

HIFU: Ready for Prime Time!

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**Cancer Centers of
Northern Arizona Healthcare**
Sedona Campus

I have nothing to disclose



Nothing else in the world . . . not
all the armies . . . is so powerful
as an idea whose time has come.

-Victor Hugo



**Cancer Centers of
Northern Arizona Healthcare**
Sedona Campus

HIFU

- * Used for at least 2 decades outside US
- * Approved in 50 countries
- * Minimally invasive
- * Ultrasound or MRI guided
- * Transrectal or transurethral systems
- * Outpatient
- * Rapid recovery
- * Minimal GU/sexual toxicity
- * No bleeding
- * No radiation to OAR's

Damage to sensitive organs often considered unacceptable after radiation or prostatectomy



Phase II/III Prospective Multicenter HIFU

- * **402 patients with mean**
 - * **Age 69.3 years**
 - * **Volume 28cc**
 - * **PSA 10.9**
 - * **Follow up 407 days**
- * **Negative re-biopsy 87.2%**
 - * **92.1% in low risk**

MRI Guided HIFU

- * **Transperineal mapping biopsy**
 - * 1-2 lesions, <10mm
- * **mpMRI**
- * **Toxicity at 2 year follow up**
- * **Slight insignificant deterioration EPIC urinary score**
- * **Trend decrease sexual function (4.4 points)**
- * **No significant change in EPIC subdomain score**

Salvage HIFU After Failed EBRT

- * **Whole gland HIFU**
- * **81% 1 year negative biopsy**
- * **AE in 91/100 patients**
 - * **67 Grade I**
 - * **80 Grade II**
 - * **20 Grade III**

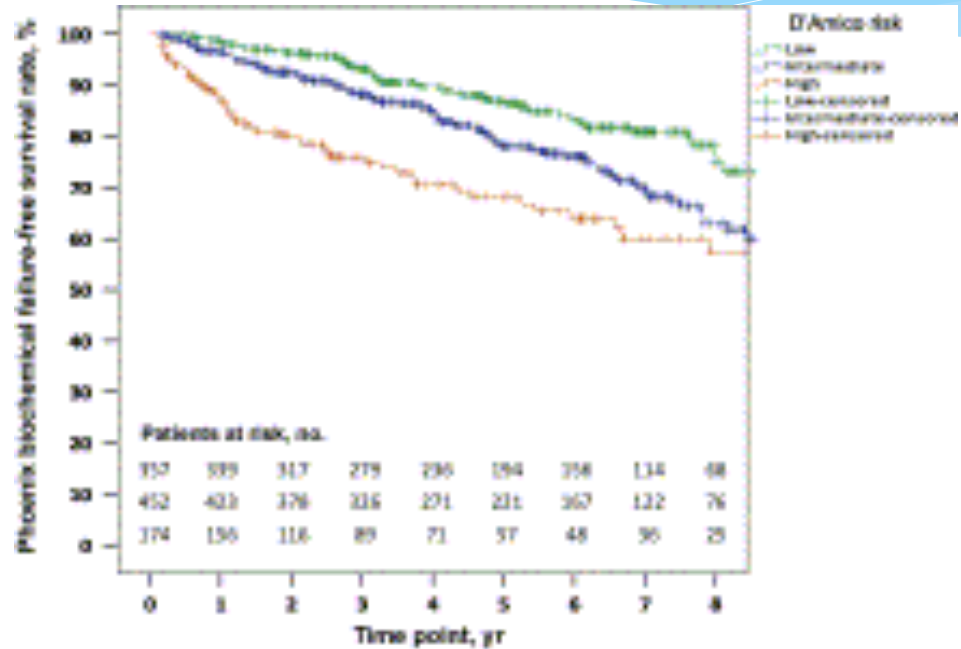
Longer follow up

- * 569 men with median age 65 yrs
- * Risk grouping: Low 28%, intermediate 56%, High 14%
- * Repeat HIFU in 163
- * Median F/U 46 months
- * 5 yr Failure Free 70%
 - * Low 87%
 - * Intermediate 63%
 - * High 58%
- * 7.7% UTI
- * 88% pad free

Whole Gland Ablation

- * 1002 patients
- * Primary prostate cancer
- * 60% 1 session 38% 2 sessions
- * 8 year biochemical free survival (Phoenix)
 - * 76% low 63% Intermed 57% high risk
- * 10 year PCa specific survival 97%
 - * Metastasis-free survival 94%

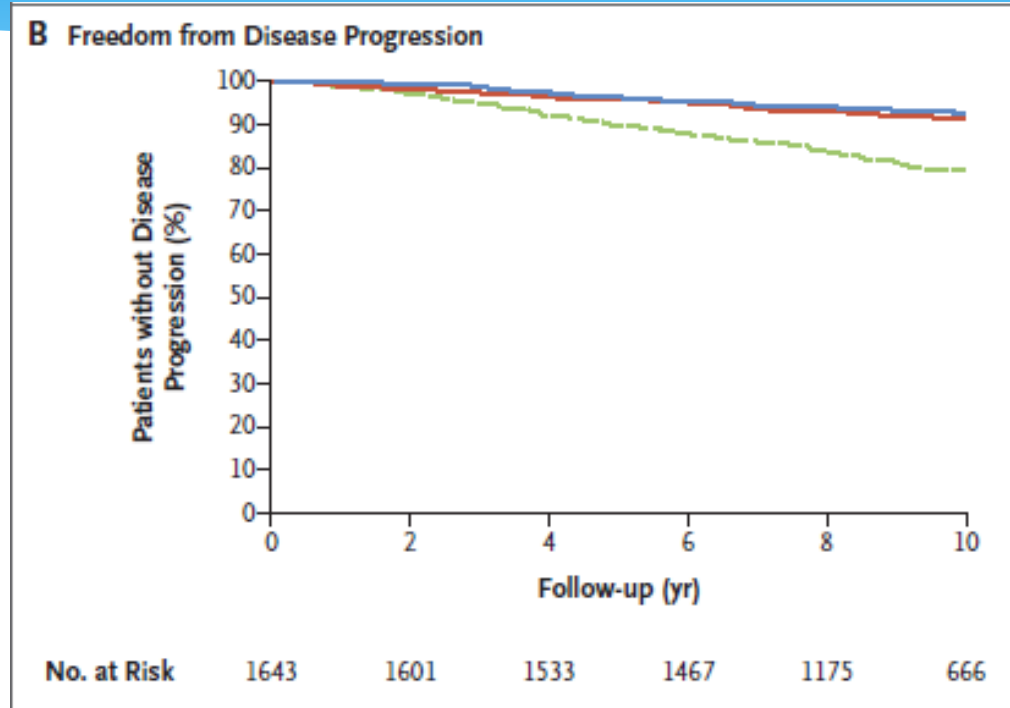
bDFS with HIFU



More late results HIFU

- * **702 patients – retrospective**
 - * **T1-2, PSA<50, no ADT**
 - * **78.5% intermediate or high risk**
 - * **Mean F/U 5.3 years**
- * **Ablatherm® HIFU**
- * **Cancer specific survival 99%**
- * **10 year freedom from salvage Tx 98% (low), 72% (intermed), 68% (high)**
- * **10 year Metastasis free survival 95%**

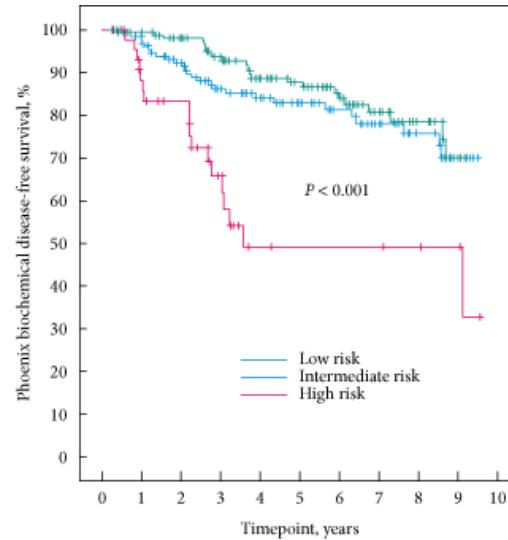
ProtecT Trial



Large Studies with Long Follow-up

- * 538 consecutive retrospective patients
- * Median F/U 8.3 years
- * Ablatherm™
- * Risk groups: Low 42.6%, Intermed 39.2% High 16.9%

Fourteen-year oncological and functional outcomes of high-intensity focused ultrasound in localized prostate cancer



Number at risk	0	1	2	3	4	5	6	7	8	9	10
Low risk	229	160	153	140	122	99	81	63	41	26	14
Int. risk	211	134	129	112	89	74	61	51	39	28	16
High risk	91	47	36	31	18	9	6	6	6	5	4

Multi-Center Trial

- * **Multicenter French study**
 - * T1c-T2, PSA<15, ≤2 sextants involved
 - * mpMRI urethra ≥ 5mm from tumor
- * **Focal HIFU**
- * **96 / 101 patients without evidence of clinically significant PCa on F/U biopsy**
 - * 87% no cancer in treated lobe
 - * 67% no cancer in entire gland
- * **97.2% without pads (stress incontinence 2.8%)**
- * **78.4% preserved erectile function**

HIFU Meta-Analysis

- * **13 studies**
 - * **11 primary**
 - * **2 salvage**
- * **543 patients**
- * **Median F/U 0.5-10.6 years**
- * **14% required subsequent oncologic therapy**

Clinical Trials Ongoing

- * **ExAblate MR Guided Focused Ultrasound**
 - * **NCT01657942**
- * **Endocare CRYOcare vs Galil Medical CRYO-HIT**
 - * **NCT00295802**

Case Selection is Key

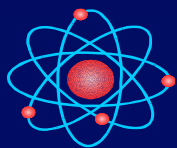
- * Treat whole gland when needed
- * Treat focally when not
- * May be bridge between active surveillance and more aggressive surgery

Approved By FDA for “prostate ablation”

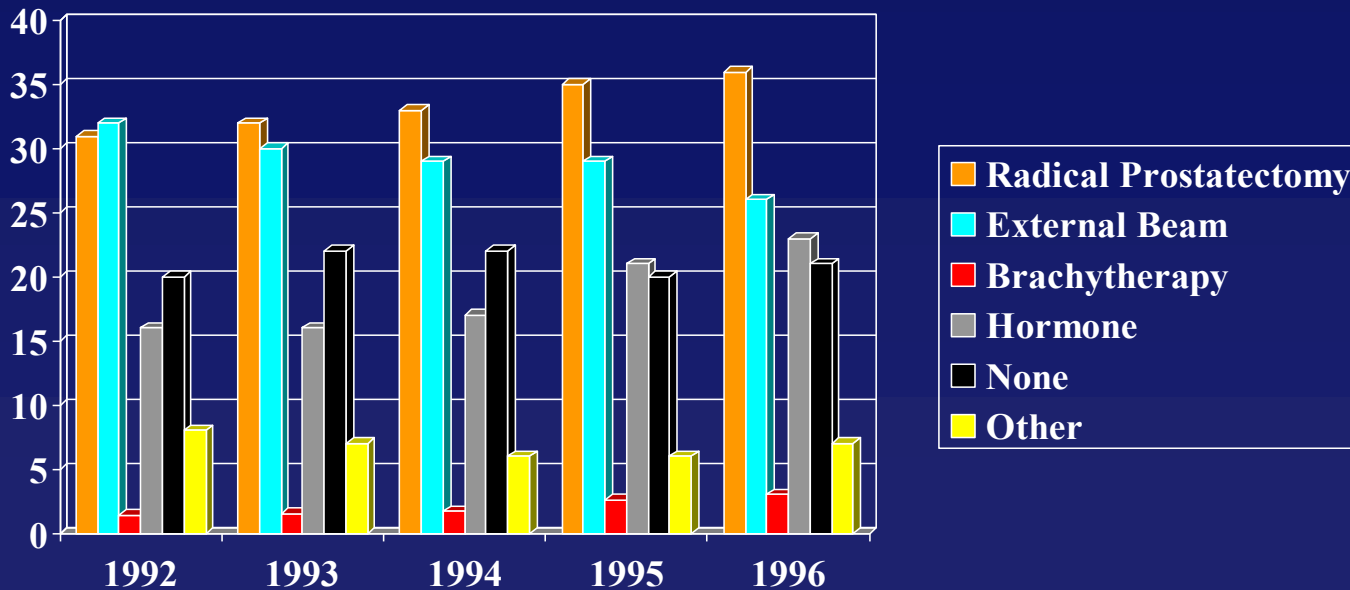
- * Different technologies and protocols
- * Lack of consensus on ideal candidate

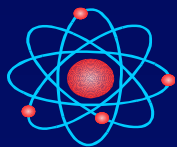
HIFU

**Are we just where brachytherapy
was 20 years ago?**



Trends in Prostate Cancer

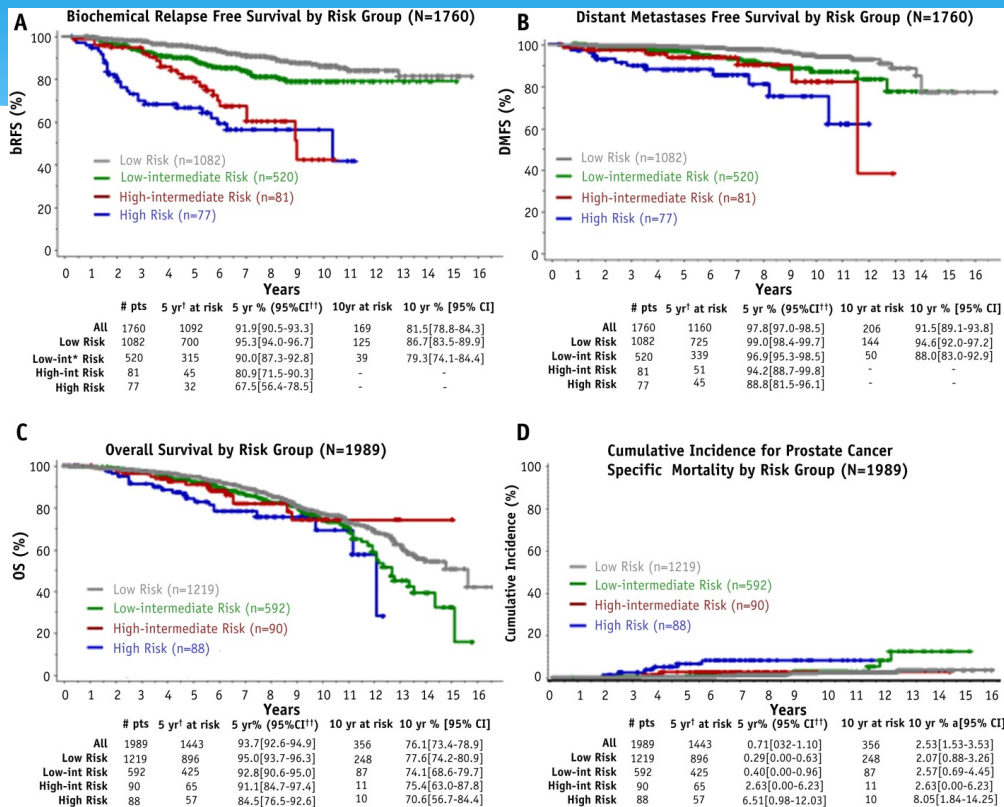




ABS Consensus Dose HDR

Center	XRT	HDR
CET	36Gy	6Gy x4
LBMCC	39.6 Gy	5.5-6.5 Gy x4
MMC	45 Gy	5.5 Gy x4
SPI	45-50.4 Gy	4 Gy x4 6 Gy x3
WBH	46 Gy	9.5 Gy x2
Kiel	50.4	15 Gy x2

LDR Brachytherapy Monotherapy



*Int = Intermediate; † yr = Year; †† CI = Confidence interval



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Keep your pecker up, Bill...new prostate cancer zapper won't wreck your love life! Pioneering soundwave treatment proves as effective as surgery

- High-intensity focused ultrasound blasts tumours with soundwaves
- Study shows its 93 per cent success rate as effective as surgery
- But rate of erectile dysfunction in HIFU patients post treatment much lower
- 'Experimental' treatment not widely available in UK and costs £10,000

By BARNEY CALMAN, HEALTH EDITOR FOR THE MAIL, ON SUNDAY
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A treatment that uses sound waves to blast away prostate tumours has been proven to cure as many men of the disease as surgery that removes the gland - while causing significantly fewer side effects.

Until now the new procedure, called high-intensity focused ultrasound (HIFU), has been considered experimental.

This has meant that the majority of British men diagnosed with the condition - who include former Rolling Stone Bill Wyman - are offered the more invasive operation called radical prostatectomy, which has a clear track record despite the risk of impotence and incontinence.

But a landmark study to be announced



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► 'Pregnant' Khloe Kardashian looks lips with boyfriend Tristan Thompson by the beach in heart-melting photo... as she gives relationship advice

When Does a New Treatment Become A Standard of Care

- * No perfect answer
- * “Appropriate Use of Advanced Technologies for Radiation Therapy and Surgery in Oncology”
 - * National Academies of Medicine Workshop, July 2015
- * The bar is higher now than ever before
- * Hypothesis generating studies
- * Multicenter studies
- * Meta Analyses
- * Widely available

DO YOU NEED COFFEE?



ARE YOU
BATMAN?

yes

no

liar

YOU
NEED
COFFEE



HIFU: Ready for Prime Time!