(Re)Design Of A Disposable Medication Delivery Device For Use With Soft Mist Inhalation Technology In An Invasive Mechanical Ventilation (IMV) Circuit

Summary

Almost 60% of all ICU patients require invasive mechanical ventilation (Dhanani et al., 2016). It also happens that 22% of these patients must have medications delivered to their lungs (Ehrmann et al., 2016). In order to do that, the solution needs to be aerosolised, using one of the existing nebulisation methods in combination with the medication delivery device (MDD). MDD serves as a connection port allowing the aerosol to be injected and combined with the airflow.

In association with Medspray, this study delved into the nuances of optimising medication delivery devices for invasive mechanical ventilation, particularly when integrated with Soft mist technology. The adopted research strategy was iterative, encompassing design, prototyping, and testing phases.

The research adopted a structured, iterative approach divided into several cycles to navigate this intricate challenge. Each cycle is built upon the insights and findings of the previous ones, thereby driving the project towards its objectives systematically. In the first cycle, the designs were based on existing market models. The primary goal was to understand the relationships between different geometries and performance, emphasising the minimisation of liquid deposition. As the cycles progressed, the designs underwent refinement, building upon the knowledge accumulated from prior iterations. This led to the identification of key design elements, such as the cross-sectional geometry, the design of the narrowing, the positioning of the aerosol inlet, and the overall length of the MDD. These elements played vital roles in determining the device's performance. For instance, elliptical geometries offered reduced deposition compared to their circular and triangular counterparts. Furthermore, devices with smaller cross-sectional areas showcased reduced deposition, attributed to the more efficient breaking of the aerosol stream and mixing the aerosol with the airflow.

When it came to testing, several different methods were used. Visual checks, Conductivity tests, Fluoresceine tests, and laser diffraction were employed to gauge the MDD's performance. Visual inspections allowed for immediate feedback on aerosol jet behaviour and deposition patterns. Conductivity tests were performed to verify the visual check results and quantify the deposition in the MDD and the rest of the circuit. Fluoresceine tests were crucial in quantifying liquid deposition in the filter but faced limitations due to pressure inconsistencies between the HPLC pump and the semi-manual syringe pump. Laser diffraction provided insights into droplet size distribution, a critical factor given the direct link between droplet size and the dose delivered to the lungs.

However, the research faced some limitations. Due to time restrictions, only a limited number of tests could be done. As the tests take only some of the details of real-life situations into account, the results of real-life testing will most likely be different.

The research recommends more extensive testing with larger sample sizes for future work. It also suggests testing under different conditions, such as varying airflow rates and humidified and heated airflow and using pressure-controlled ventilators. For mass production, the research suggests using injection moulding with materials like medical-grade Polypropylene (PP) or Polyethylene (PE).

Overall, this research provides a structured approach to MDD design and testing. While insights have been gained, further research is essential to ensure the MDD's effectiveness in real-world applications.

References

Dhanani, J., Fraser, J. F., Chan, H.-K., Rello, J., Cohen, J., & Roberts, J. A. (2016). Fundamentals of aerosol therapy in critical care. *Critical Care*, *20*(1), 269. https://doi.org/10.1186/s13054-016-1448-5

Ehrmann, S., Roche-Campo, F., Bodet-Contentin, L., Razazi, K., Dugernier, J., Trenado-Alvarez, J., Donzeau, A., Vermeulen, F., Thévoz, D., Papanikolaou, M., Edelson, A., Yoshido, H. L., Piquilloud, L., Lakhal, K., Lopes, C., Vicent, C., Desachy, A., Apiou-Sbirlea, G., Isabey, D., … AT@ICU Study Group. (2016). Aerosol therapy in intensive and intermediate care units: Prospective observation of 2808 critically ill patients. *Intensive Care Medicine*, *42*(2), 192–201. https://doi.org/10.1007/s00134-015-4114-5