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MAUDE – Analysis of Robotic-Assisted Gynecologic Surgery

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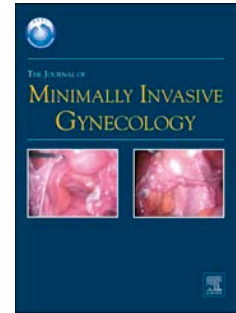
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1 **MAUDE – Analysis of Robotic-Assisted Gynecologic Surgery**

2 **Manoucheri E, Fuchs-Weizman N, Cohen SL, Wang KC, Einarsson JI**

3 **Objective:** To evaluate the adverse events encountered during robotic gynecologic surgery, as
4 reported to the FDA MAUDE database from January 2006 to December 2012.

5 **Methods:**A search of the FDA MAUDE database was performed by brand name 'da Vinci' and
6 manufacturer 'Intuitive Surgical'. Reports reflecting gynecologic procedures either by description
7 or procedure name were included. A record of reports was kept to ensure no duplicates were
8 added. The date and type of event (operator-related error, technical system failures, or surgical
9 injuries attributed to the use of the robot) as well as the clinical outcome were recorded.

10 **Results:**Twenty six percent of the reported events (n=73) resulted in injury, and 8.5% (n=24)
11 resulted in death. Notably, while adnexal procedures accounted for less than 3% of the cohort,
12 they compromised 20% of the fatality cases. Twenty-one percent of injuries were attributed to
13 operator-related error, 14% to a technical system failure, and 65% were not directly related to the
14 use of the robot.Fifteen fatal cases were reported during planned hysterectomy. Four of those
15 cases resulted in an injury to a major blood vessel (three iliac and one aortic injuries), although
16 detailed description of how the injury occurred was absent from the event description.

17 **Conclusions:** It is important to continue to evaluate the occurrence of injuries during robot-
18 assisted surgery in an effort to identify unique challenges associated with this advanced
19 technology.

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