Case Report

Technical failure of the EZ-blocker™ causing serious adverse events during one lung ventilation: a case series

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Summary

We present a case series of intra-operative adverse events while using a specific type of bronchial blocker, designed to facilitate device positioning and minimise the risk of dislocation. The Rüsch® EZ-blocker™ (Teleflex Life Sciences Ltd., Athlone, Ireland) is a Y-shaped catheter equipped with two separately inflatable cuffs at the tip – one for each bronchial lumen. In this report, we describe four cases where the use of the EZ-blocker was associated with the development of high airway pressures, hypoxaemia and expansion of the non-dependent lung. Bronchoscopic evaluation showed spontaneous inflation of the cuff within the dependent (i.e. ventilated) bronchus, causing bronchial obstruction, and volume loss of the cuff within the non-dependent (i.e. unventilated) bronchus, causing unintended expansion of the non-dependent lung. After removal of the bronchial blocker, the catheter showed no visible defect, but a bench test revealed a functional connection inside the catheter which allowed air to pass slowly from one bronchial cuff to the other. This technical defect relates to the unique design of the EZ-blocker as it is the only bronchial blocker equipped with two bronchial cuffs. Clinicians should be aware of this inherent risk since complications may develop insidiously and affect both lungs simultaneously. Early recognition and prompt intervention can prevent life-threatening intra-operative deterioration.

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Introduction

One lung ventilation can be achieved either with double-lumen tubes or bronchial blockers, both of which have advantages in specific clinical situations [1,2].

In our institution, we selected the Rüsch® EZ-Blocker™ Endobronchial Blocker (Teleflex Life Sciences Ltd., Athlone, Ireland) as the preferred bronchial blocker for one lung ventilation, although double-lumen tubes remain first choice in most of our thoracic surgical cases. The EZ-blocker consists of a semirigid Y-shaped catheter with two distal extensions, each of which has a colour-coded inflatable cuff, a central lumen and a pressure line connected to an external colour-coded balloon. The device is advanced to reach the carina from where the two cuffed extensions separate and lodge into both bronchi. The left and right lungs can then be controlled separately. It is believed that the straddling position of the EZ-blocker across the carina causes fewer dislocations as compared with other types of bronchial blocker [3].

In general, the EZ-blocker is considered a user-friendly and efficient device to facilitate one lung ventilation [4–6]. In this report, however, we describe a previously unrecognised type of technical failure, unique to the EZ-blocker.

Case Reports

Over seven months, we encountered four distinct intra-operative adverse events while using an EZ-blocker in patients undergoing thoracic (n = 3) and cardiac (n = 1) surgical procedures (Table 1). In all cases, both cuffs were tested for air leaks before insertion. Following tracheal intubation, the EZ-blocker was introduced via the multiport adapter until it was straddling the carina. The volume of air needed to obtain an adequate cuff seal (8 – 12 ml) was determined under bronchoscopic control.

The four incidents all occurred between 9 and 30 min after the successful initiation of single lung ventilation and were characterised by a triad of signs consisting of (1) increased airway pressures, (2) peripheral oxygen desaturation and (3) insufflation of the non-dependent lung. The order in which the signs appeared as well as the degree of severity differed from case to case. In case 1, the surgeon noticed progressive inflation of the non-dependent lung. High airway pressures and desaturation developed subsequently and quickly. In case 2, the onset was insidious; the diagnosis of the problem was made rapidly based on pattern recognition by the same anaesthetist involved in the first case. Prompt intervention prevented further deterioration.

After these two cases, all EZ-blocker catheters with the same lot production number were removed from service. The technical defects were reported to the vendor and the Federaal Agentschap voor Geneesmiddelen en Gezondheidsproblemen, the Belgian national quality assurance authority. During a subsequent morbidity and mortality meeting, a case with very similar characteristics which occurred during minimally invasive mitral valve surgery was presented by our cardiac anaesthesia group (case 3). Progressive insufflation of the isolated lung was noted, and surgery was interrupted when the patient developed hypotension and bradycardia. Bronchoscopic inspection revealed cuff inflation with obstruction of the dependent lung and cuff deflation in the isolated bronchus. In retrospect, this case accorded with an EZ-blocker from the same production lot number. The vendor officially responded that the *"device history records on the reported lot number identified no issues that could have contributed to the reported event."* After an event-free interval, we experienced a new incident during thoracoscopic pleurodesis (case 4) in which the lung was damaged during surgical opening of the pleura; it appeared fully inflated despite the initiation of single lung ventilation. A new incident report was filed, and the malfunctioning device was sent to the vendor. After Two months, they confirmed the reported issue and identified the root cause as "*supplier related*." It was stated that measures would be implemented; however, exact details of said measures were not provided.

In all cases, bronchoscopic evaluation was diagnostic and showed the same features: partial inflation of the dependent cuff and deflation of the non-dependent cuff. The situation was corrected by removing air from the dependent cuff and adding volume to the other one. Unfortunately, correction came too late in case 4 as lung damage occurred before diagnosis. In the other three cases, there were no postoperative complications. The length of hospital stay was not affected in any case.

The EZ-blockers used were retrieved at the completion of surgery and subjected to bench testing: the non-dependent cuff was inflated while all air was evacuated from the dependent cuff to mimic the clinical initiation of lung isolation. After a minimum of 9 min, we noticed a progressive loss of air from the non-dependent cuff towards the dependent, which progressively filled with air (Fig. 1). These findings corresponded to our clinical observations and confirmed the presence of a direct communication between both cuffs.

Table 1 Case descriptions.

	Characteristics	Procedure	Signs of device failure	Complications
Case 1	Male, 51 years old	Robot-assisted right-sided lobectomy	High peak pressure Insufflation of the isolated lung	Severe desaturation
Case 2	Female, 49 years old	Video-assisted thoracoscopic wedge resection of the right lung	High peak pressure	Subtle desaturation
Case 3	Female, 56 years old	Minimally invasive mitral valve surgery	High peak pressure Insufflation of the isolated lung	Severe desaturation Hypotension Bradycardia
Case 4	Male, 61 years old	Video-assisted thoracoscopic pleurodesis of the right lung	High peak pressure Insufflation of the isolated lung	Modest desaturation Surgical damage to non-dependent lung (iatrogenic pneumothorax)

Discussion

In this series, we describe four separate cases where the use of an EZ-blocker for initiation of one lung ventilation was associated with serious intra-operative events. We discovered a technical defect in the device, consisting of a connection or fistula between the two bronchial cuff lines, through which air can pass from one cuff to the other. This type of defect is specific for the EZ-blocker as it is currently the only bronchial blocker equipped with two bronchial cuffs. When air passes from an inflated bronchial cuff (sealing the non-dependent lung) towards the contralateral cuff (deflated to enable ventilation of the dependent lung), the consequences are severe and affect both lungs simultaneously. Indeed, in all cases presented here, we observed a triad of signs: (1) elevated airway pressures and (2) oxygen desaturation, both due to bronchial obstruction of the dependent lung, and (3) expansion of the non-dependent lung into the surgical field, due to air leaking around the partially deflated bronchial cuff. If an anaesthetist using an EZ-blocker is suspicious of a similar device failure, we propose increasing FiO_2 and temporarily ceasing ventilation. If bronchoscopy is suggestive for a technical failure of an EZ-blocker, both cuffs should be deflated, and the surgical team informed before starting gentle ventilation of both lungs at low tidal volumes. As soon as ventilatory parameters are under control, the anaesthetist can either replace the defective EZ-blocker or proceed with the defective EZ-blocker under continuous monitoring of cuff volumes using bronchoscopy.

Complications associated with the use of bronchial blockers are well known and mostly related to mispositioning of the device. The clinical manifestations of bronchial blocker mispositioning typically have a rapid onset and are usually linked to an acute event such as tracheal manipulation or patient repositioning. The bifurcated design of the EZ-blocker is considered to provide more positional stability. However, the double cuff system may have a unique, previously unreported risk. Importantly, early diagnosis of EZ-blocker device malfunction is confounded by a more insidious onset of symptoms and the absence of a trigger event. A typical and common characteristic of all cases presented in this series was the presence of an event-free interval between the start of one lung ventilation and the onset of symptoms. This interval varied from 9 to 30 min, this apparently being the time needed to produce cuff volume changes sufficiently large to cause clinical impacts. During post-hoc bench tests in all catheters, we confirmed a lag time of approximately 10 min between the inflation of one cuff and the appearance of noticeable volume changes in the contralateral cuff. The flow of air between the two interconnected cuffs is obviously determined by physical characteristics of the fistula, such as length and diameter, but will also depend on the initial pressure difference between both cuffs. As part of our routine clinical practice, we perform quick pre-insertion test to check for cuff leaks; however, we did not pick up a defect in any of the devices used. Interestingly, a standard leak test performed by the manufacturer as part of the production process is also of brief duration and is therefore unlikely to detect the slow onset phenomenon described in this report. The vendor indicated that new testing equipment will be employed soon (personal communication 29 October 2020, as quoted: *"We have started integrating a new leak tester that does detect these leaks, but it has to be calibrated first. Until then, new control instructions are added to the workflow for operators, namely 100% control, which means that the balloons must remain inflated for 6 h."*). It remains unclear if modifications to the manufacture of the EZ-blocker can or will be incorporated to prevent technical failures of this type in the future. Meanwhile, we hope that this report raises awareness and helps clinicians

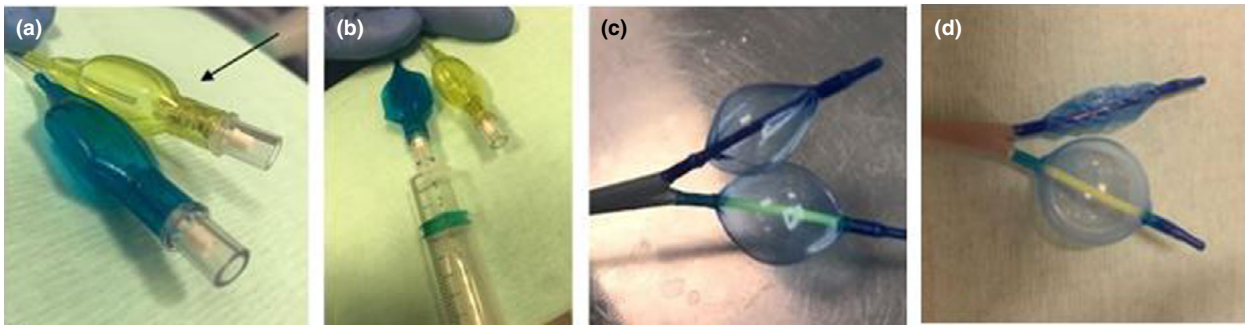

Figure 1 Unexpected behaviour of EZ-blocker's bronchial cuffs. (a) Intra-operative: intentional inflation of the yellow balloon; (b) Intra-operative: unintended inflation of the blue balloon with 3 ml of air and deflation of the yellow balloon, witnessed after 9 min; (c) Postoperative bench test: spontaneous inflation of the blue cuff with deflation of the yellow cuff due to a connection between the two bronchial cuff lines; (d) Example of a correctly functioning EZ-blocker without spontaneous inflation of the blue cuff.

recognise the characteristic pattern caused by technical failure of the EZ-blocker, since early diagnosis and correction is required to prevent serious complications.

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