

Written by Richard Lotenfoe
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Dr. Gerald Chodak recently commented for Medscape on an article published in the November 2010 issue of BJUI by Ripert et. al reporting on the six year experience of two French urologists using the Ablatherm HIFU device for the treatment of prostate cancer. On the basis of this single low volume surgeon experience reporting high oncological failure rates, Dr. Chodak questions the role of HIFU as a primary treatment for localized prostate cancer. Common sense dictates that the role of HIFU, or any treatment of prostate cancer cannot be judged solely on the basis of a single clinical experience especially when there is an abundance of other reports. In this case, there are many reports demonstrating favorable oncological outcomes following HIFU in men with clinically localized prostate cancer. Therefore, the overall implications of the Ripert study must be interpreted based on both the strengths and limitations of the study itself and in context with the totality of the literature reporting experiences with HIFU as a treatment for primary prostate cancer. I would like to take this opportunity to provide a critical review of the Ripert study together with the existing relevant literature. As you will see, my interpretation of both the article and role of HIFU in the treatment of prostate cancer will respectfully disagree with those of Dr. Chodak.

There are many glaring deficiencies in the Ripert et al study design. First, only 86 HIFU procedures were performed over a six year interval by two urologists using the Ablatherm device. Of these 86 procedures, 12 were performed following failed radiation therapy and 9 were re-treatment. Only 65 procedures were performed as initial primary treatment of clinically localized prostate cancer. Therefore, on average these two urologists together performed approximately 11 HIFU procedures on men presenting with clinically localized prostate cancer a year (mean of 5.5 procedures per surgeon), which in my opinion is far too low to gain proficiency with the technology. This will become evident when examining the poor post-treatment PSA nadir levels achieved by these French urologists, which reflects poor surgical technique and explains their poor outcomes. Twelve additional cases were excluded due to various other reasons including recognized inadequate treatment leaving only 53 evaluable cases. Half of the men had intermediate risk disease and despite the fact that the manufacturers of the Ablatherm device recommend excluding men with prostate volumes > 40 cm³, men with prostate volumes up to 50 cm³ were included in the Ripert study.

HIFU is similar to radiation therapy (RT) in that prostate tissue is ultimately destroyed and not surgically removed. Since it is virtually impossible to totally eradicate every PSA producing cell with radiation or ultrasound energy, various definitions have been recommended for defining biochemical free survival (BFS) following these treatments. The Phoenix definition which has been used to define BFS following RT has also been applied to ablative technologies.

Ripert et al provides a summary of BFS rates in their patients and other reported clinical experiences using the Ablatherm device. In those studies reporting very favorable BFS rates, the median PSA nadir following HIFU treatment was 0.1 ng/ml, suggesting that HIFU eradicated the overwhelming majority of the prostate gland. In those studies reporting poor outcomes, including the Ripert study, the median post treatment PSA nadir ranged between 1.0 ng/ml to 1.3 ng/ml. The studies consistently reporting poor outcomes following HIFU had median PSA nadir levels 10 times greater than those reporting good outcomes. These unacceptably very high post-treatment PSA nadir levels can only be explained by a totally inadequate ablation. One cannot condemn the technology but rather the surgical technique. In the subset of men in

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Ripert study who achieved post treatment PSA nadirs <0.2 ng/ml, approximately 75% of men achieved durable (six year) BFS.

Dr. Chodak asks why is it that the Sonablate, which is an alternative HIFU device manufactured by Focus Surgery, achieves superior results. In my opinion, the Sonablate is superior technology with more precise delivery and monitoring of the ablation. Uchida et al. has reported 5 year BFS rates of 84% and 64% for low and intermediate risk disease, respectively. These are impressive outcomes and clearly rival those achieved with RT. These impressive outcomes in my opinion reflect the advanced technology and the skill of the operator.

There is no doubt that successful surgical outcomes are often related to clinical experience. A rigorous community based study of outcomes following radical prostatectomy report severe incontinence rates of approximately 10%. In the community setting, the average urologist performs about 5 radical prostatectomies a year, similar to the number performed by Ripert and colleagues. I have personally performed over 4000 radical prostatectomies and my reported incontinence rate is 2%. It is therefore not surprising that experienced HIFU surgeons achieve superior results, no different than experienced surgeons who perform radical prostatectomy and any complex surgical procedure

So, in my opinion the Ripert report is consistent with the literature. When the prostate is appropriately ablated and low PSA nadir levels are achieved, the results are uniformly good. Even Ripert achieved good outcomes when the prostate was adequately treated. The challenge, as with any new technology, is to minimize the learning curve for those who embrace this new technology.

I am interested to know whether my insights and interpretation of the Ripert study discussed in context with the relevant literature on the topic would lead Dr. Chodak to a different perspective on HIFU as a primary treatment for localized prostate cancer. I am confident the answer to this question is yes.

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Article entitled, "HIFU for Prostate Cancer: New Study Results Disappointing," was published on Medscape January 12, 2011 by Dr. Gerald Chodak.