Tracking Long Term Biochemical Free Recurrence after Da Vinci Prostatectomy utilising a Web based Database

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September 4 2009

Geneva Foundation for Medical Education and Research (GFMER)

Online Database

- Web based interface allowing
  - study of clinical practices
  - multicenter and multi-user collaboration
  - providing real time statistics
  - secured access and anonymity for users/patients

Prostatectomy Database

ERUS 2005
EUROPEAN ROBOTIC UROLOGY SYMPOSIUM
Geneva, Switzerland > February 24-25, 2005

Surgical Protocol Launching the European Data Base

Live surgery

Video and interactive presentation by the participants

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GENERALE BEAULIEU   **S·M·B**   INTUITIVE
SURGICAL®

Prostatectomy Database

Forms

Prostatectomy Database
Detailed margins status/ pathologic stage
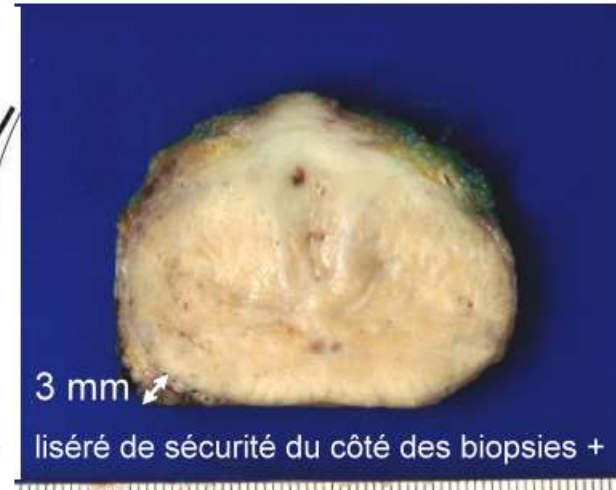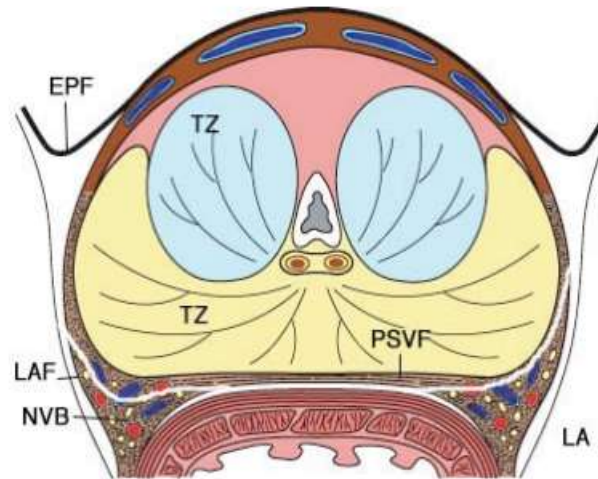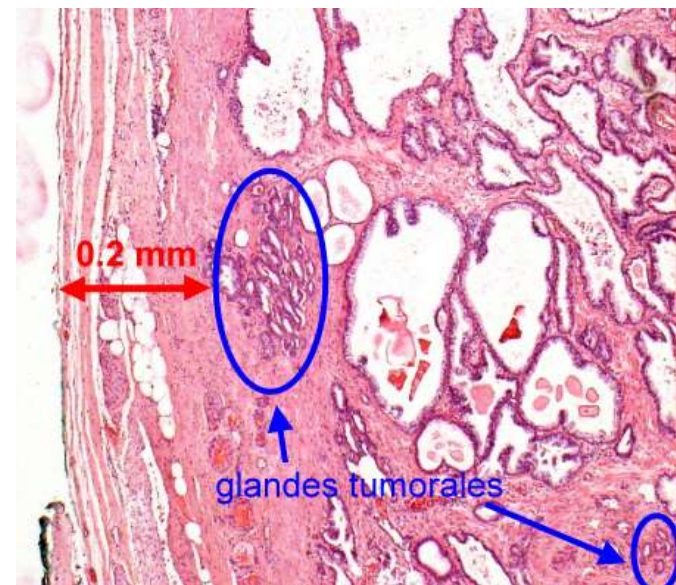
Internet based clinical trial of robotically assisted laparoscopic prostatectomy

Welcome rochat
(my account ¦ logout | help)

Instructions

Use the tabs at the top of the following area in order to access the DATA and NEW-PATIENT elements. New cases should be entered as a NEW-PATIENT. If you wish to see the data of a previously entered case, you may do so by selecting the case from the DATA area .

Currently displayed study : | Laparoscopic Prostatectomy V2 ⌄ | *(click to change)*

Pathological results	
1. Stage	○ pT2a ○ pT2b ○ pT2c ○ pT3a ○ pT3b ○ pT4
2. Pathological specimen	intact: ○ no ○ yes capsule violated: ○ no ○ yes tumor volume: [____] cc maximum diameter of tumor: [____] mm prostate weight: [____] g specimen included in totality: ○ no ○ yes number of blocks included: [____]
3. Gleason score (average)	[____] + [____] The Gleason sum will appear automatically here.
4. Secondary Gleason score (the worst)	[____] + [____] The Gleason sum will appear automatically here.
5. High grade PIN	○ no ○ yes

Internet based clinical trial of robotically assisted laparoscopic prostatectomy
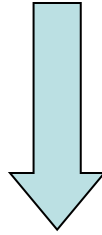
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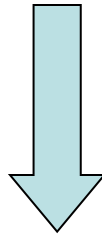
Currently displayed study : | Laparoscopic Prostatectomy V2 ∨ | *(click to change)*

6. Margins (focal ≤ 3 mm, extensive > 3 mm)		
	negative margin	○ R0
	positive margins	○ R1 (one side)
		○ R2 (two sides)

	left	right
	☐ apex focal	☐ apex focal
	☐ apex extensive	☐ apex extensive
	☐ posterolateral focal	☐ posterolateral focal
	☐ posterolateral extensive	☐ posterolateral extensive
	☐ base focal	☐ base focal
	☐ base extensive	☐ base extensive
	☐ neck focal	☐ neck focal
	☐ neck extensive	☐ neck extensive

7. Nodes	
	○ N0 Number of negative nodes: [ ]
	○ N+ Number of positive nodes: [ ]
	○ NX

Prostatectomy Database

$$\downarrow$$

Excel format

$$\downarrow$$

Statistical Analysis

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Robotic Prostatectomy
Preliminary Results N=312

- All cases completed by 2 surgeons;
  - C.H Rochat, J. Sauvain

- Robotic prostatectomy cases completed from 2003-2008

- Began participation in online database September 2006

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Robotic Prostatectomy
Preliminary Results N=312

Age (yrs)	61.9 ± 7.2 (43-77)
Preop PSA (ng/ml)	7.0 ± 4.2 (0.63, 31.8)
Operative Technique:	289 (92.6%) transperitoneal 23 (7.4%) extraperitoneal
Nerve sparing	305 (97.6%)
Conservation of the tip of the seminal vesicles	134 (43.0%)
Lymphadenectomy	151 (48.4%)

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Robotic Prostatectomy
Preliminary Results N=312

Stage (%)

Clinical		
T1c	38.4%	(n=120)
T2a	26.0%	(n=82)
T2b	16.0%	(n=51)
T2c	9.3%	(n=29)
T3	1.0%	(n=3)

Pathological		
pT2a	8.0%	(n=25)
pT2b	4.8%	(n=16)
pT2c	61.9%	(n=194)
pT3a	14.4%	(n=45)
pT3b	10.0%	(n=31)

1.0% T3

24.4% pT3

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Preliminary Results N=312

Gleason pattern (%)

Preoperative		
3+3	66.7%	(n=209)
3+4	11.9%	(n=37)
4+3	5.8%	(n=19)
4+4	3.5%	(n=11)

Postoperative		
3+3	48.4%	(n=151)
3+4	31.1%	(n=99)
4+3	10.6%	(n=33)
4+4	3.5%	(n=11)

21.2% Gleason 4

45.2% Gleason 4

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Preliminary Results N=312

Tumor volume (cc)	3.3 ± 5.1 (0.61 – 38.0)
Maximum diameter of the tumor (mm)	21.1 ± 12.4 (6.0 – 60.0)
Prostate Weight (grams)	48.3 ± 20.2 (23 – 177.0)
Positive lymph nodes (%)	5 (1.6%)

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Robotic Prostatectomy
Preliminary Results N=312

Surgical Margin Details		
	Unilateral	Bilateral
Focal (<3mm) (N=63 , 20.2%)	57	6
Extensive (N=31, 10.0%)	22	9
Positive Margin Rate N=(97/312, 31.0%)	79 (25.3%)	15 (4.8%)

**missing the focal /extensive info for 3 PSM patients

Surgical Margins by Case Series

Cases 1-150 N=150		Cases 151-312 N=162	
Overall	58/150 (38.7%)	Overall	39/162 (24.4%)
pT2	29/110 (26.4%)	pT2	19/125 (15.2%)

overall margins p=0.0078
pT2 margins   p= 0.039

Long term oncologic outcome

- Biochemical free recurrence (Defined by PSA <0.4, <0.2, and <0.1ng/ml) stratified by surgical margin status, and stage

- Secondary treatment:
  - 23/312 (7.4%)
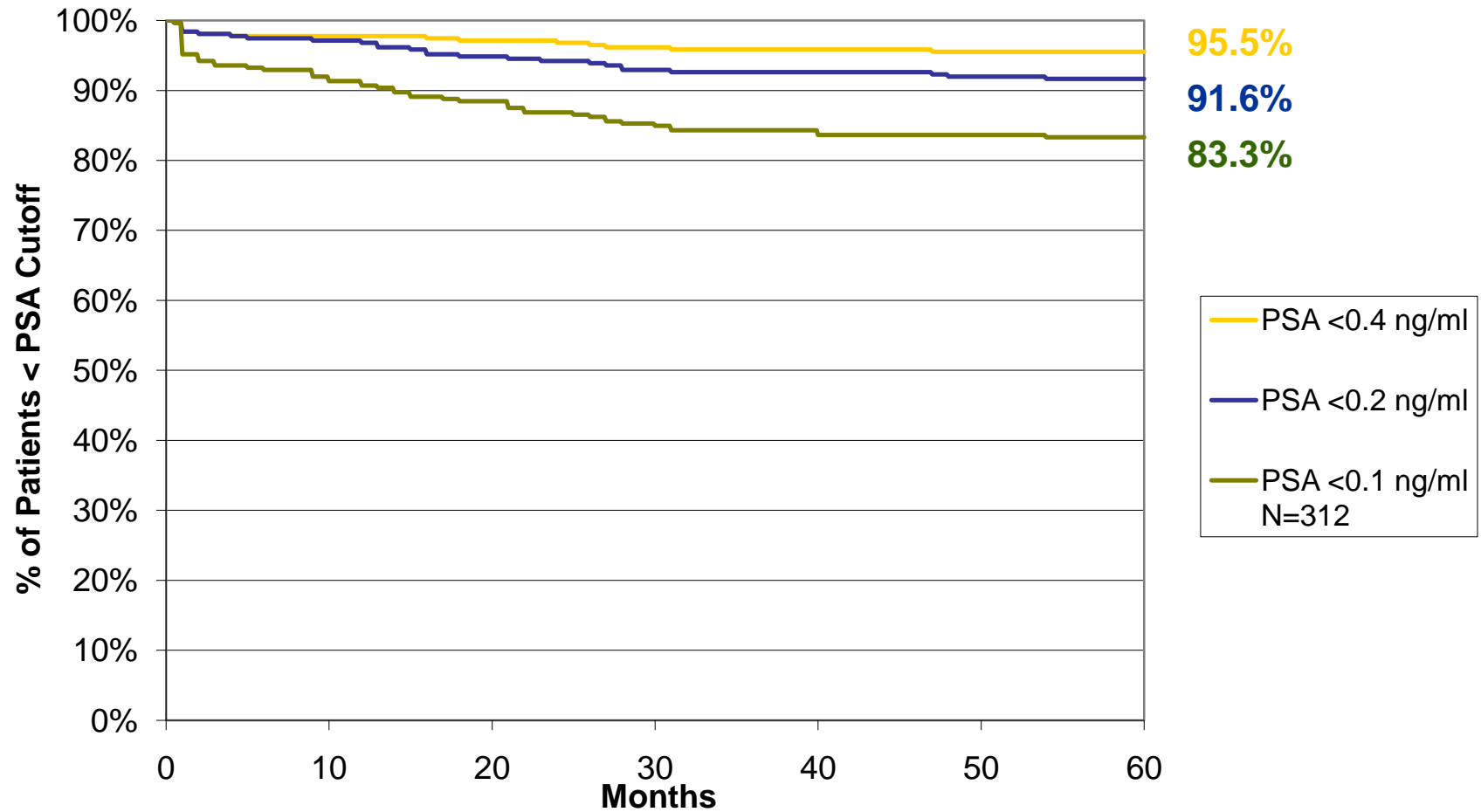   - Adjuvant 13/23 (56.5%)
    - Salvage 10/23 (43.5%)
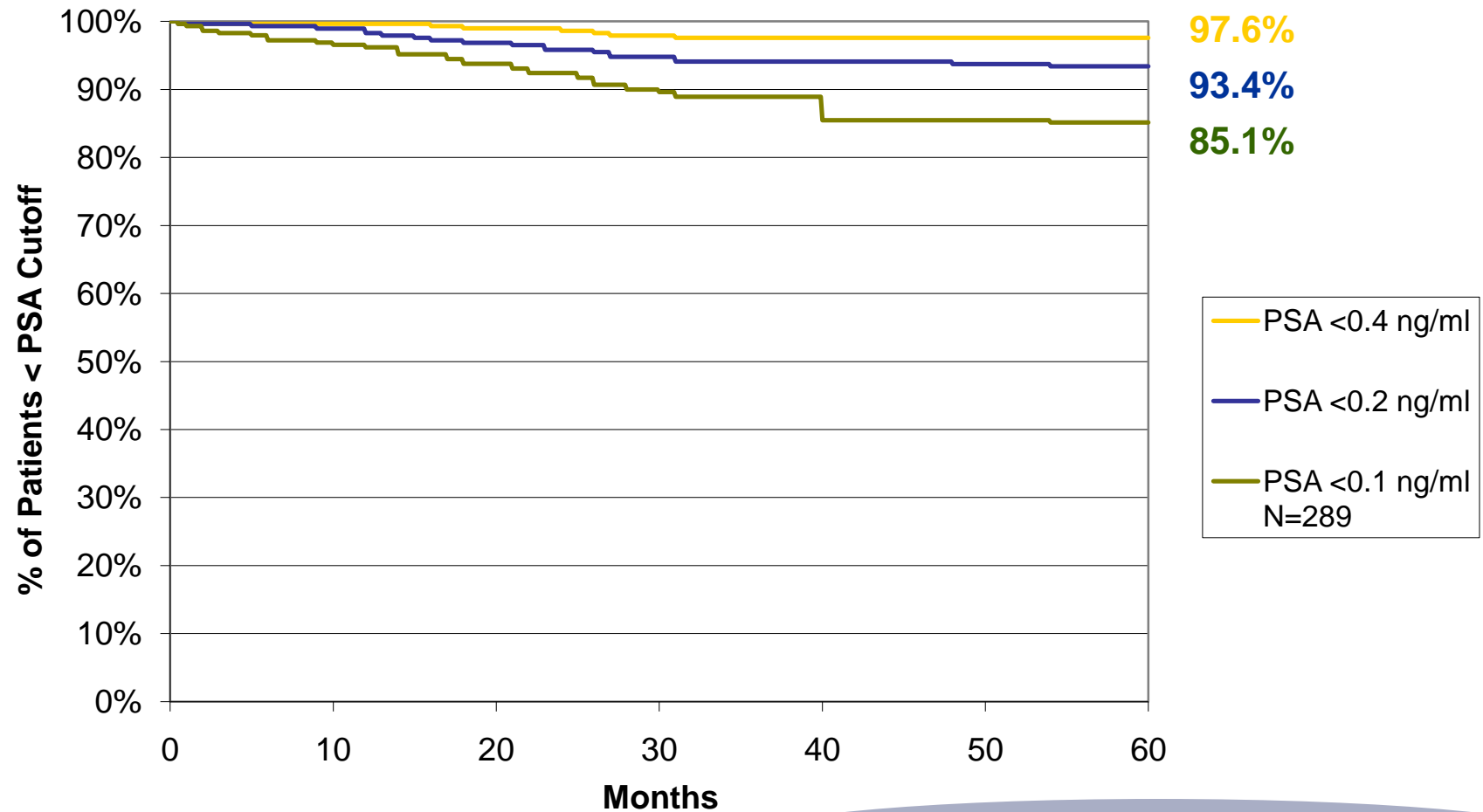
Number of Patients and Follow-up

- 273 (87.5%)   12 months
- 243 (77.8%)   24 months
- 185 (59.3%)   36 months
- 129 (41.3%)   48 months
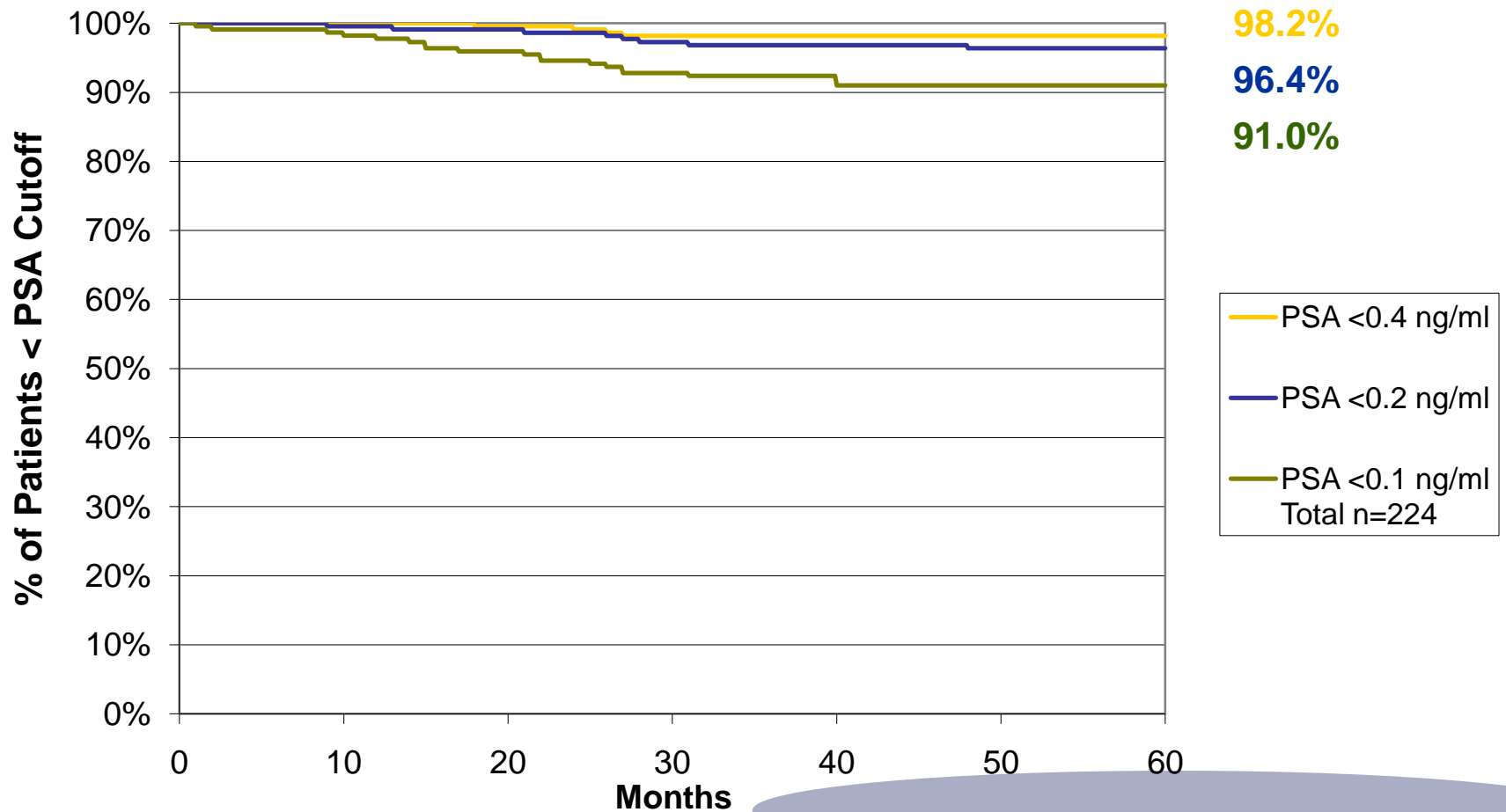- 78 (25.0%)   60 months
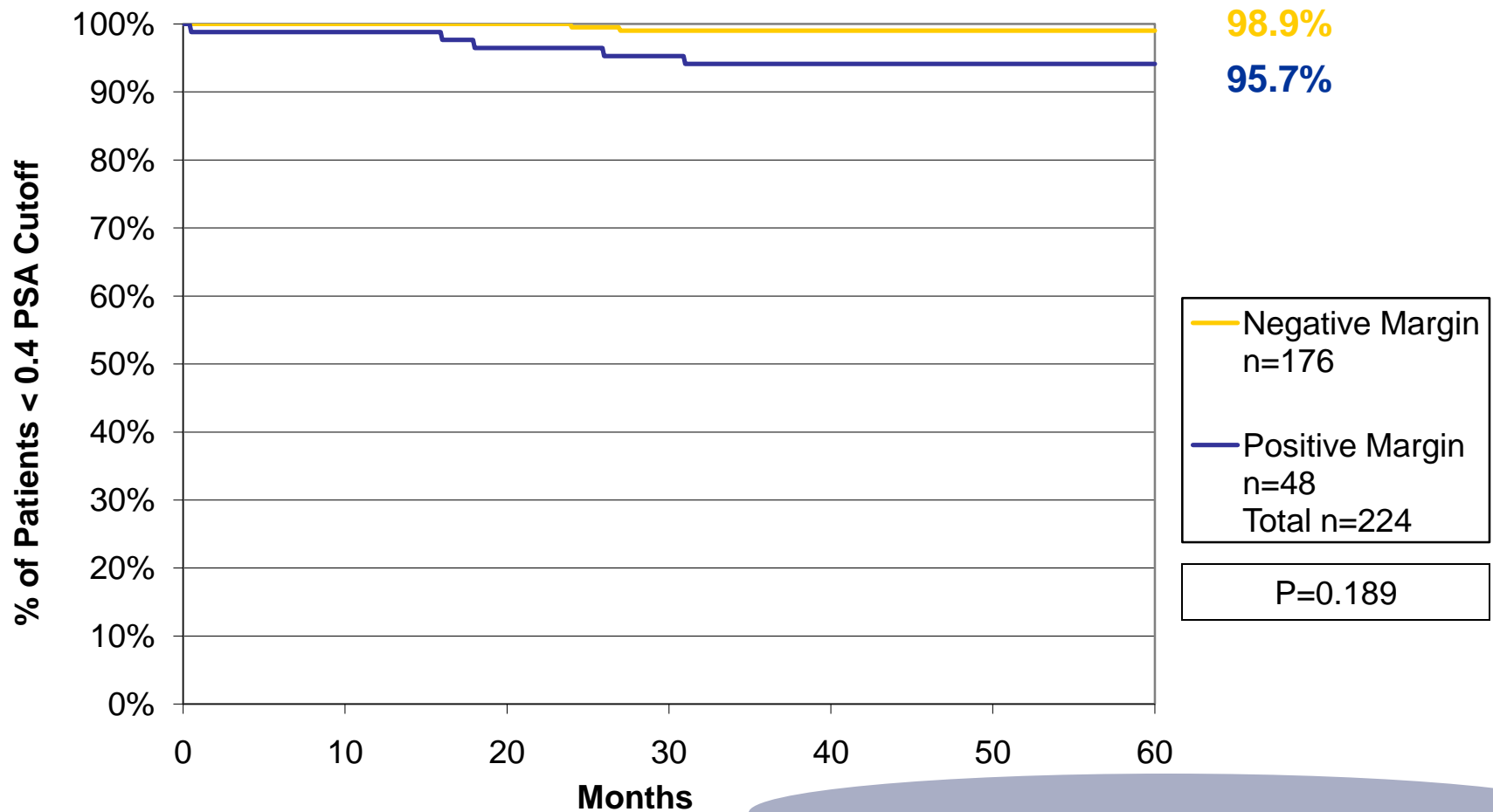
Biochemical Free Recurrence by PSA Cutoff

Biochemical Free Recurrence by PSA Cutoff (patients without secondary treatment)
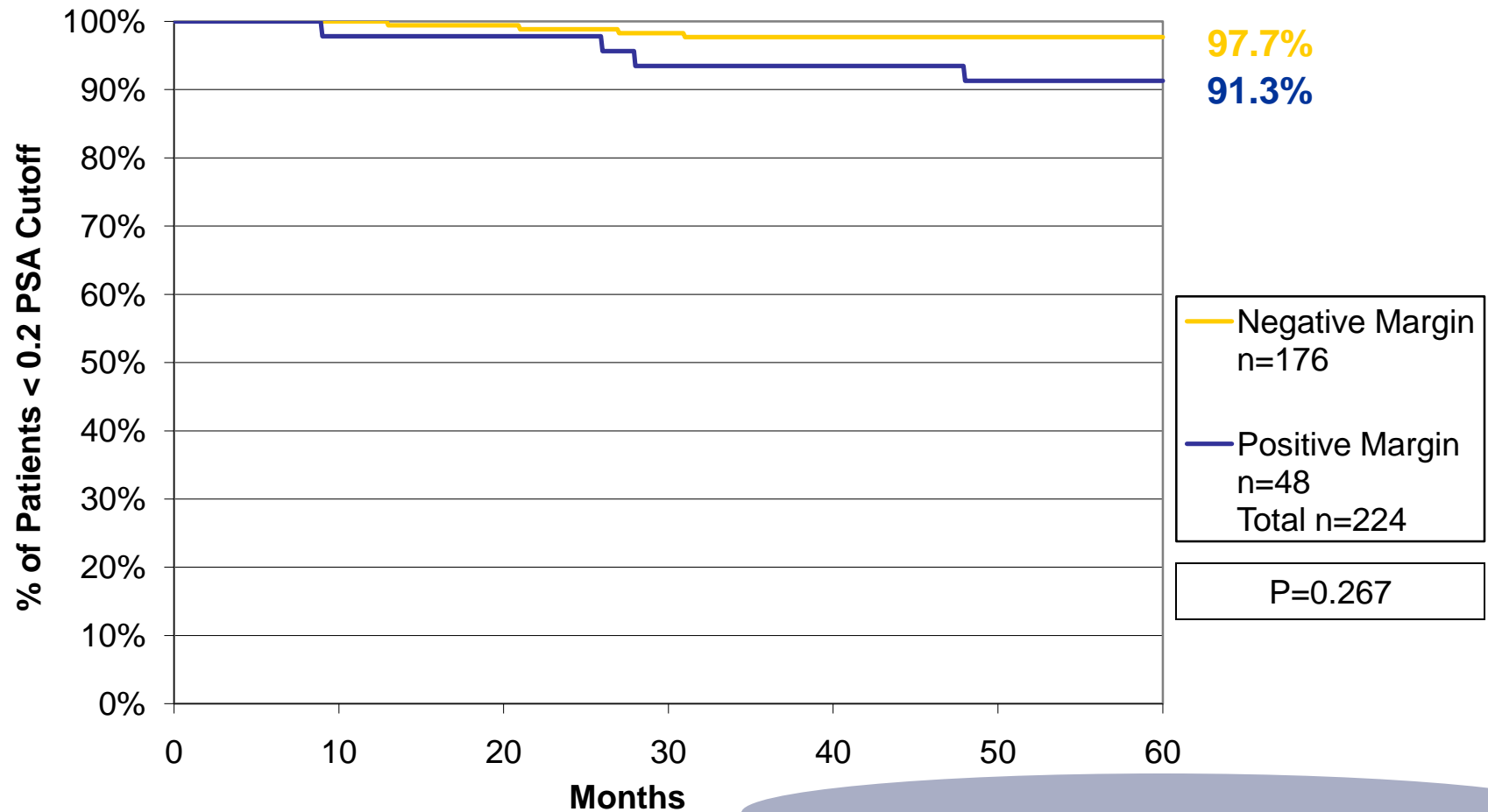
Biochemical Free Recurrence by PSA Cutoff (pT2 patients without secondary treatment)
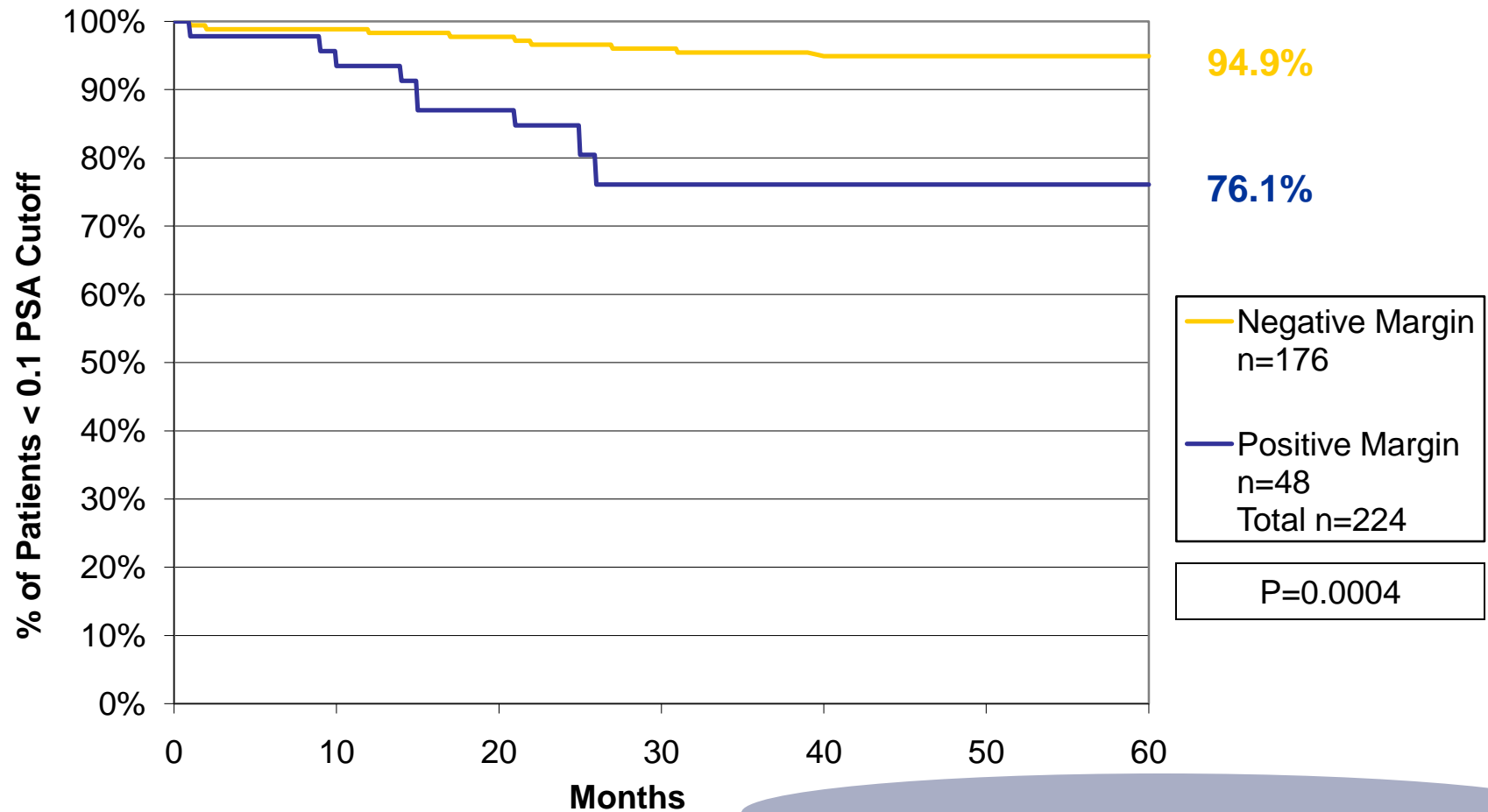
Biochemical Free Recurrence by Margin Status (pT2 patients with PSA cutoff < 0.4 ng/ml)
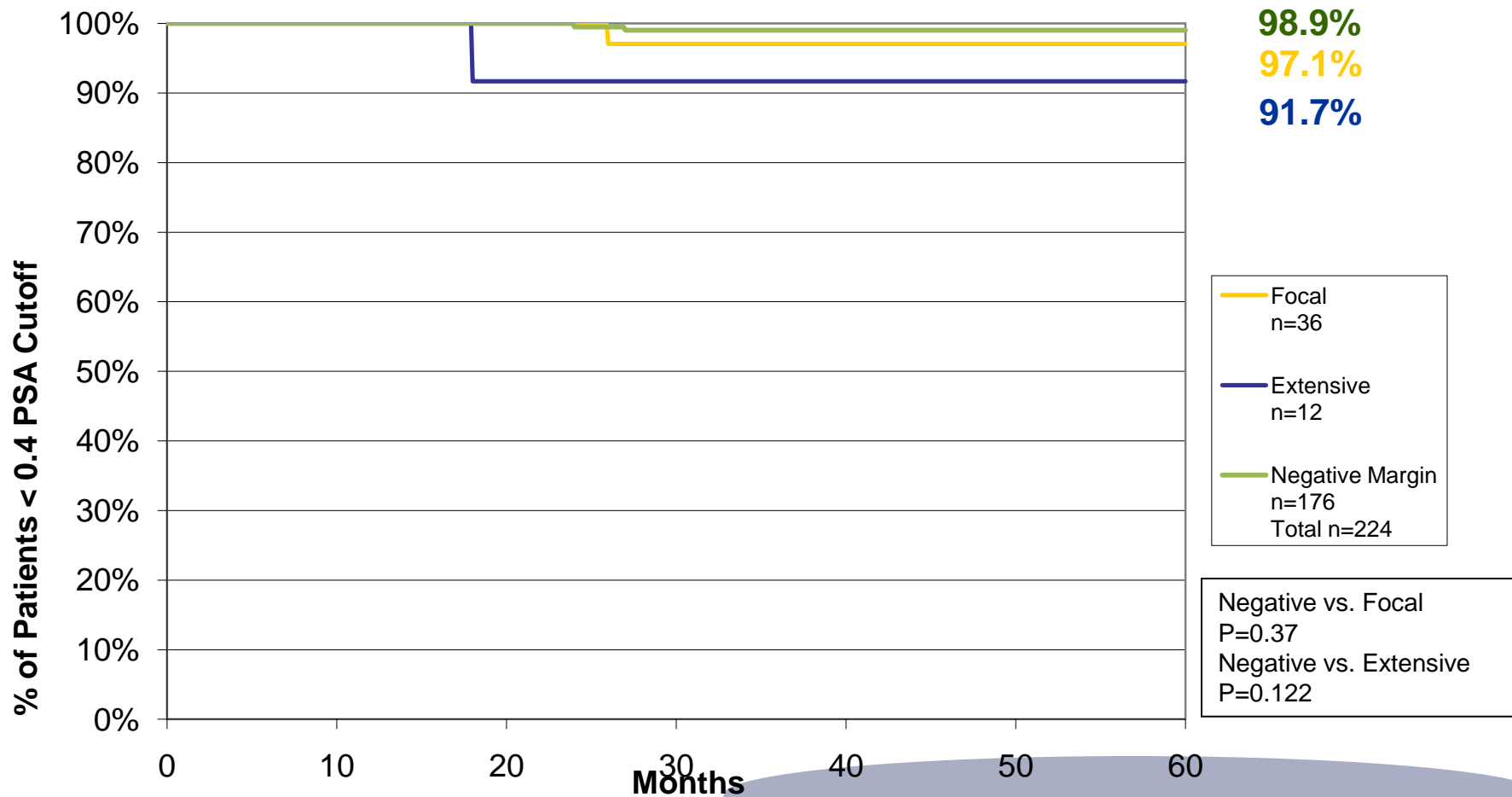
Biochemical Free Recurrence by Margin Status (pT2 patients with PSA cutoff < 0.2 ng/ml)
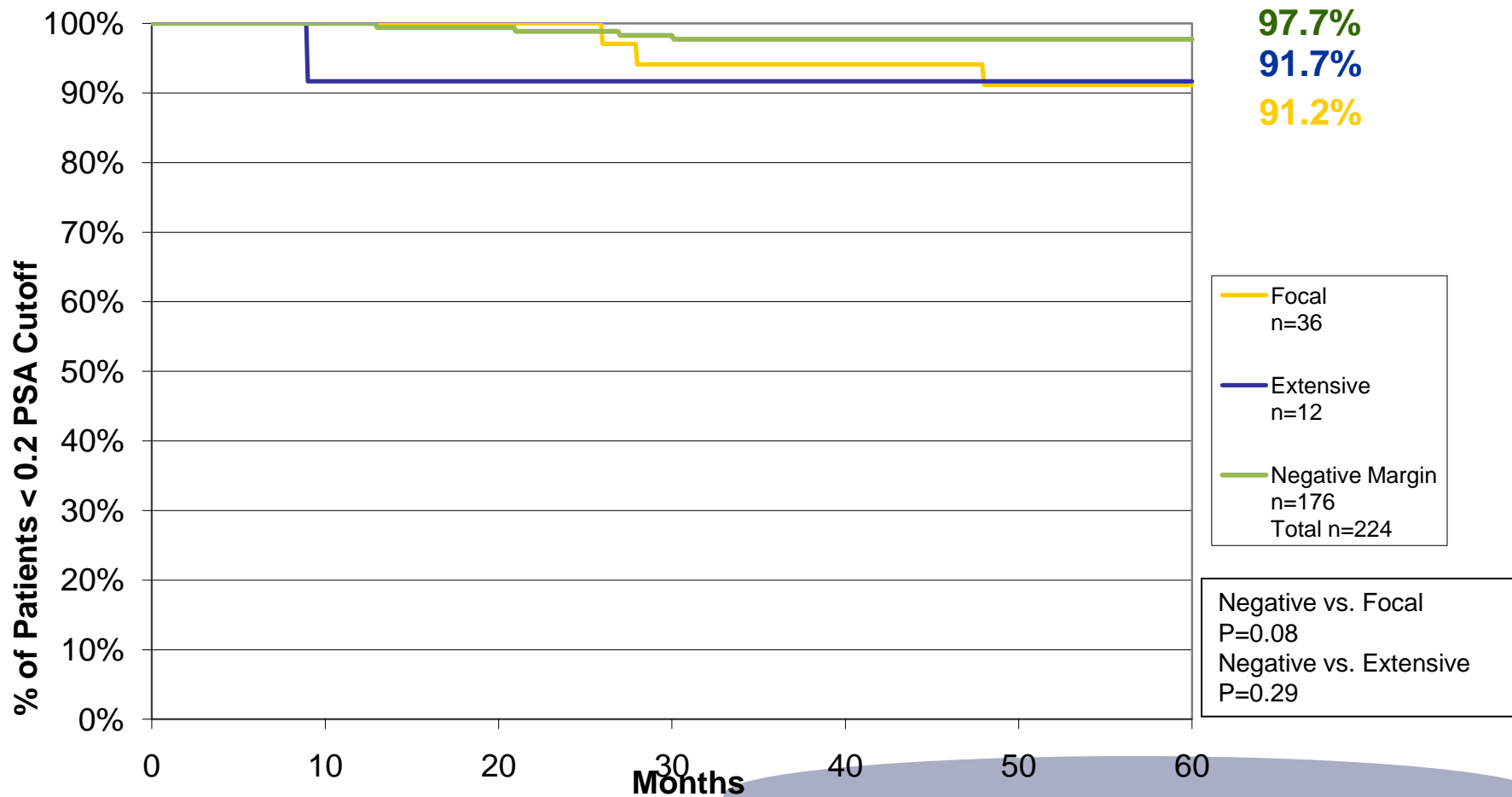
Biochemical Free Recurrence by Margin Status (pT2 patients with PSA cutoff < 0.1 ng/ml)

Biochemical Free Recurrence Among pT2 Patients with Focal and Extensive Positive Margin Status (PSA cutoff <0.4 ng/ml)
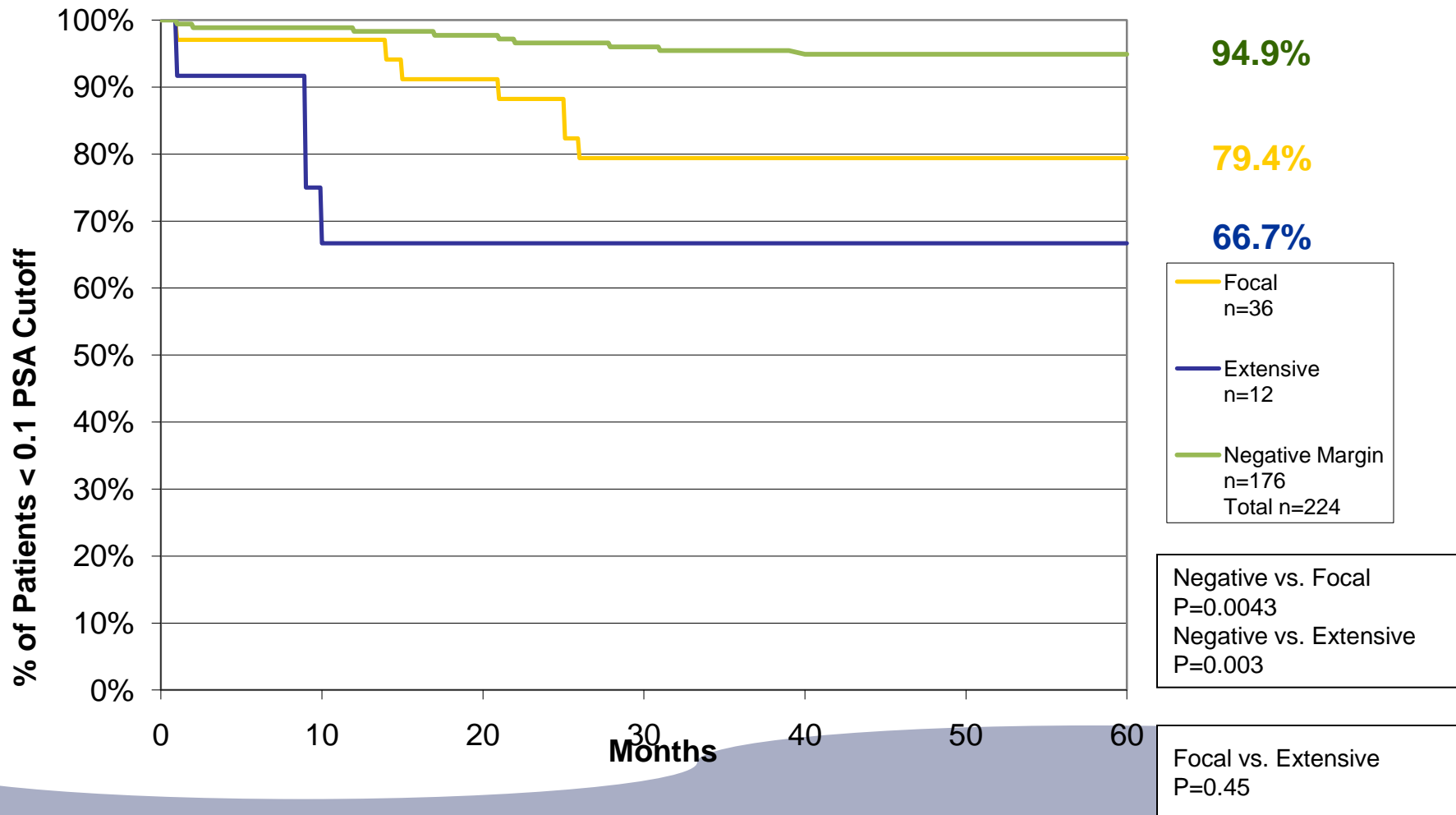
Biochemical Free Recurrence Among pT2 Patients with Focal and Extensive Positive Margin Status (PSA cutoff <0.2 ng/ml)

Biochemical Free Recurrence Among pT2 Patients with Focal and Extensive Positive Margin Status (PSA cutoff <0.1 ng/ml)

Conclusions

- The <u>choice of an appropriate PSA cutoff is critical</u> in the long term prognosis of biochemical free recurrence in patients with prostate cancer

- <u>Significant changes in biochemical free recurrence occur in the first 30 months</u> following surgery

- The <u>distinction between focal and extensive margins</u> with respect to long term prognosis is best seen using a <u>PSA cutoff of <0.1 ng/ml</u>

Conclusions

- Patients with organ confined <u>(pT2) disease have highest probability of being biochemical free if margin negative, followed by focal positive margin and extensive margin.</u>

- Continue to track prostatectomy outcomes in order to improve patient care

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