Preventing Vincristine Administration Errors: Does Evidence Support Minibag Infusions?

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Although vincristine sulfate is indicated for IV use only, it has been inadvertently administered intrathecally. Accidental vincristine administration via the spinal route (intrathecally via a lumbar puncture or intraventricularly via an Ommaya reservoir) causes rapid sensory and motor dysfunction, usually followed by encephalopathy, coma, and death (Schulmeister, 2004). Autopsy findings include grossly edematous and congested brain and spinal cord tissue, with axonal degeneration and myelin loss of the spinal nerves (Kwack et al., 1999; Williams et al., 1983).

The incidence of this type of “wrong route” medication error is unknown, but 37 cases have been reported in the literature and 8 were reported to the United States Pharmacopeial (USP) Convention, Inc., and Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Additional cases have not been reported but have prompted litigation or appeared in the media (Joint Commission on Accreditation of Healthcare Organizations [JCAHO], 2005; Schulmeister, 2004).

Inadvertent intrathecal vincristine administration occurs when a syringe containing vincristine intended for IV administration is mixed up with another syringe that contains a drug to be given intrathecally, such as methotrexate or cytarabine. It also can occur when a vincristine-filled syringe is placed in close proximity to a syringe containing intrathecal chemotherapy and healthcare providers incorrectly assume that vincristine is an additional intrathecal drug to be injected. Mislabeling of syringes, failure to check a prescriber’s treatment plan and medication orders, and unfamiliarity with cancer chemotherapy also may cause or contribute to this type of error (Fernandez, Esau, Hamilton, Fitzsimmons, & Pritchard, 1998; JCAHO, 2005).

Vincristine administration errors prompted USP labeling requirements and standards for vincristine packaging, which include cautionary labeling that states “FATAL IF GIVEN INTRATHECALLY. FOR IV USE ONLY. DO NOT REMOVE COVERING UNTIL MOMENT OF INJECTION.” Vincristine syringes also are placed in overwraps imprinted with the warning. Despite the USP standard, a patient died when vincristine was dispensed without a warning label on the syringe or outer wrapper and the drug was inadvertently administered intrathecally along with the patient’s prescribed intrathecal chemotherapy (ISMP, 2003).

Various recommendations to eliminate the risk of inadvertent intrathecal vincristine administration have been proposed. Consensus is that (a) healthcare providers who prescribe, prepare, and administer intrathecal chemotherapy should receive specialized training; (b) orders for intrathecal chemotherapy should be written separately from orders for IV chemotherapy, and, ideally, an order form should be designed specifically for intrathecal chemotherapy; (c) intrathecal chemotherapy should be packaged and transported separately from IV or other drugs; (d) intrathecal chemotherapy should be delivered to patient care areas immediately before administration and should not be stored in patient care areas, (e) “time out” should be conducted immediately preceding intrathecal chemotherapy administration; and (f) a “do not disturb” sign should be posted while intrathecal chemotherapy is being administered (Department of Health, 2003; Gilbar & Carrington, 2004; ISMP, 2003; JCAHO, 2005; Root & the British
Vincristine Infusions

In July 2005, JCAHO issued a recommendation to “dilute intravenous vincristine in a volume—ideally for IV infusion in a minibag—that precludes administration via the intrathecal route” (JCAHO, 2005, p. 2). Some clinicians have interpreted the recommendation to mean that vincristine should not be placed in syringes and note that infusing vincristine via minibags is a major practice change.

The majority of hospitals in Australia prepare vincristine in minibags. Stefanou and Dooley (2003, p. 2044) noted that “this is the only method of completely eradicating the risk of this drug accidentally being given intrathecally ... since all published reports of intrathecal vincristine administration have been associated with preparation of the drug in a syringe.” Vincristine is prepared in 50 ml normal saline infusion bags and administered to adults over 5–10 minutes. The same approach is used for pediatric patients but with a smaller volume and slower rate of infusion (Stefanou & Dooley). Womer and Bickert (2003) disputed that approach, noting that pediatric patients commonly receive vincristine via peripheral IV devices, and vincristine infusion greatly increases the risk of extravasation injuries.

In the United Kingdom, syringes are used for vincristine administration. However, larger syringes (e.g., 10 ml or larger instead of 3–5 ml syringes) are used. For adults and children 10 years of age and older, vincristine is diluted to a concentration of 0.1 mg/ml and doses are provided in 10 ml or larger syringes. For children younger than age 10, vincristine is provided undiluted at a concentration of 1 mg/ml in syringe sizes appropriate for measurement of the doses (Department of Health, 2003).

Diluting and placing vincristine in 10 ml or larger syringes is thought to be a deterrent to inadvertent intrathecal administration. However, in two case reports, vincristine was placed in a 10 ml and a 20 ml syringe and accidentally administered intrathecally (Alcaraz, Rey, Concha, & Medina, 2002; Meggs & Hoffman, 1998). The case reports led Gilbar and Carrington (2004) to conclude that “the safest method of eliminating the potential for spinal installation of vincristine remains the abolition of the syringe as a means of administration” (p. 464).

Although banning the use of syringes for vincristine administration would eliminate the risk of inadvertent intrathecal administration, other issues must be considered. The first issue is patient safety. Womer and Bickert (2003) expressed concern that administering vincristine as minibag infusions greatly increases the risk of extravasation injuries. Many clinicians share the concern. However, does any evidence support the concern?

Data suggest that the risk of vincristine extravasation injuries is very low regardless of how vincristine is administered. In December 2005, researchers reported the results of a retrospective survey of 68 cancer treatment centers in Australia that examined the incidence of vinca alkaloid extravasations. When syringes were used to administer 37,084 doses of vincristine, 11 extravagations occurred (0.03%). When 7,255 doses of vincristine were administered as minibag infusions, 3 extravagations occurred (0.041%). The researchers concluded that the extravasation incidence was similar and infrequent. Although errors occur infrequently, they are often lethal and almost always are preventable.

Consensus exists that the JCAHO recommendation to administer vincristine as IV infusions via minibags has the greatest potential to reduce the risk of inadvertent intrathecal vincristine administration when compared to other risk-reduction strategies. However, for many clinicians, minibag vesicant infusions represent a major practice change and raise the issues of extravasation risk, cost, and patient monitoring.

Diluting vincristine in volumes that preclude administration via the intrathecal route also is an option that is consistent with JCAHO recommendations. Placing vincristine in 10 ml syringes or larger and consistently adhering to USP labeling requirements are safety strategies that reduce the likelihood that vincristine-filled syringes will be administered intrathecally.

Despite vincristine labeling requirements and increased awareness of harm that occurs when vincristine is accidentally administered intrathecally, wrong route vincristine errors continue to occur.
Regardless of which approach is used in clinical practice (larger size syringes versus minibags), additional measures are needed to avoid accidental intrathecal vincristine administration. They include staff education and training; policies that address chemotherapy dispensing; protocols that delineate IV and intrathecal chemotherapy preparation and administration procedures; general safeguards, such as triple-checking all doses of prepared chemotherapy prior to their administration; and close patient monitoring.

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References


