Accuracy in Intrathecal Drug Delivery with an Implanted Infusion System – Important Clinical Considerations

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BACKGROUND

Chronic intrathecal drug delivery requires an implanted device to dispense drugs safely, accurately and consistently to achieve and maintain therapeutic effect. As part of ongoing management, clinicians must understand the potential sources for variability, and then take steps to identify and minimize variability where possible. Variability in the refill process can be affected by 3 main areas: Environmental Factors, In Clinic Refill Variables, and Device and Refill Equipment Tolerances or Failures (Fig. 1). The fluid volume withdrawn from the pump at the time of refill compared to the expected volume displayed by the pump programmer should be similar. Discrepancies that are outside device accuracy specifications or greater than 2 mL should be evaluated to ensure patient safety.

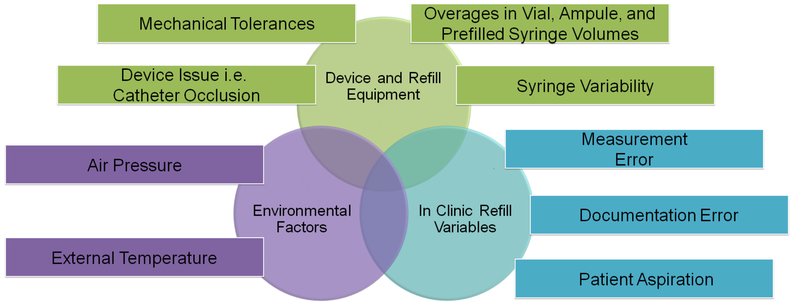

Figure 1: Potential sources of volume discrepancies.

OBJECTIVES

The objectives of this poster are to provide an overview of the potential known sources for variability that can contribute to a volume discrepancy at refill, context and guidance around situation assessment in the clinical refill process, and practical recommendations for clinical management.

MATERIALS AND METHODS

Published research evidence and best practice publications were reviewed, as were available internal and public databases providing relevant information on clinical practice and common issues encountered.

RESULTS

Assessing Refill Discrepancies in Published Literature

Prospective clinical studies typically assess accuracy from a cumulative perspective and provide a single result for system accuracy, such as 12-month accuracy of 1.01±0.04[1] (See Table 1) or 97.8±3.5[2].

Assessing Refill Discrepancies in a Clinical Setting

In the clinical setting, individual refill to refill variability is observed. This is potentially more reflective of the experience of the clinician in an "uncontrolled" setting. Careful monitoring of expected and actual refill volumes over time may help identify changes in device function that could impact therapy delivery and patient safety.

DISCUSSION

Recommendations for Reducing Variability

Ensure consistency during refill process

- Follow Best Practices[3] to ensure patient safety at every refill
- Reduce the number of variables in refill procedure:
  - Train staff to perform refill the same way each time
  - Maintain good documentation practices; track and trend actual and expected volumes
  - Utilize consistent suppliers for refill equipment (ie., syringes and tubing)
  - Utilize the same supplier for medication to minimize variation in tolerances and overages

Follow manufacturer's recommended refill procedure (Fig. 2)

Screen patients/caregivers for aberrant behavior, including potential drug diversion

Observe expected mechanical/performance characteristics of the infusion device used.

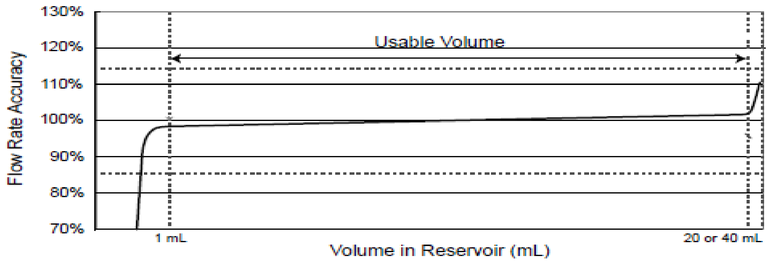

Figure 2: Infusion rate can vary based on reservoir volume; IFUs indicate not overfilling reservoir and not allowing volumes to drop below 1 mL

Table 1: SynchroMed II Clinical Accuracy[1]

Months from Implant	Subjects	Mean ± SD	95% Confidence interval of the mean	Median	Range (Min-Max)	Error
6	65	1.01 ± 0.05	1.00 – 1.03	1.01	0.88 – 1.24	1%
12	54	1.01 ± 0.04	1.00 – 1.02	1.00	0.91 – 1.10	1%

CONCLUSIONS

Some variation in observed volume discrepancies at refill (expected volume – actual volume) is to be expected in infusion therapy based on any number of potential sources. Further, prospective clinical studies that have evaluated refill accuracy indicate that a volume discrepancy may be observed in a single point in time, but may not reproduce itself in subsequent refill occurrences. In order to ensure patient safety, the refill clinician should follow the product recommendations, and then track and trend volumes, taking note if an observed discrepancy falls outside a defined range, such as a product specification percentage or an absolute volume recommendation of 2 mL for enhanced evaluation. As always, paying particular attention to any patient presenting with symptoms of withdrawal or overdose at the time of refill is most important to ensure patient safety.

REFERENCES

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