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Utilization of Cysteine and Selenious Acid in Total Parenteral Nutrition Patients After FDA Approvals and Price Increases

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Background

The Unapproved Drugs Initiative (UDI) was launched by the Food and Drug Administration (FDA) in 2006. UDI required manufacturers to seek approval for products available on the market prior to stricter regulatory requirements. An unintentional consequence of UDI has been price hikes or shortages.[1] Cysteine and selenious acid are two examples of this initiative and subsequent price increases which occurred in 2019.

Cysteine is indicated as an additive in neonates and infants requiring parenteral nutrition (PN) to meet nutritional requirements when enteral or oral protein intake is inadequate.[2] It is also indicated for adults and pediatric patients who have severe liver disease and require PN. This new approval was aimed towards lowering the aluminum content in the product. Aluminum is a contaminant in PN components, which poses a risk for toxicity.[3] The average whole sale price (AWP) of the previous cysteine product was $28 per 10 mL vial compared to the approved product AWP of $99.80 per 10 mL vial.

Selenious acid is indicated as an additive for adult and pediatric patients receiving PN when oral or enteral nutrition is not possible to achieve recommended values.[4] This new product is a Pharmacy Bulk Package vial rather than a single use vial, and is a higher concentration.[5] The AWP of the previous selenious acid product was $2 per mL ($20 per 10 mL vial) compared to the newer product cost of $41.16 per mL ($412 per 10mL vial).[5]

To ensure optimal use, clinical guidelines were developed internally for these products.

Purpose

The study purpose was to assess the utilization of cysteine and selenious acid in PN patients by comparing usage before and after FDA approval for each additive.

Methods

This study is a multi-center, retrospective chart review of PN patients from a home infusion organization receiving either additive during Q1 and Q2 of 2019, 2020, and 2021. Usage of cysteine and selenious acid in patients receiving PN before and after FDA approvals of the products will be investigated. The new products were approved in Q2 2019, but not utilized until after Q2 2019.

Results

Usage of cysteine in years 2019, 2020, and 2021 occurred in 0.89%, 0.87%, 1.1% of PN patients, respectively *(Figure 1)*. The percentage of PN patients receiving cysteine who were less than one year of age in years 2019, 2020, 2021 was 15%, 25%, 25% respectively. Usage of selenium in years 2019, 2020, 2021 was 14.5%, 18.2%, and 16.9% of PN patients, respectively *(Figure 2)*.

Figure 1:

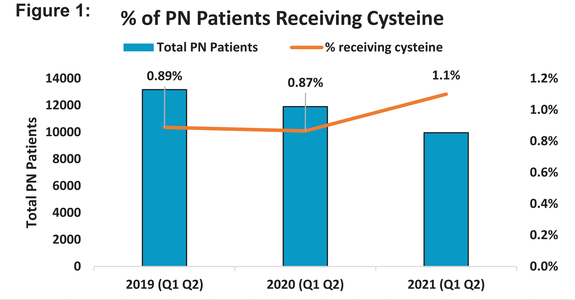


Figure 2:

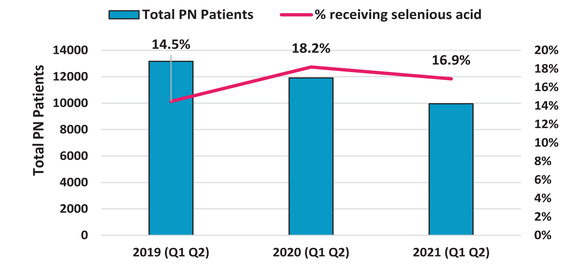
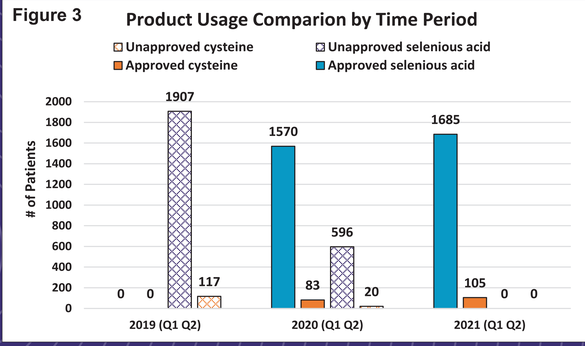


Figure 3



Discussion

Lower utilization was expected due to the goal to ensure more appropriate use. Overall, usage varied throughout the study period, however the change was marginal *(Figure 3)*. This may reflect appropriate usage of these products throughout the study period, including prior to development of clinical guidelines. A limitation of this study was the inability to calculate waste associated with the new vial size.

Conclusion

Usage of the products did not change significantly after FDA approval. After development of clinical guidelines, the study did not demonstrate a significant decrease in product usage. Further detailed analysis would provide further insight into adherence to the clinical guideline developed.

References

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Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Veronica Badani and Maria Giannakos. Nothing to disclose.

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