Characterising capsule puncture of different capsule types following patient actuation of a dry powder inhaler

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PURPOSE

Gelatin capsules have been used in dry powder inhalers (DPI) since 1971. More recently hypromellose capsules have also been used. Laboratory studies have compared the puncture properties of these two capsules and have shown that hypromellose capsules have superior puncturing properties in terms of the better uniformity of the holes and less shell particles shed in the process. No work has been published on their in-use performance. The aim of this study is to characterise the puncture performance of HPMC and gelatin capsules when perforated by a two-pin DPI operated by a member of the public to determine the inter- and intra-individual variability.

METHODS

Purpose of methods: Previous experience with inhalers, None 24, with MDI 11 and with a non-capsule DPI 1: Witnessed inhalers in use, 17 had and 19 never.

Test equipment:
- Plastiape® Monodose Dry Powder Inhaler Mod. 7, 2-pin
- Inhalation grade empty hard capsules, Qualicaps Europe, size 3, gelatin and HPMC (Quali-V®-I).

Capsules were packed, 5 at a time, in screw-cap plastic bottles labelled with a code.

Punctured capsules were placed in a bespoke holder to ensure the capsule was orientated vertically. The dome of the cap and body of each one was imaged using a light microscope (Amscope®, USA).

Total areas of the capsule ends and puncture holes were measured by Image J analysis of the micrographs. The puncture area was defined as the puncture hole and excluded the area were the flap was visible and partly blocking the opening. The puncture area was expressed as a percentage of the dome area.

RESULTS

Punctures in HPMC capsules (cap 1.88 ± 0.80%, body 1.72 ± 1.08%, body 2.89% ± 1.34%), see Figure 1.

Results for gelatin were influenced by their brittleness; 2 capsules (1cap & 1 body) had large holes where pieces of shell wall had broken off.

The punctures were not all central in the capsule domes. The deviation was greater for the bodies. 50% for HPMC and 35% for caps, probably being caused by the body having a smaller diameter than the cap, allowing this end to move more in the capsule chamber, see Figures 2 & 3.

CONCLUSIONS

Both the size and shape of punctures created in a capsule when people used a two-pin DPI were more reproducible for hypromellose than for gelatin capsules. Patient factors such as age, gender and previous experiences with an inhaler appear to have little influence on the puncture characteristics of capsules.

BIBLIOGRAPHY


Figure 1. Mean puncture area for each participant for both capsules

Figure 2. HPMC capsules: A, central hole, B, C & D, non-central holes. B flap partly closed

Figure 3. Gelatin capsules: A, central hole, B, C & D, non-central holes. B flap partly closed, C, flap missing, D broken cap