

OUTCOMES ASSESSMENT

An Empirical vs Risk-Based Approach Algorithm to Intracavernosal Injection Therapy: A Prospective Study



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ABSTRACT

Introduction: Intracavernosal injection (ICI) therapy is widely used for the treatment of erectile dysfunction (ED). Its use in practice is largely empirical and has not been validated with evidence-based approaches.

Aim: To compare two strategies for ICI, specifically a risk-based approach and an empiric-based approach, and assess the efficacy, patient satisfaction, and complication rates of the two treatment approaches.

Methods: After obtaining approval from the institutional review board, a prospective database of patients enrolled in the ICI program at the Johns Hopkins Hospital (Baltimore, MD, USA) from May 2012 through May 2014 was amassed. Demographic information, treatment outcomes, and subjective patient evaluations of sexual function (International Index of Erectile Function erectile function domain [IIEF-EF], Quality of Erection Questionnaire [QEQ], Sexual Quality of Life [SQoL], and Erectile Dysfunction Inventory of Treatment Satisfaction [EDITS]) were obtained at baseline and at 3 and 6 months. Two approaches were compared. Group 1 received empiric ICI treatment initially with prostaglandin E₁ (PGE1) 10 μ g irrespective of ED etiology or severity. After initial dosing with PGE1 in the clinic, adjustments were made to titrate or change formulations pending on patient results. Group 2 received a risk-based approach, in which an algorithm that factored in ED etiology and number of ED risk factors was used for a bimix (papaverine 30 mg/mL, phentolamine 1 mg/mL), a low-dose trimix (papaverine 30 mg/mL, phentolamine 1 mg/mL, PGE1 10 μ g/mL), or a high-dose trimix (papaverine 30 mg/mL, phentolamine 2 mg/mL, PGE1 40 μ g/mL). Dose titration was permitted in the two groups. Statistical analysis was carried out using t-test and χ^2 analysis.

Main Outcome Measures: The study design was powered for a non-inferiority comparison of the two approaches, in which the primary end point was a 15-point difference on the EDITS score or a 20% difference in the IIEF-EF score.

Results: One hundred seventy-five patients were enrolled (57 in group 1, 118 in group 2) with 3- and 6-month follow-up at 57% and 35%, respectively, and similar between groups. Baseline patient characteristics and sexual function questionnaire responses were similar between groups 1 and 2, although group 1 reported higher-quality erections at baseline (QEQ score = 14.3 vs 7.3, $P = .05$) and had a smaller proportion of patients with prostatectomy (54.4% vs 74.6%, $P = .02$). In the two groups, QEQ score (mean = 10.78 vs 56.76, $P < .05$), SQoL score (mean = 38.41 vs 50.25, $P < .05$), and IIEF-EF score (mean = 7.51 vs 18.48, $P < .05$) improved with treatment. However, at 3 and 6 months, there were no statistically significant differences in responses for IIEF, QEQ, SQoL, or EDITS scores and no difference in failure or medication switch rates between groups. There were no significant differences in complication rates, although at 3 months group 2 reported a higher incidence of priapism and pain (23% vs 7.4%, $P = .08$).

Conclusion: Empiric and risk-based strategies for ICI therapy resulted in significant improvements across multiple domains of sexual function. Complication rates, satisfaction, and efficacy overall were similar between the two approaches. Clinicians can be reassured that no one approach to ICI therapy for ED management appears inferior to another. **Bernie HL, Segal R, Le B, et al. An Empirical vs Risk-Based Approach Algorithm to Intracavernosal Injection Therapy: A Prospective Study. Sex Med 2017;5:e31–e36.**

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Key Words: Intracavernosal Injection Therapy; Phosphodiesterase Type 5 Inhibitor; Erectile Dysfunction; Treatment; Algorithm

INTRODUCTION

Erectile dysfunction (ED) affects roughly 20 million men in the United States and is predicted to affect more than 300 million men worldwide by 2025.^{1,2} Various forms of therapy have been developed to treat ED, including oral pharmacotherapy,^{3,4} transurethral suppositories, vacuum constriction devices, intracavernosal injection (ICI) therapy, and implantation of an inflatable penile prosthesis.^{5,6} Traditional first-line treatment for ED includes oral phosphodiesterase type 5 inhibitors (PDE5-Is).^{4–6} Although these agents have a proved track record for enhancing erectile function, many patients will have failed treatment or will discontinue treatment, often requiring a second-line option.^{3,6–8} In addition, patients with ED and diabetes or after radical prostatectomy are considered hard to treat and might be true non-responders to PDE5-I therapy.

ICI therapy is a widely used second-line treatment for ED, although using it in practice is largely empirical and has not been validated with evidence-based approaches. Although there is a variety of literature on the efficacy and long-term outcomes of patients using ICI therapy, a standard approach to medication selection and dosing has never been investigated.⁹ In addition, data on patient satisfaction with this treatment are lacking. Patients with failed first-line therapies often have various risk factors contributing to the development of ED, such as medical comorbidities (diabetes, peripheral vascular disease, hypertension, dyslipidemia, or cardiovascular disease), lifestyle factors such as smoking, a history of pelvic surgery for the prostate, bladder, or colon or rectum, and radiation therapy for pelvic malignancies.^{10–13} It is unclear whether accounting for such risk factors would help with the initial agent choice and dose selection when using ICI therapy and whether a risk-based approach would help define maximal efficacy and patient satisfaction.

The purpose of this study was to compare two strategies for ICI therapy to determine whether a risk-based approach differs in efficacy, satisfaction, or complication rate compared with an empiric approach.

Table 1. Baseline characteristics of patients

	Group 1, empiric	Group 2, risk based	<i>P</i> value
Men, n	57	118	N/A
Age (y), mean (SEM)	61.9 (1.4)	61.3 (0.7)	.66
QEQ score, mean (SEM)	14.3 (3.5)	7.3 (1.8)	.05
SQoL score, mean (SEM)	37.7 (3.3)	39.2 (2.2)	.71
IIEF-EF score, mean (SEM)	8.1 (0.9)	6.9 (0.6)	.28

IIEF-EF = International Index of Erectile Function erectile function domain; N/A = not applicable; QEQ = Quality of Erection Questionnaire; SEM = standard error of the mean; SQoL = Sexual Quality of Life.

METHODS

After obtaining approval from the institutional review board, a prospective database of patients enrolled in the ICI program at the Johns Hopkins Hospital (Baltimore, MD, USA) from May 2012 through May 2014 was amassed. Baseline demographic information (Table 1), comorbidities (Table 2), treatment outcomes, and subjective patient self-evaluations of sexual function using the International Index of Erectile Function erectile function domain (IIEF-EF), Quality of Erection Questionnaire (QEQ), Sexual Quality of Life (SQoL), and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) were obtained at baseline and 3 and 6 months after initiation of ICI therapy.

In brief, these surveys assess the following aspects of patient satisfaction and sexual function. The IIEF survey is a 15-item questionnaire designed to assess for ED. It is broken down into domains to include erectile function, orgasmic function, sexual desire and intercourse, and overall satisfaction.¹⁴ The QEQ is a six-item patient-report measurement that solely evaluates the satisfaction of men with the quality of their erection.¹⁵ The SQoL domain from the Sexual Life Quality Questionnaire consists of 10 questions comparing patients' current sexual

Table 2. Baseline characteristics and comorbidities of patients

Characteristics	Group 1, empiric (n = 47), n (%)	Group 2, risk based (n = 90), n (%)	<i>P</i> value
Smoking history	8 (17.0)	30 (33.3)	.047
EtOH abuse	1 (2.1)	6 (6.7)	.42
DM2	6 (12.8)	16 (17.8)	.62
Atherosclerosis	7 (14.9)	12 (13.3)	.80
HTN	22 (46.8)	48 (53.3)	.48
Dyslipidemia	22 (46.8)	39 (43.3)	.72
OSA	3 (6.4)	9 (10)	.54
Renal failure	1 (2.1)	7 (7.8)	.26
Renal transplantation	1 (2.1)	3 (3.3)	1.0
Prostate cancer	32 (68.1)	65 (72.2)	.69
Prostatectomy	26 (55.3)	66 (73.3)	.037
Radiation	7 (14.1)	6 (6.7)	.13
Cryotherapy	1 (2.1)	0 (0)	.34
ADT	0 (0)	0 (0)	1.0
Priapism	1 (2.1)	0 (0)	.34
Peyronie disease	0 (0)	2 (2.2)	.54
Pelvic trauma	0 (0)	0 (0)	1.0
Penile trauma	0 (0)	0 (0)	1.0
Spinal cord injury	1 (2.1)	1 (1.1)	1.0
Depression	2 (4.2)	4 (4.4)	1.0
Hypogonadism	6 (12.8)	6 (6.7)	.34

ADT = androgen deprivation therapy; DM2 = type 2 diabetes mellitus; EtOH = ethanol; HTN = hypertension; OSA = obstructive sleep apnea.

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