



# **DON MILLS SURGICAL UNIT**

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# PROSTATE CANCER TREATMENT

- ◆ What is HIFU?
- ◆ Who is a candidate?
- ◆ Why HIFU?
- ◆ What is the cost?



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# HIGH INTENSITY FOCUSED ULTRASOUND (HIFU)

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- ◆ “Image Guided Ablation”
- ◆ Ablatherm vs Sonoblat
- ◆ U/S Imaging: U/S Ablation
- ◆ Software (Computer) Directed

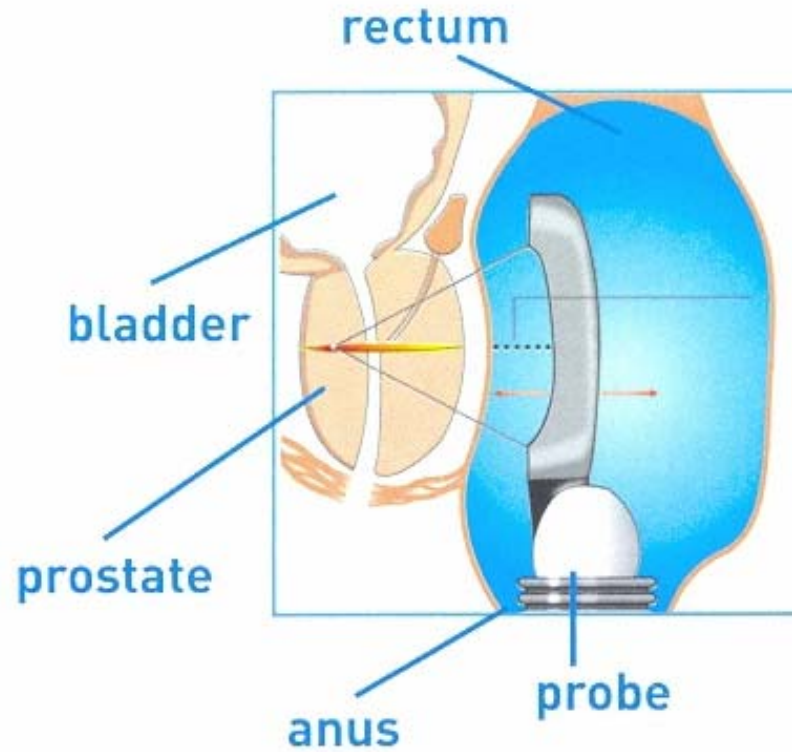


# PROCEDURE



1. Spinal Anaesthetic/IV Sedation
2. Right Lateral Decubitus Position
3. Transrectal Probe
4. Catheter Intra/Post Op

# PROCEDURE













# COMPUTER GUIDANCE



## 1. Ultrasound Imaging

- Prostate mass
- Rectal wall thickness
- Treatable segments
- Nerve sparing targeting

# COMPUTER GUIDANCE

## 2. Ultrasound Treatment

- By segment
- Catheter in/out/in
- Time 2 – 2 ½ hours Rx

# TREATMENT PLAN

- ◆ Pre Op Assessment
  - Biopsy results (cores)
  - TRUS (mass)
  - Gleason grade
  - PSA
  - Staging studies
  - EKG & routine blood work

# TREATMENT PLAN

- ◆ Two patients per day
  - Arrive clinic 1 hour in advance
  - Total stay 7 – 8 hours
  - Discharge with foley catheter
  - Script on discharge

# TREATMENT PLAN

## ◆ Post Op Visit

- Post Op Day #1 at clinic
- Arrangements re catheter
- Follow up Q  $3/12$  x 2 years / Q  $3/12$  afterward

# WHO IS A CANDIDATE

- ◆ Organ confined disease T-1/T-2
- ◆ Prostate mass < 30 grams
  - TURP
  - Hormone Rx
- ◆ General good health
- ◆ Low risk/High risk

# WHO IS A CANDIDATE

- ◆ Primary Disease/XRT failure
- ◆ Relative Contraindications
  - Co Morbid Medical Condition
  - Obesity
  - Lumbar Spine Problem
  - Anal Stricture
  - Latex Allergy

# WHY HIFU?

- ◆ Curative Options:

  - Surgery (RP/RRP/LRP)

  - XRT (External/brachy)

  - CRYO Rx

  - HIFU

- ◆ Watchful Waiting



# OUTCOMES

- ◆ No large randomized trials
- ◆ Low risk/high risk
- ◆ 5 year data/10 year data
- ◆ Treatment morbidity
- ◆ Disease specific survival/overall survival

# RISK CATEGORIES

	<u>PSA</u>	<u>Gleason</u>	<u>Stage</u>
<b>Low</b>	$\leq 10$	$\leq 6$	$\leq T2A$
<b>Medium</b>	$\leq 20$	7	T1/T2
<b>High</b>	$> 20$	$\geq 8$	$\geq T3$

# XRT OUTCOMES

## (Kupelian et al, 2002)

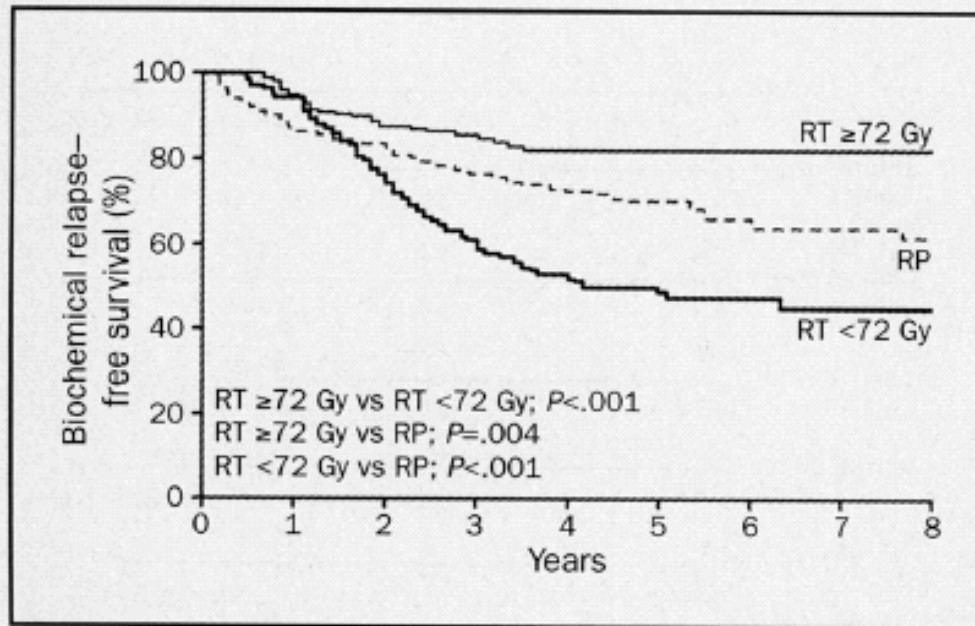


FIGURE 2. Results of treatment for patients with at least 1 unfavorable prognostic factor (T2b-T2c, Gleason score  $\geq 7$ , or prostate-specific antigen  $>10$  ng/mL) according to therapeutic modality and radiotherapy (RT) dose level. RP = radical prostatectomy. From Kupelian et al.<sup>16</sup> Reprinted with permission from the American Society of Clinical Oncology.

# XRT OUTCOMES

## RROG and others

- ◆ 47% biochemical failure at 8 years
- ◆ 78-86% “disease specific” 10 year survival (low risk)

# XRT OUTCOMES

## (Wei et al, 2002)

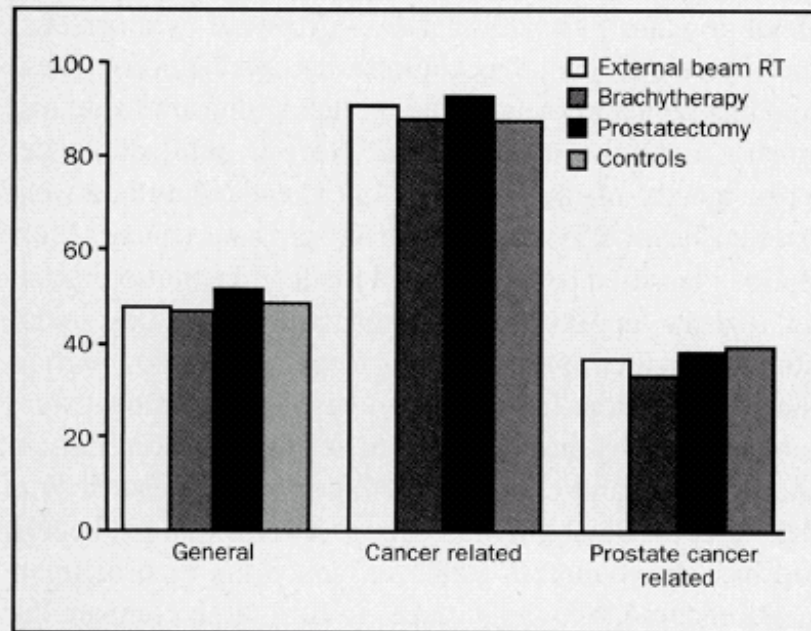


FIGURE 5. Quality of life among patients more than 1 year after undergoing external beam radiotherapy (RT) (147 patients), brachytherapy (84), or prostatectomy (671) for prostate cancer or among controls (112) without prostate cancer. Raw values represent the mean of the treatment group, with higher values indicating better quality of life. The difference between brachytherapy and controls was significant only in the prostate cancer-related domain; no other significant differences were identified. Data from Wei et al.<sup>55</sup>

# XRT OUTCOMES

- ◆ Higher dosage levels > 72 Gy
- ◆ Neo adjuvant (LHRH/androgen suppression)
- ◆ Adjuvant (RTOG/EORTC)

# SURGERY OUTCOMES

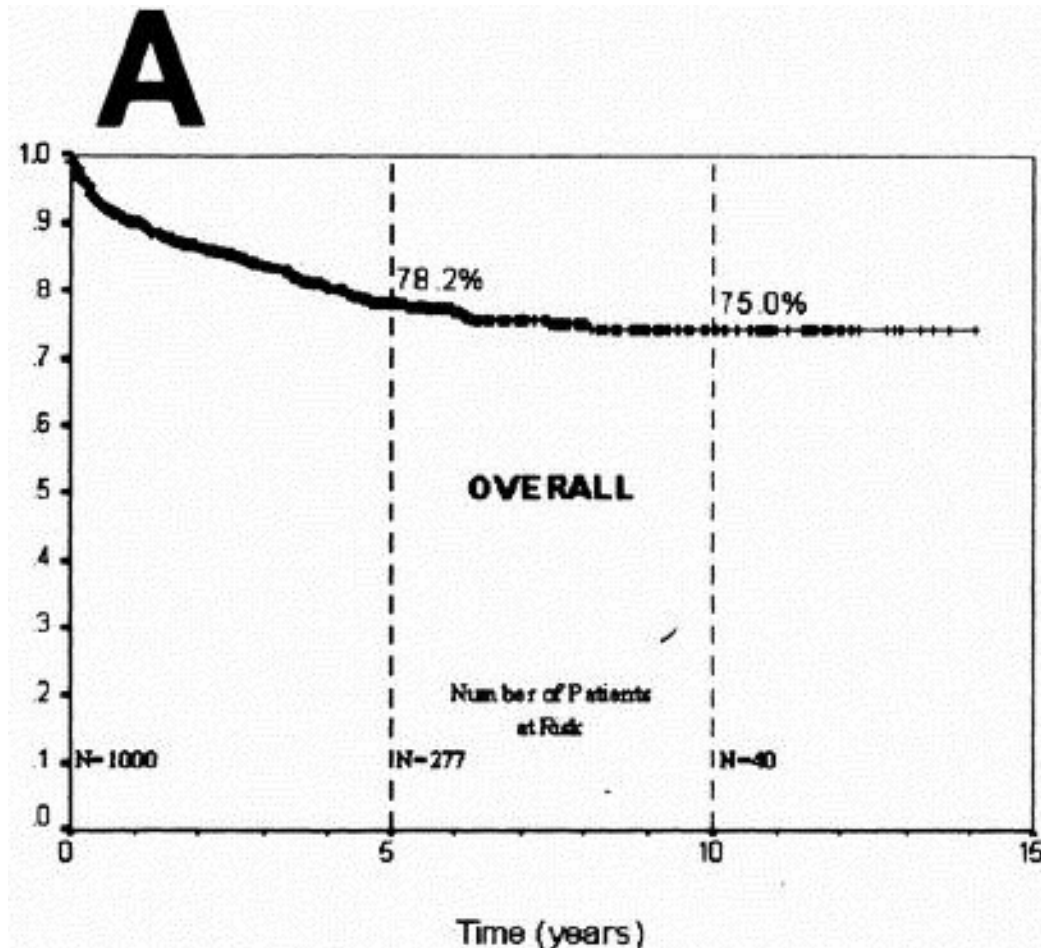
(Hull et al, 2002)

TABLE 3. *Actuarial overall, cancer specific, and metastasis-free survival rates, and progression-free probabilities*

End Point	Mean $\pm$ 2 SE or 95 CI (No. pts. at risk)	
	5 Yrs.	10 Yrs.
Cancer specific	99.1 $\pm$ 0.78 (372)	97.6 $\pm$ 1.71 (55)
Metastasis-free	89.9 $\pm$ 2.29 (328)	84.2 $\pm$ 4.41 (47)
Progression-free	78.2 $\pm$ 3.10 (277)	75.0 $\pm$ 3.72 (40)
Overall	95.5 $\pm$ 1.71 (372)	86.6 $\pm$ 4.43 (56)

# SURGERY OUTCOMES

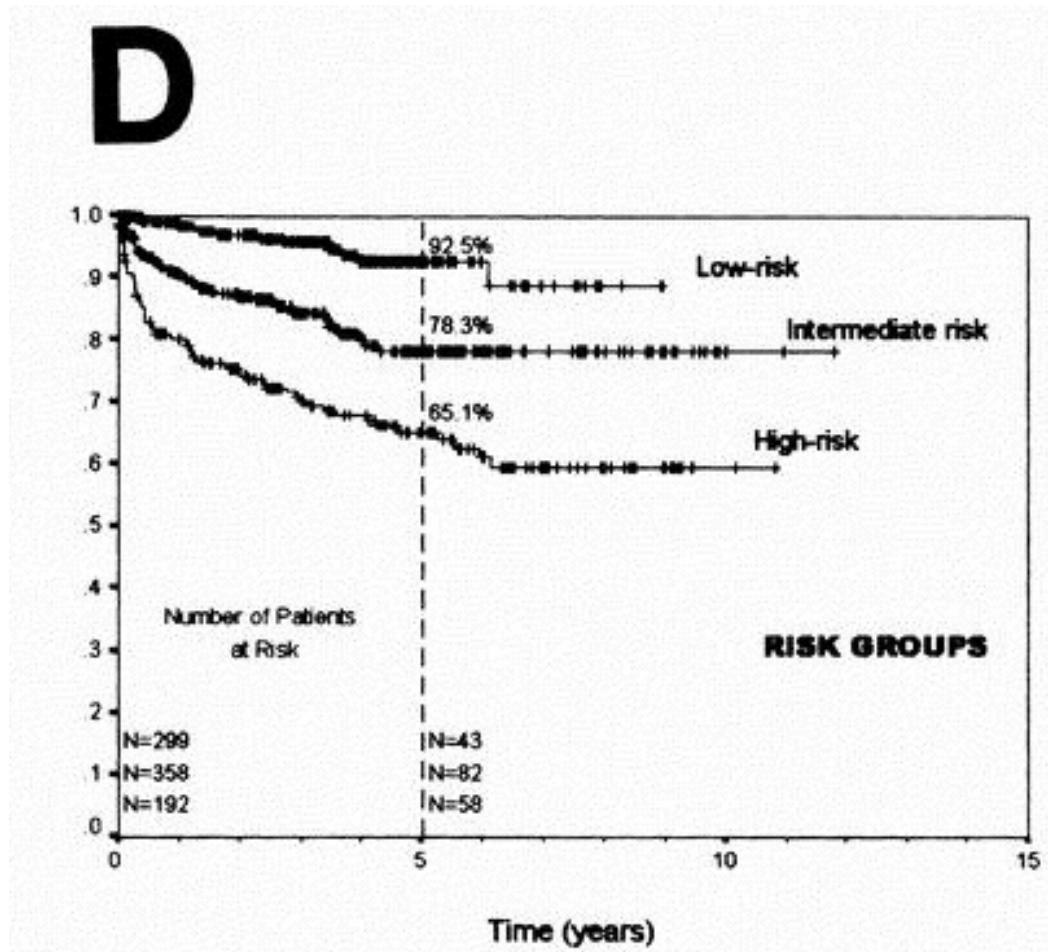
(Hull et al, 2002)





# SURGERY OUTCOMES

(Hull et al, 2002)



# HIFU OUTCOMES

(Blana, 2004)

- ◆ 146 patients – moderate risk group
- ◆ 171 sessions for 146 patients
- ◆ Mean treatment time - 160 minutes
- ◆ Whole prostate treatment (146%)

# PRE OP ASSESSMENT

- ◆ TRUS and Biopsy
- ◆ Digital Rectal Examination
- ◆ Cat Scan or MRI
- ◆ Bone Scan
- ◆ PSA

# PATIENT PROFILE

- ◆ Age  $66.9 \text{ Years} \pm 6.7$
- ◆ PSA  $7.6 \pm 3.4$
- ◆ Gleason  $5 \pm 1.2$
- ◆ P. Volume  $23 \pm 7.7 \text{ cm}^3$

# PATIENT FOLLOW UP

- ◆ PSA                      Q <sup>3</sup>/<sub>12</sub>
- ◆ Biopsy                    3, 12 and 24 Months
- ◆ Mean f/u                22.5 mth. – Range 4-6%

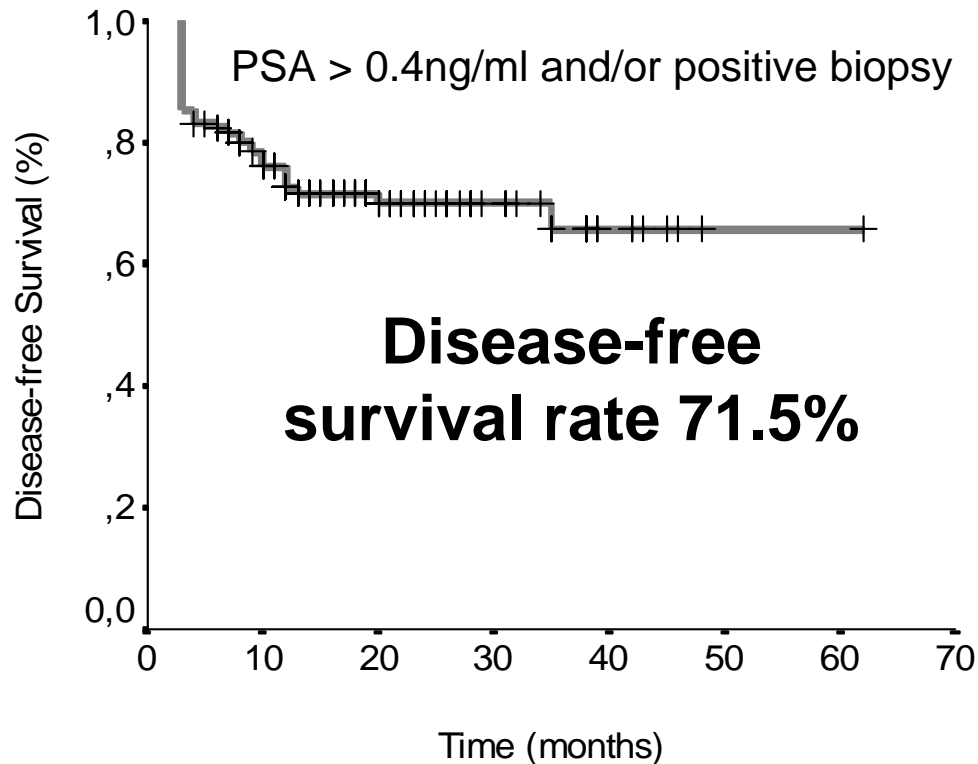
# OUTCOME MEASURE

- ◆ End Point:
  - PSA (Biochemical failure)
  - Or
  - Biopsy proven failure
- ◆ 93.4% Constant Negative Biopsy
- ◆ 87% Constant PSA  $\leq$  1 ng/ml

# OUTCOME MEASURE

(Blana et al, 2004)

HIFU for localized prostate cancer (Results n=137)



# COMPLICATIONS OF HIFU

(Blana, 2004)

TABLE I. *Adverse effects after HIFU*  
(*n = 137*)

Adverse Effect	Patients (n)	%
Symptomatic UTI	6	4.8
Chronic pelvic pain	2	1.5
Infravesical obstruction	16	11.7
Stress incontinence		
Grade 1	8	5.8
Grade 2–3	0	0
Rectourethral fistula	1	0.7

KEY: HIFU = high-intensity focused ultrasound; UTI = urinary tract infection.



# ADVERSE EFFECTS

## (Blana, 2004)

Multiple HIFU (adverse effects after 1. HIFU n = 223)

	<b>Patients (n)</b>	<b>%</b>
<b>Urinary tract infection</b>	9	0.4
<b>Chronic pelvic pain</b>	2	0.9
<b>Infravesical obstruction</b>	44	19.7
<b>Stressincontinence I°</b>	16	7.2
<b>Stressincontinence II°</b>	1	0.4
<b>Stressincontinence III°</b>	0	0
<b>Rectourethral fistula</b>	0	0
<b>Rate of impotence</b>		49.8

# QUALITY OF LIFE IN HIFU

(Lunz et al., EAU 2005)

A questionnaire was sent by mail to 179 patients after HIFU and 206 patients after radical prostatectomy

## **Inclusion criteria:**

- ◆ localized disease at time of treatment
- ◆ minimal follow-up of 6 months after last treatment
- ◆ written informed consent

# QUALITY OF LIFE IN HIFU

## Questionnaire

(Lunz et al., EAU 2005)

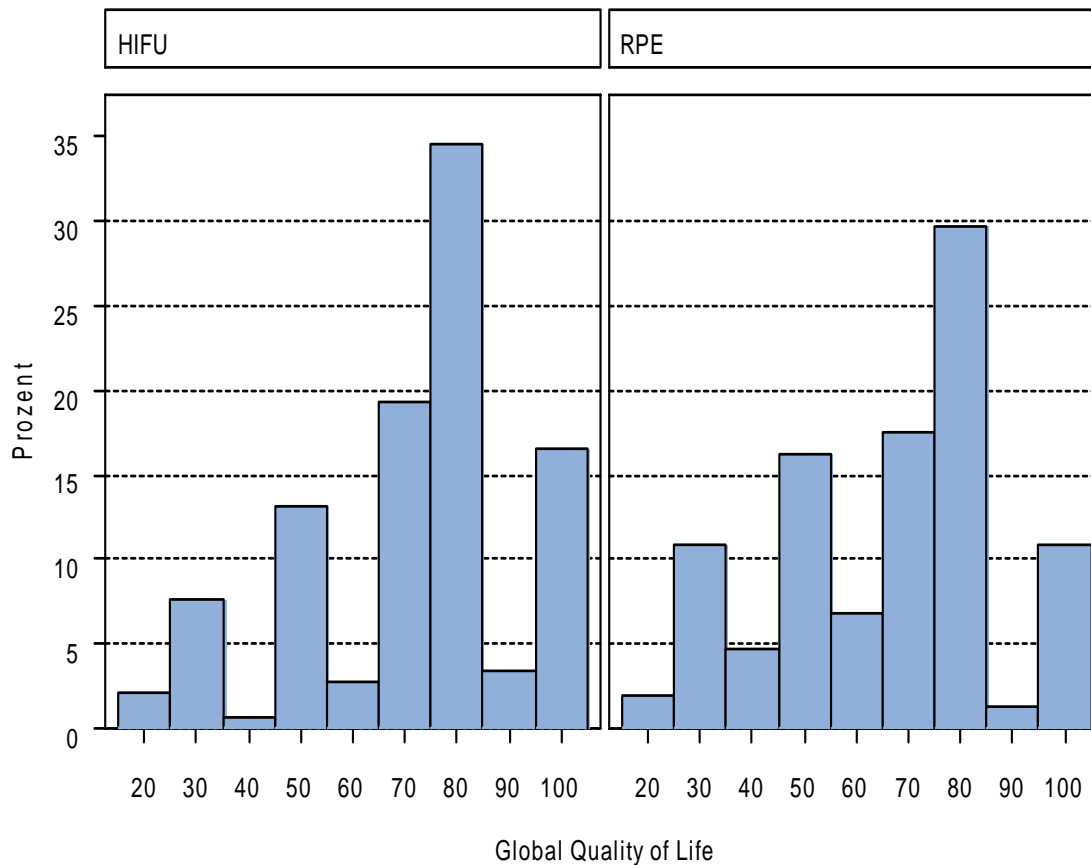
The questionnaire consisted of 62 questions and was compiled from:

- ◆ The EORTC-QLQ C30 version 3.0
- ◆ The IPSS
- ◆ The IIEF-5
- ◆ Self-constructed questions for
  - orgasm
  - urinary incontinence
  - therapy satisfaction
  - co morbidity
  - education and profession

# QUALITY OF LIFE IN HIFU

## HRQOL

(Lunz et al., EAU 2005)



The HRQOL, based on the EORTC-QLQ C30, resulted in a significant better value for patients after HIFU ( $p = 0.023$ )

# QUALITY OF LIFE IN HIFU

(Lunz et al., EAU 2005)

- ◆ Erectile function
- ◆ Continence
- Significantly better in the HIFU group
  
- ◆ IPSS comparable in both groups

# SALVAGE THERAPY: WHY?

(D'Amico, 2003)

- ◆ 415 patients treated with EBRT (1998-2001)

**PSA failure : 39%**

- ◆ prostate cancer specific death 5 years after PSA failure
  - **Gleason 2-6 : 24%**
  - **Gleason 3+4 : 40%**
  - **Gleason 4+3 or higher : 59%**

# SALVAGE THERAPY

## Patient's Characteristics

Patients : 123

Age :  $68 \pm 6$  years

Mean PSA :  $7.88 \pm 8$  ng/ml

Gleason score:

2-6 : 41	} <b>67%</b>
7 : 29	
8-10 : 53	

Mean prostate volume :  $18.4 \pm 9.2$  cc

No Metastasis on bone-scan and CT-scan

# SALVAGE HIFU:

## Global Characteristics

HIFU session : 1.2 /patients

Mean follow up : 16 months (3-112)

**Negative biopsies rate : 82 % (101/123)**

Prostate volume:

Before HIFU :  $18.4 \pm 9.2$  cc

After HIFU :  $13.2 \pm 9.42$  cc



# INDICATIONS

- ◆ Organ confined prostate Ca
- ◆ Unwilling or unfit for RP or XRT
- ◆ Recurrence after primary Rx XRT
- ◆ A serious option for patient consideration