[ News * Analysis * Commentary * Controversy ]

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## ASCO: Make Palliative Care Standard for Metastatic NSCLC Patients, Starting at Diagnosis

BY LOLA BUTCHER

The Society's new "provisional clinical opinion" recommendation was triggered by research showing longer survival, improved quality of life, and other measurable positive results compared with patients receiving only standard care. And although the PCO is specifically for NSCLC, the document states that concurrent palliative care should be considered for other patients as well.

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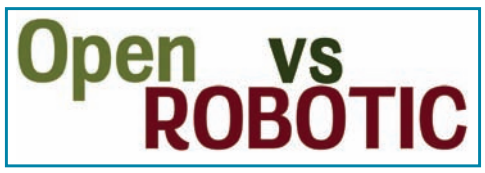
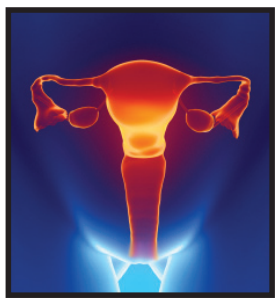



Complications No Less with Robotic vs Open Prostatectomy p.12



Thomas Herzog, MD, Picks the Year's Best Ovarian Cancer Research p.15

Pro-Con: Maintenance Rituximab for Patients with Follicular Lymphoma p.36

[ALSO]



PERIODICALS

# Complications No Less with Robotic vs Open Prostatectomy

Open vs ROBOTIC

BY ROBERT H. CARLSON

Robotic-assisted laparoscopic radical prostatectomy, introduced only in 2000, now accounts for the vast majority of radical prostatectomies in the U.S., according to recent **data** ***(Cancer 2012:118:371-377)*** . As with the standard laparoscopic procedure, the robotic-assisted procedure is known to reduce blood loss and length of convalescence. Conventional wisdom also has been that men undergoin`g the robotic procedure have less post-surgical urinary incontinence and erectile dysfunction compared with men who undergo the open radical prostatectomy procedure.

Now, however, a study, published last month in the *Journal of Clinical Oncology* (***2012;30:513-518***), has challenged that, finding that the rate of these complications was no different at 14 months among the 685 men who underwent one or the other of the procedures.

The researchers, led by Michael J. Barry, MD, Clinical Professor at Harvard Medical School and Medical Director of the John D. Stoeckle Center for Primary Care Innovation at Massachusetts General Hospital, found that 8.9% of the men reported a "big problem" with continence after open survey versus 11.7% of the robotic-assisted group; and that 71.4% reported a "big problem" with sexual function after open surgery versus 65.8% for the robotic-assisted group.

"The risk of problems with continence and sexual function is high after both procedures, and Medicare-age men should not expect fewer adverse effects following robotic prostatectomy," he and his authors concluded, noting, though, that there was a non-significant trend towards greater problems with continence after robotic prostatectomy.

The population-based sample was drawn from the 20% Medicare claims files from August through December 2008. (For research purposes, Medicare makes available a random sample of 20% of all claims files, which these authors considered a sufficient data set for most questions because of the large sample size, they said.)

At a median of 14 months postoperatively, men identified as having either type of surgery were sent self-reporting questionnaires regarding problems with continence or sexual function.

Of the 685 men who returned surveys (an 86% response rate), 220 said they had received an open procedure, and 406 a robotic-assisted procedure. Baseline demographic characteristics for the men were similar in age, race, and marital status, although respondents who had a robotic-assisted procedure reported significantly more education, with 43% college graduates versus 31% among open-procedure participants.

Robotic-assisted laparoscopic radical prostatectomy, introduced only in 2000, now accounts for the vast majority of radical prostatectomies in the United States.

The study led by MICHAEL J. BARRY, MD, found that about 9% of the men who had open retropubic radical prostatectomy said they had a "big problem" with continence after the procedure versus about 12% of men who had robotic-assisted laparoscopic radical prostatectomy; and that 71% reported a big problem with sexual function after open surgery versus 66% for the robotic-assisted group.

## Study Specifics

Among the 220 men who had undergone the open procedure:

- 19.2% said they had no problem with continence versus 13.2% among the 406 who had the robotic-assisted procedure;
- 29.4% versus 29.8% reported it a very small problem;
- 24.2% versus 23.7% reported a small problem;
- 18.2% versus 21.6% reported a moderate problem; and 8.9% of men reported a big problem with continence after open survey versus 11.7% of the robotic-assisted group.

On the sexual function question:

- 2.9% of the open-procedure group and 2.3% of the robotic-assisted group reported no problem;
- 3.8% versus 2.0% reported a very small problem;
- 4.3% versus 7.3% reported a small problem;
- 17.6% versus 21.7% reported a moderate problem; and
- 71.4% reported a big problem after open surgery versus 65.8% for the robotic-assisted group.

## Accompanying Editorial: 'Sobering' Results, but 'Significant' Limitations

An accompanying editorial (***JCO 2012;39:476-478***), subtitled "Is It the Singer, the Song, or Both?," called the results "sobering" and to be methodologically sounder than a 2009 study that used claims data alone. But, said Matthew R. Cooperberg, Anobel Y. Odisho, and Peter R. Carroll of the University of California, San Francisco Helen Diller Comprehensive Cancer Center, the study does have significant limitations:

- All participants were age 65 or older;
- All operations were performed in 2008, when many surgeons may have still been "climbing the leaning curve" for robotic-assisted prostatectomy;
- Since there was no assessment of baseline function, and the two study groups may not have had comparable baselines; and
- The researchers used a survey instrument that assessed only "bother" and not also function.

Asked for his response for this article, Barry said, "We acknowledge that our men were over age 65, and that side effects in general are less in younger men, but I don't see that robotics would cause more incontinence in older men than in younger men." Nonetheless, he acknowledged that the study's results have to be confirmed in younger men.

The questions about the learning curve and surgical volume is an important one, Barry said, but the study results apply to the average Medicare patient seeing the average surgeon who offers either of these procedures: "I do worry that before men have procedures, they should know if their surgeon is at the low point of the learning curve." Rather than asking whether a surgeon offers the robotic technique, a man should ask how much experience the surgeon has had with whatever procedure will be used for a radical prostatectomy.

Barry said the methodology used in the study could not include a baseline for complications, but that that concern would apply more to sexual function than incontinence. "A small percentage of men have bothersome incontinence before prostate surgery, so it's unlikely there would be a difference between baseline and post surgery [between the two groups]," he said.

## Critiques from Urologic Surgeons

Asked for their opinion, two urologic surgeons specializing in robotic-assisted radical prostatectomy downplayed the study and predicted that it would have very little impact on the field.

"This paper is not as important as it appears on the surface," said Ronney Abaza, MD, Co-Director of the Ohio State University Center for Advanced Robotic Surgery and Director of Robotic Urologic Surgery at Ohio State University Medical Center, who estimated that he has performed more than 2,000 robotic-assisted genitourinary surgeries, primarily for prostate cancer.

*continued on page 14*

## →ROBOTIC-ASSISTED

*continued from page 12*

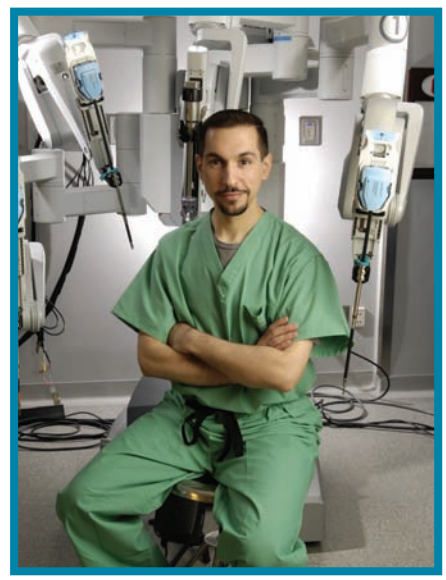
"This is not new information. Several population-based studies have looked at the question over time," he noted, also questioning the use of Medicare data: "I think the medical community in general has learned to look at data taken from Medicare data bases with a little bit of skepticism."

A positive feature in the study was a point of contact, a questionnaire mailed to patients identified in the Medicare database who reported on their own symptoms. "Thinking as a scientist and not as a clinician, [I feel that] the downside to that study was that the researchers asked the patients about the degree of 'bother' from incontinence or sexual dysfunction, which is a subjective measure."

Abaza said he agreed with one of the criticisms in the editorial, that patients could have higher expectations going into robotic surgery than men undergoing the open procedure such that the same objective amount of postoperative bother could be perceived as more bothersome. Also, the fact that the men in the study who chose robotic surgery were more educated could present a selection bias, since perhaps they were more discerning, did more research before making a choice of procedures, or were exposed to more marketing data.

"Again, this makes the reader more skeptical about results," said Abaza.

"There are some things we need scientific studies to tell us, some things that scientific studies cannot tell us, and some things that we really don't need scientific studies to tell us because they are obvious enough on their own. In my opinion, the benefits of robotic surgery are likely something that science will have a very difficult time proving, and we probably don't need science to prove because we see those benefits on a daily basis."



RONNEY ABAZA, MD: "There are some things we need scientific studies to tell us, some things that scientific studies cannot tell us, and some things that we really don't need scientific studies to tell us because they are obvious enough on their own. In my opinion, the benefits of robotic surgery are likely something that science will have a very difficult time proving, and we probably don't need science to prove because we see those benefits on a daily basis."

He said that as a surgeon trained in open surgery when it was the standard of care, he can compare that with the level of care he can provide with robotic surgery, "and it is obvious to me that robotic surgery is a better way to do the operation. As the soldier on the battlefield, I see the benefits every day and I don't need to be convinced."

Similarly, another surgeon asked to comment on the study, Timothy Wilson, MD, Professor of Surgery and Chief of the Division of Urology at City of Hope Cancer Center, agreed that although he didn't think that the study would have much impact on practice, "it would allow a higher-volume open surgeon to reassure patients that the outcomes are the same."

> "The risk of problems with continence and sexual function are high after both procedures, and Medicare-age men should not expect fewer adverse effects following robotic prostatectomy," the authors concluded, noting, though, that there was a non-significant trend towards greater problems with continence after robotic prostatectomy.

Wilson estimated that he has performed about 2,500 robotic prostate procedures; City of Hope stopped doing open procedures in 2000 in favor of laparoscopic procedures, he said, and has done about 6,000 robotic-assisted laparoscopic procedures since 2003.

Wilson also brought up the issue of the lack of baseline function: "Functional outcomes in men at any age worsen after prostate cancer, and like many things in medicine, surgery in particular, experience makes a difference and we don't know what kind of effect that had in these men."

On the positive side, Wilson said some of the study's results "aren't so bad—for example, about 10 percent of the men in the study reported incontinence to be a big problem, and are thus likely to have some intervention to fix it. And while that's higher than what might be reported by a specialty care center, where it might be just one or two percent, it's not much worse that men treated in a low-volume setting."

TIMOTHY WILSON, MD (shown here with colleagues at City of Hope, which, he said, stopped doing open prostatectomies in 2000 in favor of laparoscopic procedures) noted that about 50% of prostatectomies of either technique are done by surgeons who perform fewer than five a year—"That's a huge problem nationally, and stresses the need for experience in training, which continues to be a problem."

He noted that approximately 50% of prostatectomies of either technique are done by surgeons who perform fewer than five per year—"That's a huge problem nationally, and it stresses the need for experience in training, which continues to be a problem."

Regarding the issue of Medicare data, Barry responded that his team only selected men from Medicare claims—they did not use outcomes from that data but rather asked patients directly about their assessment: "If you want to know how patients are feeling and whether they are bothered, you have to ask them. We pretested the questions to make sure patients understood them, and similar questions have been used in previous studies."

Patients were asked about their outcomes in exactly the same way in the two groups, so the results are comparable, he said. Different patient expectations may have influenced the outcomes measured, but the bottom line is that outcomes were no better after robotic surgery, with a trend towards worse incontinence.

And on the issue of baseline data, he agreed that would have been helpful, but "it's extremely unlikely," he said, "that men choosing to undergo robotic surgery would have been more incontinent beforehand than men undergoing open surgery."

## Correction

In the February 10th issue, in the article about treatment of locally advanced esophageal cancer, the dose of radiation noted as used in the Dutch CROSS trial that was combined with chemotherapy should have been 41.4 Gy (not 4.14 Gy).