Prospective study comparing a risk-based injection regimen versus an empiric approach to intracavernosal injection therapy

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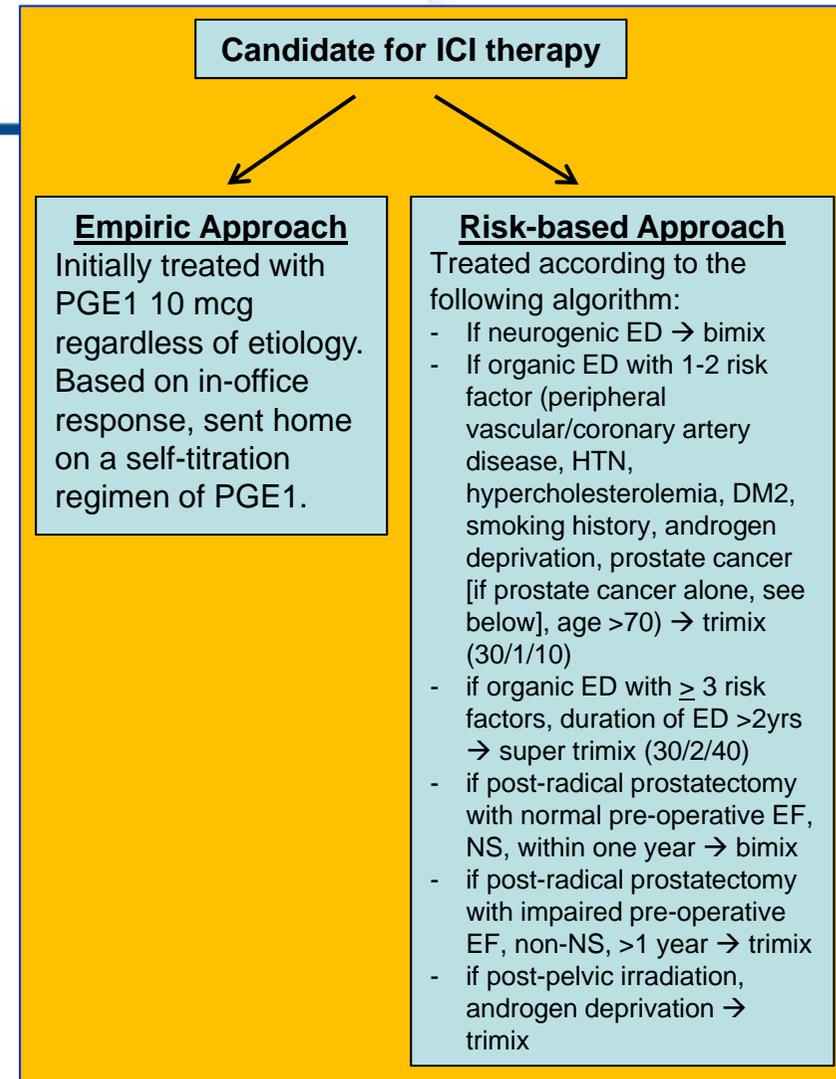Trinity J. Bivalacqua M.D. Ph.D.

Introduction

- Employing ICI in practice is largely empirical, and has not been validated with evidence-based approaches

- We sought to evaluate if an algorithm that incorporates ED risk factors can help with initial agent ICI choice and dose selection

Objectives

- To compare two strategies for ICI to determine whether a risk-based approach is more efficacious, increases satisfaction and/or results in fewer treatment complications than an empiric approach.

- Primary outcome measure:
  - Difference in EDITS (Erectile Dysfunction Inventory and Treatment Satisfaction) at 3 and/or 6 months

- Secondary outcome measures:
  - Differences in IIEF-EF, SQoL or QEQ at 3 or 6 months
  - Complication rates

Methods

- A prospective IRB-approved database of patients enrolled in the ICI program at the Johns Hopkins Hospital from May 2012-2014 was amassed.

- Baseline demographic information, treatment outcomes and subjective patient evaluations of sexual function (IIEF, QEQ, SQoL and EDITS questionnaires) were obtained and analyzed at baseline, and at 3 and 6 months.

- Two approaches were compared: an empiric approach (group 1) vs. a risk-based approach (group 2)

- Dose titration was permitted in both groups.

- Statistical analysis was carried out using t-test, ANOVA and chi-squared analysis.

Candidate for ICI therapy

Empiric Approach
Initially treated with PGE1 10 mcg regardless of etiology. Based on in-office response, sent home on a self-titration regimen of PGE1.

Risk-based Approach
Treated according to the following algorithm:
- If neurogenic ED → bimix
- If organic ED with 1-2 risk factor (peripheral vascular/coronary artery disease, HTN, hypercholesterolemia, DM2, smoking history, androgen deprivation, prostate cancer [if prostate cancer alone, see below], age >70) → trimix (30/1/10)
- if organic ED with $\geq$ 3 risk factors, duration of ED >2yrs → super trimix (30/2/40)
- if post-radical prostatectomy with normal pre-operative EF, NS, within one year → bimix
- if post-radical prostatectomy with impaired pre-operative EF, non-NS, >1 year → trimix
- if post-pelvic irradiation, androgen deprivation → trimix

Results - Demographics

- 175 patients were enrolled with 3 and 6 month f/u at 57% and 35% respectively.

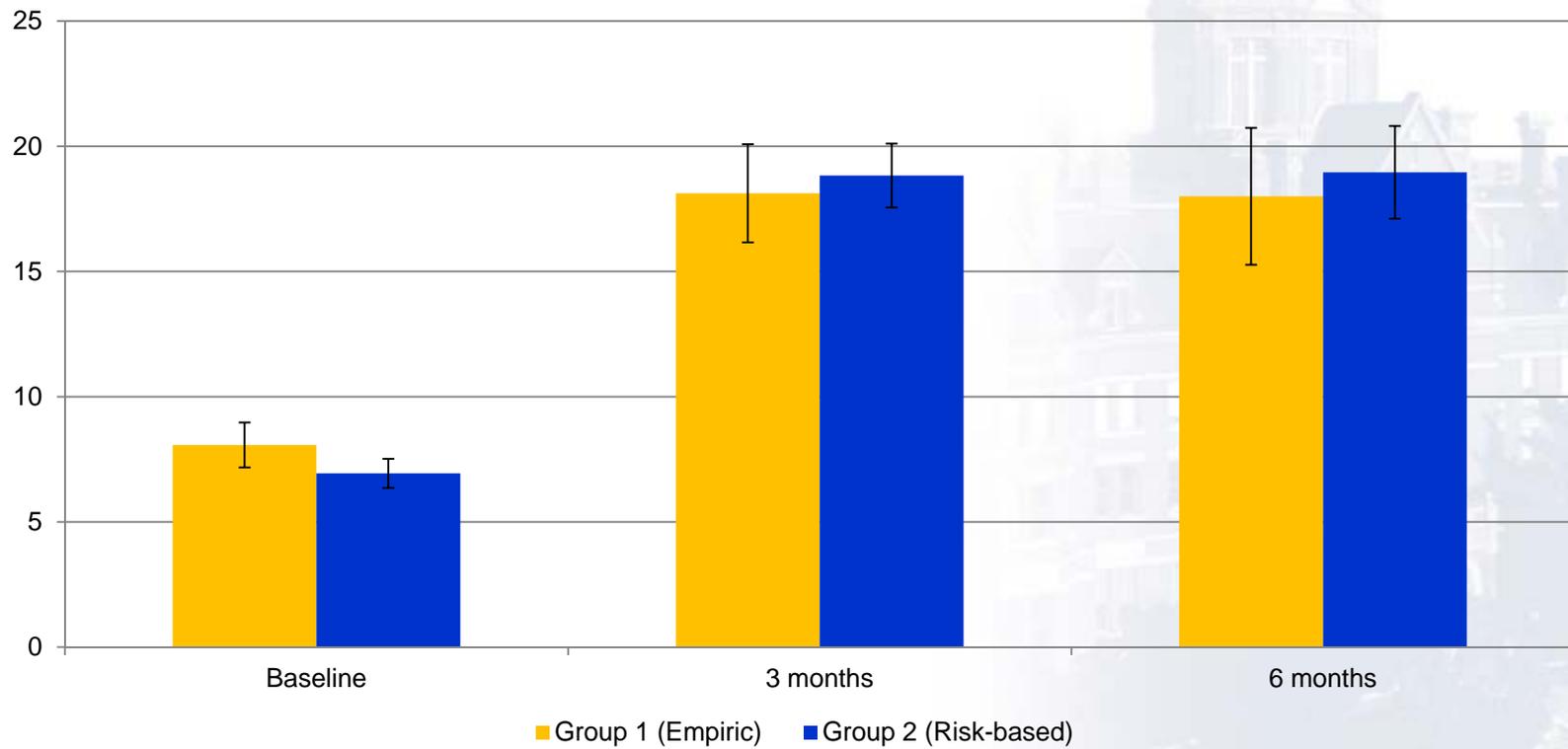| Baseline Demographics			
	Group 1 – Empiric (SE)	Group 2 - Risk-Based (SE)	p-value
Number of Men	57	118	
% post prostatectomy	54.4	74.6	
Mean Age	61.9 (1.4)	61.3 (0.7)	0.66
Mean QEQ	14.2 (3.5)	7.2 (1.8)	0.08
Mean SQoL	37.3 (3.3)	39.2 (2.2)	0.65
Mean IIEF-EF	8.1 (0.9)	7.0 (0.6)	0.30

Primary Outcome EDITS

Erectile Dysfunction Inventory of Treatment Satisfaction
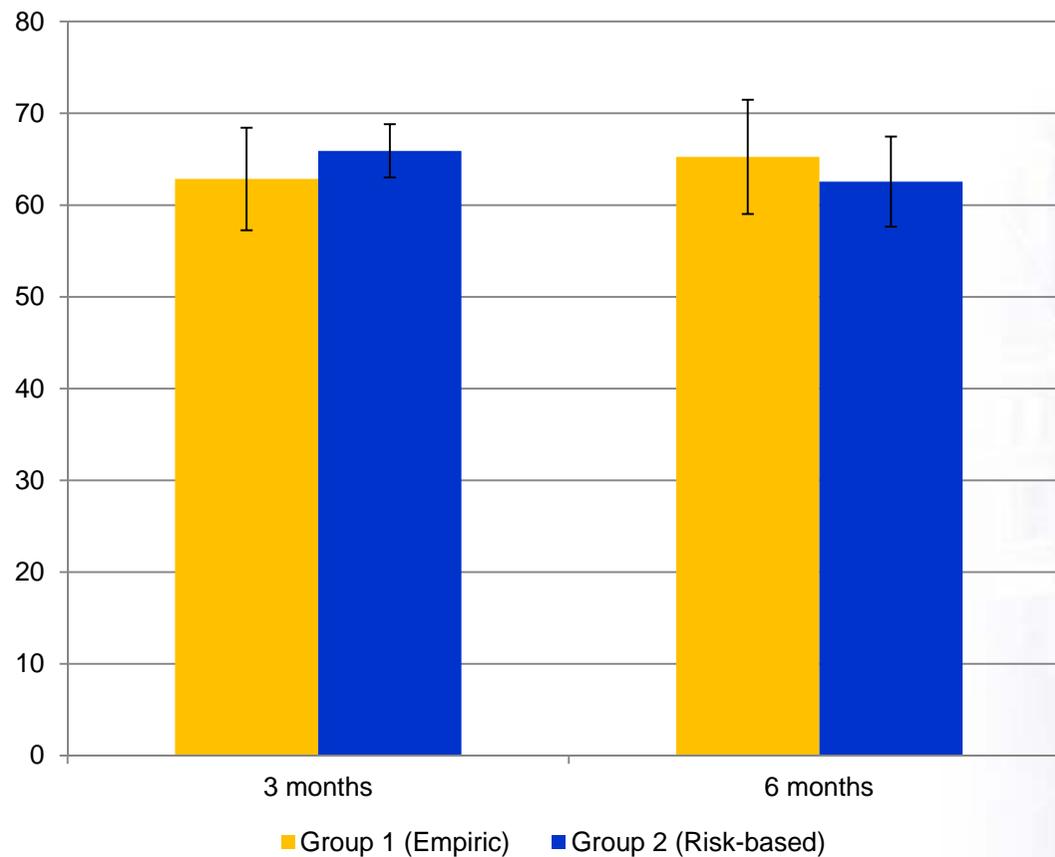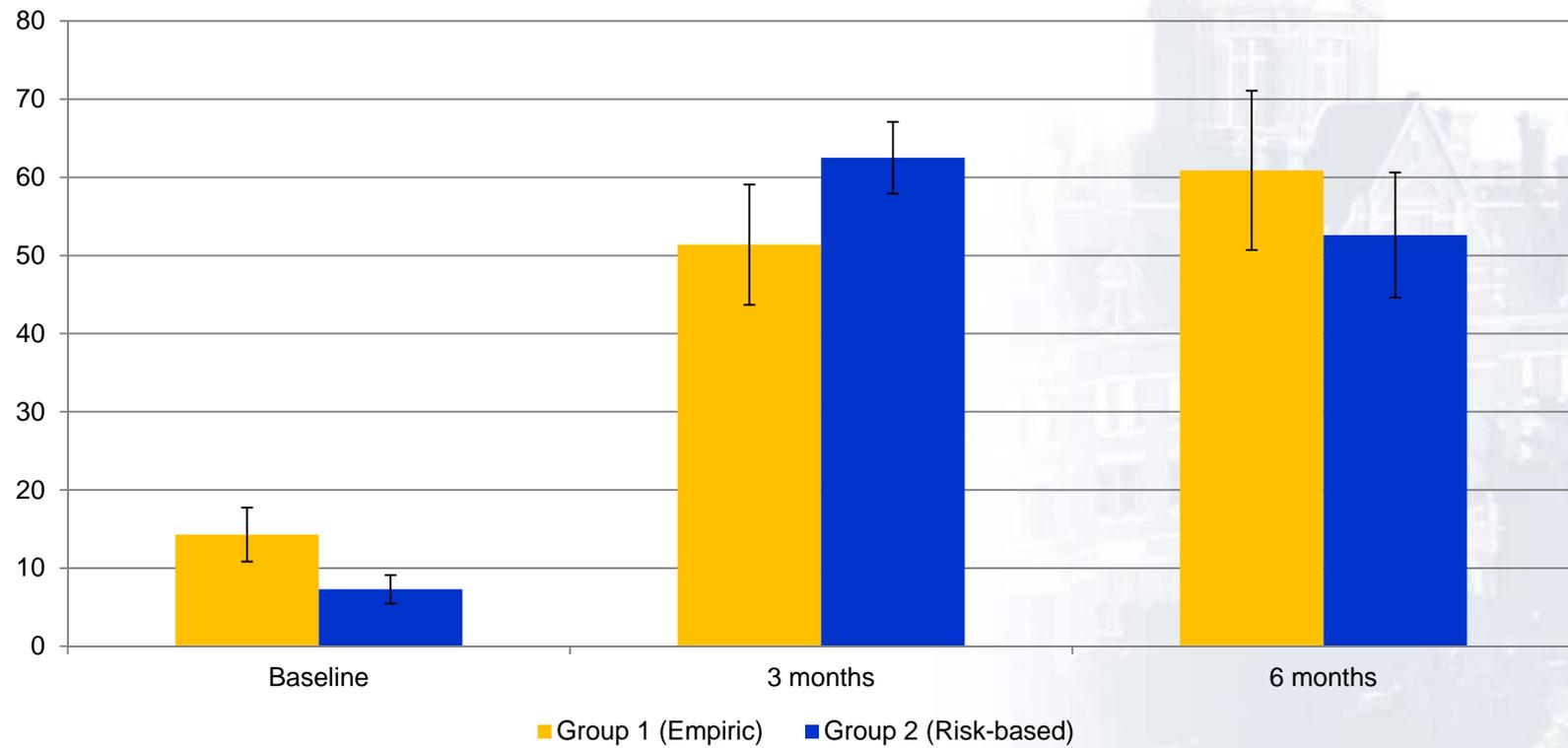

No difference in treatment satisfaction between groups.
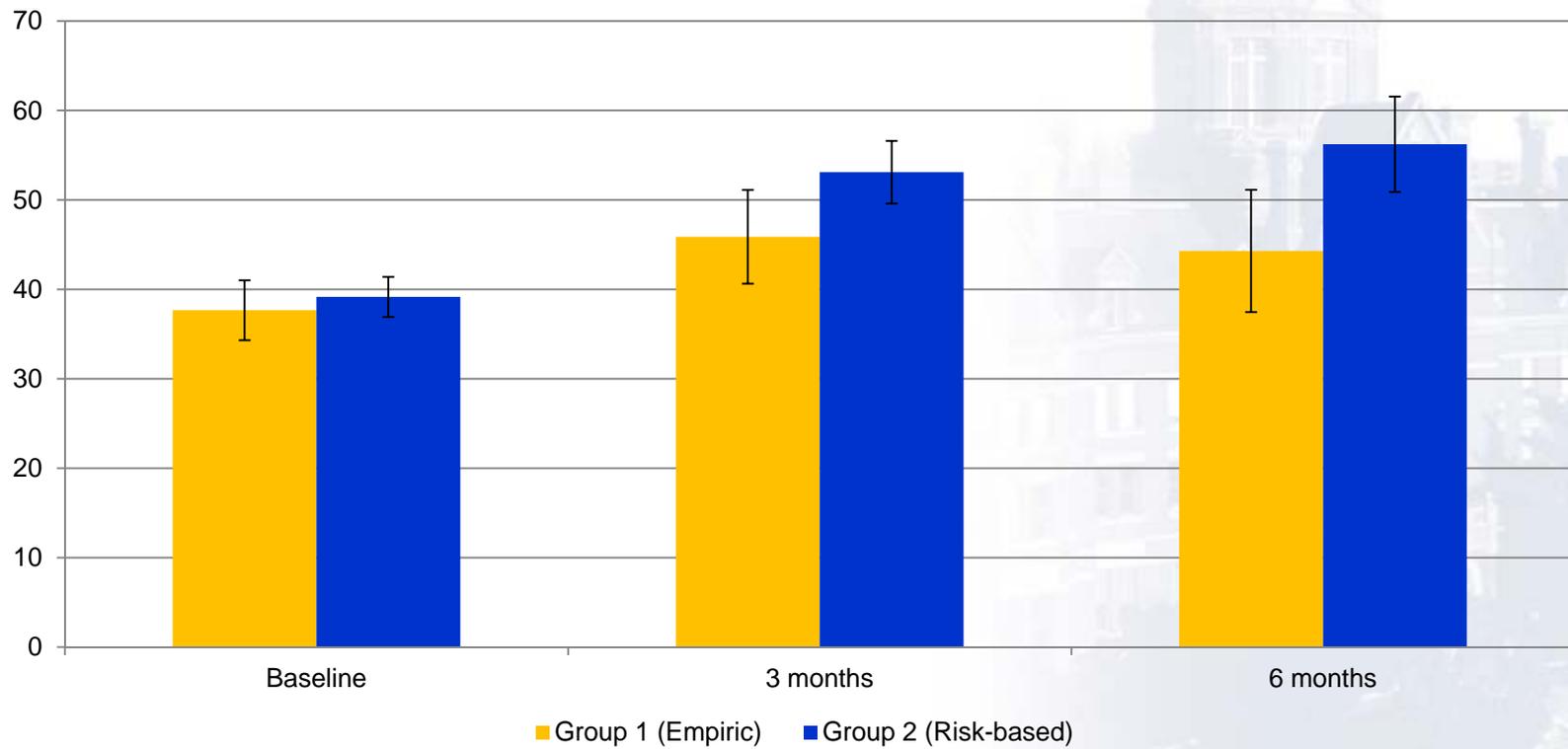
Results

IIEF-Erectile Function Domain

Legend: Group 1 (Empiric) ■ (yellow), Group 2 (Risk-based) ■ (blue)

Results

Quality of Erections Questionnaire

Legend: Group 1 (Empiric), Group 2 (Risk-based)

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Results

Sexual Quality of Life Questionnaire

Legend: Group 1 (Empiric) — Group 2 (Risk-based)

Results – D/C Tx and Medication switches

Table 2. Failure and Medication Switch Rate				
	3 month		6 month	
	N	%	N	%
Group 1 Failure rate	12	40%	8	40%
Switch rate	6	20%	4	20%
Group 2 Failure rate	25	37%	11	28%
Switch rate	14	21%	5	13%

Priapism and Penile Pain

Complications		Baseline (%)	3 months (%)	6 months (%)
Priapism	Group 1	0/57 (0)	1/30 (3.3)	1/20 (5)
	Group 2	4/118 (3.4)	7/68 (10.8)	0/39 (0)
Penile Pain	Group 1	-	1/30 (3.3)	2/20 (10)
	Group 2	-	8/68 (11.8)	2/39 (5.1)

- There was a slightly higher rate of priapism complications at 3 months though it did not reach statistical significance (p = 0.06) when using the risk-based approach

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Discussion

- While ICI therapy certainly improves quality of erections and sexual quality of life in both treated groups, patient subjective satisfaction with treatment was no different between the empiric approach and the risk-based approach.

- The EDITS survey is specifically designed to assess patient satisfaction with the treatment received and noted no differences at 3 or 6 months.

- An empiric approach may have a reduced risk of priapism complications.

Limitations

- Due to high degree of variability in subjective responses, study may be underpowered
- Poor follow-up rates at 6 months may be due to the therapy working or due to dissatisfaction and failure which could bias our results

Conclusion

- We compared a risk-based vs. empiric approach to ICI therapy and found overall satisfaction with treatment and quality of erections, complication and failure rates to be similar between both approaches.