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Long-term satisfaction and predictors of use in patients using intracorporeal injections (ICI) for post-prostatectomy erectile dysfunction (PPED)

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Abstract

Purpose—ICI has low utilization and high discontinuation rates. We examined factors associated with ICI use, long-term satisfaction with ICI, and reasons for discontinuation in men having undergone radical prostatectomy.

Materials and Methods—Between October 2000 and September 2003, 731 men undergoing open radical retropubic prostatectomy were enrolled in a prospective outcomes study. The eight-year follow-up evaluation included the UCLA-PCI and a survey capturing ICI use, satisfaction, and reasons for discontinuation. Logistic regression was utilized to determine associations between ICI use and pre-operative variables.

Results—Eight-year self-assessment was completed by 368 (50.4%) men; 140 (38%) of these indicated prior or current ICI use, with only 34 using ICI at eight years. Forty four percent of men were satisfied with ICI. Discontinuation reasons included: dislike (47%), pain (33%), return of erection (19%), inefficacy (14%), and no partner (6%). Men trying ICI had greater pre-operative UCLA-PCI sexual function scores (75.2 vs. 65.62, $p = 0.00005$) and greater declines in this score at three months ($p = 0.0002$) and two years ($p = 0.003$). Higher pre-operative sexual function scores were independently associated with utilization of ICI in a model adjusted for age, marital status, nerve sparing status, and BMI (OR = 1.021, 95% CI 1.008–1.035).

Conclusions—Men pursuing ICI have better baseline erectile function and experience greater deterioration in erectile function during the early post-operative period. Despite high efficacy, many discontinue ICI due to dislike or discomfort. Satisfaction rates with ICI indicate its long-term role in restoring sexual function in men with PPED.

Keywords

prostate; prostatectomy; injections; erectile dysfunction; postoperative complications

Introduction

Because of the excellent long-term survival rate after RP for clinically localized prostate cancer,¹ the impact of surgical treatment-related side effects on HRQOL represents a major concern. PPED is a significant problem for many men undergoing RP. A recent study reported that 60% of previously potent men suffer PPED at 2 years post-prostatectomy.² For numerous reasons, including its high incidence, PPED can have a major impact on HRQOL.^{3–5}

There are a variety of treatment options for men with PPED, including PDE5i, vacuum erection devices, intraurethral suppositories, ICI, and penile prostheses.⁶ Since its first introduction in 1982, ICI has become a well-established treatment for ED.⁷ When treatment with PDE5i is ineffective, ICI is often the preferred second-line option for motivated individuals and couples interested in resuming sexual intercourse. Despite reports that ICI achieves functional erection rates of 68–74% independent of etiology for ED, many men either do not elect ICI or drop out after initiating therapy.^{2,8–12}

Prior studies have assessed experience with ICI in men with ED^{8,13–21} and specifically PPED,^{10,22} but none have reported outcomes beyond a mean of four years. Additionally, no study to date has examined preoperative factors associated with the characteristics of those men undergoing RP who elect a trial of ICI. The objective of the present study was to address these two information gaps using a cohort of men undergoing ORRP enrolled in an IRB-approved longitudinal and prospective outcomes study, all with at least eight years of follow-up.

Materials and Methods

From October 2000 through August 2003, 731 men undergoing ORRP by a single surgeon provided informed consent to participate in an institutional review board approved, longitudinal outcomes study. The UCLA-PCI was self-administered pre-operatively and at designated intervals following ORRP. The questionnaires were administered during scheduled office visits or returned via postal delivery to a research study coordinator whose sole responsibility is maintenance of the ORRP database. An effort was made by the study coordinator to contact and encourage all eligible men to complete and return the questionnaires at designated time intervals.

All previously potent men were encouraged to take a PDE5i following removal of the urinary catheter (sildenafil 50 mg daily or tadalafil 10mg qod) for the first two years following ORRP, or until return of adequate spontaneous erections. A monthly challenge with full dose sildenafil (100 mg) or tadalafil (20 mg) was recommended to determine the therapeutic benefit of PDE5i. Men were also encouraged to return to the operating surgeon at varying time intervals during the first three years of follow-up.

The overwhelming majority of “continent” men independent of their pre-operative erectile function were offered ICI beginning three months after surgery if erections were not adequate for sexual intercourse on full-dose PDE5i therapy. Instruction for the use of ICI was provided by a Urologist. Varying test dosages were administered based on individual history. A dedicated nurse specialist was available to manage subsequent questions and concerns. Most commonly, patients were started on a mixture of three drugs (Trimix- papaverine 30 mg/mL, phentolamine 2 mg/mL, and prostaglandin E₁ 20 mcg/mL). In some cases, a two drug regimen (Bimix- without prostaglandin E₁) or four drug regimen (Quadmix- addition of atropine 0.15 mg/mL) drug mixture was administered. In circumstances where pain was problematic, the two drug mixture was offered or men were pretreated with ibuprofen. Efforts were made to titrate the dose to a maximal therapeutic

level. For those who were nonresponsive or unsatisfied, ICI was abandoned, and a penile implant was offered.

The eight year follow-up survey captured current and prior treatments for ED, satisfaction with ICI, and reasons for ICI discontinuation. These included: did not like injections, pain with injections, regained erections, failure to achieve an erection, or no sexual partner. Bivariate analyses using chi-square and independent sample t-tests were performed to determine differences between men who ever used ICI and men who never used ICI, in order to define the characteristics of men who embark on an ICI regimen. The specific covariates tested included pre-operative factors: UCLA-PCI sexual function score, age, race (Caucasian or other), marital status (married or unmarried), BMI, prostate-specific antigen, pathologic Gleason score (2–6, 7, or 8–10) and stage (0–2 or 3–4), number of nerve bundles spared (0, 1, or 2), length of hospital stay, and estimated blood loss. Multivariate analysis included all variables significant in the bivariate analysis, including potential confounders. A variable was considered to be a significant predictor at a two-sided $p < 0.05$.

Results

Baseline characteristics of all 731 eligible men are reported in Table 1. All 731 eligible men were included independent of baseline erectile function. A total of 368 men (50.4%) completed both the baseline and eight year self-assessment. Only 7 and 8 of these men received neoadjuvant or adjuvant androgen deprivation therapy, respectively. Survey respondents and non-respondents differed only with respect to pathologic Gleason score (data not shown).

Of the men completing both surveys, 140 (38%) indicated ICI use. Men ever having used ICI had significantly greater pre-operative UCLA-PCI sexual function scores (75.2 vs. 65.62, $p = .00005$) than those never having used ICI. ICI users also had greater declines in sexual function scores from baseline to three months (-53.5 vs. -44.5 , $p = 0.0002$) and baseline to two years (-33.9 vs. -26.1 , $p = .003$) (Table 2). Results of our multivariate logistic regression are reported in Table 3. Higher pre-operative UCLA-PCI sexual function scores were independently associated with ICI use in a multivariate model adjusted for age, marital status, nerve sparing status, and BMI (OR = 1.021, 95% CI 1.008–1.035).

Eight year satisfaction with ICI use was reported for 135 men: 10% were very satisfied, 34% satisfied, 35% unsatisfied, and 21% very unsatisfied. Overall, 44% of men expressed some level of satisfaction with ICI.

Reasons for discontinuation of ICI were reported by 102 men. Only 14% failed to achieve an erection using ICI. Forty seven percent disliked giving injections, 33% experienced pain associated with injections, 19% regained adequate erections without ICI, 6% had no sexual partner, and 3% reported other reasons. Overall, only 34 (24%) of the 140 men exposed to ICI indicated that they were using ICI at the eight year assessment. Nine (8%) of the 106 men who discontinued ICI underwent implantation of a penile prosthesis.

Discussion

Many studies have addressed satisfaction and discontinuation rates following administration of ICI in men with ED of unspecified etiology. Only two studies have examined four year outcomes of ICI among men with PPED.^{10,22} To our knowledge, our report represents the longest follow-up experience with ICI, independent of the etiology for ED.

Men undergoing RP must contend with dynamic ED throughout their post-operative course: most are potent pre-operatively, almost all are rendered impotent immediately after surgery,

many spontaneously improve up to five years post-prostatectomy,^{23,24} and there is access to and variable usage of a myriad of treatment options.⁶ Shorter follow-up studies may therefore fail to capture the full impact of ICI post-RP. A unique aspect of the present study design is its long-term follow-up of a single surgeon experience with pre- and post-operative assessment of erectile function using validated instruments. This is also, to our knowledge, the first study to identify pre-operative factors associated with ICI usage, thereby suggesting insights into likely candidates for ICI therapy.

Despite high success rates in restoring erectile function, many men do not attempt ICI as a method of treatment for their ED; contributing factors likely include reluctance to inject a drug into the penis, lack of a motivated partner, or concerns regarding discomfort or development of priapism. A recent study indicated that only 15% of men tried ICI at two years post-RP, in contrast to a much larger proportion trying PDE5i (68%) and vacuum erection devices (19%).² Many men with PPED soon after RP likely do not embark on ICI initially because of an optimism that their erections may spontaneously improve. In our cohort of men with eight year follow-up, 38% had experience using ICI. Our higher rate of ICI utilization may reflect our tertiary referral practice or motivation of the surgeon to restore erectile function for those with PPED.

A higher pre-operative sexual function score was independently associated with use of ICI (OR = 1.021, $p = 0.002$); for every one point increase in pre-operative UCLA-PCI sexual function score, there was a 2% greater likelihood a man in our cohort tried ICI. Men with better baseline erections may be more inclined to try a more invasive therapy such as ICI, especially early on in their post-operative course. Declines from baseline scores at three and 24 months were also significant in bivariate analysis, suggesting that the magnitude of the early and more permanent loss in erectile function attributable to the RP is another factor that drives the use of ICI. Presumably, those men suffering from ED prior to RP were not motivated to attempt ICI prior to, or after, RP. We did not include the changes in UCLA-PCI sexual function scores at three and 24 months in our final model as they were highly correlated with pre-operative sexual function scores. Interestingly, age or marital status did not influence usage of ICI.

Reported dropout rates for ICI users are highly variable, ranging from 20% to 80%.^{8,10,13–22,25–27} This variability may be attributed to differences in: duration of follow-up, etiology for ED, timing of initiating treatment for PPED, physician comfort administering ICI, the degree of counseling or education received prior to initiating therapy, and number and structure of follow-up visits. While it has been suggested that high dropout rates associated with ICI may be improved with comprehensive training and education as well as regular follow-up,^{8,10} the results of a recent randomized trial evaluating the use of extra counseling suggest otherwise.²⁸ In the two studies evaluating ICI use in men with PPED, 49–52% discontinued ICI after a mean follow-up of four years.^{10,22} Our dropout rate is approximately 50% greater than prior reports (76%). The reasons for ICI discontinuation following RP are likely dependent on characteristics of the study cohort, length of follow-up,¹⁶ the timing of initiating treatment, and the number of men regaining erectile function. Our follow-up is considerably longer. Many men in our cohort also started treatment in the early post-operative period, giving them even more time either to recover erectile function or tire of self-administering injections. Specific reasons for discontinuing ICI unrelated to dissatisfaction with ICI include: lack of an active sexual partner, lack of desire to engage in sexual activity, and spontaneous improvement in erectile function. Further analysis of our data shows that 31 of the 60 men who were satisfied with ICI eventually discontinued therapy. Almost half of these men reported that they discontinued due to spontaneous improvement of erection, lack of a partner, or no need/desire for engaging in sexual intercourse. If we eliminate these men, who would have likely continued therapy if not for

the above reasons, then our adjusted discontinuation rate is 66%. In other words, only a third of men embarking on ICI who maintain an interest in sexual activity and require ED treatment remain on therapy long-term.

Spontaneous return of erections has been reported in only 6–25% of men on ICI to treat ED of all etiologies.^{8,16,17} The one PPED study that measured this outcome reported that only 1% of patients experienced return of erectile function.¹⁰ We have previously reported that erectile function improves in 42.3% of men between two and four years post-ORRP,²³ and may continue to improve even beyond that.²⁴ Therefore, the greater increase in spontaneous return of erectile function in our study (19%) is potentially attributable to earlier intervention with ICI in men destined to recover erectile function as well as our follow-up interval.

One prior study reported that 27.6% of men discontinued ICI because they did not like the idea of injecting their penis.⁸ By far, the most common reason for discontinuation in our study was “dislike of” injections (47%). One limitation of the present study is that we did not ascertain specific reasons why men disliked ICI. The response “did not like giving injections” likely encompasses a number of domains, including cost, side effects (curvature, lump), preference for other therapies, and needle phobia.

Pain with ICI is also a well documented reason for discontinuation, ranging from 5–21%.^{8,17,22} Our rate of discontinuation due to pain (33%) is the highest reported to date. A greater proportion of men in our study may have received ICI with higher concentrations of prostaglandin E1, known to be associated with more pain than other mixtures.^{7,29} While many men in our cohort may have received relatively high concentrations of prostaglandin E1, our questionnaire did not capture what specific formulation was administered, making this explanation speculative.

Prior studies have reported that 14–48% of men discontinue because they fail to get erections from ICI.^{2,8,10,17,22} Our treatment failure rate was only 14%, on the low end of this range. The primary reason for failure of ICI is vascular insufficiency. Our observed low rate of treatment failure with ICI is expected for PPED since few men had baseline ED due to vascular insufficiency.

Studies have reported short and intermediate time-dependent satisfaction rates with ICI that range between 68–84.8%.^{10,17,26} The only PPED study reporting satisfaction rate was on the lower end, at 68%.¹⁰ Our cohort exhibited a much lower satisfaction rate of 44%. The restoration of erectile function by ICI in men rendered impotent following RP is less satisfying than restoring erectile function in men with a long-standing history of ED. Hsiao et al observed that older age, younger partner age, clinically significant increase in erectile function domain score, and attainment of “fully rigid erection” were significant predictors of satisfaction with ICI.²⁵ Since only 60 men in our study were satisfied with ICI, it was difficult to assess the determinants of satisfaction.

There are several limitations to our study. First, while the UCLA-PCI was administered and recorded in real time, questions about ICI usage were included only at the eight year follow-up assessment, leading to potential recall bias. Second, we did not capture the specific reasons why men “did not like giving injections.” Third, since men initiated therapy at different times, we were unable to correlate potential post-operative factors associated with ICI use or the influence of ICI use on UCLA-PCI sexual function score. Finally, pain was a significant reason for discontinuation of ICI. We did not record the composition of the injection therapies, which may explain our relatively high discontinuation rates attributable to pain. The major strengths of our study are the large single surgeon experience, the use of self-administered, validated instruments, and our long follow-up interval.

Conclusions

Our study demonstrates that approximately half of men who initiate ICI report satisfaction at eight years with this management of their PPED. Despite high treatment efficacy, the most common reason for discontinuation of ICI is dislike or discomfort. Men who pursue ICI had better pre-operative erectile function and experienced the greatest deterioration in erectile function in the early post-operative period. The observation that 44% of men treated with ICI are satisfied with the treatment eight years after ORRP suggests the durability of the initial favorable response to ICI, which likely improves long-term HRQOL for the post-prostatectomy patient.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline characteristics of respondents versus non-respondents to our eight year prostatectomy outcomes questionnaire.

VARIABLE	Respondents (n=384)	Non-Respondents (n= 347)	p-value
Age	58.9 ± 0.316	58.8 ± 0.453	.912
Race	African American: 10 Asian: 6 Caucasian: 362 Hispanic: 2 Other: 2	African American: 13 Asian: 6 Caucasian: 312 Hispanic: 8 Other: 6	.165
Marital Status	Divorced: 15 Married: 344 Separated: 3 Single: 15 Widowed: 5 No Response: 2	Divorced: 14 Married: 305 Separated: 2 Single: 19 Widowed: 5 No Response: 2	.947
BMI	26.8 ± 0.190	27.3 ± 0.277	.192
PSA	6.13 ± 0.253	6.58 ± 0.249	.206
Pathologic Gleason Score	2-6: 234 7: 141 8-10: 9	2-6: 198 7: 125 8-10: 24	.012*
Pathologic Stage	0-2: 323 3-4: 61	0-2: 277 3-4: 70	.131
Nerve Sparing Status	None: 12 Unilateral: 52 Bilateral: 318	None: 4 Unilateral: 57 Bilateral: 283	.117
Length of Hosp Stay	2.08 ± 0.0349	2.17 ± 0.0666	.223
EBL	760.2 ± 18.8	786.7 ± 20.1	.336

VARIABLE	Respondents (n=384)	Non-Respondents (n= 347)	p-value
Pre-operative UCLA-PCI Score	69.14 ± 1.14	66.33 ± 1.25	.096

* significant

Table 2

Comparison between men undergoing ORRP who have ever used ICI versus those who have never used ICI.

VARIABLE	Users (n=140)	Non-Users (n=228)	p-value
Age	58.7 ± 0.523	59.0 ± 0.409	.671
Race	African-American: 5 Asian: 0 Caucasian: 133 Hispanic: 2 Other: 0 No Response: 0	African-American: 5 Asian: 6 Caucasian: 214 Hispanic: 0 Other: 1 No Response: 2	.094
Marital Status	Divorced: 7 Married: 123 Separated: 1 Single: 6 Widowed: 2 No Response: 1	Divorced: 8 Married: 206 Separated: 2 Single: 8 Widowed: 3 No Response: 1	.975
BMI	26.8 ± 0.309	26.9 ± 0.255	.666
PSA	5.79 ± 0.299	6.40 ± 0.382	.265
Pathologic Gleason Score	2-6: 83 7: 51 8-10: 6	2-6: 141 7: 84 8-10: 3	.199
Pathologic Stage	0-2: 115 3-4: 25	0-2: 194 3-4: 34	.455
Nerve Sparing Status	None: 5 Unilateral: 20 Bilateral: 115	None: 6 Unilateral: 30 Bilateral: 190	.842
Length of Hosp Stay	2.08 ± 0.0497	2.07 ± 0.0489	.957

VARIABLE	Users (n=140)	Non-Users (n=228)	p-value
EBL	743.1 ± 27.8	784.0 ± 25.8	.301
Pre-operative UCLA-PCI Score	74.9 ± 1.59	65.6 ± 1.57	.00005 *
Pre-operative minus 3 Month UCLA-PCI Score	53.5 ± 1.72	44.5 ± 1.60	.0002 *
Pre-operative minus 2 Year UCLA-PCI Score	33.9 ± 2.19	26.1 ± 1.58	.003 *
Pre-operative minus 8 Year UCLA-PCI Score	30.7 ± 2.84	25.9 ± 1.68	.149

* significant

Table 3

Results of our multivariate logistic regression. The dependent variable was trying (past or current) ICL. Only pre-operative UCLA-PCI sexual function score was independently associated with trying ICL.

Variable	p-value	Odds Ratio (95% CI)
Age	.506	1.015 (.972, 1.059)
Marital Status	.169	1.701 (.798, 3.625)
Nerve Sparing Status	.262	2.285 (.540, 9.676)
Pre-operative UCLA-PCI Score	.002 *	1.021 (1.008, 1.035)
Body mass index	.712	1.013 (.947, 1.083)

* significant.