to health care providers.[6-8]

For the most part, existing technologies have not adequately addressed these issues, so where has the sludge gone? This article presents the results of Norfolk Medical's pilot study.

Methods

At the onset of the study, a mailer was sent to Association for Vascular Access members describing the study and requesting that explanted ports be sent to Norfolk Medical for examination. All Health Insurance Portability and Accountability Act of 1996 guidelines were followed. Members were encouraged to provide 1 or more of the following: a photo of an explanted port, an explanted port with the septum intact, or an explanted port with the septum removed and containing sludge. A prepaid return envelope along with appropriate packaging, conforming to regulations concerning handling and transportation of biohazardous waste, was supplied on request to participants. In addition, a kit with gloves, scalpel, biohazard bag, and cotton swabs was supplied.

Participants were asked to complete a form identifying the port and the catheter; if possible, the implantation site; the reason for placement; the length of use; and the reason for explantation. Information pertaining to flushing frequency, chemotherapy regimen, or problems related to the use of the port was not requested because the goal of this work was just to determine the presence of sludge. Upon receipt of the explanted port(s), the information on the form was recorded and a photograph of the port was taken. The port septum was carefully removed to examine for the presence of debris under the septum. Another photograph was taken of the removed septum and the exposed port chamber. Gross inspection of the port was also performed and observations recorded. No analysis of the debris was performed.

Explanted ports were received between March 2012 and September 2012. Following port analysis, a report with photographs of the removed septum and the port chamber was sent to the participant.

Results

The study was undertaken as a limited, uncontrolled prospective study requesting recently explanted ports for examination. There were no exclusion criteria. Explanted ports (N = 82) were received from several locations in both the United States and Canada. The results of the study indicated:

- Sludge exists: 18.6% of explanted vascular access ports examined contained sludge in the port chamber.
- Sludge was found in ports from all manufacturers represented in the study.
- Sludge does not have a common appearance or consistency. Gross examination revealed that some sludge is dull and irregular, some bright and smooth with evidence of what appears to by crystals, and some irregularly colored with white areas throughout. Sludge consistency varied from thick and viscous to gelatinous to thin and fluid.

The Figure highlights some sludge-filled examples of explanted ports received during the study.

Conclusions

Sludge does occur in today's ports. Although our pilot study confirmed the incidence of sludge in explanted ports, it did not attempt to answer many vital questions related to the occurrence of sludge. That is, only gross analysis was performed and any sludge found was not cultured.

The occurrence of sludge in implanted VAPs may have a significant influence on patient outcomes as well as patient satisfaction. We believe our study lays the groundwork for this program/analysis to be continued and enhanced by an independent medical organization, such as the Association for Vascular Access, that focuses on the significance of sludge and its effect on patient outcomes, both clinically and from a cost standpoint. With significant cost containment measures coming, the need for methods and improved practices to reduce the costs related to complications should be paramount in clinical settings. The results of our work indicate that a randomized prospective clinical study should be undertaken to answer specific medical clinic-related prevention questions and to determine:

- The makeup of sludge and how drugs and/or infusates, including contrast media used during power injections, contribute to the buildup of sludge.
- Risks associated with sludge formation related to intravascular device-related infection as well as thrombotic and nonthrombotic partial and complete occlusion.
- Best practices for flushing and locking implanted ports and or ways to reduce the incidence of sludge.

Although more than 1,000 requests to participate were mailed to Association for Vascular Access members and other health care professionals, we believe our pilot study was largely limited because it was performed by a medical device manufacturer with a specific agenda. Although the ports received covered a wide variety of manufacturers and models, statistically, the number of ports received (N = 82) was insignificant compared with the number of ports implanted per year (~400,000). In any case, the results indicate that sludge does indeed exist in today's ports and that the incidence seen in the pilot study strongly suggests that this is an area where further study is appropriate. Furthermore, we believe that given a viable solution that reduces the incidence of sludge buildup and resulting infections in addition to the costs related to the