Lubricious polymer coatings are increasingly used on intravascular devices to facilitate easier access and navigation through tortuous blood vessels. Recent reports highlight the separation and downstream embolism of polymer particles affecting the vasculature and various organs” Chopra (2019).

Abstract:

Lubricious polymer coatings are increasingly used on intravascular devices to facilitate easier access and navigation through tortuous blood vessels. Recent reports highlight the separation and downstream embolism of polymer particles affecting the vasculature and various organs. The Food and Drug Administration (FDA) acknowledges polymer coating embolism as an iatrogenic complication of intravascular devices and continues to close gaps in standards related to coating integrity. The Association for the Advancement of Medical Instrumentation established particulate testing as an industry standard for evaluating coating integrity of intravascular devices. The FDA recognizes this standard; however, challenges exist in setting particulate limits that may compromise device function without sufficient clinical data. The microscopic nature of polymer emboli not visible with available imaging modalities has impacted reporting. This has also resulted in a reduced number of manufacturer-driven product development projects related to coating integrity. On the other hand, recent procedural trends have supported the innovation of coated devices with expanded indications, requiring particulate evaluations and release limits. This article
proposes a methodology to set particulate limits for intravascular devices given existing clinical, regulatory, and manufacturing challenges. The approach with standardization requirements enables characterization, comparison, and evaluation of lubricious coatings from various manufacturers. It incorporates a step-by-step procedure that adds scrutiny to the application of coatings while ensuring device function is not impacted. Together with particulate assessments, clinicopathologic and animal studies permit an understanding of particulate ranges from commercially available devices and setting of particulate limits for new device evaluations.

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