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LETTER TO EDITOR/LED REPLY

Reporting Adverse Medical Device Events Is an Obligation and Not a "Fashion"

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We thank George et al. for their interest in our recent publication of a case series of patients that developed acute pancreatitis after the insertion of intragastric balloons [1]. Reporting adverse medical device events (AMDEs) is an important aspect that is overlooked by the medical community; a recent paper by Gagliardi et al. [2] demonstrated that practitioners perceived reporting AMDEs as unnecessary, not possible, or futile. The aim of reporting such AMDEs includes increasing awareness among healthcare practitioners, healthcare regulators, and industry, as well as patients about potential AMDEs. This is in an attempt to optimize the selection of cases, and hopefully mitigate these risks either through smarter designs of devices, or patient selection, or a combination thereof. At least practitioners and patients would have more details and a better-informed decision about interventions that are offered.

The reporting of AMDEs is usually a voluntary act, but is an important one, and is limited by under-reporting as well as by the variability in the quality of the reports that are submitted [3]. Over the last few years, the culture of reporting of adverse events has increased with the emergence of numerous organizations focusing on patient safety. Also, locally in Saudi Arabia, the Saudi Food and Drug Authority (SFDA) maintains an online national medical devices reporting system to capture AMDEs, such a culture is to be commended.

Thus we would rephrase the concern of George et al. that it should not be towards the increased publications on the topic at hand, but rather it should focus on the increased incidence of AMDEs associated with the use of balloons, including a few fatalities that have been reported in association with intragastric balloons.

If we were to agree with George et al. that the number of balloons inserted in Saudi Arabia was much less than those inserted in Brazil, which most probably is true, that would cause more concern as this would indicate a higher incidence than what would be anticipated. We are also aware about the Brazilian intragastric balloon consensus statement [4], and although it is a good beginning it does not describe what evidence it was based on. Also, there were neither numbers nor literature cited to back these recommendations apart from agreement by experts in the field. As such, case series such as this and others would help in bridging that gap.

The speculated mechanisms of acute pancreatitis in individuals who have intragastric balloons inserted are interesting but might over-simplify the concept as there remain too many variables that cannot explain why one individual would develop this adverse event while another would not. We believe that there are numerous component causes and in their sum would become a sufficient cause for acute pancreatitis [5].

In conclusion, we believe that this publication achieved numerous positive outcomes, some of which are increasing awareness of AMDEs associated with intragastric balloons, grabbing the attention of scholars in the field, and initiating a positive debate on the potential mechanisms of this AMDE. As such, we think that these publications are of value and thankfully there are platforms, such as this journal, that provide a space for these scientific debates.

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Compliance with Ethical Standards

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