escaped quality control measures implemented at that time.

What can be done for timely recognition of such errors? Obviously, any abnormally high CVP signals volume overload, right heart failure, cardiac tamponade, superior caval vein obstruction, and/or catheter or pressure line kinking/obstruction. In addition, results of all technical measurements should be checked for making sense in the individual patient’s clinical setting. Furthermore, suspicious pressure measurements should be crosschecked by measurements via another catheter or catheter lumen, or against a second independent method.

We recommend that pressure transducers should also be checked routinely before connection to a patient for an improperly high continuous flow of rinsing solution during zero calibration with the transducer’s stopcock open to atmosphere. Specifically, the flow observed should not exceed two drops per minute. Furthermore, during anesthesia, any implausible high CVP, in addition to a check for free aspiration of blood via the respective catheter, should be checked by clamping the transducer’s rinsing line. If the CVP remains unchanged, the described error can be excluded.

Otherwise, faulty pressure measurements can evoke misinterpretation of the patient’s cardiovascular situation and wrong treatment regimen with potentially disastrous effects.

References

4. Meyer RM, Kimovec MA, Hefner GG: Cable-testing device fails to indicate that hypertension is artifactual. J Clin Monit 1993; 9:54–9

In Reply:—We would like to make the following comments in response to the article by Dr. Görlinger et al. (Görlinger K, Kehren CJ, Peters J: Mini-epidemic of erroneous central venous pressure measurements due to malproduction of a specific part of a pressure transducer system. Anesthesiology 2009; 110:1417–8).

In 2008, Smiths Medical became aware of a manufacturing fault with its pressure monitoring kits; this fault has since been rectified. The products involved were LogiCal®, NovaTrans®, and TranStar® invasive pressure monitoring kits with trigger flush device, product codes DPSxxx/XX/XXX/XX/XXX/XX/XXX and SXxxxx and manufactured between October 2007 and February 2008. In the affected kits, flow rates were higher than the product specification of 3 ml/h due to communication between the slow-flow orifice and the flush. The cause of the fault was identified as an assembly problem, and corrective actions were implemented to prevent reoccurrence.

Customers who had purchased sets manufactured within the specified timeframe were notified of the problem via a field safety notice, and regulatory bodies were informed.

Customers were advised to perform a precheck during priming of each device and before connecting to the patient to identify whether the issue was present. Separate instructions to assess kits already in use were also provided. Customers with affected kits were advised to contact their sales representative for free collection and replacement.
The following procedure is recommended for testing the flow rates of these kits:

**Pretest:**

1. Prime the set under gravity as described in the Instructions for Use.
2. Pressurize the set to 300 mmHg as described in the Instructions for Use and operate the trigger flush device for 2-3 s and observe the device, as follows:
   a. During flushing, fluid should flow freely from the end of the set, and fluid flow will be visible in the drip chamber.
   b. After flushing, fluid should not be visibly flowing from the end of the set, and flow in the drip chamber should be between 2 drops per minute and 7 drops per minute for the upper end of the performance specification. This flow rate is affected by the number of lines being used; for 2 lines, 12 drops per minute will be equivalent to the upper end of the performance specification; for 3 lines, 14 drops per minute are equivalent to the upper end of the performance specification; for 4 lines, 18 drops per minute are equivalent to the upper end of the performance specification.
   c. If a higher flow is observed after flushing, the device is not functioning correctly and should not be used.

Devices already in use with patients can be checked by observing the flow rate in the drip chamber as described above. When the flush is not being operated, the flow rate observed in the drip chamber should be:

- No more than 7 drops per minute for a single line
- No more than 12 drops per minute for a double line
- No more than 14 drops per minute for three lines
- No more than 18 drops per minute for 4 lines

If the flow rate in the drip chamber is greater than this, it should be discarded and replaced with a new device that has passed the pretest.

Smiths Medical takes the quality of its products and the satisfaction of its customers very seriously. If a product fails to meet expectations, they should not hesitate to contact us. We investigate all complaints thoroughly and undertake any necessary corrective actions.

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