

# Comparative evaluation of Bortezomib consumption based on the dosage form and the collection device used for reconstitution.

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## Context and purpose

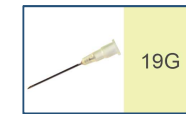
- Context :**
  - Vials of Bortezomib EG ready-to-use solution, 3.5mg/1.4ml vials
  - Use of Spike CH-72<sup>®</sup>ICU Medical for the preparation of Bortezomib needles : feedback from the preparers in favour of better needle efficiency
  - Low volumes handled : loss of product
- Purpose :**
  - Evaluate the consumption of Bortezomib EG (3.5mg/1.4ml in solution) according to the device used under isolator :
    - Spike CH-72<sup>®</sup>ICU medical, one spike per vial
    - Needle 40 mm 19G with a dead volume of 0.071 ml, one needle per preparation

## Matériel et méthode

- Monocentric comparative study**  
**Two periods of 6 and 3 weeks respectively :**
  - Period A Spike CH-72<sup>®</sup>ICU medical exclusive use of Spikes (one per vial) from 01/11/2019 to 21/11/2019 and 02/12/2019 to 20/12/2019
  - Period B Needle 40 mm 19G exclusive use of needles (one per preparation) from 03/02/2019 to 21/02/2020
  - The main evaluation criterion: percentage of loss of volume of Bortezomib in relation to the total volume used for the preparation



Spike CH-72<sup>®</sup>ICU medical



Needle 40 mm 19G

## Résultats

	Period A : Spikes	Period B : Aiguilles
Number of preparations	230	110
Total prescribed dose in mg	450,73	209,38
Average prescribed dose in mg (IC 95%)	1,9597 (1,9097-2,010)	1,9035 (1,8219-1,9851)
Theoretical number of vials	128,78	59,82
Number of vials used	156	73
Total dose used in mg	546	255,5
Loss of mass in mg	95,27	46,12
Percentage of loss	17,45 %	18,05 %
Average volume lost per vial in ml	0,244	0,253
Annual estimate of additional costs in euros	38 900	40 200



Bortezomib EG<sup>®</sup> vial's  
3,5mg/1,4ml

## Discussion

- Bias :**
  - All the preparers are trained to use both devices but...
    - Handling bias depending on the operator
    - Different frequency of manipulators according to A/B periods
  - Taking into account product losses for various reasons (expired residues, broken bottles, ...)
    - Two leftovers not used during the needle period: 1.1 ml and 0.67 ml leftover
  - Error in the choice of the device used according to the period
    - No cases reported to the preparers
- Compared to the CHARRA F study, SFPO 2017 congress, which similarly studied VELCADE lyophilisate :**
  - Confirmation of the probable superiority of spikes (10.70% loss of material compared to 12.86% for needles)
  - Savings of 16,000 euros per year compared to needles
  - Impact of dead volume of needles: 50% of material loss is due to dead volume
- Our study shows a slight superiority of the spikes:**
  - 17.45% against 18.05% loss of material
  - 40,200 extra cost to the community for needles compared with 38,900 for spikes saving of 1,300 euros on average per year in favour of spikes
  - 42.34% of the material loss due to this dead volume (Vm for 0.071ml needles)
  - Average loss of 0.244 ml and 0.253 ml per vial for spikes and needles respectively
  - Two solutions
    - Overfilling of the bottles by the laboratory ? 1.7 ml compensates for the loss ?
    - Vials with a higher volume (5 ml / 10 ml) to minimise the relative loss per vial ?

## Conclusion

- Significant pharmaco-economic impact Significant cost to the community
- Losses multiplied by the number of vials used and opened

### Solutions to compensate for these losses?

- Overfilling of vials by the laboratory
- Vials with a higher volume (5ml / 10ml) would not change the absolute loss but would decrease the relative loss

- Needles no more or less effective than spikes...
- Despite the feelings of the preparers