Is Better Patient Selection the Key to Successful HIFU Therapy for Prostate Cancer?

Preliminary Results of an Optimization Study Designed to Find the Therapeutic “Sweet Spot”

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**Objectives**

High Intensity Focused Ultrasound (HIFU) therapy offers significant advantages over conventional definitive treatments for localized prostate cancer. Side effects from HIFU are substantially reduced compared to radical prostatectomy or radiation therapy and the total cost is considerably less. Efficacy of HIFU, however, remains a question. We developed a model HIFU prostate cancer protocol to improve outcomes using Multi-Parameter (MP) MRI localization and modified patient screening criteria. Early results are presented.

**Advantages of an MP-MRI Prostate Scan**

- Offers total gland assessment while improving sensitivity and specificity
- Image advantage over biopsies for anterior and apical cancers
- Provides an excellent metric for determining which patients may need treatment and which are candidates for CDM (Chronic Disease Management) or AS (Active Surveillance) protocols.
- Assesses lymph nodes and bone integrity in the true pelvis

**Clinical Value of an MP-MRI Prostate Scan**

- Shows a 98-100% PPV for diagnosing prostate cancer¹
- Defines the true extent of the disease without trauma or risk to the patient
- MP-MRI scanning takes the guess work out of diagnostics
- In a clinical setting, it enables a better definition of patient selection for AS, as well as an adjunct to surgical intervention including HIFU
- CAPSURE data demonstrates the need for diagnostic help: there is only a 70% success rate with radical prostatectomy and a 63% recurrence rate following radiation treatment
- Understanding the extent of the cancer is critical to the outcome

**Results**

After treatment, mean PSA nadir dropped to 0.28 ng/mL. The Phoenix definition for cure (nadir PSA level + 2), often used to determine efficacy of definitive radiation therapy, was used. Urethral narrowing or bladder neck contractures occurred in about 20% of patients but were easily treatable. No other significant side effects from HIFU therapy were noted. There were no reports of incontinence, rectal wall injury, fistulas or new erectile dysfunction. Duration of follow-up was 3 to 72 months. To date, just a single patient (Gleason 6 group) has shown a significant PSA increase since his HIFU procedure. This patient was successfully treated with radiation therapy.

**Conclusions**

Excellent diagnostics and outcomes are associated with physician technical skill and imaging skill while using ultrasound and a 3.0 MP-MRI scan. It is reasonable to say that reproducible outcomes will be seen when using the Ablatherm™ HIFU technology in properly selected patients.

**Table 1.** The goal was to look for the best candidates to yield the best outcomes. Entry criteria were as follows:

- Prostate size < 40 g, AP diameter < 32 mm, PSA < 8.5 ng/mL, Gleason Score of 6, 7, 8, or 9, and primary treatment within 3.5 years of diagnosis

**Biochemical Disease Free Rates (BDFR) with Comparison to CAPSURE Data**

<table>
<thead>
<tr>
<th>Research Author(s)</th>
<th>Country</th>
<th>BDFR Rates Minimum of 34 months (mean)</th>
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<tbody>
<tr>
<td>Blana, A. et al</td>
<td>Germany (2008)</td>
<td>77% Low and Intermediate Grades at 5 years 69% Low and Intermediate Grades at 7 years</td>
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<tr>
<td>Blana, A., Chaussey, C. et al</td>
<td>Germany (2009)</td>
<td>75% Low and Intermediate Grades</td>
</tr>
<tr>
<td>Orovan, W. et al. (Cleveland Clinic)</td>
<td>Canada (2012)</td>
<td>76% - Low Grade 69.5% - Intermediate Grade</td>
</tr>
<tr>
<td>Wheeler, R. (Sweet Spot Study’ in Press) 2014</td>
<td>USA</td>
<td>99% Low, Intermediate and High Grades</td>
</tr>
<tr>
<td>Uchida, T., Shoji, S., Nakono, M., et al</td>
<td>Japan (2008)</td>
<td>84% - Low Grade 64% Intermediate Grade</td>
</tr>
<tr>
<td>Crouzet, S. et al.</td>
<td>France (2010)</td>
<td>83% - Low Grade 75% - Intermediate Grade</td>
</tr>
<tr>
<td>Agarwal, P., Sadetsky, N., Konety, B. et al.</td>
<td>CAPSURE Data (2008)</td>
<td>37% - All treatment Grades – EBRT 70% - All treatment Stages -Surgical</td>
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</tbody>
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Reference: