ELECTROMANOMETRIC blood pressure measurements are routine in critically ill patients, and many interventions are based on correct measurements. We report a mini-epidemic of erroneous central venous pressure measurements due to faulty pressure transducer manufacturing resulting in wrong therapeutic decisions.

Case Report

For invasive pressure monitoring in patients undergoing cardiovascular surgery, we use a color-coded multitransducer system with a single pressurized bag of normal saline for line rinsing. On one day three patients undergoing cardiac surgery attracted attention because central venous pressure (CVP) measured via the atrial port of a pulmonary artery catheter (model 680100, 7.5-French, 110-cm; Becton Dickinson Critical Care Systems, Singapore) was much higher than mean pulmonary artery pressure. This persisted after transducer recalibration and assurance of normal gain settings and also when the pressure recording line was connected to an indwellig trilumen CVP catheter (model UE-24703-ND, 7-French, 30-cm; Arrow Deutschland, Eding, Germany). A change of the pressure transducer system and of connecting cables to the monitor did not alter these findings.

However, CVP readings were considered implausible because there were no history or clinical signs of venous congestion or of tricuspid valve regurgitation, and transesophageal echocardiography revealed no right ventricular distention.

After clamping the transducer’s rinsing line, CVP decreased substantially in all patients (27 ± 4 mmHg to 10 ± 4 mmHg, mean ± SD), and a typical CVP tracing was seen on the monitor’s display. After declamping, measured CVP again increased to abnormal values (fig. 1). Moreover, rinsing solution leaked continuously out off the transducer’s stopcock during transducer zeroing. Accordingly, false pressure readings resulting from excessive flow of rinsing solution were suspected.

After withdrawal of the pulmonary artery catheter tip to a right atrial position, CVP measured via its distal lumen showed normal CVP values similar to the measurements obtained with the CVP transducer with its rinsing line clamped (fig. 1).

Only one of the system’s three pressure transducers (the CVP transducer) was affected in each patient. Four additional dysfunctional transducers were identified after they had already been connected to patients, and further nine faulty transducers were detected during an implemented check of the systems before connection.

Accordingly, we mailed alert warnings to all intensive care units of our hospital, the transducer system’s manufacturer (Smiths Medical Deutschland GmbH, Kirchseeon, Germany), and to regulatory institutions. Chart review of patients treated before problem detection revealed at least one patient treated inappropriately because of erroneously high CVP readings. Treatment by diuretics and fluid restriction had been stopped only in a preshock state, when transesophageal echocardiography had demonstrated cardiac volume depletion rather than suspected volume overload or cardiac tamponade.

Subsequent investigations showed that all affected transducer systems derived from the same charge and had been delivered to various German hospitals. Upon activation of a transducer’s trigger flush knob, 60 ml/min of isotonic saline is normally delivered with the rinsing solution’s pressure maintained at 200 mmHg. With the trigger flush knob in its resting position, rinse solution continuously flows through a laser drilled hole only at 5 ml/h and flow does not interfere with correct pressure measurements.

Microscopic examination of the dysfunctional transducers’ inside by the manufacturer revealed a roughened surface and additional holes resulting from excess amounts of solvent agent applied manually during production. This was responsible for an increased flow of rinsing solution (up to 120 ml/h) and for subsequently and artifactually increasing CVP measurements, as outlined schematically in figure 2.

Discussion

This report shows that errors in manufacturing or quality control of pressure transducers can be responsible not only for an occasional complication related to a random malfunction of a single transducer, but also have the potential to evoke an epidemic-like outbreak evoking false treatment and to affect critical care areas of whole hospitals.

This is even more troublesome because the error described cannot be detected by checking the transducer’s correct zeroing at atmospheric pressure and its gain by electrical or mechanical means (saline column). In fact, if the patients had not simultaneously received pulmonary artery and CVP monitoring in side-by-side operating rooms, erroneously high measurements of CVP might have gone unnoticed or attributed to cardiac disease.

The manufacturing fault reported here has not been previously described. According to an initial verbal communication of the transducer manufacturer’s representative, this kind of malproduction has a frequency of 1 of 1,000 transducer systems. In the present outbreak, however, a single worker by application of too much solvent had manufactured faulty blue transducers that were later assembled to a multitransducer setup, and this fault had
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 regimens 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 DPSxxxxxx/MX95xxxx/MX96xxxx/MXxxx and Sxxxxxxx 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 recurrences.

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.