

# Innovazione e appropriatezza:come valutarle e come introdurle

La Robotica: Potenzialità e Criticità

Prof. Ciro Imbimbo Napoli 27 Novembre 2018

# "YESTERDAY"....



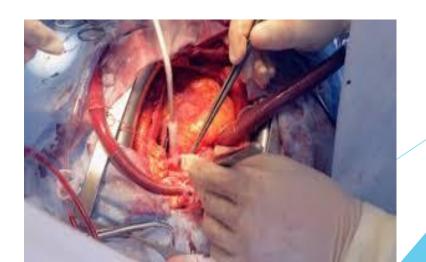
LAPAROSCOPIA







CHIRURGIA OPEN



# TODAY.....ROBOT

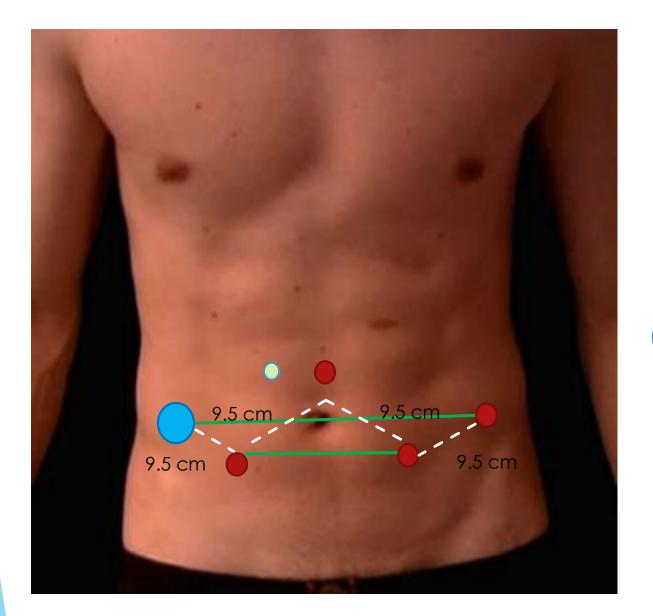








### - Posizionamento delle porte



8 mm robotic trocar

12 mm assistant trocar

5 mm assistant trocar



#### -SOLUZIONE ALLE LIMITAZIONI ERGONOMICHE E VISIVE DEI SISTEMI DI LAPAROSCOPIA

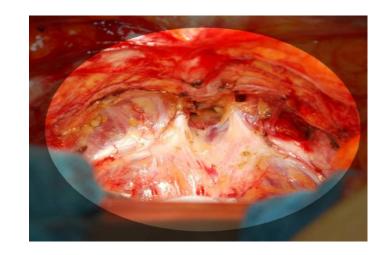
(più gradi di libertà, visione 3D)

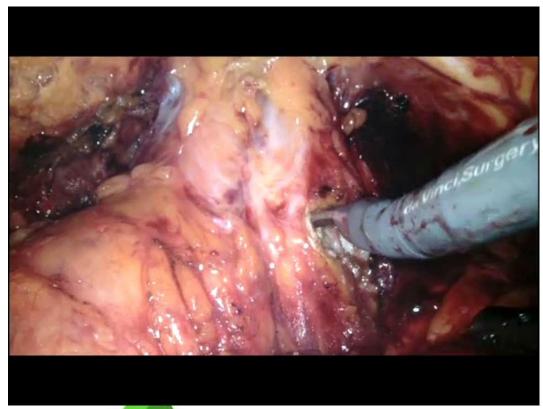
-PRECISIONE DEI MOVIMENTI

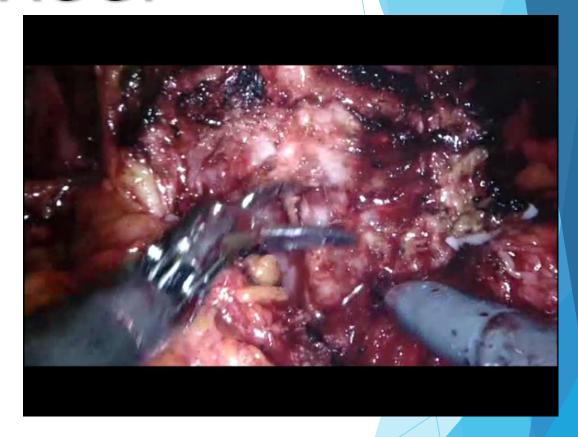
(filtraggio del tremore, motion scaling)

-PRECISIONE DELLA DISSEZIONE ANATOMICA











-PRECISIONE DELLA DISSEZIONE ANATOMICA

-RIDOTTA INVASIVITA'

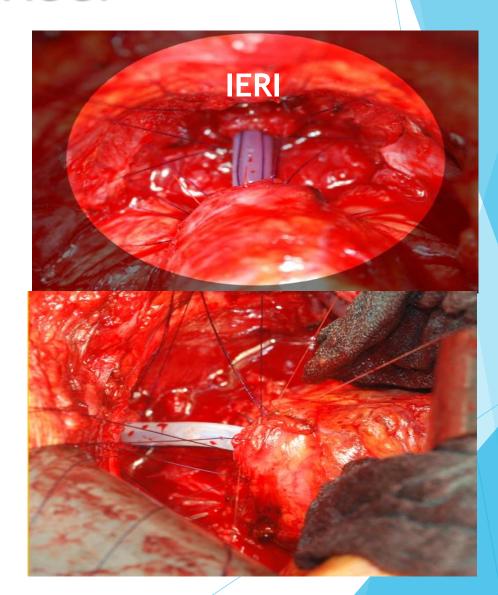
-RIDUZIONE DELLE PERDITE DI SANGUE

# -MINOR IMPIEGO DI PERSONALE DI SALA OPERATORIA

-MIGLIORE ACCESO A SEDI ANATOMICHE (retroperitoneo-angoli costofrenici)

-ACCURATEZZA DELLE SUTURE



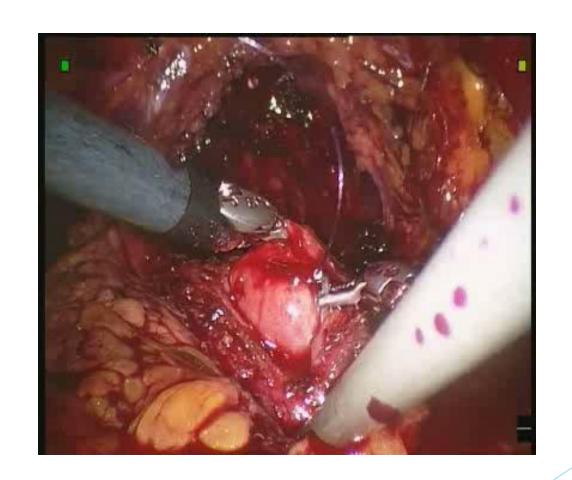


# Linfadenectomia





# **ANASTOMOSI**









-PROCEDURE DI NERVE SPARING

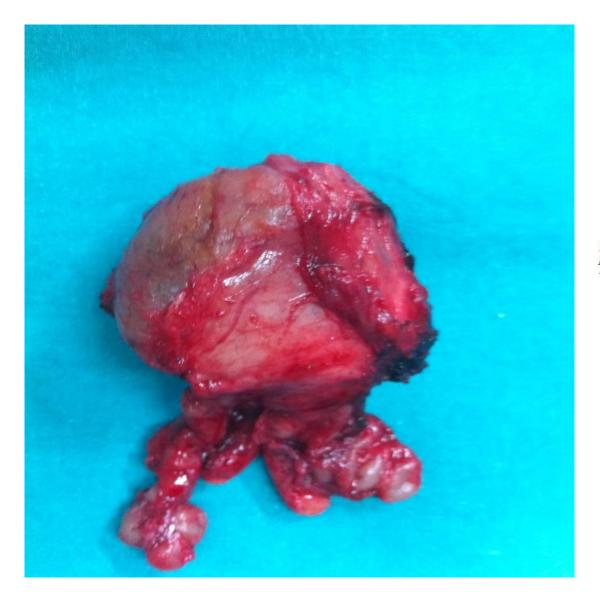
-MIGLIORE PRECISIONE NEL CONFEZIONARE ANASTOMOSI

-MAGGIORE PRECISIONE NELLA LINFOADENECTOMIA

-MINIMIZZAZIONE COMPLICANZE POST OPERATORIE (continenza urinaria, potenza sessuale)

-RIPRESA RAPIDA DELLA FUNZIONE INTESTINALE

# Planning preoperatorio



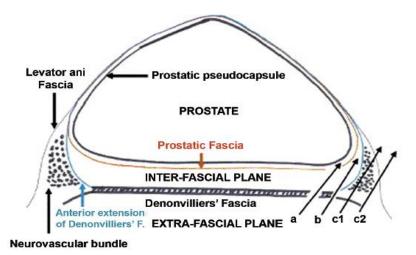
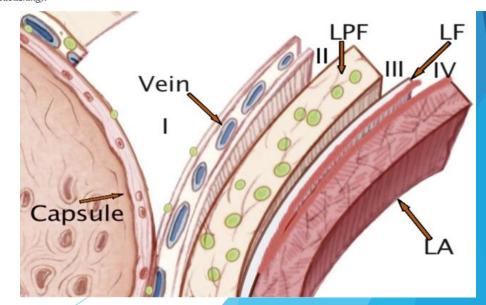


Figure 2 – Axial view of prostatic fascial anatomy. a = intrafascial plane; b = interfascial plane; c1 = extrafascial plane with partial preservation of neurovascular bundle; c2 = extrafascial plane with no preservation of neurovascular bundle. (9) (with permission from Elsevier publishing).



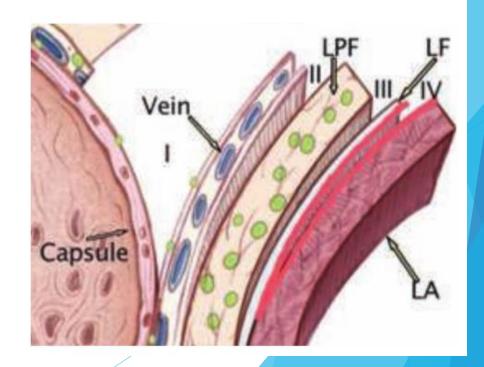
### 8 - Nerve-sparing

#### **ANATOMY**

According to Tewari et al., **four grades** of nervesparing are recognized:

- ✓ Grade 1: incision of the Denonvilliers and lateral pelvic fascia (LPF) is taken just outside the prostatic capsule.
- ✓ Grade 2: incision through the Denonvilliers (leaving deeper layers on the rectum) and LPF is taken just outside the layer of veins of the prostate capsule.
- ✓ Grade 3 (partial/incremental): incision is taken through the outer compartment of the LPF (leaving some yellow adipose and neural tissue on the specimen), excising all layers of Denonvilliers' fascia.
- ✓ Grade 4 (non-NS): a wide excision of the LPF and Denonvilliers' fascia containing most of the periprostatic neurovascular tissue is performed.

FIG. 4. Layers of fascia enveloping the prostatic capsule, showing the planes of dissection for differing NS grades (1–4). LPF, lateral pelvic fascia medial layer, i.e. the prostatic fascia; LF, lateral pelvic fascia lateral layer, i.e. the levator fascia; LA, levator ani.



### Tutto questo si traduce in.....

RISULTATI CLINICI SUPERIORI

RIDUZIONE DEL RISCHIO DI COMPLICAZIONI

PERIODO DI RECUPERO PIU' RAPIDO

PICCOLE INCISIONI

**CICATRICI MINIME** 

RIDUZIONE DEL DOLORE POST OPERATORIO

RAPIDO RITORNO ALLE ATTIVITA' QUOTIDIANE





-FACILITA' DI INSEGNAMENTO

BREVE LEARNING CURVE (20-30 casi)



### **PENTAFECTA**

- Oncological results
- Continence
- Potency
- Pain , Qol and Cosmetics
- Costs

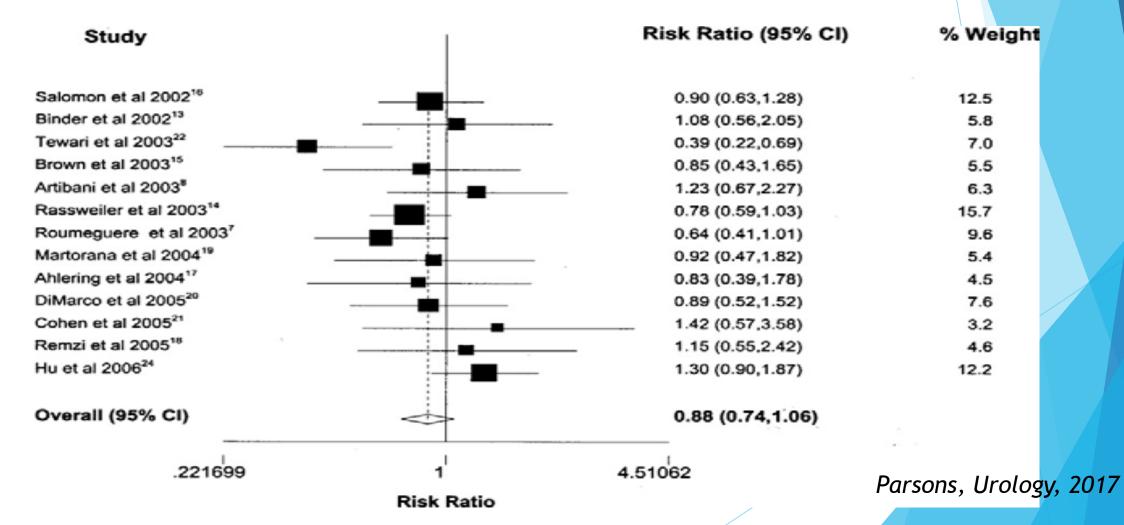
# Positive Surgical Margins

Thirteen studies

3039 patients











Platinum Priority – Review – Prostate Cancer Editorial by Peter C. Albertsen on pp. 365–367 of this issue

#### Systematic Review and Meta-analysis of Studies Reporting Oncologic Outcome After Robot-assisted Radical Prostatectomy

Level of evidence	First author	Cases, n	Overall PSM, %	pT2 PSM,%
3	Ficarra, 2009 [77]	105 RRP	21	12
		103 RARP	34	12
	Di Pierro, 2011 [78]	75 RRP	32	24
		75 RARP	16	8
	Kim, 2011 [79]	235 RRP	25	8 9
		528 RARP	27	13
4	Caballero-Romeu, 2008 [80]	62 RRP	52	_
		60 RARP	31	
	Drouin, 2009 [81]	83 RRP	18	7
		71 RARP	17	10
	Laurila, 2009 [82]	84 RRP	14	15
		88 RARP	12	10
	Ou, 2009 [83]	30 RRP	20	0
		30 RARP	50	3
	White, 2009 [84]	50 RRP	36	34
		50 RARP	22	19
	Breyer, 2010 [85]	695 RRP	16	_
		293 RARP	18	
	Barocas, 2010 [86]	491 RRP	30	_
		1413 RARP	20	
	Doumerc, 2010 [87]	502 RRP	17	10
		212 RARP	21	12
	Lo, 2010 [88]	20 RRP	25	_
		20 RARP	20	
	Magheli, 2011 [89]	522 RRP	14	7
		522 RARP	20	9

Comparative studies suggests that PSMs rates are likely to be similar regardless of the different possible surgical approaches

# Impact of surgical technique on pathological and biochemical outcomes



open vs laparoscopic vs robotic

1500 Pz

pT3 → LRP and RARP had higher positive surgical margins

		Surgical grou				
r	Pathological stage	SM	RRP	LRP	RARP	$p^*$
	pT2 n (%)	SM positive	24 (6.6)	29 (6.7)	36 (9.3)	0.264
	pT3 n (%)	SM positive	51 (32.1)	39 (43.8)	66 (48.5)	0.013
	All patients $n(\%)$	SM positive	75 (14.4)	68 (13.0)	102 (19.5)	0.010

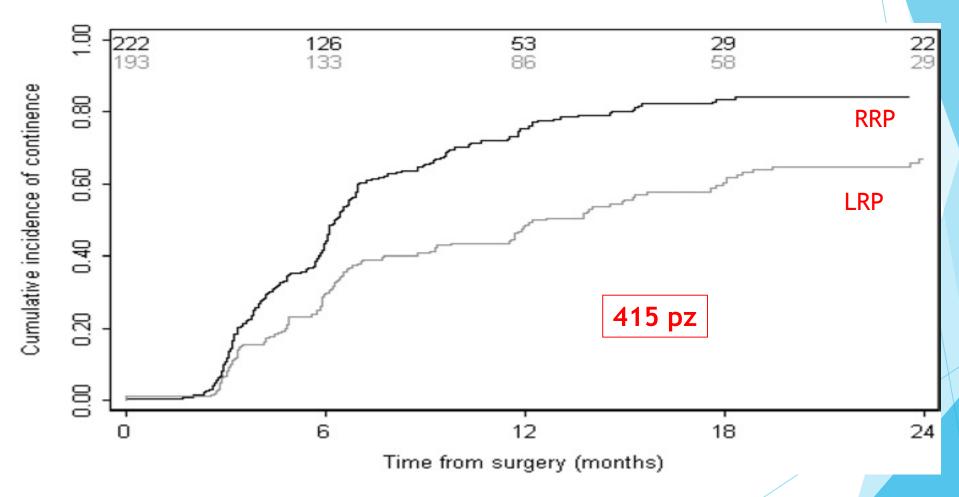


**Tactile Feedback** 



### **PENTAFECTA**

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Statistically significant difference in favour of RRP

#### **RALP vs RRP**

Complication	RARP	RRP	P
Continence at 1 year+			0.344
N	252	496	
With continence	224 (91.8)	446 (93.7)	
No pads	199 (81.6)	419 (88.0)	
Security pad only	25 (10.3)	27 (5.7)	
Without continence	20 (8.2)	30 (6.3)	
1-2 pads/day	17 (7.0)	23 (4.8)	
3 pads/day	3 (1.2)	7 (1.5)	
Previous incontinence	1	6	
Unknown	7	14	

882 Pz

### At 1-year → no significant difference in continence

Review: Radical prostatectomy: comparisons of different approaches

Comparison: 06 Continence rate

Outcome: 07 12-mo continence rate: RRP vs RARP

Study	RRP	RARP	OR (fixed)	Weight	OR (fixed)
or subcategory	n	n	95% CI	%	95% CI
Krambeck, 2008	50/496	28/252		75.71	0.90 [0.55, 1.46]
Ficarra, 2009	13/105	3/103	T ——	6.02	4.71 [1.30, 17.06]
Ou, 2009	1/30	0/30		1.08	3.10 [0.12, 79.23]
Rocco, 2009	26/217	2/79		5.85	5.24 [1.21, 22.62]
Di Pierro, 2011	15/75	5/45	-	11.34	2.00 [0.67, 5.94]
Total (95% CI)	923	509		100.00	1.53 [1.04, 2.25]
Total events: 105 (RRP), 38	(RARP)				
Test for heterogeneity: $\chi^2$ =	$10.64$ , $df = 4$ ( $p = 0.03$ ), $l^2 = 62$	.4%			
Test for overall effect: $Z = 2$	2.15 (p = 0.03)				
		(	0.1 0.2 0.5 1 2	5 10	
			RRP RARP		

The cumulative analysis showed a statistically significant advantage in favor of RARP

First author	Cases, n	Study design	Continence definition	Data collection	Urinary continence recovery, %	
					6 mo	12 mo
Tewari, 2003 [11]	RRP, 100 RARP, 200	Prospective comparison	0 pad	Interview		n: 160 d an: 44 d
Ficarra, 2009 [44]	RRP, 105 RARP, 103	Prospective comparison	0 pad	Validated questionnaire	-	88 97
Di Pierro, 2011 [45]	RRP, 75 RARP, 75	Prospective comparison	0 pad	Institutional questionnaire	-	80 89
Kim, 2011 [46]	RRP, 235 RARP, 528	Prospective comparison	0 pad	Validated questionnaire		n: 4.3 mo n: 3.7 mo
Krambeck, 2008 [47]	RRP, 564 RARP, 286	Retrospective, contemporary series	0 pad	Institutional questionnaire	-	93.7 91.8
Ou, 2010 [48]	RRP, 30 RARP, 30	Retrospective contemporary series	0 pad	Unspecified	83 97	97 100
Caballero, 2008 [49]	RRP, 62 RARP, 60	Historical control	0 pad	Unspecified	54 40	-
Rocco, 2009 [50]	RRP, 240 RARP, 120	Historical control	0-1 safety pad	Interview	84 93	88 97

KARP = robot-assisted radical prostatectomy; KRP = retropublic radical prostatectomy.

Urinary continence may be influenced by the patient's preoperative condition

Available studies do not provide an adequate comparison of postoperative continence rates in patients treated by RARP versus RRP.



### **PENTAFECTA**

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- Costs

# **Potency**

Review: Radical prostatectomy: comparisons of different approaches

Comparison: 11 Potency rate

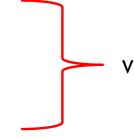
Outcome: 01 12-mo potency rate: RRP vs RARP

Study or subcategory	RRP n	RARP n	OR (ra 95%	ndom) 6 Cl	Weight %	OR (random) 95% CI
Krambeck, 2008 Ficarra, 2009 Ou, 2009 Rocco, 2009 Di Pierro, 2011 Kim, 2011	155/417 21/41 1/2 126/214 35/47 65/122	61/203 12/64 10/16 30/78 10/22 60/373	•		22.40 16.71 4.03 20.71 14.60 21.56	1.38 [0.96, 1.97] 4.55 [1.89, 10.94] 0.60 [0.03, 11.47] 2.29 [1.35, 3.90] 3.50 [1.21, 10.15] 5.95 [3.79, 9.33]
Total (95% CI) Total events: 403 (RRP), 18 Test for heterogeneity: $\chi^2$ = Test for overall effect: z = 3	28.01, $df = 5 (p < 0.0001), l^2 = 82.5$	756 1%	0.1 0.2 0.5 1	2 5	100.00	2.84 [1] 48, 5.43]
			RRP	RARP		

### Potency

Lack of well-controlled prospective studies of functional outcomes

- level of surgeon experience,
- institutional volume of surgery
- means of outcome assessment
- patient's preoperative condition
- postoperative rehabilitation



varied considerably between studies



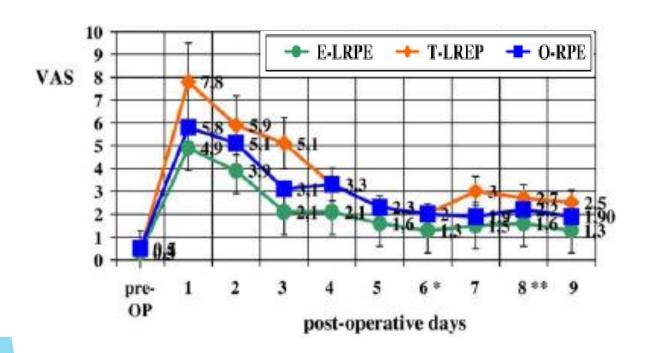
Goal should be a return to a patient's presurgical level

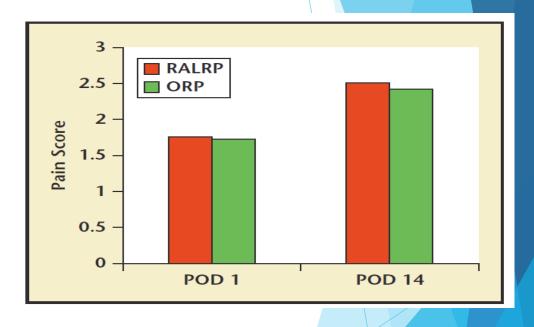


### **PENTAFECTA**

- Oncological results
- Continence
- Potency
- ▶ Pain , Qol and Cosmetics
- Costs

# Pain





Remzi M, Eur Urol, 2005
Webster, J. Urol, 2005

### Cosmetics

#### **RRP**

Incision (4 - 6 Inches)



### **RALP**

4 incisions → surgical instruments

(1 Inch each ones)

1 Incision → infraumbilical (2 Inches)

Tot. 4 - 6 Inches







#### Prostate Cancer

#### Satisfaction and Regret after Open Retropubic or Robot-Assisted Laparoscopic Radical Prostatectomy

400 pz

84% satisfied

18 % regretted

Table 4 - Characteristics of nonregretful and regretful patients

	No regret			Regret		
	No. (%)	Median (IQR)	No. (%)	Median (IQR)		
Type of procedure					0.031	
RRP	177 (85.1)	<del>-</del>	31 (14.9)	-		
RALP	132 (75.9)	_	42 (24.1)	-		

Patients who underwent RALP were more likely to be regretful and dissatisfied, possibly because of higher expectation of an "innovative" procedure.

# It's show business!





# **CRITICITA'**



### Costi.....



-SPESA DI ACQUISTO DELLA MACCHINA

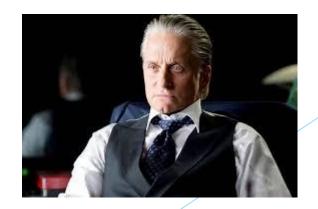
-COSTO ANNUO DI ESERCIZIO LEGATO AL CONSUMO DEGLI STRUMENTI

-COSTO LEGATO ALL'ASSISTENZA TECNICA

-TEMPI DI SALA OPERATORIA PIU' LUNGHI

### MA....

- -RIDUZIONE DELLA MORBILITA' PERIOPERATORIA
- -DEGENZE MEDIE OSPEDALIERE BREVI
- -UTILIZZO MULTIDISCIPLINARE DEL ROBOT



### Ed ancora....

#### -MANCANZA DI FEEDBACK TATTILE

(sebbene stupefacente, rimane una grossa limitazione della robotica).

pT3 → LRP and RARP had higher positive surgical margins

Pathological St.

pT2 n (%)

SM positive

SM positive

SM positive

SM positive

T5 (14.4) 68 (13.0)

All patients n (%)

SM positive

T5 (14.4) 68 (13.0)

SM positive

T5 (14.4) 68 (13.0)



**Tactile Feedback** 

Ed ancora....

-NECESSITA' DI TEMPI LUNGHI IN CASO DI EMERGENZA PER PASSARE ALL'INTERVENTO OPEN



Massimo beneficio
Paziente con malattia organo confinato con buona funzione sessuale.



Minimo beneficio
Paziente con malattia localmente avanzata

### Ma soprattutto.....

-ADEGUATA FORMAZIONE DEL PERSONALE DI SALA

-INTEGRAZIONE E SINCRONISMO DELL'EQUIPE



#### **Review Article**

ICUrology 2016;57:75-83. http://dx.doi.org/10.4111/icu.2016.57.2.75 pISSN 2466-0493 • eISSN 2466-054X

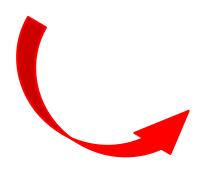


### Past, present and future of urological robotic surgery

Wooju Jeong, Ramesh Kumar, Mani Menon

Vattikuti Urology Institute, Henry Ford Health System, Detroit, MI, USA

The first urologic robotic program in the world was built at the Vattikuti Urology Institute, Henry Ford Hospital Din 2000 under the vision of surgical innovator, Dr. Mani Menon for the radical prostatectomy. The robot-assisted retomy continues being modified with techniques to improve perioperative and surgical outcomes. The application cal technique has since been expanded to the bladder and upper urinary tract surgery. The evolution of surgical technique has since been expanded to the bladder and upper urinary tract surgery. The evolution of surgical technique has since been expanded to the bladder and upper urinary tract surgery.



#### CONCLUSIONS

Minimally invasive surgical techniques have been expanding the boundary of application on urologic surgeries, because of the decreasing rate of perioperative outcomes and similar oncological results. Due to intuitive movements with advanced wrist movements, 3-dimensional vision and surgeon's ergonomics, the robotic surgical technique has replaced the laparoscopic technique in many urological applications. Robotic surgery continues to evolve into newer techniques and refine the past techniques.

The market growth and the competition of newer surgical systems should translate to improvement of surgical technique and clinical outcomes.

#### L'EVOLUZIONE DEL SISTEMA

#### DA VINCI SINGLE PORT



Unico braccio con i tre strumenti e l'ottica per l'acquisizione di immagini 3D

Diametro di soli 2,5 cm con notevole riduzione rispetto ai precedenti Braccio completamente mobilizzabile con angolo di rotazione di 360°

Strumenti che possono addentrarsi fino a 24 cm in profondità dal sito di ingresso, raggiungendo virtualmente qualsiasi organo o apparato

Stessa console che non richiede nuovo training ai chirurghi



#### Actas Urológicas Españolas



www.elsevier.es/actasuro

#### **NEW TECHIQUES AND TECHNOLOGIES**

### Initial experience with the new da Vinci single-port robot-assisted platform\*



R. Ballestero Diego\*, S. Zubillaga Guerrero, D. Truan Cacho, C. Carrion Ballardo, G. Velilla Diez, P. Calleja Hermosa, J.L. Gutierrez Banos

Servicio de Urología, Hospital Universitario Marqués de Valdecilla, Santander, Spain



**DISCUSSION:** In our initial experience with the da Vinci device, R-LESS surgery was feasible and safe. There are still a number of limitations in its use, which require new and improved R-LESS platforms.

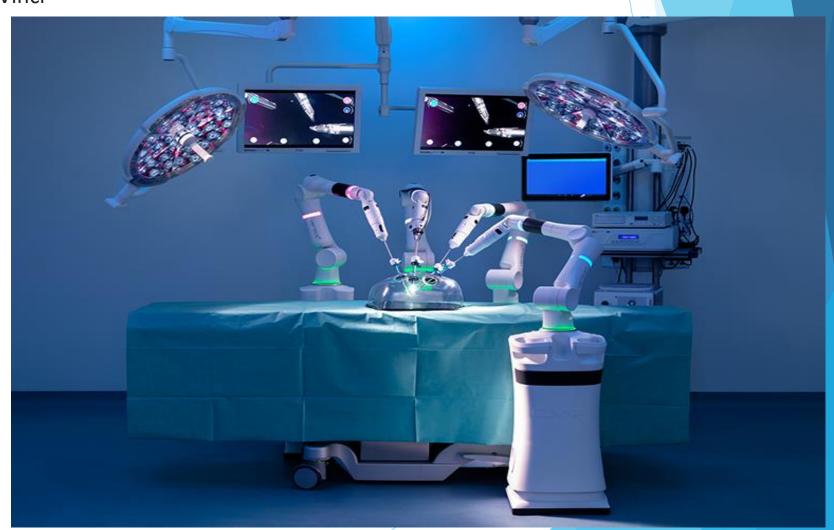
### **VERSIUS**

Robot multifunzionale, facile all'uso, ergonomico, modulare

Più economico del suo "fratellone" Da Vinci

Ridotto tempo di apprendimento

Movimenti su 4 assi di 540 gradi



### Biopsie prostatiche più precise con il robot "Mona Lisa"

#### iSR'obot™ Mona Lisa

- -capacità di fusione di RMI-ultrasuono,
- -visualizzazione ottimale della regione di interesse (ROI).
- -il medico crea un piano su ordinazione di biopsia





#### Il sistema robot:

- -guida il posizionamento e la profondità dell'ago di biopsia
- -ottimizzazione accurata aiuta i medici ad individuare presto il carcinoma della prostata
- -fiducia per iscrivere il paziente al programma attivo di sorveglianza.

### TO BE CONTINUED.....



#### I futuri sviluppi:

Miglioramento delle caratteristiche degli strumenti .

Nuove indicazioni agli interventi chirurgici.

Sviluppo di nuove tecnologie.