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Impact of **Neoadjuvant Degarelix** on Pathological Finding after Robotic Assisted Radical Prostatectomy for Advanced Prostate Cancer

林威宇
嘉義長庚



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半年會展望



2017
2/18 嘉義長庚 × 故宮南院
傳承與創新

Neoadjuvant Androgen deprivation therapy (ADT) +radical prostatectomy (RP) for advanced prostate cancer -----Pathological Response

- Neoadjuvant ADT+ RP VS. Immediate RP
- Neoadjuvant ADT (Degarelix vs. LHRH agonist) + RP
- Intense Neoadjuvant ADT + RP

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- Patients with prostate cancer with a **Gleason score of 8 to 10** have a **greater than 30% risk of 20-year** prostate cancer mortality after radical prostatectomy.

J Urol 2011

J Clin Oncol 2009

*Consequently, an urgent need exists to develop novel **multimodality strategies** to improve outcomes for patients with prostate cancer **at high risk of recurrence.***

J Clin Oncol 2019

- **Neo adjuvant systemic** therapy targets **micrometastatic disease** responsible for the **majority of recurrences** and has demonstrated improved outcomes for several **solid tumor**

Breast cancer.

Clin Cancer Res 2014

J Clin Oncol 2008

Esophageal ca

J Clin Oncol 2005

Bladder cancer

Eur Urol 2014



REVIEW ARTICLE

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Neoadjuvant therapy in high-risk prostate cancer

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Adelaide, South Australia, Australia

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Table 1: Definitions of high-risk prostate cancer

Classification system	PSA (ng/ml)	Grade group	Clinical stage
D'Amico ^[11]	>20	4-5	T2c
AUA/ASTRO/SUO ^[2]	≥20	4-5	≥T3
EAU (localized) ^[3]	>20	4-5	T2c
EAU (locally advanced) ^[3]	Any	Any	T3-4 or N1
NCCN (high) ^[12]	>20	4-5	T3a
NCCN (very high) ^[12]	Any	Primary 5 or >4 cores of 4-5	T3b-4

PSA=Prostate-specific antigen, AUA=American Urological Association, ASTRO=American Society for Radiation Oncology, SUO=Society of Urologic Oncology, EAU=European Urology Association, NCCN=National Comprehensive Cancer Network

Table 2: Types of neoadjuvant systemic therapies

Type	Mechanism of action	Examples
Nonsteroidal Antiandrogen	Inhibit binding of DHT and testosterone to androgen receptor	Bicalutamide, Flutamide, Nilutamide
Steroidal antiandrogen	Inhibit binding of DHT and testosterone to androgen receptor	Cyproterone acetate
CYP17A1 inhibitor	Inhibit testosterone synthesis in adrenal and prostate glands	Abiraterone
LHRH agonist	Suppress hypothalamic-pituitary-gonadal axis	Leuprolide Acetate, Triptorelin Pamoate, Goserelin Acetate, Histrelin Acetate
LHRH antagonist	Suppress hypothalamic-pituitary-gonadal axis	Degarelix
Chemotherapy	Cytotoxicity	Docetaxel
Immunotherapy	Variable based on agent	GVAX, bevacizumab

LHRH=Luteinizing hormone-releasing hormone, DHT=Dihydrotestosterone, GVAX=granulocyte-macrophage colony-stimulating factor (GM-CSF)-secreting allogeneic cellular vaccine

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Goldenberg <i>et al.</i> ^[51]	1996	213	T1b-T2c	Cyproterone	3 months			Neo 42, RP 20	Neo 28, RP 65	Neo 28, RP 14	Neo 7, RP 3
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Yee <i>et al.</i> ^{*, [61]}	2010	148	T1b-T3	Goserelin, Flutamide	3 months			Neo 85, RP 80	Neo 19, RP 38	Neo 4, RP 6	Neo 1, RP 3

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Table 3: Pathology specimen findings in randomized trials of neoadjuvant androgen deprivation therapy and radical prostatectomy versus immediate radical prostatectomy alone for clinically localized prostate cancer

Author	Year	n	Clinical Stage	Neoadjuvant therapy	Therapy duration	Clinical downstaging (%)	Pathological downstaging (%)	Organ confined (%)	Positive margins (%)	Seminal vesicle invasion (%)	pN+ (%)
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Table 4: Oncological outcomes in randomized trials of neoadjuvant androgen deprivation therapy and radical prostatectomy versus immediate radical prostatectomy alone for clinically localized prostate cancer

Author	Year	Total patients	Clinical stage	Neoadjuvant therapy	Therapy duration	BCR/PSA progression (%)	Local recurrence (%)	Met disease (%)	Follow-up	Overall survival (%)
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Aus <i>et al.</i> ^{*[62]}	2002	126	T1b-3aNxM0	Triptorelin, Cyproterone	3 months	Neo 33, RP 29		Neo 5, RP 3	7 years	Neo 83, RP 86
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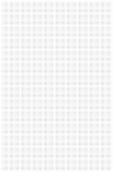
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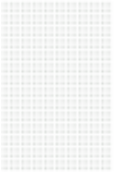


Neoadjuvant therapy in high-risk prostate cancer

Indian J of Urology 2020



- Several randomized trials have shown that nADT prior to RP significantly **improves pathologic findings**
downsizing of the tumor,
reduced positive surgical margin rates
tumor downstaging,
without a demonstrable intermediate-term oncological benefit.
- These trials were limited by **short follow-up periods** and included large cohorts of men with **low- and intermediate-risk PCa**, which may have **diluted the potential survival benefits in the higher risk PCa.**



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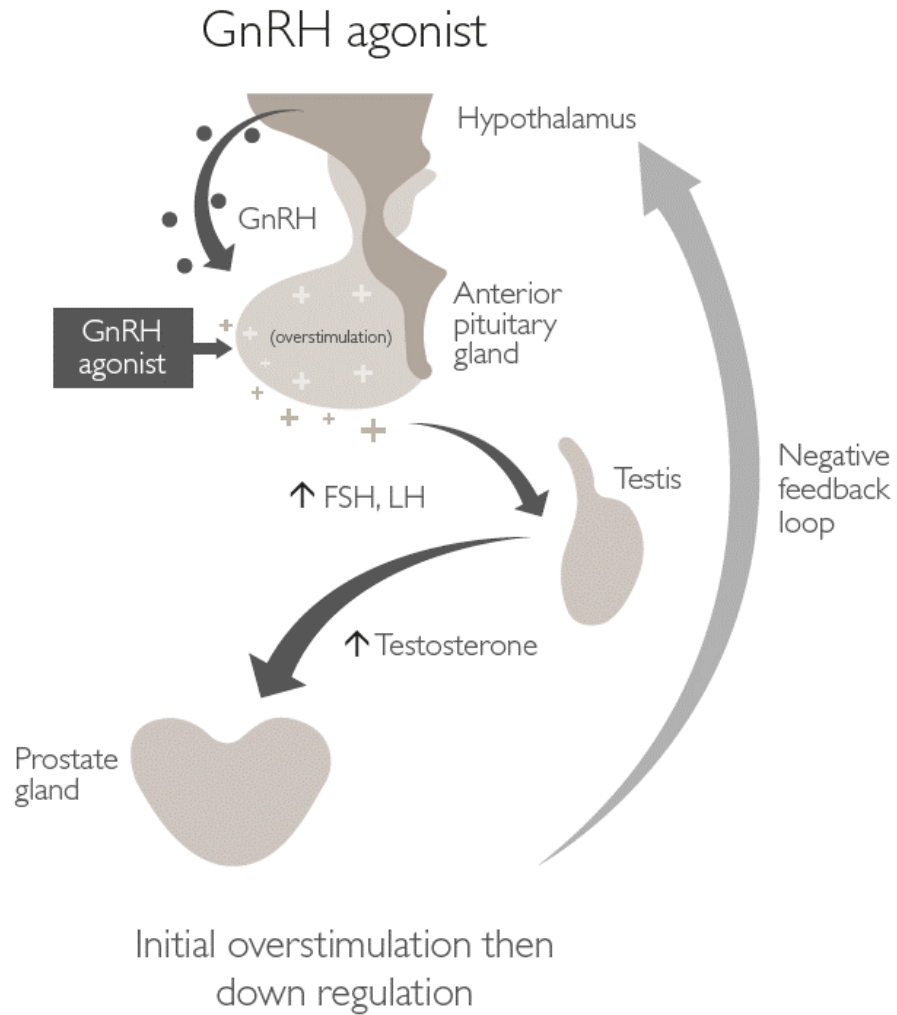
- Retrospective and nonrandomized prospective studies in patients with **high-risk PCa demonstrate promising longer-term survival outcomes.**
- More recently, an increasing body of literature including level 1 evidence suggests that nCHT may be associated with **pathological downstaging, and improved longer-term recurrence-free and overall survival in high-risk PCa.**

Neoadjuvant Androgen deprivation therapy (ADT) +radical prostatectomy (RP) for advanced prostate cancer -----Pathological Response

- Neoadjuvant ADT+ RP VS. Immediate RP
- Neoadjuvant ADT (Degarelix vs. LHRH agonist) + RP
- Intense Neoadjuvant ADT + RP

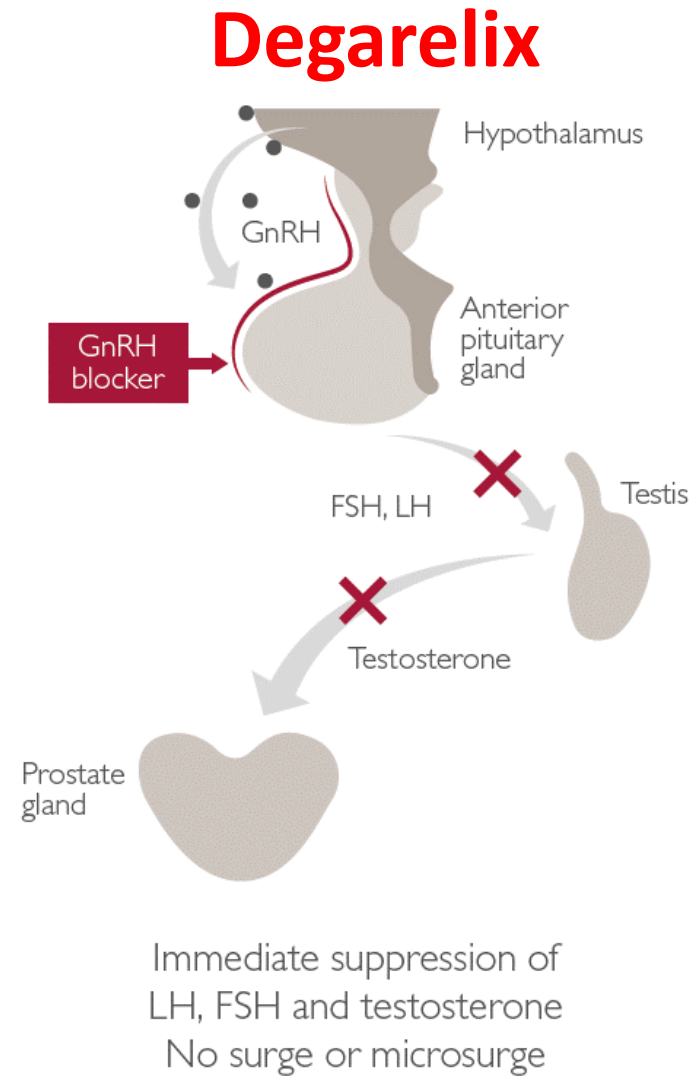
A Phase II, Randomized, Open-Label Study of Neoadjuvant Degarelix versus LHRH Agonist in Prostate Cancer Patients Prior to Radical Prostatectomy

- Randomized, open-label
- Localized prostate cancer
 - T stage $\geq$ T2, Gleason score $\geq$ 7
 - Intermediate and high risk
- 3 arms for 3 months neoadjuvant ADT
 - Degarelix (N=13)
 - Degarelix + Bicalutamide (N=14)
 - LHRH agonist (L or G) + Bicalutamide (N=12)



GnRH agonists

Initial overstimulation of GnRH receptors leads to an increase in LH and testosterone production
Chronic administration eventually leads to suppression of LH, resulting in suppression of testosterone

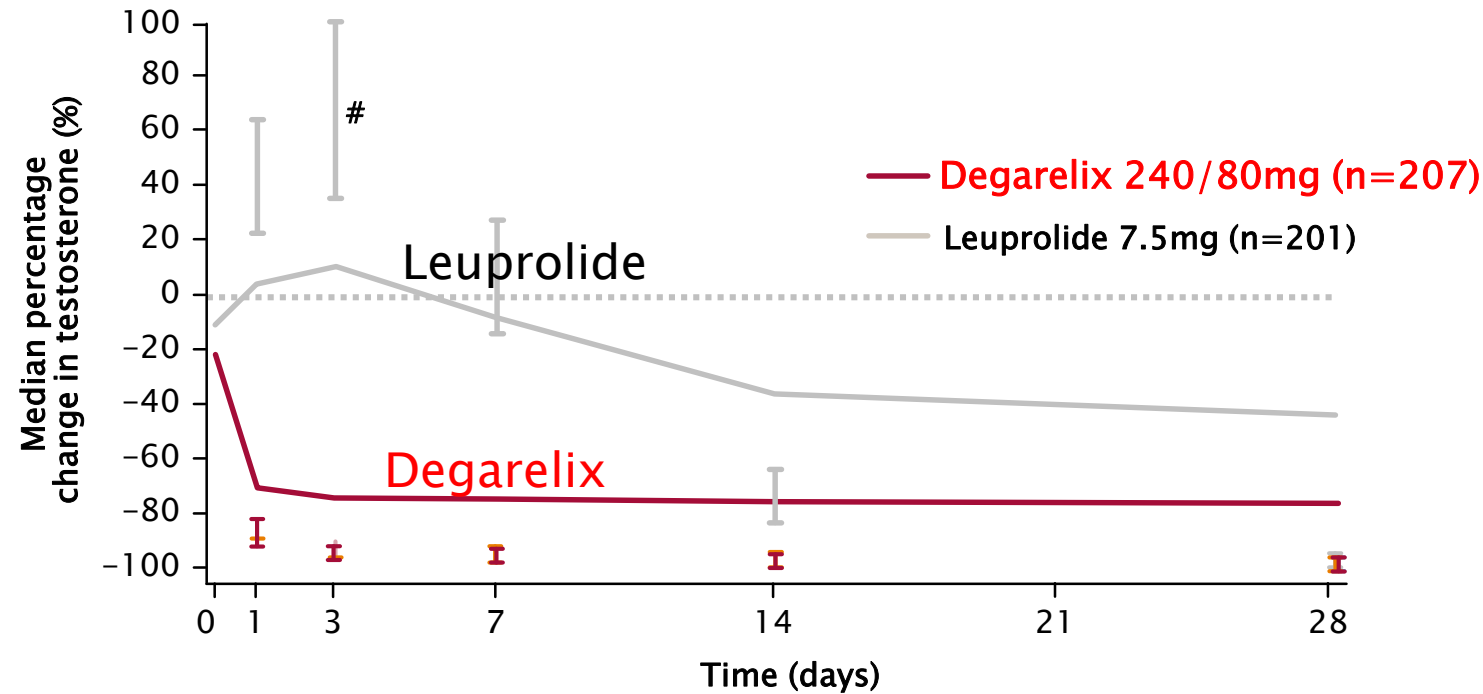


GnRH antagonists

GnRH antagonists have an immediate onset of action, preventing gonadotrophin release through receptor blockade, leading to rapid suppression of LH and testosterone

Rapid Testosterone Reduction and No Risk of Clinical Flare

Median Percentage of patients with testosterone levels ≤ 0.5 ng/mL during the first month of treatment



- 96.1% patients with FIRMAGON achieved median $T \leq 0.5$ ng/mL by Day 3
- No risk for a testosterone surge or clinical flare with FIRMAGON

#p<0.001 degarelix versus leuprolide

ITT population. Data are median $\pm$ standard error.

A Phase II, Randomized, Open-Label Study of Neoadjuvant Degarelix versus LHRH Agonist in Prostate Cancer Patients Prior to Radical Prostatectomy

Table 2. Pathologic and clinical outcomes

	Degarelix (<i>n</i> = 13)	Degarelix + bicalutamide (<i>n</i> = 14)	LHRH agonist + bicalutamide (<i>n</i> = 12)	<i>P</i> ^a
Pathologic stage, <i>n</i> (%)				0.449
pT0	0 (0.0)	2 (14.3)	1 (8.3)	
pT1	0 (0.0)	0 (0.0)	0 (0.0)	
pT2	5 (38.5)	4 (28.6)	4 (33.3)	
pT3	8 (61.5)	8 (57.1)	6 (50.0)	
pT4	0 (0.0)	0 (0.0)	1 (8.3)	
Extraprostatic extension, <i>n</i> (%)	8 (61.5)	8 (57.1)	6 (50.0)	0.843
Positive margins, <i>n</i> (%)	5 (38.5)	3 (21.4)	4 (33.3)	0.615
Positive nodes, <i>n</i> (%)	3 (23.1)	0 (0.0)	3 (25.0)	0.136
RP failure, <i>n</i> (%)	1 (7.7)	1 (7.1)	1 (8.3)	0.994
PSA failure (≥ 0.2 ng/mL) or use of adjuvant ADT or XRT, <i>n</i> (%)	2 (15.4)	4 (28.6)	6 (50.0)	0.169
Change in baseline Gleason score ^b				0.090
Upstaging	0	1	0	
No change	4	2	0	
Downstaging	3	0	0	
Median cancer mass, grams (range)	3.44 (0.24–33.60)	1.00 (0.00–12.06)	1.10 (0.00–24.25)	0.413

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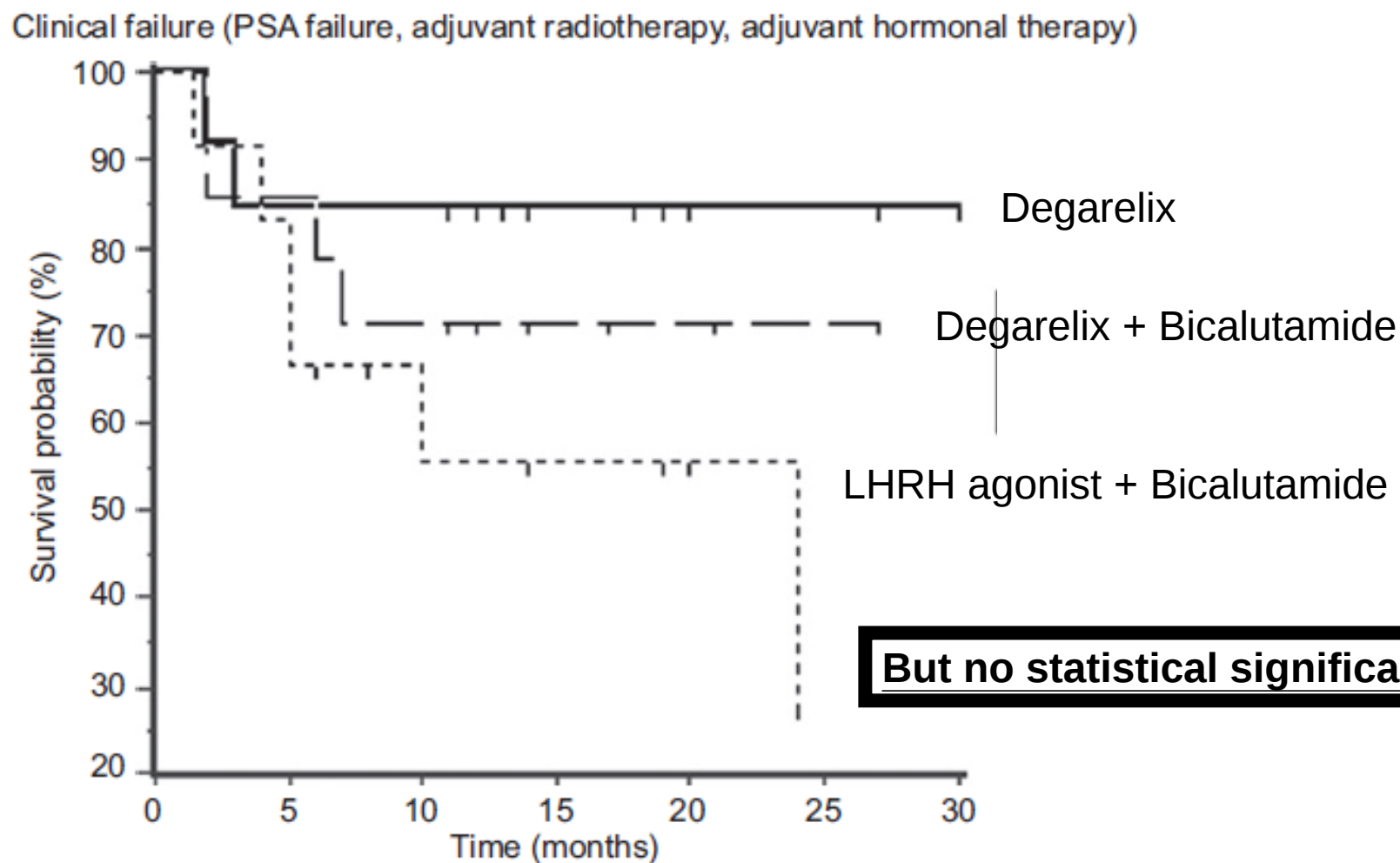
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Downstaging	3	0	0	
Median cancer mass, grams (range)	3.44 (0.24–33.60)	1.00 (0.00–12.06)	1.10 (0.00–24.25)	0.413

A Phase II, Randomized, Open-Label Study of Neoadjuvant Degarelix versus LHRH Agonist in Prostate Cancer Patients Prior to Radical Prostatectomy

Table 2. Pathologic and clinical outcomes

	Degarelix (<i>n</i> = 13)	Degarelix + bicalutamide (<i>n</i> = 14)	LHRH agonist + bicalutamide (<i>n</i> = 12)	<i>P</i> ^a
Pathologic stage, <i>n</i> (%)				0.449
pT0	0 (0.0)	2 (14.3)	1 (8.3)	
pT1	0 (0.0)	0 (0.0)	0 (0.0)	
pT2	5 (38.5)	4 (28.6)	4 (33.3)	
pT3	8 (61.5)	8 (57.1)	6 (50.0)	
pT4	0 (0.0)	0 (0.0)	1 (8.3)	
Extraprostatic extension, <i>n</i> (%)	8 (61.5)	8 (57.1)	6 (50.0)	0.843
Positive margins, <i>n</i> (%)	5 (38.5)	3 (21.4)	4 (33.3)	0.615
Positive nodes, <i>n</i> (%)	3 (23.1)	0 (0.0)	3 (25.0)	0.136
RP failure, <i>n</i> (%)	1 (7.7)	1 (7.1)	1 (8.3)	0.994
PSA failure (≥ 0.2 ng/mL) or use of adjuvant ADT or XRT, <i>n</i> (%)	2 (15.4)	4 (28.6)	6 (50.0)	0.169
Change in baseline Gleason score ^b				0.090
Upstaging	0	1	0	
No change	4	2	0	
Downstaging	3	0	0	
Median cancer mass, grams (range)	3.44 (0.24–33.60)	1.00 (0.00–12.06)	1.10 (0.00–24.25)	0.413

A Phase II, Randomized, Open-Label Study of Neoadjuvant Degarelix versus LHRH Agonist in Prostate Cancer Patients Prior to Radical Prostatectomy



Efficacy of a neoadjuvant gonadotropin-releasing hormone antagonist plus low-dose estramustine phosphate in high-risk prostate cancer: a single-center study

Int Urol Nephrol (2017) 49:811–816

- Retrospective study, from 2005-2016
- D'Amico High risk patients
- At least 6 months neoadjuvant ADT
 - Degarelix + estramustine (N=136)
 - LHRH agonist (L or G) + estramustine (N=270)

Pathological outcome

	Degarelix	+ EMP (<i>N</i> = 136)	LHRH agonist + EMP (<i>N</i> = 270)	<i>P</i>
Pathological T, number (%)		Preop T	Preop T	0.0070
T0	15 (11.0)	T1c 35 (25.7)	24 (8.9) T1c 82 (30.4)	
T2	94 (69.1)	T2 29 (21.3)	142 (52.6) T2 96 (35.6)	
T3	27 (19.9)	T3 65 (47.8)	103 (38.1) T3 92 (34.1)	
T4	0 (0)	T4 7 (5.2)	1 (0.4) T4	
Treatment effect, number (%)				
0	3 (2.2)		1 (0.4)	0.1986
1	20 (14.7)		65 (24.1)	
2	98 (72.1)		180 (66.7)	
3	15 (11.0)		24 (8.9)	
Positive surgical margin, number (%)	7 (5.2)		22 (8.1)	0.2560
LN count, median (IQR)	6 (2–8)		6 (2–9)	0.5421
LN involvement, number (%)	1 (0.7)		4 (1.5)	0.5199

Pathological outcome

	Degarelix	+ EMP (N = 136)	LHRH agonist + EMP (N = 270)	P
Pathological T, number (%)		Preop T	Preop T	0.0070
T0	15 (11.0)	T1c 35 (25.7)	24 (8.9) T1c 82 (30.4)	
T2	94 (69.1)	T2 29 (21.3)	142 (52.6) T2 96 (35.6)	
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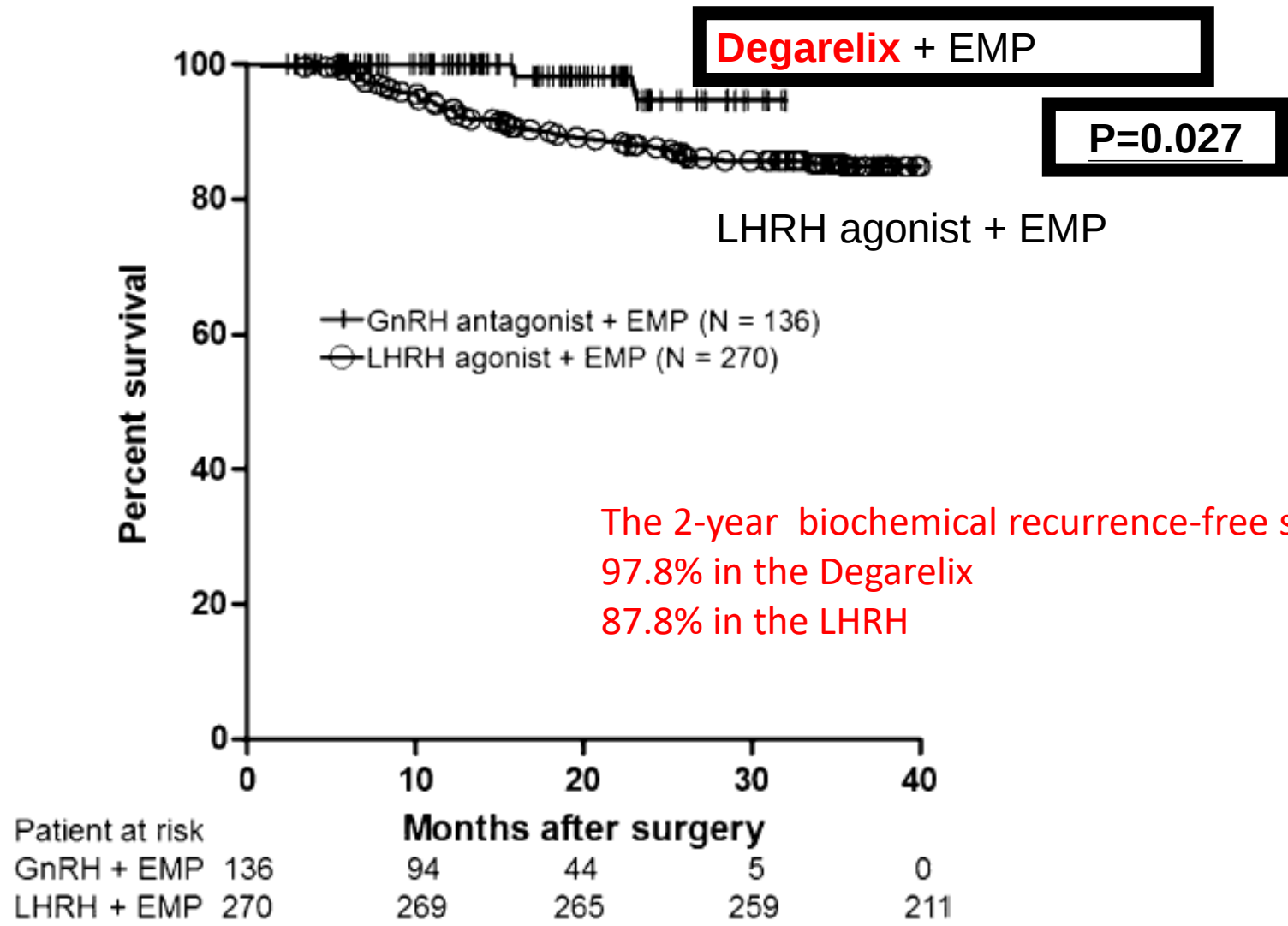
Pathological outcome

	Degarelix	+ EMP (N = 136)	LHRH agonist + EMP (N = 270)	P
Pathological T, number (%)		Preop T	Preop T	0.0070
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T3	27 (19.9)	T3 65 (47.8)	103 (38.1) T3 92 (34.1)	
T4	0 (0)	T4 7 (5.2)	1 (0.4) T4	
Treatment effect, number (%)		Pathological Downstaging		
0	3 (2.2)		1 (0.4)	0.1986
1	20 (14.7)		65 (24.1)	
2	98 (72.1)		180 (66.7)	
3	15 (11.0)		24 (8.9)	
Positive surgical margin, number (%)	7 (5.2)		22 (8.1)	0.2560
LN count, median (IQR)	6 (2–8)		6 (2–9)	0.5421
LN involvement, number (%)	1 (0.7)		4 (1.5)	0.5199

Biochemical recurrence free survival



Efficacy of a neoadjuvant gonadotropin-releasing hormone antagonist plus low-dose estramustine phosphate in high-risk prostate cancer: a single-center study

Int Urol Nephrol (2017) 49:811–816

- Neoadjuvant **Degarelix**+ EMP followed by RP may improve the **pathological outcomes** and reduce the risk of **biochemical recurrence** in patients with **high-risk Pca**.

Prostate cancer received Neo+RARP vs.RARP

(Retzius sparing 2019.7~2021.3)

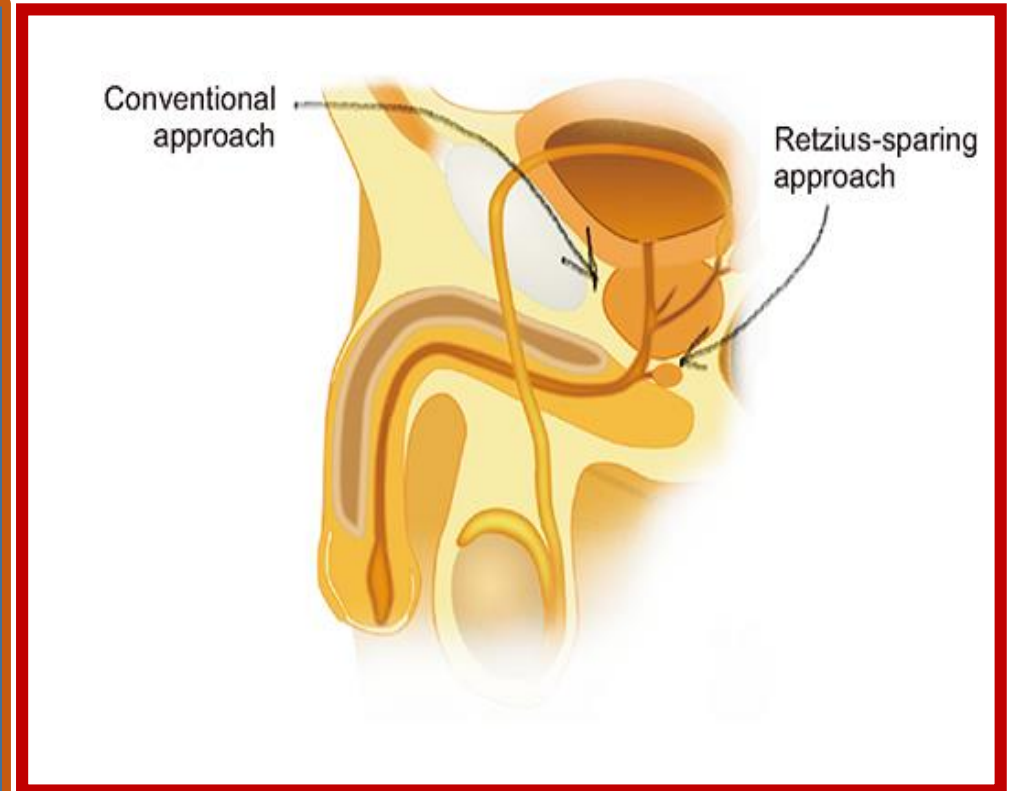
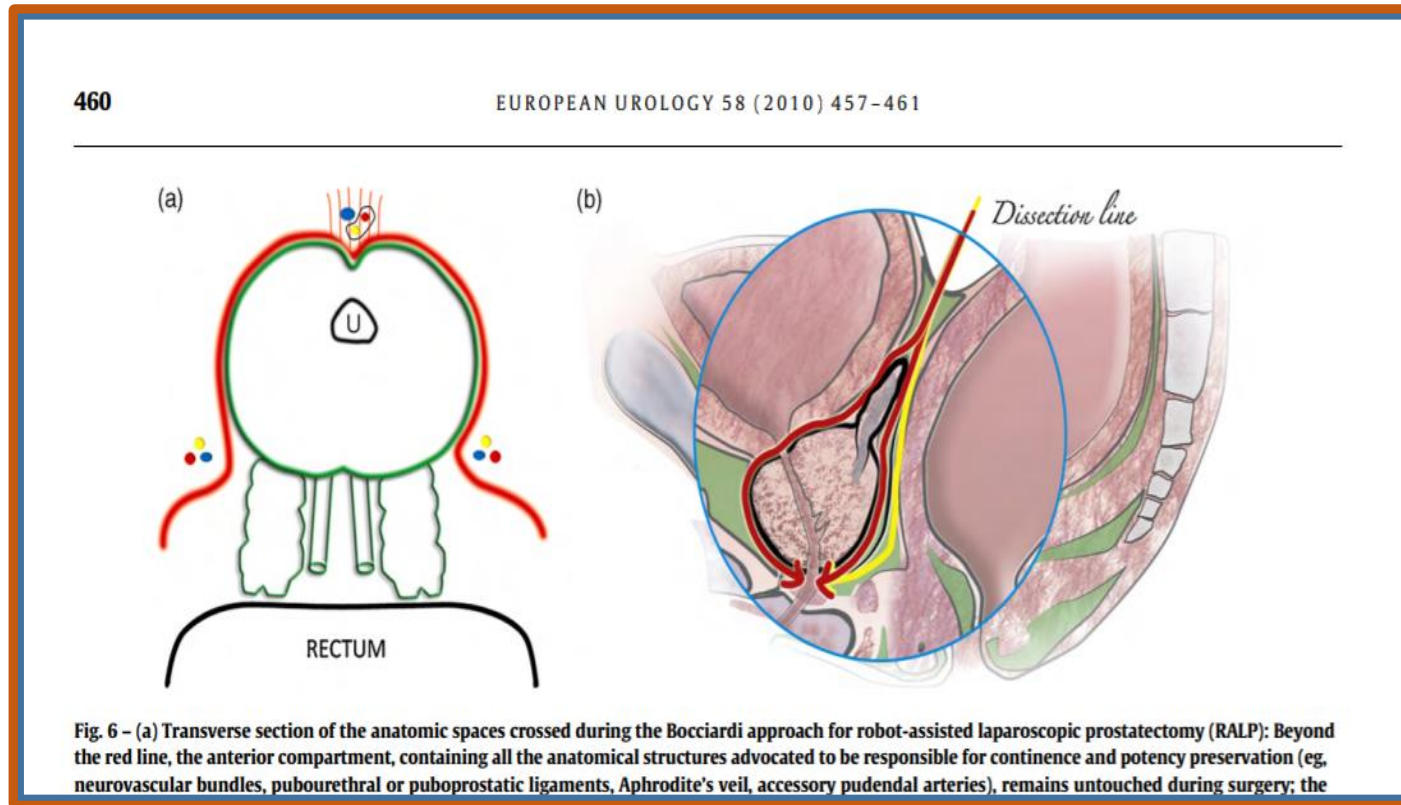
	Neo +RARP	RARP
No .(%)	9	26
cT stage		
T0	0	0
T1	0	1
T2	4	21
T3	5	4
ypT stage		
T0		
T2	6	14
T3a/T3b	3	12
cN stage		
N0	6	26
N1	3	0
pNstage		
N0	6	21
N1	3	5
cMstage		
M0	1	26
M1	8	0

	Neo +RARP	RARP
No.(%)	9 (100)	26(100)
Margin		
positive	2 (22)	5 (19)
negative	7 (78)	21 (81)
Staging		
Downstaging	4 (44)	0 (0)
stable staging	4 (44)	14 (54)
upstaging	1 (12)	12 (46)

Prostate cancer received Neo+RARP vs.RARP

(Retzius sparing 2019.7~2021.3)

A **New Anatomic Approach** for Robot-Assisted Laparoscopic Prostatectomy:



義大利式後方切除
讓尿失禁更快復原
2019~

2020 永慶路跑

攝護腺癌病患



案例1:攝護腺指數 1500 → <0.008

案例2:攝護癌第4期 → <0.008

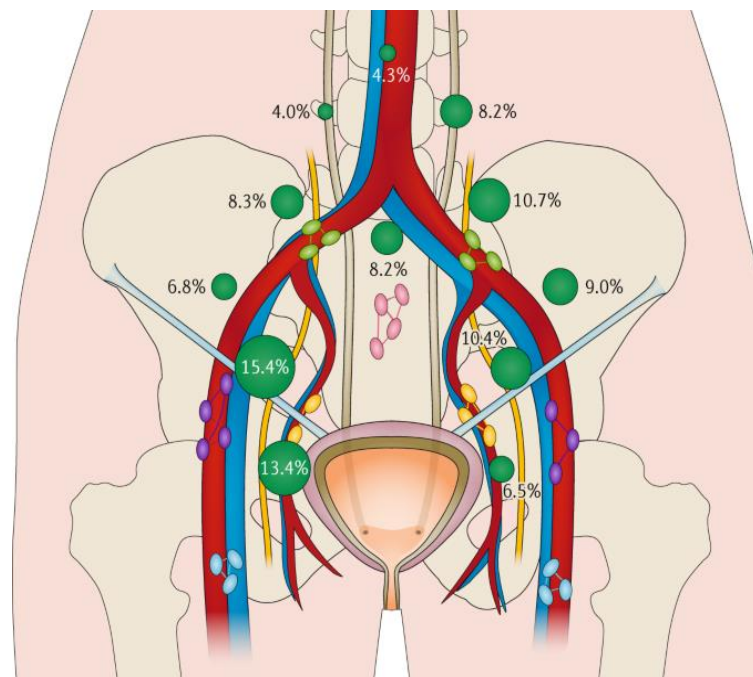
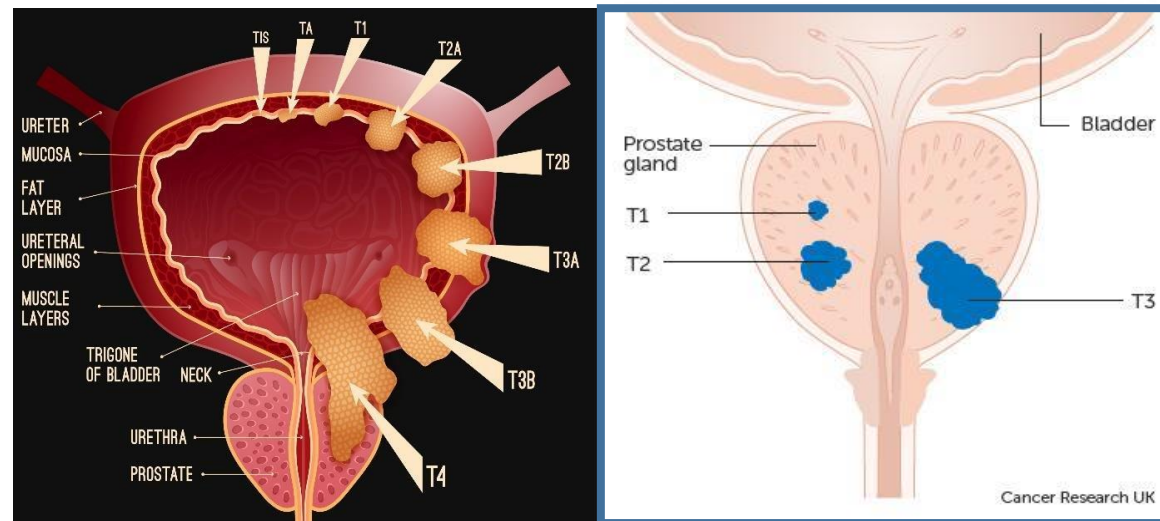
案例3:攝護癌手術後2個月 → 打羽毛球

達文西手術後



- 此攝護腺 & 膀胱周圍的淋巴結一併清除，許多CT & MRI上判定沒有異常小淋巴結，最後透過病理科在顯微鏡下的檢驗確定癌症轉移
- 這檢驗結果，大大影響到癌症嚴重度的分級，進而決定後續的治療方向

EAU 2018 & EAU 2020



Neoadjuvant Androgen deprivation therapy (ADT) +radical prostatectomy (RP)
for advanced prostate cancer -----Pathological findings

- Neoadjuvant ADT+ RP VS. Immediate RP
- Neoadjuvant ADT (Degarelix vs. LHRH agonist) + RP
- Intense Neoadjuvant ADT + RP

Evaluation of **Intense** Androgen Deprivation **Before Prostatectomy**: A Randomized Phase II Trial of **Enzalutamide** and **Leuprolide** With or Without **Abiraterone**

JCO2020

TABLE 4. Pathologic Outcomes at RP (on the basis of central review)

Variable	ELAP, No. (%)	EL, No. (%)
No. of patients	50	25
ypT stage		
T0	5 (10)	2 (8)
T2	20 (40)	9 (36)
T3a	16 (32)	7 (28)
T3b	9 (18)	7 (28)
Pathology N stage		
N0	45 (90)	22 (88)
N1	5 (10)	3 (12)
Positive surgical margins		
No	41 (82)	22 (88)
Yes	9 (18)	3 (12)

TABLE 4. Pathologic Outcomes at RP (on the basis of central review)

Variable	ELAP, No. (%)	EL, No. (%)
Pathologic response		
pCR	5 (10)	2 (8)
MRD (≤ 5 mm)*	10 (20)	2 (8)
pCR or MRD	15 (30)	4 (16)
Downstaging	3 (6)	1 (4)
Stable staging	10 (20)	5 (20)
Upstaging	21 (42)	15 (60)
Unevaluable†	1 (2)	—
Median total tumor volume, mL (range)	0.6 (0-10.4)	0.8 (0-10.1)
Median cellularity, % (range)	5 (0-60)	7 (0-50)

Patients were randomly assigned 2:1 to abiraterone (1,000mg/d), enzalutamide (160 mg/d), leuprolide (22.5 mg every12 weeks), and prednisone (5 mg/d) versus enzalutamide(160 mg/d) and leuprolide (22.5 mg every 12 weeks) for

6 Months followed by RP

Evaluation of Intense Androgen Deprivation Before Prostatectomy: A Randomized Phase II

Trial of **Enzalutamide** and **Leuprolide** With or Without **Abiraterone**

JCO2020

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Evaluation of Intense Androgen Deprivation Before Prostatectomy: A Randomized Phase II
Trial of **Enzalutamide** and **Leuprolide** With or Without **Abiraterone**JCO2020

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JCO2020

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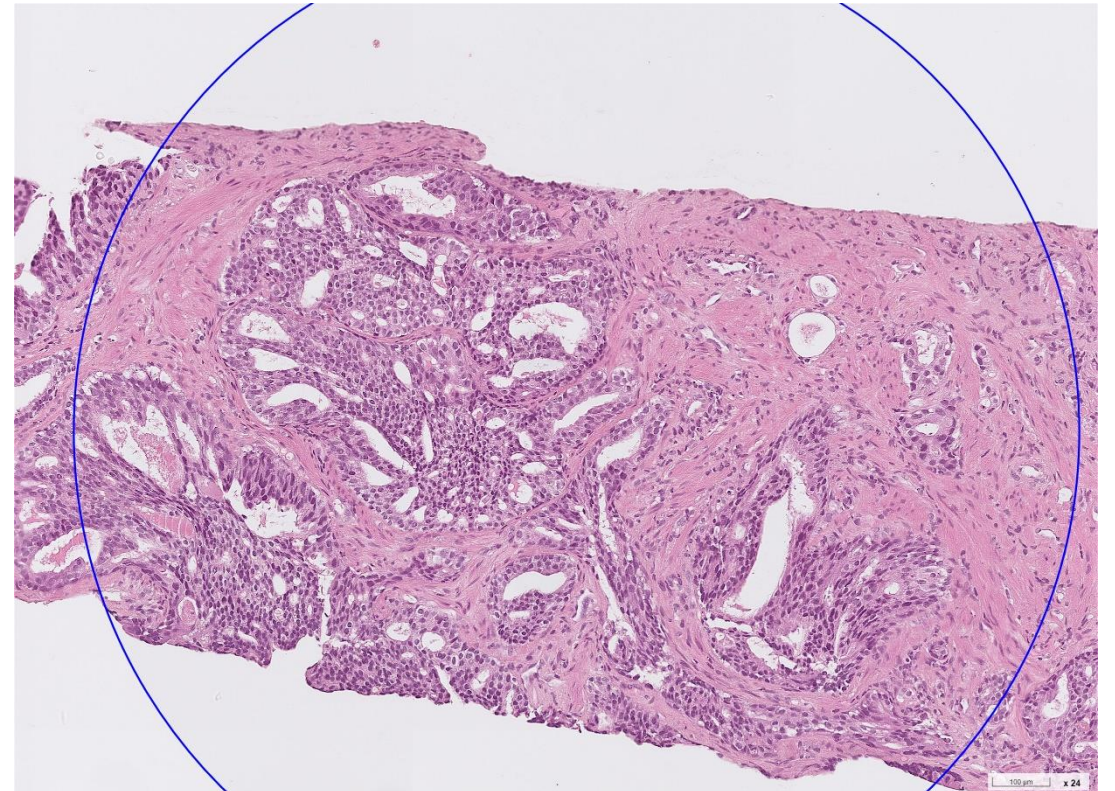
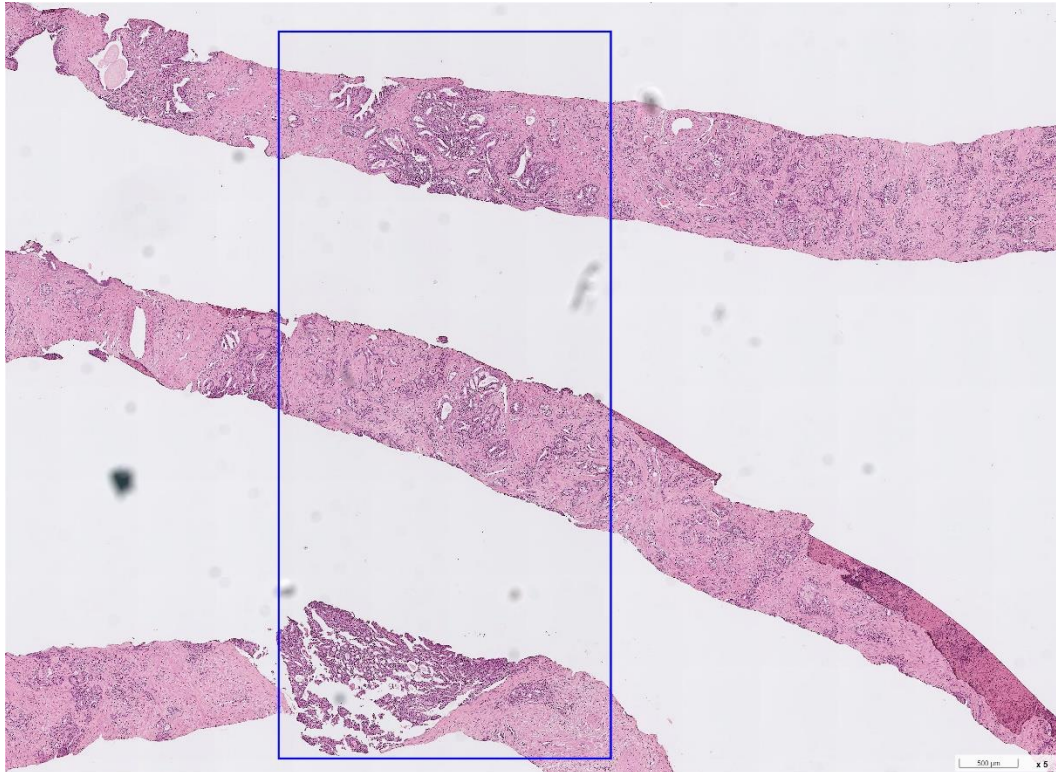
6 Months followed by RP

Evaluation of Intense Androgen Deprivation Before Prostatectomy: A Randomized Phase II Trial of **Enzalutamide** and **Leuprolide** With or Without **Abiraterone** *JCO2020*

- Neoadjuvant hormone therapy followed by RP in locally advanced prostate cancer resulted in **favorable pathologic responses** in some patients, with a trend toward improved pathologic outcomes with ELAP.

- 72y/o male
- iPSA 180
- Prostate biopsy right 4+3, Left 4+4

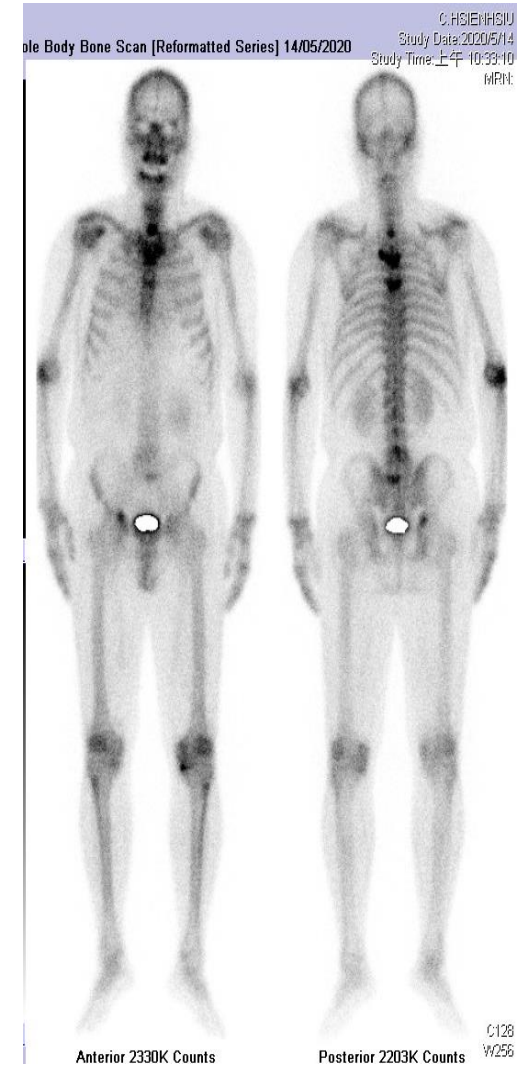
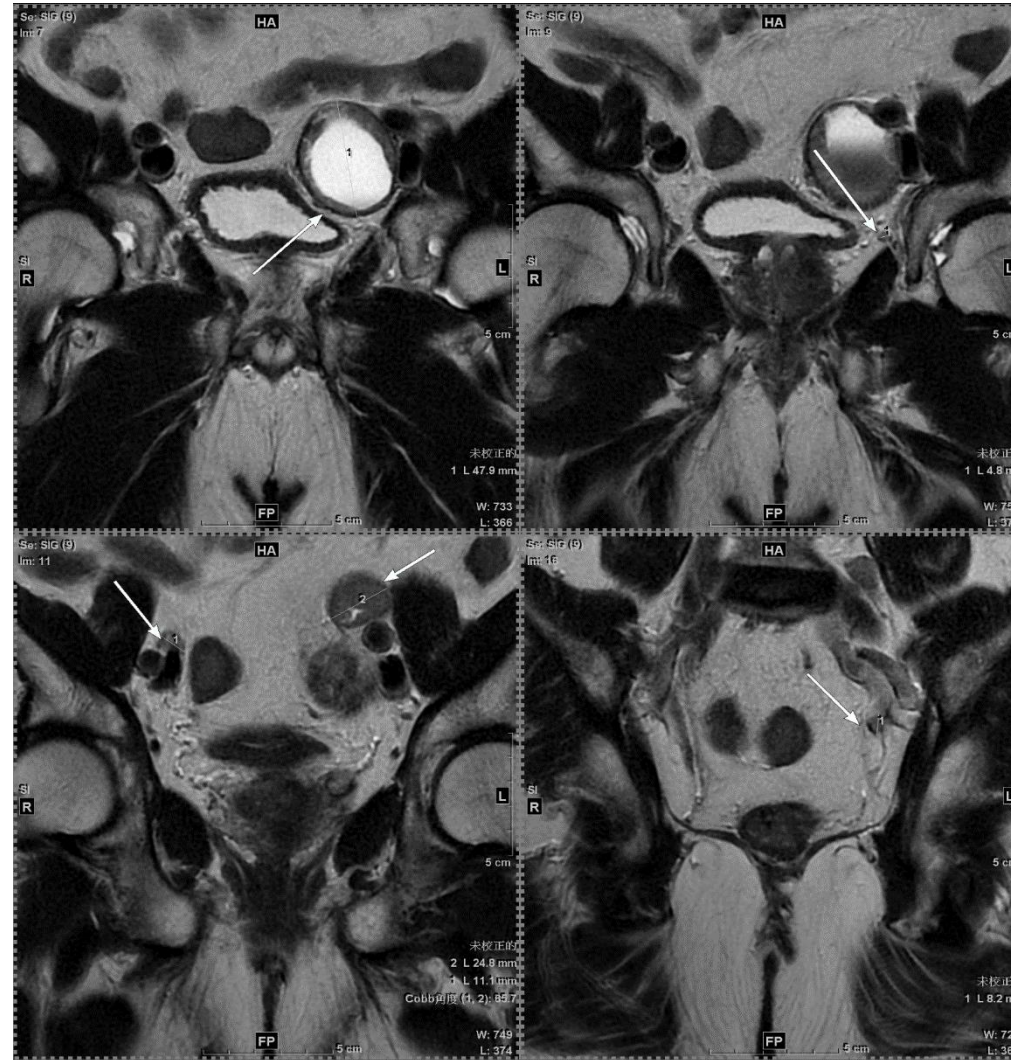
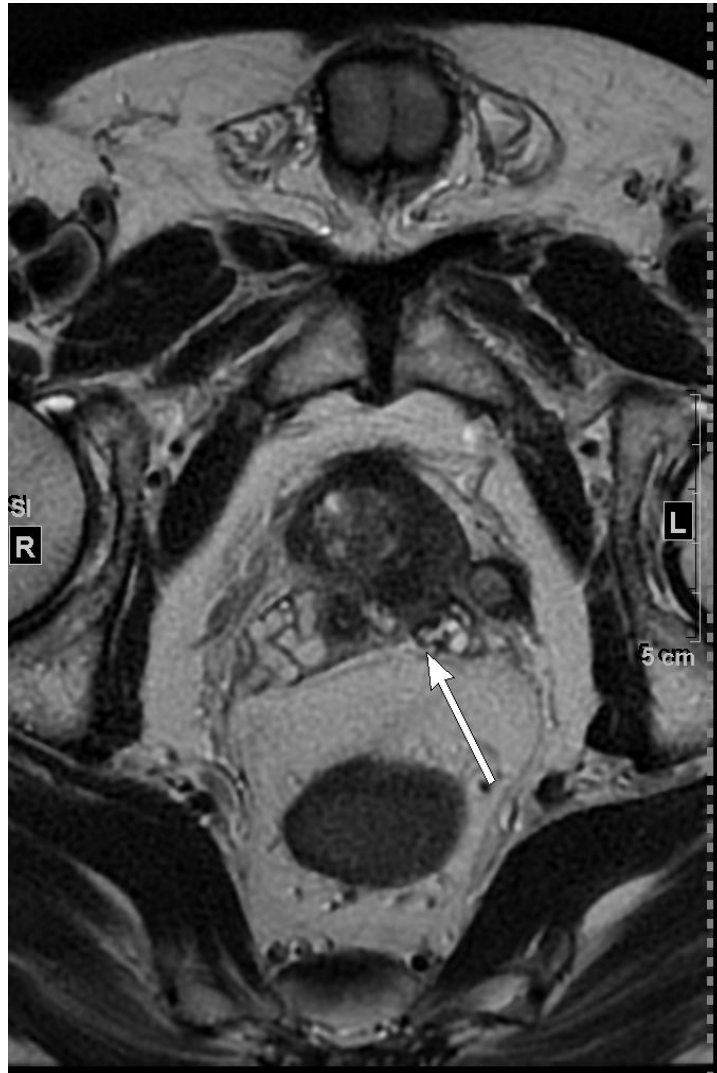
Prostate Biopsy G:4+4



72y/o male
iPSA 180

biopsy R't 4+3 / L't 4+4

cT3N1M1



72y/o male

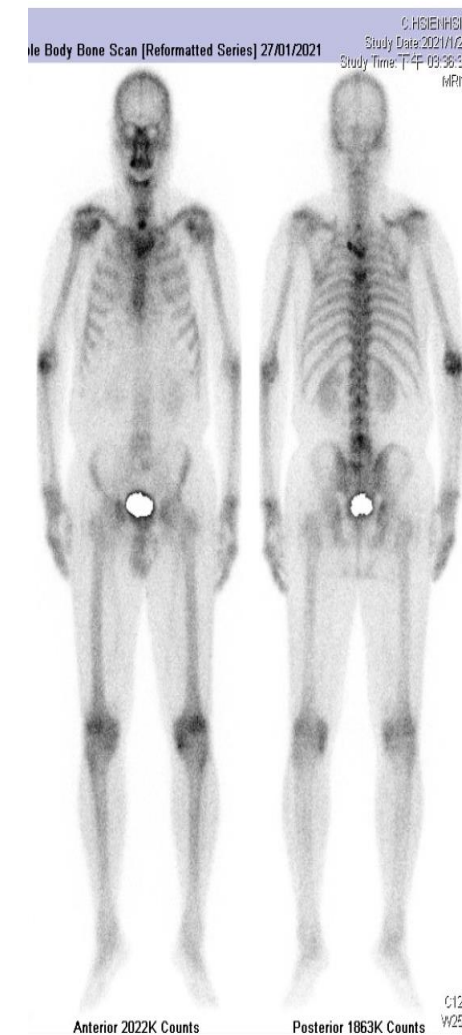
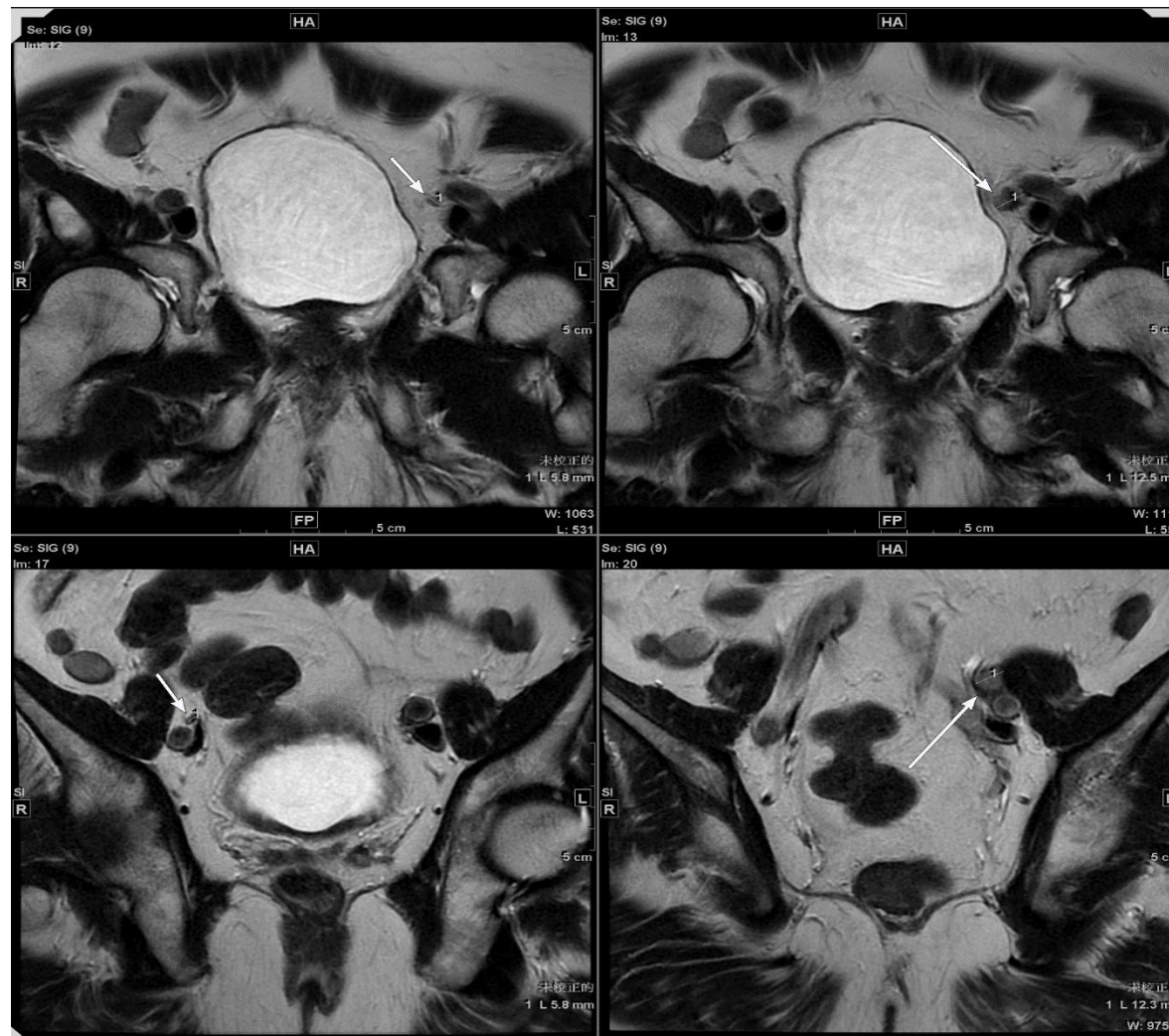
iPSA 180

biopsy R't 4+3 / L't 4+4

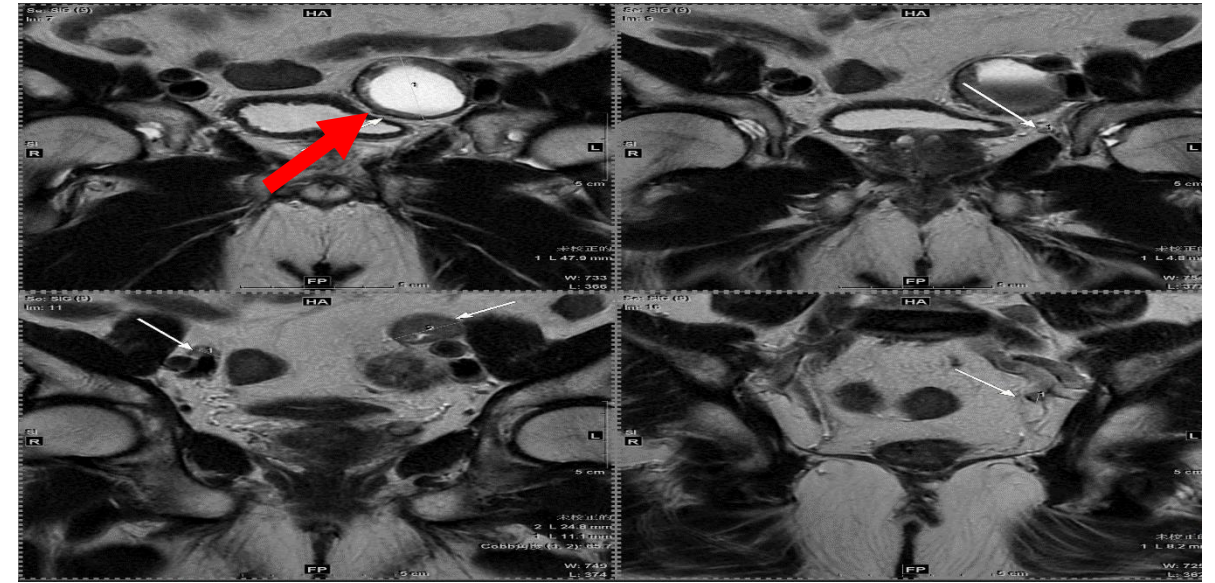
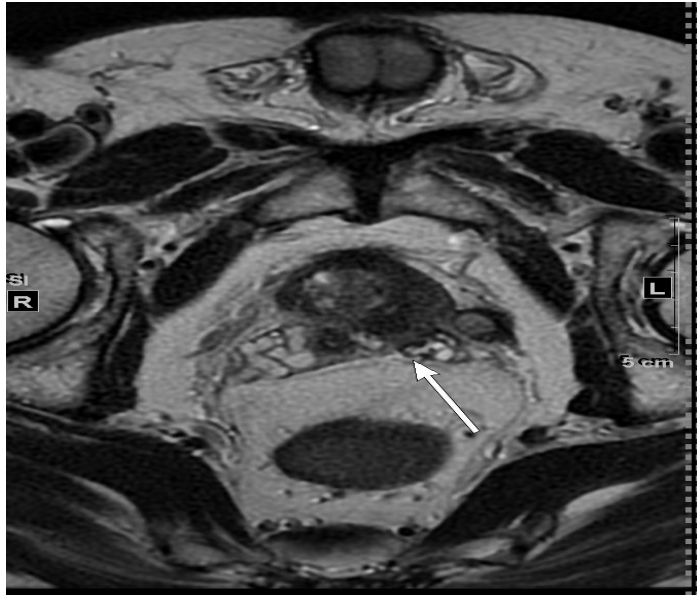
cT3N1M1

Degarelix + Abiraterone + Prednisolone ~2 year~

PSA 1.2

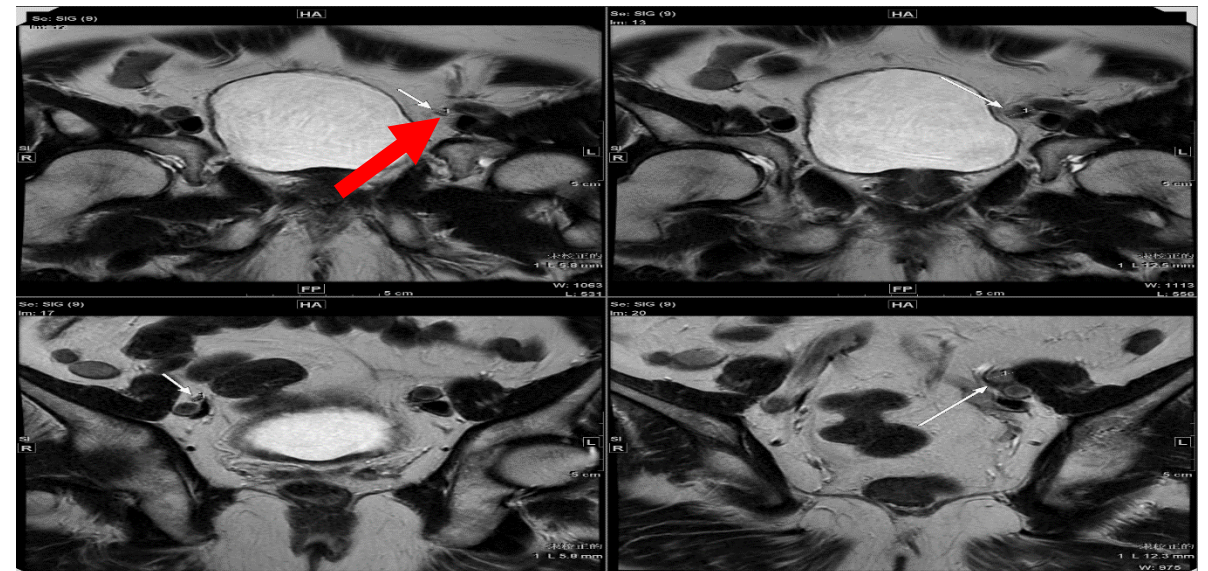
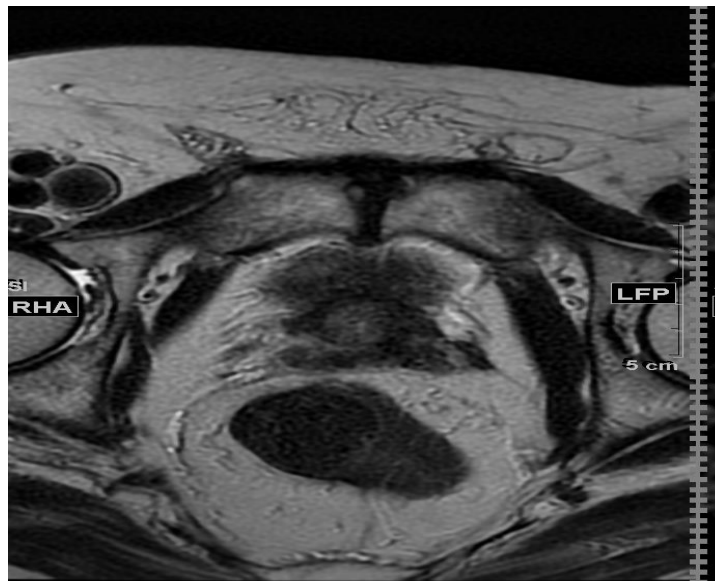


72y/o male
iPSA 180
biopsy R't 4+3
L't 4+4
cT3N1M1



Degarelix + Abiraterone + Prednisolone ~2 year~

PSA 1.2



72y/o male
iPSA 180

biopsy R't 4+3 / L't 4+4

cT3N1M1

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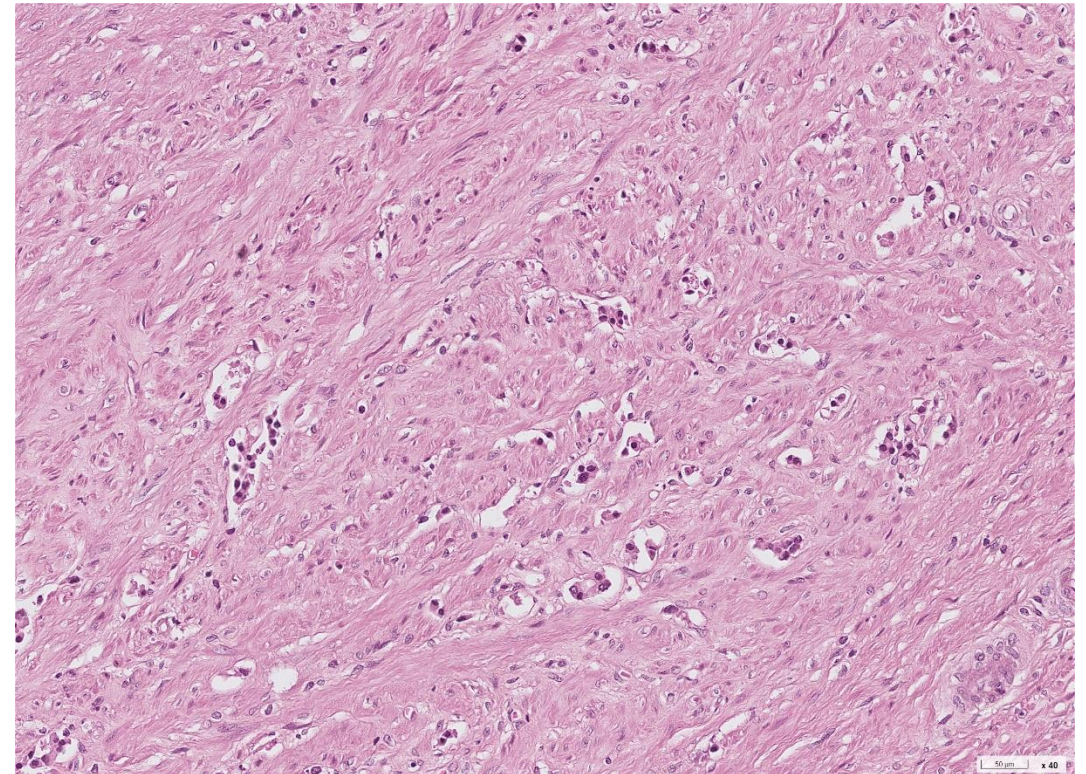
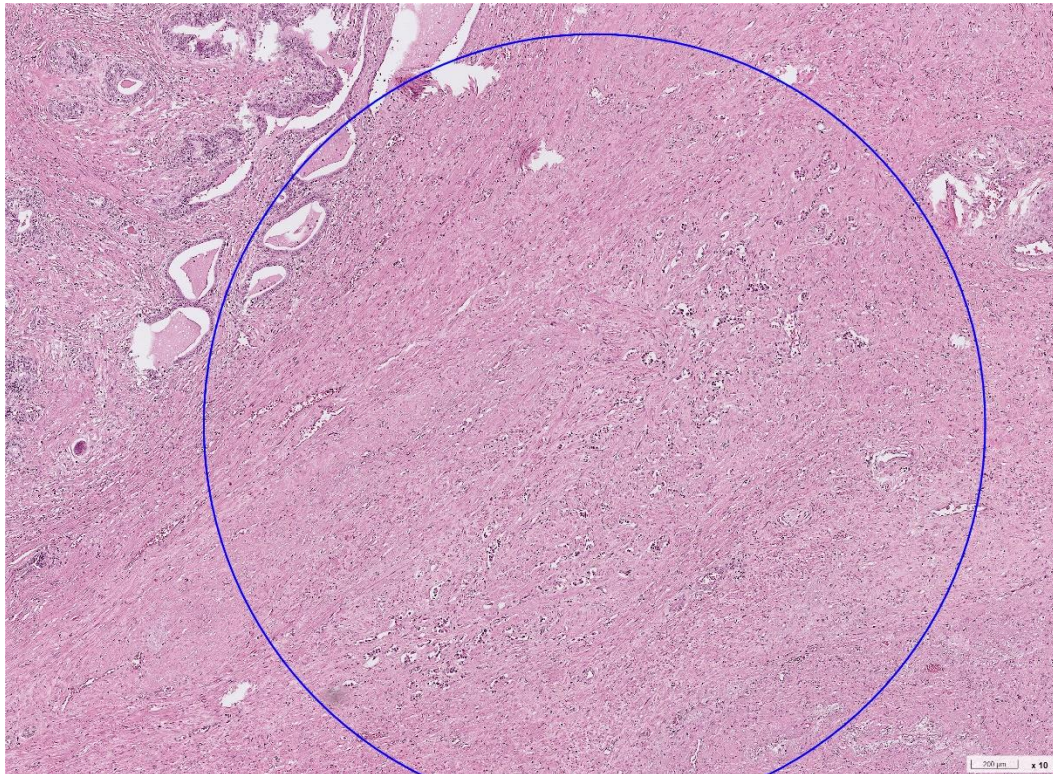
PSA 1.2

RARP

Path: 3+4

ypT2N1M1

margin (-)



72y/o male

iPSA 180

biopsy R't 4+3 / L't 4+4

cT3N1M1

Degarelix + Abiraterone + Prednisolone ~2 year~

PSA 1.2

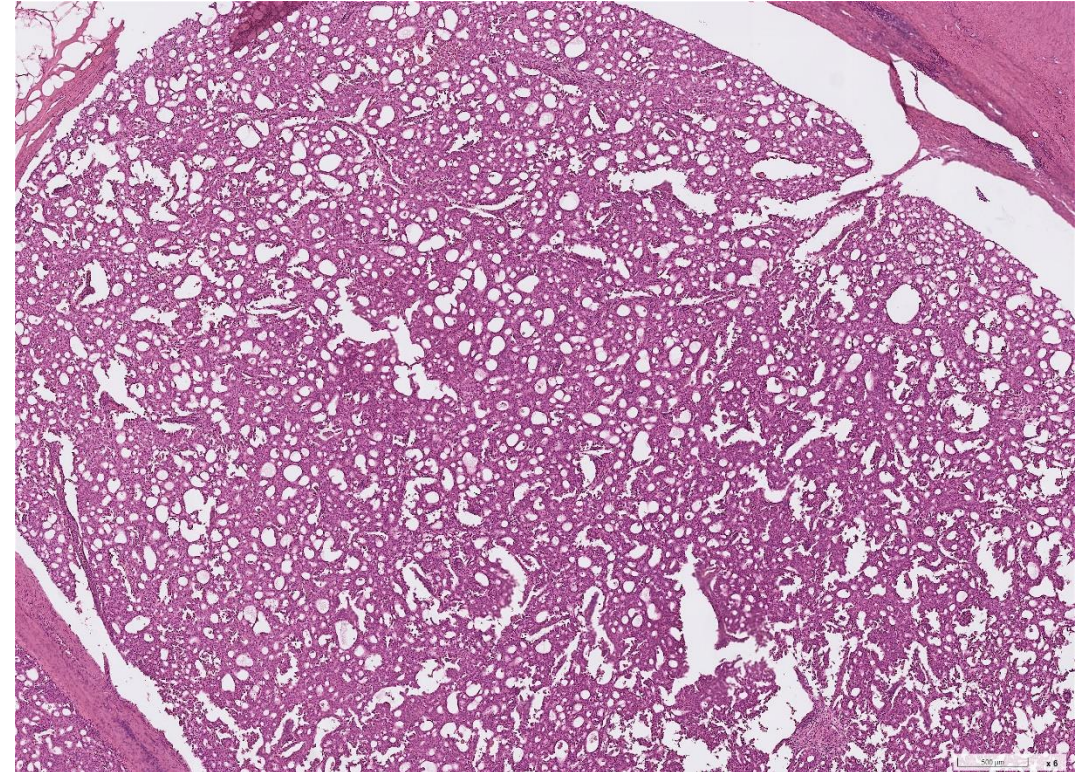
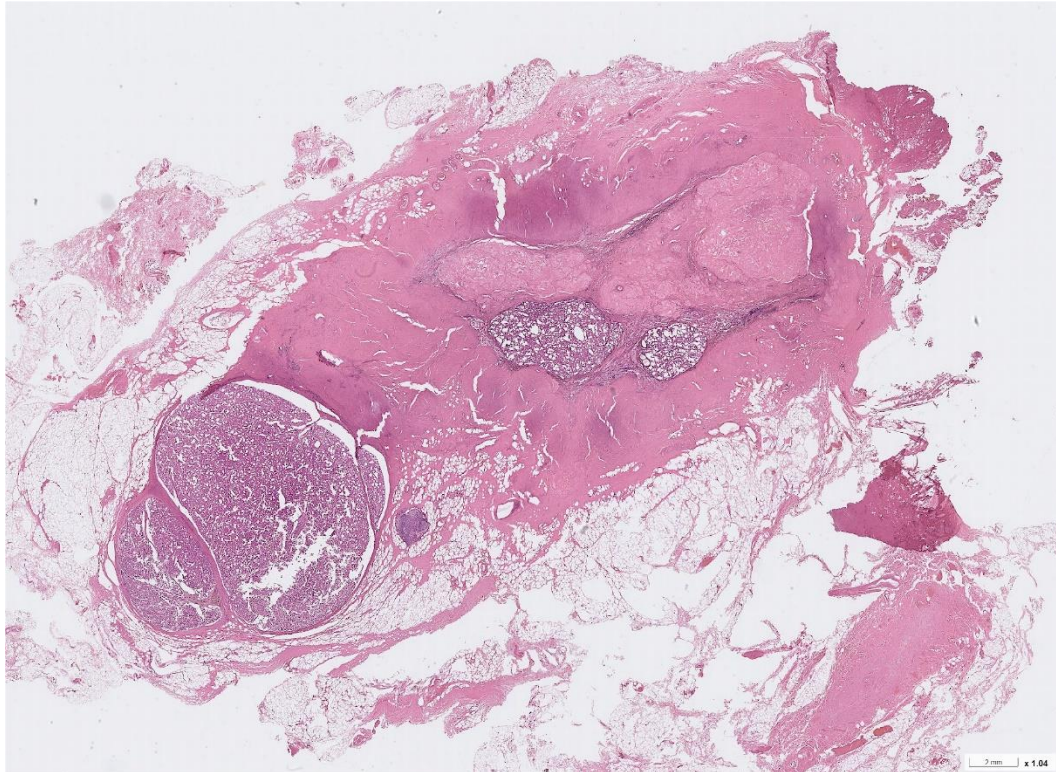
RARP

path: 3+4

ypT2N1M1

margin (-)

Lymph node G 3+4 R't (1/12) L't (1/6)



Neoadjuvant Androgen deprivation therapy (ADT) +radical prostatectomy (RP)
for advanced prostate cancer -----Pathological Response

- Neoadjuvant ADT+ RP VS. Immediate RP
- Neoadjuvant ADT (Degarelix vs. LHRH agonist) + RP
- Intense Neoadjuvant ADT + RP



嘉義長庚紀念醫院
Chang Gung Memorial Hospital, Chiayi

達文西百例里程碑頒發

泌尿科 林威宇醫師





In Recognition of
100th da Vinci Surgery
一百例達文西手術紀念

Dr. Wei-Yu Lin

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INTUITIVE

2020 永慶路跑

攝護腺癌病患



達文西手術後





專長：攝護腺雷射手術
泌尿道癌微創手術(腎臟、膀胱、攝護腺)

門診時間表

嘉義長庚醫院						
星期 時間	一	二	三	四	五	六
上午	●			●		
下午		●				

部立嘉義醫院						
星期 時間	一	二	三	四	五	六
上午		●				
下午						

TAIWAN PRECISE MEDICINE ASSOCIATION
台灣精準醫療醫學會

清除攝護腺癌&膀胱癌
保有收放自如的人生
淺談達文西手術與人工膀胱

林威宇 副教授
Wei-Yu Lin MD, PhD

0:48 / 10:03

淺談達文西手術與人工膀胱 / 林威宇主任 / 台灣精準醫療醫學會製作 (精準醫字第1100002號)

網址: www.longlifebetterlife.com

- Neoadjuvant ADT before RP
 - pathological downstaging,
 - decreased PSM,
 - positive LNs
- Degarelix (GnRH antagonist) is beneficial for neoadjuvant therapy before RP.
- **Intense** Neoadjuvant hormone therapy followed by RP in **locally advanced** prostate cancer resulted in **favorable pathologic responses** in some patients

Efficacy of a neoadjuvant gonadotropin-releasing hormone antagonist plus low-dose estramustine phosphate in high-risk prostate cancer: a single-center study

- **Positive surgical margins** has been found to be a **predictor of PSA recurrence** and secondary cancer treatment including adjuvant ADT or RT.
- As such, **neoadjuvant** therapies prior to RP have been investigated in an attempt **to decrease cancer volume** and potentially **downstage** the disease before surgery.

Loeb S et al Urology. 2010;76:710–4.

Abdollah F. et al Eur Urol. 2015;68:497–50525

Pound CR et al JAMA. 1999;281:1591–7

Grossfeld GD et al J Urol. 2000;163:1171–7.

- Neoadjuvant ADT before RP
 - Showed evidence of
 - pathological downstaging,
 - decreased PSM,
 - positive LNs
 - may be beneficial in high risk prostate cancer patients
 - in terms of PSA recurrence free survival and cancer specific survival
- GnRH antagonist may be a better choice than LHRH agonist for neoadjuvant therapy before RP.

Impact of **neoadjuvant Degarelix**
on
section margin and pathological staging
after
robotic assisted radical prostatectomy
for
advanced prostate cancer

林威宇
嘉義長庚

A Phase II, Randomized, Open-Label Study of Neoadjuvant Degarelix versus LHRH Agonist in Prostate Cancer Patients Prior to Radical Prostatectomy

- LHRH agonists leading to an increase in **PSA ("flare" phenomenon)**, followed by the downregulation of the receptor with decreased testosterone levels.
- LHRH antagonists (degarelix) **directly block LHRH receptors** leading to a reduction in LH and testosterone levels, **without the flare phenomenon.**