Background Case into the FDA Class 1 Recall for the 18x40 mm Acclarent Inspira AIR Balloon Dilation System

INTRODUCTION

• Balloon dilation of airway stenosis has been performed in both children and adults.[1-4]
• Balloon dilation of the trachea was described by Cohen et al. in 1984 and is generally reported to be a safe, rapid and minimally invasive intervention.[5-6]
• On March 13, 2012, the FDA issued a Class 1 recall of the 18x40 mm Acclarent Inspira AIR Balloon Dilation System because of 4 reported incidents of difficulty deflating the balloon, one of which resulted in patient injury.
• We report one life-threatening device failure resulting from inability of the balloon to deflate and catheter failure. To our knowledge, this is the first report of this complication in the literature.

CASE PRESENTATION

• 39 year-old female with progressive dyspnea secondary to recurrent Idiopathic Subglottic Stenosis (ISS) was intubated with a pediatric 4.0 cuffless endotracheal tube and placed in suspension under the microscope.
• The ET tube was removed and the CO2 laser was used to perform radial cuts in two positions.
• 18x40mm balloon was passed through the stenotic segment, and held with its midpoint across the narrowest point of the cicatricial fibrosis.
• The balloon was inflated to 8 ATM with 16 cc of saline.
• While inflated, the balloon migrated distal to the constricted area, a phenomenon known as "watermelon seeding".
• Counter-traction on the catheter was required to ensure continued proper placement.
• On the third dilation, saline was observed at the distal end of the laryngoscope.
• The inflation device was unable to remove the saline from the balloon and the catheter was noted to be detached from the balloon, resulting in retention of the inflated balloon in the patient’s subglottis.
• Multiple attempts to remove the firmly fixed balloon in the subglottis were finally successful after 2 large forceps were used to grasp, manually deflated.
• The airway was then secured with a 6.5 adult endotracheal tube and all instruments were removed, the patient was extubated and brought to the recovery room in stable condition.

DISCUSSION

• The inflated balloon produces radial forces rather than shearing forces and rapid expansion and deflation as opposed to serially passing of the bougie.
• Lesions that cannot be easily bypassed with an endotracheal tube or tracheotomy at increased risk.[7]
• Reported complications include granulation tissue, tracheitis, bleeding, pneumothorax, atelectasis, pneumomediastitis, and death. Although recurrent stenosis may be seen as a complication, repeated balloon laryngoplasty is often necessary and should be anticipated.[8]

LEGENDS FIGURES 1-3

Figure 1: The Inspira AIR™ Balloon Dilation System
Figure 2: The Acclarent™ Balloon Inflation Device
Figure 3: Detached balloon: Arrows showing points of detachment. Stretching depicted by bracket

Figures 1&2: Courtesy of Acclarent, Inc.

LEGENDS FIGURES 4-6

Figure 4: The catheter is inserted into the area of stenosis
Figure 5: Radial forces are applied as the balloon inflated. The catheter begins to move distally.
Figure 6: Balloon moves distally and catheter stretches and ruptures

REFERENCES