The Port Clearance Test: Why it is Important to the Clinician

Mike Dalton MSIA, Natan Pheil BSBE, Jim Lacy BSN/RN/CRNI

Background / Abstract

In October, 1990, the US Food and Drug Administration (FDA) Center for Devices and Radiological Health Office of Device Evaluation; Division of Gastroenterology/Urology and General Use Devices, under the direction of Dr. Catharine Ulatowski, published the Guidance on 510(k) Submissions for Implanted Infusion Ports (Ports). According to the FDA, Guideline elements are recommendations to the manufacturer and non-binding. That is, a manufacturer may choose alternative approaches if the approach satisfies the requirements of applicable statutes and regulations. The Guidance describes the minimum requirements for testing of new technologies, based on studies of Class I (clinical experience), Class II (clinical experience and animal data), and Class III (animal and human data). In this investigation, however, only the clearance time was calculated. System filling and flushing were repeated 5 times beginning and ending of the conductance change; and total clearance time, the sum of delay time and dilution time. For elapsed between the onset of flushing and a change in conductance; dilution time, the amount of time elapsed from the

Introducation

Norfolk Medical Products, Inc., Skokie, IL, has developed a new port with a spherical chamber. The spherical chamber shape eliminates all corners where ‘sludge’ buildup has been shown to occur, simultaneously reducing the dead space, or chamber volume, compared to similar sized ports. It was hypothesized that the spherical chamber would have a minimal impact on CFV. To determine the validity of this hypothesis, the Port Clearance Test was performed on ports from two leading port manufacturers as well as the spherical chamber port (Norfolk Medical). These ports were tested because they provide a wide range of chamber shapes, from cylindrical to toroidal to spherical (see Figure 1, below), they provide a wide range of port manufacturers, and they are all of similar size. Note, the images in Figure 1 are representations only and are not meant to imply exact chamber shapes and/or volumes.

Methods

The Port Clearance Test was based on the FDA document ‘Guidance on 510(k) Submissions for Implanted Ports; October 1990.’ The document suggests creating two different idependent impedence solutions, a fluidic solution of 160 ohms and a flushing solution that has a resistance less than the filling solution; filling the port with the filling solution; then rejecting the flushing solution at a constant rate. The results produce a record of impedance change, dilution time, and clearance volume for a given flow rate. Similarly, one can arrive at the same results by using an alternative approach that measures the change in conductivity between the two solutions. Conductivity, measured in micro-ohms per centimeter (micro-ohm/cm) for this study, is a measure of how well a solution conducts electricity. The filling solution selected was a salicylic acid and sodium nitrate solution at a concentration of 0.565 M. Conductivity (mmhos/cm) for this study, is a measure of how well a solution conducts electricity. The flushing solution selected was deionized water. To measure the conductivity of both of these solutions, and therefore, accurately monitor the conductivity change that occurs when the flushing solution replaces the filling solution, a conductivity cell/meter attached to the end of the catheter was used. Prior to testing, both solutions conductivity was measured. The glycerine/saline/saltwater solution measured 160 mmhos/cm and the deionized water measured 0 mmhos/cm. Both beakers of solution were placed in a water bath at 37°C ± 2°C to ensure temperature equilibrium.

To measure the conductivity of both of these solutions, and therefore, accurately monitor the conductivity change that occurs when the flushing solution replaces the filling solution, a conductivity cell/meter attached to the end of the catheter was used. Prior to testing, both solutions conductivity was measured. The glycerine/saline/saltwater solution measured 160 mmhos/cm and the deionized water measured 0 mmhos/cm. Both beakers of solution were placed in a water bath at 37°C ± 2°C to ensure temperature equilibrium.

Using the deionized water as the reference solution, we were able to determine the conductivity change that occurs when the flushing solution replaces the filling solution. This change is expressed in terms of percent change from the reference solution.

Results

The figures above represent the average Chamber Flushing Volumes (CFV) obtained during testing.

Discussion

Data from this study confirms the hypothesis that the chamber geometry offered by the spherical chamber results in a lower CFV. Using the Norfolk Medical 'Rounded – “A”' chamber port, the results showed the highest CFV, clocking in at 33.4% of the total volume flushed. The next highest CFV was determined by the 'Cylindrical – B', which was measured at 20.7% of the total volume flushed. The spherical chamber port had the lowest CFV, clocking in at 9.8% of the total volume flushed. This sets it apart from the other ports, which, according to the data, are independent of the flow rate to reduce their CFV. As such, this adds another level of safety to the flushing of the port as hand-delivered flow rates in the field are most certainly variable, and a minimum hand-delivered flow rate does not have the same impact of a CFV based on port size and manufacturer; however, typical recommended flushing volumes range from 5 – 50 mL. Based on the current data, the flushing volumes required for the spherical chamber port (2.5 mL) provides a safety factor of 2 – 50. While it is difficult to conclude what constitutes a “good” safety factor or an adequate flush volume, Norfolk Medical recommends a flushing volume for its ports of 3x the CFV.

Further review of the data indicates that the higher the flow rate, the less the average clearance volume. This does not hold true, however, in the case of the spherical chamber port. The data suggests that its clearance volume is independent of flow rate. That is, regardless of the flow rate, the port will clear with the same volume of fluid. This result is not attributed to the flow rate, according to the data, as the flow rate to reduce their CFVs. As such, this adds another level of safety to the flushing of the port as hand-delivered flow rates in the field are most certainly variable, and a minimum hand-delivered flow rate does not have the same impact of a CFV based on port size and manufacturer; however, typical recommended flushing volumes range from 5 – 50 mL. Based on the current data, the flushing volumes required for the spherical chamber port (2.5 mL) provides a safety factor of 2 – 50. While it is difficult to conclude what constitutes a “good” safety factor or an adequate flush volume, Norfolk Medical recommends a flushing volume for its ports of 3x the CFV.

Clinical Significance

While the primary aim of the study was to determine the efficacy of the Norfolk Medical spherical chamber port design, the data suggests that the CFV is a very important figure to know and understand. If port manufacturers are not recommending adequate flushing volumes, this may lead to sludge build-up and further complications. Withdrawal occlusion, sluggish flow, and complete occlusion may be directly related to inadequate flushing protocols, allowing for trapping of particulate matter, drug residual, blood, minerals, and lipids. Such complications can be both dangerous and costly to the patient and Institution. It is up to the clinician to recognize that flushing volume may vary from port to port to achieve the best patient outcomes. It may be important to ask the Port manufacturer for Port Clearance testing data to determine the minimum flushing requirements.

Conclusions

• The spherical chamber port has the lowest CFV
• Hand-delivered flow rates are required to lower the CFV for all ports EXCEPT the spherical chamber port
• The spherical chamber port CFV is independent of flow rate
• Inadequate flushing volumes and protocols may lead to sludge build-up and other complications which can be both dangerous and costly
• To determine minimum flushing requirements, it may be important to ask the Port manufacturer for Port Clearance testing data
• This procedure offers useful data for the comparative analysis of clearance volumes in Vascular Access Systems

References


"Guidance on 510(k) Submissions for Implanted Infusion Ports." (October 1, 1995). Center for Devices and Radiological Health, Office of Device Evaluation Division of Gastroenterology/Urology and General Use Devices, pp. 4-8
