Adverse Events Associated with Robotic Total Hip Arthroplasty: Analysis of the FDA MAUDE Database

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INTRODUCTION: The Food and Drug Administration (FDA) maintains the Manufacturer and User Facility Device Experience (MAUDE) database for reporting adverse events associated with medical devices. This is a valuable tool for analyzing adverse events from emerging technologies such as robotics in total hip arthroplasty (THA). While the current literature notes improved component positioning with similar complication rates when comparing robotic to manual THA, although data remains limited. The goal of this study is to evaluate the MAUDE database for adverse events associated with robot THA.

METHODS: The FDA's MAUDE database was queried for adverse events involving robotic THA from 2017 to 2021. Adverse events were recorded if the report contained the product classifier for orthopedic stereotactic equipment (OLO) and described arthroplasty of the hip. Variables collected included adverse event type, surgical delay, and conversion to manual technique.

RESULTS:

In total, 521 adverse event reports were identified, with some event reports including multiple adverse events. The most common adverse event reported was due to broken impaction devices (90/521, 17.27%), followed by foreign bodies from damaged equipment (12.86%, 67/521). Most foreign bodies reported were from broken or retained pelvic pins or checkpoints (53.73%, 36/67). Additionally, multiple event reports involved cup malposition (9.98%, 52/521) with 61.5% of these identified by the surgeon intraoperatively (32/52) and 38.5% found postoperatively on radiographs (20/52). Surgical delay was noted in 28.0% (146/521) of event reports, which ranged from 1 to 60 minutes and averaging 16.0 minutes. Furthermore, 71 events reported conversion to manual THA (71/521, 13.6%). The most common reason for converting to manual THA was software error (17/71, 23.9%), followed by cup malposition (9/71, 12.7%).

DISCUSSION AND CONCLUSION: Robotic THA is an emerging technology and the FDA's MAUDE database provides a valuable perspective regarding the range of complications that can occur with robotics in this setting. Awareness of these adverse events may aid in improving technology and equipment, prevent surgical delays, and reduce adverse events.