in terms of urinary QOL, however SF and SB scoring is better for IF NSP group at 6 month.

Source of Funding: None

999

DEVICE FAILURES AND PATIENT INJURIES ASSOCIATED WITH ROBOT-ASSISTED LAPAROSCOPIC SURGERIES: A REVIEW OF THE FDA DATABASE

Sero Andonian, Zeph Okeke, Deidre A Okeke, Ardeshir Rastinehad, Brian A Vanderbrink, Lee Richstone, Benjamin R Lee. New Hyde Park, NY.*

INTRODUCTION AND OBJECTIVE: Robot-assisted laparoscopic surgery has become increasingly utilized, especially in the areas of cardiac and urologic surgery. The purpose of the study was to determine the number of reported adverse incidents in which the failure of the robotic system led to patient injuries.

METHODS: A review of the Manufacturer and User Facility Device Experience Database (MAUDE) of the United States Food & Drug Administration (US FDA) was performed. The terms "ZEUS", "DaVinci", "da Vinci" and "Intuitive" were used in the search. All incidents involving either the ZEUS or da Vinci surgical robots were analyzed.

RESULTS: MAUDE Database of the US FDA was last accessed on August 27, 2007. A total of 189 adverse events were reported from January 1, 2000 till August 27, 2007. Twenty one events were reported for the ZEUS robotic system between 2001 and 2003, while 168 events were reported for the da Vinci robotic system between 2000 and 2007. For the da Vinci system, there were 7 cases re-scheduled, 4 cases done with non-assisted laparoscopy, and 97 (58%) open conversions. Of the adverse events reported, the rate of open conversions decreased from 94% in 2003 to 16% in 2007. Of the adverse events reported, only 9 (4.8%) cases involved patient injury. There was one unrelated death 27 days post-prostatectomy. Another patient developed hematoma when the camera moved unintentionally due to software error.

CONCLUSIONS: The increasing acceptance and use of robotic-assisted surgery has led to an increase in the number of reported adverse events associated with its use. With experience, the rate of open conversions decreased. Only a small percentage of these adverse occurrences were associated with patient injury.

Source of Funding: None

1000

ANALYSIS OF CONTINENCE RATES FOLLOWING ROBOTIC RADICAL PROSTATECTOMY: STRICT LEAK- AND PAD-FREE CONTINENCE RATES OUTCOMES

W Stuart Reynolds, Sergey A Shikanov, Ofer N Gofrit, Mark H Katz, Michael K Eng, Andrew J Bernstein, Gregory P Zagaja, Arieh L Shalhav, Kevin C Zorn. Chicago, IL.*

INTRODUCTION AND OBJECTIVE: Post-prostatectomy incontinence (PPI) has been ill-defined in the literature and a wide range of outcomes have been reported depending on the definition of continence employed. Based on the UCLA-Prostate Cancer Index (UCLA-PCI) questionnaire, a patient self-reported, validated instrument, we evaluated our robot-assisted laparoscopic prostatectomy (RALP) outcomes using the strictest definition available, that of leak- and pad-free (L/PF) continence.

METHODS: A review of a single institution's RALP database was performed concerning patient-reported continence variables as prospectively recorded by the UCLA-PCI administered to all patients undergoing RALP. Specific responses to items concerning urinary function and continence (Items #12-16) were reviewed at baseline and 1, 3, 6, 12, and 24 months post-operatively.

RESULTS: Of over 1200 RALP performed since February 2003, 885 patients were available for review. Patient demographics for this cohort have previously been reported and are similar to other institutions. At baseline, only 642/885 (73%) of men were L/PF before surgery. This decreased to 19/504 (4%), 56/656 (9%), 92/585 (16%), 97/408 (24%), and 37/128 (27%) at 1, 3, 6, 12, and 24 months postoperatively, respectively. Of those that were not L/PF at baseline, 237/882 (27%) reported leakage and 28/882 (3%) wore pads. Patients who reported L/PF at baseline disproportionately regained L/PF continence post-operatively vs. those who were not L/PF at baseline: 4 vs. 3% (NS), 10 vs. 6% (NS), 19 vs. 9% (p=0.005), 29 vs. 13% (p=0.0009), and 33 vs. 13% (p=0.0146), at 1, 3, 6, 12 and 24 months, respectively. Overall, when continence is defined more liberally as leak-free ± security pad, 19%, 50%, 73%, 86% and 85% of patients were continent at 1, 3, 6, 12, and 24 months, respectively.

CONCLUSIONS: As expected, a stricter definition of urinary continence results in more conservative post-operative outcomes reporting. Our data suggest that baseline urinary incontinence can be predictive of a failure to regain L/PF continence starting at 6 months postoperatively. However, only one third of patients who were L/PF at baseline achieved this state at 24 months. Continued evaluation and standardization of the definition of PPI is warranted and should be applied to outcomes after RALP.

Source of Funding: None

1001

SINGLE SURGEON COMPARISON BETWEEN CONVENTIONAL LAPAROSCOPIC AND ROBOT-ASSISTED RADICAL PROSTATECTOMY: PATHOLOGICAL AND FUNCTIONAL OUTCOMES

Mark L Gonzalgo, Ahmed Magheli, Michelle Brotzman, Li-Ming Su. Baltimore, MD.*

INTRODUCTION AND OBJECTIVE: Few studies have directly compared outcomes between conventional Laparoscopic Radical Prostatectomy (LRP) and Robot-Assisted Laparoscopic Prostatectomy (RALP). We investigated a single surgeon experience with LRP and RALP with respect to nerve sparing technique, pathological outcomes, urinary continence, and erectile function.

METHODS: A group of 200 consecutive patients who underwent LRP were compared to a contemporary series of 200 consecutive patients who underwent RALP between 2003 and 2007 at our institution by a single surgeon. Differences in nerve sparing technique and positive surgical margin rates (+SM) were examined between the two groups. Urinary continence and erectile function were assessed using the Expanded Prostate Cancer Index Composite (EPIC) questionnaire collected preoperatively, 3, 6, and 12 months following surgery.

RESULTS: Preoperative demographics and pathologic stage distributions were similar between LRP and RALP groups. Similar overall (13.5% vs. 17.0%) and pT2 (10.4% vs. 6.8%) +SM rates were observed for LRP and RALP, respectively. Bilateral nerve preservation was performed in 54.5% and 56.0% of LRP and RALP patients, respectively. Return of urinary continence for men undergoing LRP and RALP was similar. Urinary continence rates (defined as 0 to 1 dry pad per day) at 3, 6, and 12 months postoperatively were 72% vs. 76%, 89% vs. 87%, and 93% vs. 93% for LRP and RALP, respectively. There was a trend toward improved erectile function following RALP compared to LRP. Among men who were potent preoperatively who underwent bilateral nerve sparing surgery, report of successful intercourse at 3, 6, and 12 months following surgery was 33% vs. 50%, 57% vs. 73%, and 67% vs. 88% for LRP compared to RALP, respectively.

CONCLUSIONS: Pathologic and functional outcomes between LRP and RALP are similar with respect to +SM rates, urinary continence, and recovery of erectile function. Although a trend toward higher potency rates was observed at each time point postoperatively in the RALP group compared to LRP, this finding was not statistically significant. Further prospective studies are warranted to determine whether RALP is superior to LRP with regard to long term functional outcomes.

Source of Funding: None

1002

ROBOTIC RECONSTRUCTION OF THE URINARY TRACT

Patrick W Mufarrij, Ojas D Shah, Basir Tareen, Michael E Lipkin, Mark A Perlmutter, Michael D Stifelman. New York, NY.*

INTRODUCTION AND OBJECTIVE: Reconstructive surgery of the urinary tract can be complicated. Over the last two decades, minimally invasive techniques have emerged as viable options for these complex procedures. Herein, we review our experience using robotic surgery for urinary tract reconstruction.