



## Major Study: Minimally Invasive Prostate Surgery Safer than Open Surgery

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### Robotic-Assisted Surgery Significantly Reduces Complications Compared to Open Surgery

SUNNYVALE, Calif., Sept. 16, 2013 (GLOBE NEWSWIRE) -- An independent study published online in the journal [Urology](#) found that minimally invasive surgery for prostate cancer significantly reduces complications when compared to open surgery. The study found that minimally invasive surgery for prostate cancer, including laparoscopic and robotic-assisted surgery, was associated with lower transfusion rates, shorter length of hospital stay, and lower serious postoperative complication and mortality rates compared to open prostatectomy.

In the study, the authors (Liu JJ, Maxwell BG, Panousis P, Chung BI) evaluated the National Surgical Quality Improvement Program (NSQIP) database, a national, prospective perioperative database reflecting diverse practice settings, from 2005 to 2010, for laparoscopic or robotic-assisted prostatectomy and open retropubic prostatectomy. Compared with other administrative databases that capture only inpatient events, the NSQIP database identifies complications up to 30 days postoperatively, providing more detailed characterization of complications after prostatectomy. The perioperative outcomes that were examined included surgical and total operation duration, transfusion rates, length of stay, major morbidity (cardiovascular, pulmonary, renal and infectious) and mortality.

"When evaluating minimally invasive surgery techniques, particularly robotic-assisted surgery, which is now the standard of care in the United States for prostatectomies, it is important to use the surgery it is replacing as a comparator," said Myriam Curet, MD, Chief Medical Advisor, Intuitive Surgical. "The introduction of laparoscopic urologic surgery and subsequent development of robotic techniques have dramatically increased the use of minimally invasive radical prostate surgery. This examination of the most robust, independent surgical database clearly demonstrates that a minimally invasive radical prostatectomy can be safely performed with low complication rates, particularly when compared to alternative procedures."

The study identified 5319 radical prostatectomies: 4036 minimally invasive radical prostatectomy (laparoscopic and robotic-assisted) and 1283 open. Although operating time was longer in the minimally invasive robotic-assisted prostatectomy group (270 minutes vs. 252 minutes, p-value = <.0001), there were significantly fewer perioperative blood transfusions (21% vs. 1.3%, p-value = <.0001) and shorter mean length of stay (1.8 vs. 3.2 days).

The overall complication rate after minimally invasive radical prostatectomy was 5% compared with 9% in open prostatectomy (P <.0001). Mortality was low in both groups, although it was significantly lower in the minimally invasive radical prostate surgery group (0.05%) compared with the open prostatectomy group (0.4%, p-value = .01).

Prior to the introduction to robotic-assisted surgery, 95% of prostate surgeries were performed open through a midline incision. Today, more than 85% of the prostate surgeries performed in the United States are done robotically through small incisions.<sup>1</sup>

In late 2011 and 2012, several large-scale clinical studies on *da Vinci* Surgery were published and demonstrated the benefits of *da Vinci* Surgery. Since *da Vinci* Surgery for prostatectomy is the most mature procedure, many of these large studies used population databases to assess the clinical impact of *da Vinci* Surgery for prostate surgery when compared to the prior standard, open surgery. As other clinical areas of *da Vinci* Surgery mature, clinical evidence continues to trend toward lower complication rates compared to open surgery.<sup>2,3,4,5,6,7</sup> While many studies' findings favor *da Vinci* Surgery, some do not.<sup>8,9,10</sup> Medical research requires careful analysis of patient populations, appropriate statistical technique and robust data collection. In these analyses, it's also important to note that robotic-assisted surgery may provide a minimally invasive option for more complex cases. We encourage those interested in clinical evidence on the use of *da Vinci* Surgical Systems to explore relevant literature critically. For examples of such studies, please visit: <http://intuitivesurgical.com/company/clinical-evidence>.

#### 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*<sup>®</sup> 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*<sup>®</sup> 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/](http://www.intuitivesurgical.com/company/clinical-evidence/).

All surgery presents risk, including *da Vinci* Surgery. Results, including cosmetic results, may vary. Serious complications may occur 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. Risk specific to minimally invasive surgery may include: a longer operative time; the need to convert the procedure to an open approach; or the need for additional or larger incision sites. Converting the procedure to open could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery. 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 associated with all surgical approaches. They should talk to their doctors about their surgical experience and to decide if *da Vinci* is right for them. For more complete information on surgical risks, safety and indications for use, please refer to <http://www.davincisurgery.com/safety>.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our medical device reporting practices, related device malfunction filings, product performance and the speed at which instrument changes can be accomplished. 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 the following: the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; our ability to expand into foreign markets; and other risk factors under the heading "Risk Factors" in our 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 to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

<sup>1</sup> MIP percentage prior to introduction of robotic prostatectomy: Premiere Prospective Database 2004-2010 as cited by Davis et. al. BJUI 2013 (accepted for publication).

<sup>2</sup> Boggess, J. F., et al. (2008). "A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy." American Journal of Obstetrics and Gynecology 199(4): 360.e1-9.

<sup>3</sup> Paley, P. J., et al. (2011). "Surgical outcomes in gynecologic oncology in the era of robotics: Analysis of first 1000 cases." American Journal of Obstetrics and Gynecology 204(6): 551.e551-551.e559.

<sup>4</sup> Seamon, L, et al. (2009). "Comprehensive surgical staging for endometrial cancer in obese patients." Gynecologic Oncology. 114 16-21.

<sup>5</sup> Kang, J., et al. (2012). "The impact of robotic surgery for mid and low rectal cancer: A case-matched analysis of 3-arm comparison--open, laparoscopic, and robotic surgery." Annals of Surgery.

<sup>6</sup> Trinh QD, et al. "Perioperative outcomes of robot-assisted radical prostatectomy compared with open radical prostatectomy: results from the nationwide inpatient sample." Eur Urol. 2012 Apr; 61(4):679-85.

<sup>7</sup> Tewari A, et al. "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 Feb 24.

<sup>8</sup> Wright JD, Ananth CV, Lewin SN, et al. "Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease." JAMA 2013;309:689-98.

<sup>9</sup> Barbash GI, Glied SA. "New technology and healthcare costs: the case of robot-assisted surgery." N Engl J Med. 2010;363(8):701-704.

<sup>10</sup> Schroeck FR., Krupski TL, Sun L., et al. "Satisfaction and Regret after Open Retropubic or Robot-Assisted Laparoscopic Radical Prostatectomy." Eur Urol 2008 Oct; 54(4):785-93.

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