**BACKGROUND**

- The presence of learning curves (LCs) in the performance of clinical procedures has been firmly established, and their implications on clinical and economic outcomes have been highlighted in the literature.
- There is also evidence suggesting the presence of LCs in the context of clinical procedures.

Although the presence of LCs has long been accepted as a fact of medical device trials, recent studies suggest that clinical trial LCs can be underestimated. These underestimations may have a significant impact on clinical outcomes, especially when the success of outcomes depends on patient selection and LCs.

**OBJECTIVE**

- To understand whether the LC effect present in the PROWESS trial influenced the estimated cost-effectiveness of DrotAA in patients with severe sepsis.
- To determine if the LC effect influenced the incremental cost-effectiveness ratio (ICER) for DrotAA using the data that excluded LC patients.

**METHODS AND FINDINGS**

- To understand whether the LC effect present in the PROWESS trial influenced the estimated cost-effectiveness of DrotAA in patients with severe sepsis, we reviewed the product labels and HTAs for DrotAA.
- We also reanalyzed the incremental cost-effectiveness ratio (ICER) for DrotAA using the data that excluded LC patients.

**DISCUSSION**

- Although follow-up studies to the PROWESS trial indicated that DrotAA was effective in patients with severe sepsis, the impact of LCs on the cost-effectiveness of DrotAA may have been underestimated.
- This finding suggests that the presence of LCs in clinical trials may have implications for the cost-effectiveness of medical devices and drugs.

**REFERENCES**


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**Clinical Trial Learning Curves May Impact Both Clinical and Economic Outcomes and Influence Health Technology Assessment and Reimbursement Decision Making**

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**Abstract**

- The presence of learning curves (LCs) in the performance of clinical procedures has been firmly established, and their implications on clinical and economic outcomes have been highlighted in the literature. There is also evidence suggesting the presence of LCs in the context of clinical procedures.
- Although the presence of LCs has long been accepted as a fact of medical device trials, recent studies suggest that clinical trial LCs can be underestimated. These underestimations may have a significant impact on clinical outcomes, especially when the success of outcomes depends on patient selection and LCs.

- To understand whether the LC effect present in the PROWESS trial influenced the estimated cost-effectiveness of DrotAA in patients with severe sepsis, we reviewed the product labels and HTAs for DrotAA. We also reanalyzed the incremental cost-effectiveness ratio (ICER) for DrotAA using the data that excluded LC patients.

**Conclusions**

- Although follow-up studies to the PROWESS trial indicated that DrotAA was effective in patients with severe sepsis, the impact of LCs on the cost-effectiveness of DrotAA may have been underestimated.
- This finding suggests that the presence of LCs in clinical trials may have implications for the cost-effectiveness of medical devices and drugs.