



Database Study Shows Shorter Hospital Stay, Fewer Complications for Robotic-Assisted Prostate Surgery Versus Open Surgery

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Results Immediately Evident Even in Surgeons' Initial Robotic-Assisted Prostatectomy Cases

SUNNYVALE, Calif., Jan. 9, 2014 (GLOBE NEWSWIRE) -- New findings from a large, population-based study show that robotic-assisted radical prostatectomy (removal of the prostate and surrounding tissue) results in a shorter average hospital stay and lower overall complication rate compared to open surgery. Even in surgeons' initial robotic-assisted prostatectomy cases, robotic-assisted prostatectomies resulted in fewer complications and shorter hospital stays than open surgery. Researchers further documented that key proficiency measures, such as surgery time, complication rates and length of hospital stay, continued to improve as a surgeon's robotic-assisted case volume increased. Mean operating time remained longer for the robotic-assisted group.¹

This retrospective study also showed that open prostatectomies performed at multiple hospitals with a robotics program exhibited an overall lower complication rate than open prostatectomies performed at hospitals without a robotics program (15.8 percent versus 17.9 percent, respectively).

The authors indicate that limitations of the study include a lack of cost figures, functional outcomes, pathologic endpoints, and disease-free status, which therefore result in only a partial analysis of comparative effectiveness. In addition, unknown patient selection differences may exist between the open and robotic-assisted groups.

These results were published in the December 18 electronic edition of the *Journal of Endourology*.

Surgeons most commonly perform radical prostatectomy to treat prostate cancer in men expected to live for 10 or more years.² Prostate cancer is the most common cancer in men other than skin cancer, and approximately one man in six will be diagnosed with prostate cancer during his lifetime.³

In this study, researchers used a patient database to identify 71,312 radical prostatectomies performed between 2004 and 2010 by 3,739 surgeons at more than 300 U.S. hospitals, using either open or robotic-assisted techniques. The study found that, compared to open prostatectomy, robotic-assisted radical prostatectomy was associated with a shorter average hospital stay, lower overall complication rate and fewer blood transfusions. These findings are summarized in the table below:

| | Open Prostate Surgery (Non-Robotic Hospital) n=13,840 | Open Prostate Surgery (Robotic Hospital) n=30,124 | Robotic-Assisted Prostate Surgery n=27,348 |
|-------------------------------------|--|--|---|
| Mean surgery time (hours) | 3.2 | 3.4 | 4.4 |
| Mean length of hospital stay (days) | 3.7 | 3.4 | 2.2 |
| Transfusion rate | 17.1% (n=2,360) | 11.5% (n=3,449) | 2.3% (n=638) |
| Overall complications | 17.9% (n=2,474) | 15.8% (n=4,759) | 10.6% (n=2,892) |

P-values for parameters listed above between each group – robotic-assisted vs. open at robotic hospitals, robotic-assisted vs. open at non-robotic hospitals, and open at robotic vs. non-robotic hospitals – were statistically significant with p < 0.0001.

These results were evident even early in the learning curve.

"The study shows that *even in the first 25 cases*, robotic-assisted prostatectomies resulted in fewer complications and shorter hospital stays than open surgery," said Myriam Curet, MD, Chief Medical Advisor, Intuitive Surgical.

The study also found that as surgeons completed more robotic-assisted surgeries, there were decreases in overall surgery time, with less experienced surgeons averaging 5.0 hours for a case and more experienced surgeons averaging 3.9 hours. Decreases in complication rate (from 11.75 percent to 8.95 percent), and conversion rate (from 1.13 percent to 0.18 percent) were also found.

"Our analysis shows that outcomes of robotic-assisted radical prostatectomy improve as surgeons gain more experience with the procedure, and generally can be favorable relative to open surgery," said lead study author John W. Davis, M.D., of the MD Anderson Cancer Center in Houston.

Intuitive Surgical paid for access to the Premiere database and Axistat consulting services. Lead author Dr. Davis was reimbursed for travel expenses related to this study. Author Jessica Gabbert is employed by InClin (formerly Axistat). Author Usha Kreaden, Principal Biostatistician, is employed by Intuitive Surgical.

Important Information for Patients

All surgery presents risk, including *da Vinci* Surgery. Potential risks of any prostatectomy procedure may include but are not limited to urinary and/or sexual dysfunction due to nerve damage⁴, rectal or bowel injury⁵, blocked artery in the lung⁵, or blocked bowel⁵. Results, including cosmetic results, may vary.

Serious complications may occur in any surgery, up to and including death. Examples of serious and life-threatening complications, which may require

hospitalization, include injury to tissues or organs, bleeding, infection, and internal scarring that can cause long-lasting dysfunction or pain. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery. Patients should understand that risks of surgery include potential for human error and potential for equipment failure. Risks specific to minimally invasive surgery may include: a longer operative time, the need to convert the procedure to other surgical techniques, the need for additional or larger incision sites, a longer operation or longer time under anesthesia than your surgeon originally predicts. Converting to open surgery could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Patients who bleed easily, have abnormal blood clotting, are pregnant or morbidly obese are typically not candidates for minimally invasive surgery, including *da Vinci* Surgery.

Other surgical approaches are available. Patients should review the risks of all surgical approaches and the risks of *da Vinci* procedures to decide if *da Vinci* Surgery is right for them. It is important to talk to your doctor about his/her surgical experience. For complete information on surgical risks, safety and indications for use, please refer to www.davincisurgery.com/safety.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the global leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets the *da Vinci*[®] Surgical System. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to those patients who can and should benefit from it.

About the *da Vinci* Surgical System

The *da Vinci* Surgical System is a surgical platform designed to enable complex surgery using a minimally invasive approach. The *da Vinci* Surgical System consists of an ergonomic surgeon console or consoles, a patient-side cart with three or four interactive arms, a high-performance vision system and proprietary *EndoWrist*[®] instruments. Powered by state-of-the-art technology, the *da Vinci* Surgical System is designed to scale, filter and seamlessly translate the surgeon's hand movements into more precise movements of the *EndoWrist* instruments. The net result is an intuitive interface with improved surgical capabilities. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, the *da Vinci* Surgical System makes it possible for skilled surgeons to perform more minimally invasive procedures involving complex dissection or reconstruction. For more information about clinical evidence related to *da Vinci* Surgery, please visit www.intuitivesurgical.com/company/clinical-evidence/.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements comparing robotic-assisted prostatectomy procedures to prostatectomy procedures performed by open surgery. These forward-looking statements are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including those under the heading "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2012, as updated from time to time by our quarterly reports on Form 10-Q and our other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

¹ Davis J, Kreaden U, Gabbert J, Thomas R. Learning Curve Assessment of Robot-Assisted Radical Prostatectomy Compared to Open Surgery Controls from the Premier Perspective Database. *J Endourol*. 2013 Dec 18. [Epub ahead of print]

² Medline Plus. Radical Prostatectomy. <http://www.nlm.nih.gov/medlineplus/ency/article/007300.htm>. Accessed November 13, 2013.

³ American Cancer Society. What are the key statistics about prostate cancer? American Cancer Society. <http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics>. Last revised August 26, 2013. Accessed November 15, 2013.

⁴ Health Information and Quality Authority (HIQA), reporting to the Minister of Health-Ireland. Health technology assessment of robot-assisted surgery in selected surgical procedures, 21 September 2011.

⁵ Tewari A, Sooriakumaran P, Bloch DA, Seshadri-Kreaden U, Hebert AE, Wiklund P. Positive surgical margin and perioperative complication rates of primary surgical treatments for prostate cancer: a systematic review and meta-analysis comparing retropubic, laparoscopic, and robotic prostatectomy. *Eur Urol*. 2012 Jul;62(1):1-15. Epub 2012 Feb 24

CONTACT: Intuitive Surgical Corporate Communications
408-523-7337
corpcomm@intusurg.com

Intuitive Surgical, Inc.