

**I. Appendix 9: Intracavernous Injections for Erectile Dysfunction (ED)**

**A. RCTs only, single-dose studies**

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants and Etiology of Impotence	Outcomes	Adverse Events
Linnet (1996)	Alprostadil (PGE1) 2.5 µg, 5 µg, 10 µg, 20 µg or placebo.	Multi-center, randomized, double blind, placebo-controlled, single fixed dose, parallel group. Dose administered in clinic by researcher.  Overall N=296 (100% follow-up) Placebo n=59 PGE1 2.5 µg n=57 PGE1 5 µg n=60 PGE1 10 µg n=62 PGE1 20 µg n=58	Inclusions: ED of vasculogenic, neurogenic, psychogenic or mixed origin; duration of ED ≥ 4 months. Exclusions: penile deformity; history of priapism; sickle-cell trait; recent major illness; uncontrolled diabetes or hypertension; major psychiatric disorder; infection with HIV or "other transmittable disease"; smoking >40 cigs/day; endocrine etiology of ED. Demographics: Ages 21 - 74 (mean 54) Etiology of ED: Vascular 44% Psychogenic 14% Neurogenic 13% Mixed 29% Previous therapy for ED: 2% had prior injection treatment	RigiScan response defined as ≥ 70% rigidity at tip or base of penis lasting ≥ 10 consecutive minutes. Clinical response defined as penile rigidity sufficient for intercourse as assessed by researcher palpation. No response to placebo. For both outcomes the differences between each dose of PGE1 and placebo were statistically significant (p<0.01). There was a statistically significant dose-response relationship for clinical response (p<0.001) but not RigiScan response.	DOSE-RESPONSE PGE1 (all doses): Penile pain 23% Priapism 1% Prolonged erection 3% Placebo: No data given
Colli (1996)	PGE1 5 µg, 10 µg or placebo.	Single center, randomized, double blind, placebo-controlled, fixed single dose administered by researcher, cross-over study (1 week washout).  Overall N=296 (100% follow-up) Placebo n=59 PGE1 2.5 µg n=57 PGE1 5 µg n=60 PGE1 10 µg n=62 PGE1 20 µg n=58	Inclusions: ED > 6 months Exclusions: Penile deformity; history of priapism; low free testosterone; elevated prolactin; BP > 150/100 or hypotension; smoking > 40 cigs/day; uncontrolled diabetes; sickle cell disease; coagulopathy; systemic or psychiatric disease of recent onset; hematologic disease; current use of intracavernous PGE1.  Demographics: Ages 18 - 65 (mean 54) Etiology of ED: Vasculogenic 27% Psychogenic 53% Mixed 11% Neurogenic 4% Diabetes 4%	Erectile response outcomes included: (1) reaching and maintaining 70% rigidity per RigiScan for ≥ 10 minutes at tip or base of penis; (2) researcher palpation and rating of erection as 'full'; and (3) subject rating of erection as 'good' or 'excellent'.  RigiScan: Placebo 0% PGE1 5 µg 39% PGE1 10 µg 56%  Researcher palpation: Placebo 0% PGE1 5 µg 27% PGE1 10 µg 51% Subject rating: Placebo 0% PGE1 5 µg 41% PGE1 10 µg 56%	Penile pain: Placebo 0% PGE1 5 µg 0% PGE1 10 µg 7% Hematoma: Placebo 0% PGE1 5 µg 2% PGE1 10 µg 0%

**Appendix 9A (continued)**

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants and Etiology of Impotence	Outcomes	Adverse Events
<b>Bechara (1997)</b>	(1) PGE1 30 µg (2) Papaverine 30 mg + Phentolamine 0.5 mg (PP) (3) Placebo	Single center, randomized, double blind, placebo-controlled, fixed single dose self-injected, cross-over study (subjects received one dose of each treatment; 1 week washout).  Overall N=60 (100% completed)	Inclusions: ED > 6 months  Exclusions: ED from spinal cord injury or radical pelvic surgery; treatment with vasoactive injections  Demographics: Ages 22-78 (mean 58)	Responses evaluated to manual and visual stimulation. Erections "allowing penetration" considered positive.  Response rates: Placebo 0% PGE1 50% PP 56% (p>0.05)	Prolonged erections: Placebo 0% PGE1 15% PP 18%  Pain: Placebo 0% PGE1 35% * PP 15% *  *(p<0.05 vs placebo)
<b>Bechara (1996)</b>	(1) PGE1 40 µg (2) PGE1 5.8 µg + Papaverine 17.6 mg + Phentolamine 0.6 mg (PPP)	Single center, randomized, patient-blind, active-controlled, fixed single dose, researcher injected, cross-over study (≥ 1 week washout).  Overall N=32 (19 completed)	Inclusions: ED > 6 months; nonresponse to high doses of papaverine + phentolamine combo.  Demographics: Ages 26 - 71 (mean 61.3)  ED duration (months): Mean 30.8 (range 6-51)	Erections defined as response at 15 minutes after dose adequate to "allow... penetration" (rating categories stated but manner in which erections placed into categories not given)  Erections: PGE1 22% PPP 50% (p<0.05)	Pain: PGE1 41% PPP 12.5% (p<0.05)
<b>Shenfeld (1995)</b>	(1) Papaverine 4.5 mg + Phentolamine 0.25 mg + PGE1 5 µg (PPP) (2) Papaverine 9 mg + Phentolamine 0.5 mg (PP)	Single center, randomized, double blind, fixed single dose, administered by researcher, cross-over study (washout 2 wks).  Overall N=20	Inclusions: Patients "newly entering our intracorporeal injection program"  Exclusions: None given  Demographics: Ages 44 - 71 (mean 57.5)  Etiology of ED: Arteriogenic 60% Neurogenic 15% Other 25%	Erections rated by physician palpation 15 minutes after injection as either "full", "suboptimal... but sufficient for penetration" or "not sufficient".  Full erections: PPP 73% PP 28% (p<0.05)	Penile pain: PPP 15% PP 0% (p>0.05)  Erection > 60 mins: PPP 10% PP 5% (p>0.05)

Appendix 9A (continued)

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants and Etiology of Impotence	Outcomes	Adverse Events
<b>Vanderschuere n (1995)</b>	3 unique formulations of PGE1: (1) pediatric sterile solution, (2) sterile powder, (3) nonalcohol sterile solution. For each formulation the following doses were available: PGE1 2.5 µg, 5 µg, 10 µg, 20 µg and placebo.	Multi-centered, stratified [subjects using low doses of PGE1 at home prior to study (<10 µg) received one of 3 possible doses within the study: placebo, 2.5 µg PGE1 or 5 µg PGE1; subjects using high doses of PGE1 at home prior to study (≥10 µg) were eligible to receive placebo, 10 µg PGE1 or 20 µg PGE1], randomized double blind, placebo-controlled, fixed single dose, cross-over (washout ≥ 3 days)  N=210 (11 dropouts)	Inclusions: ED > 4 months; known stable responders to intracavernous PGE1. Exclusions: Penile deformity; Peyronie's disease; history of priapism; "suffering from major diseases or took drugs that could substantially affect the evaluation of the ED." Demographics: Ages 29 - 70 (mean 53.1) ED duration (years): Mean 4.8 (range 0.5-41) Etiology of ED: Vasculogenic 21% Psychogenic 36% Neurogenic 7% Diabetes 7% Mixed 15% Other 15%	Erectile response outcomes included: (1) penile radial rigidity ≥ 70% for ≥10 minutes; (2) patient assessment, 0 = not effective to 3 = very effective; (3) investigator evaluation that erection is sufficient for vaginal penetration. For all these measures, there were no significant differences between the 3 formulations at any dose. (p>0.1)	Penile pain: Placebo 11% Pediatric solution 9% Sterile powder 14% Nonalcohol 17%
<b>Sogari (1997)</b>	(1 = PPPA) PGE1 10 µg + papaverine 50 mg + Phentolamine 0.2 mg + Atropine 0.075 mg  (2 = PPP) PGE1 10 µg + papaverine 50 mg + Phentolamine 0.2 mg	Single center, randomized, non-blinded, active-controlled, fixed single dose, parallel group study. Dose administered by researcher.  Overall N=230 (2 excluded after randomization) PPPA n=114 PPP n=114	Inclusions: consecutive ED patients seen in a Urology clinic Exclusions: partial penile amputation Demographics: Age in years (mean (range)): PPPA 53.2 (24 - 75) PPP 52.7 (22 - 78) Mean ED duration in months: PPPA 32.2 (range 1 - 240) PPP 33.5 (range 2 - 360) Comorbid conditions: No difference between treatment groups in number of risk factors for ED, or in prevalence of any individual risk factors except stroke.	Erectile response assessed 15 minutes after injection by examiner palpation as "full erection", "poor erection", or "tumescence". % with full erection: PPPA 45.6% PPP 45.6% (p = 1.0)	Painful sensation: PPPA 50.0% PPP 53.8% (p = 0.4)
<b>Kattan (1995)</b>	(1) PGE1 20 µg (2) PGE1 20 µg + Lidocaine 1% (P + L)	Single center, randomized, double blind, active-controlled, fixed single dose, administered by researcher, cross-over study (washout 1 week)  Analysis not intention to treat.  N=25 (3 dropouts)	Inclusions: Previously experienced pain with intracavernosal injections of PGE1 Exclusions: MI; uncontrolled hypertension Demographics: Ages 40-60 (mean 53)	Investigator rated erection as "normal", "adequate", "inadequate" or "none". % adequate or normal erections: PGE1 27.2% P + L 63.6% (p < 0.01)	Penile pain: PGE1 87.5% P + L 47.8% (p < 0.01)

**B. Long-term RCTs only**

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants	Outcomes	Adverse Events
Buvat (1998)	Alprostadil alpha-cyclohexanone or Moxisylyate chlorhydrate 5-20 µg or 5-20 mg .	Multi-centered, active-control, parallel-group study of self-injections  DOSING PHASE Subjects were randomized to either Alprostadil or Moxisylyate. Optimal treatment dose was determined via double blinded in-clinic titration. OPEN-LABEL PHASE Responders from dosing phase performed up to 6 at-home self-injections of the treatment to which they had been randomized in the dosing phase. Dose was that determined in the dosing phase as their optimum dose.  186 subjects screened; 156 randomized in dosing phase: Alprostadil=75, Moxisylyate=81; 129 achieved adequate response in dosing phase by at least one measure: Alprostadil=68/75 Moxisylyate=61/81; The 129 responders were enrolled in open-label at-home phase. Follow-up in open-label phase was complete.	Inclusions: age 18-70; ED ≥6 months  Exclusions: drug or alcohol addiction; unstable angina or MI <3 months prior to study; urologic or hormonal etiology for ED; concomitant vasoactive therapy  Age, mean yrs (range): Overall 53.7 (18-70)  Duration of ED, mean years: Alprostadil 4.6 Moxisylyate 4.3  Etiology of ED (%): Psychogenic Organic Mixed Alprostadil 51 27 23 Moxisylyate 43 26 32	Erectile response outcomes in clinic were: (1) "bucking test", and (2) physician evaluation of adequacy of erection for intercourse. Only outcomes from the at-home phase are detailed here:  % of subjects with at least 1 rigid erection after self-injection: Alprostadil* 85 Moxisylyate 61  Mean % successful self-injections: Alprostadil* 61 Moxisylyate 44  Mean score subject's opinion of treatment on visual analog scale (scale is 0-100: 0="treatment does not suit me at all" to 100="treatment suits me perfectly"): Alprostadil* 52.8 Moxisylyate 36.1  * (p<0.05)	Penile pain during injection(%): CL AH Alprostadil 13 25 Moxisylyate 15 15 Penile pain during erection(%): CL AH Alprostadil* 17 24 Moxisylyate 3 5 Penile pain after erection(%): CL AH Alprostadil* 7 19 Moxisylyate 0 5 Bleeding(%): CL AH Alprostadil 3 15 Moxisylyate 3 5 Erection > 2 hours: CL AH Alprostadil 5 4 Moxisylyate 0 2  * (p<0.05)

ED = erectile Dysfunction      CL = in-clinic      AH = at-home

**Appendix 9B (continued)**

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants	Outcomes	Adverse Events
Soderdahl (1997)	<p>(1) Alprostadil 1.5µg + Papaverine 4.4mg + Phentolamine 0.15mg (Trimex)</p> <p>(2) External vacuum device (Osbon ErecAid)</p>	<p>Single center, quasi-randomized (by social security number), nonblinded, active-controlled, crossover study (no washout described)</p> <p>Each treatment used at least 15 times</p> <p>N=50 (44 completed study)</p>	<p>Inclusions: Previously untreated organic impotence; stable sexual partnership; Exclusions: Using testosterone replacement; psychogenic etiology; failure to respond with erection; "satisfactory for penetrator" to either injection or vacuum while in office; stated preference for 1 of the treatments;</p> <p>Age, mean yrs (range): Overall 62.3 (38-84)</p> <p>Duration of ED, mean mos.(range): Overall 40 (6-120)</p> <p>Etiology of ED(%): vascular 30 surgical 26 diabetes 18 unknown 14</p>	<p>Erectile response outcomes included (1) patient satisfaction "with the sexual experience" on a scale of 0-10; (2) partner satisfaction "with the sexual experience;" (3) patient preference for one method over the other.</p> <p>Patient satisfaction: Injection 6.5 Vacuum 5.4 (p&lt;0.05)</p> <p>Partner satisfaction: Injection 6.5 Vacuum 5.1 (p&lt;0.05)</p> <p>Patient preference(%): Injection 57 Vacuum 27 Both 14 None 2</p> <p>Partner preference(%): Injection 50 Vacuum 27 Both 14 Neither 9</p> <p>Subgroup analysis suggests injection superior to vacuum in subjects with ED of shorter duration or secondary to radical prostatectomy (p&lt;0.05).</p>	<p>Bruising, injury or skin changes sufficient to stop or decrease treatment(%): Injection 9 Vacuum 16</p> <p>Penile pain: "experienced rarely"</p> <p>Priapism: 1 patient had priapism after first injection (treatment arm not specified) and withdrew.</p>

**C. Abstracts**

Study Name	Drugs and Doses	Study Design, Duration and Size	Participants	Outcomes	Adverse Events
<p>Su (1998) J Urol 159 (suppl): 238, Abstract 909</p>	<p>Intracavernous injection of Alprostadil 5µg or 10µg; or Transurethral Alprostadil 500µg or 1000µg.</p>	<p>Randomized, active controlled, crossover study (washout not specified)  Duration not stated  45 subjects enrolled; to date 22 have completed follow-up</p>	<p>Inclusions: Men with organic erectile dysfunction.  Exclusions: Not given</p>	<p>Overall treatment preference (%): Injection 64 Transurethral 36  Quality of erection as assessed by subject, scale from 0=(no erection) to 5=(rigid, adequate for penetration): Comparison 1: Injection 5µg vs. Transurethral 500µg Injection * 2.8 Transurethral 1.5 Comparison 2: Injection 10µg vs. Transurethral 1000µg "no statistical difference"  Subject satisfaction, scale from 0-5: Injection 5µg * 3.2 Transurethral 500µg 1.5  * (p&lt;0.01)</p>	<p>No information given.</p>

## II. Appendix 10: Impotence Treatments [RCTs (33 articles, 18 abstracts)]

### Oral (16 articles, 13 abstracts)

#### Apomorphine

Padma-Nathan, H.; Fromm-Freeck, S.; Ruff, D. D.; McMurray, J.G. and Rosen, R.C. Efficacy and safety of apomorphine sl vs. placebo for male erectile dysfunction. *Journal of Urology*. 1998 Jun; 159(suppl):241 [meeting abstract #920].

#### Phentolamine [Vasomax] vs. placebo (1 article, 2 abstracts)

Becker, A. J.; Stief, C. G.; Machtens, S.; Schultheiss, D.; Hartmann, U.; Truss, M. C., and Jonas, U. Oral phentolamine as treatment for erectile dysfunction. *Journal of Urology*. 1998 Apr; 159(4):1214-6.

Becker, A. J.; Stief, C. G.; Schultheiss, D.; Truss, M. C.; and Jonas, U. Double blind study on oral phentolamine as treatment for erectile dysfunction. *Journal of Urology*. 1997; 157(suppl):202 [meeting abstract #785].

Goldstein, I. Efficacy and safety of oral phentolamine (Vasomax) for the treatment of minimal erectile dysfunction. *Journal of Urology*. 1998; 159(suppl):240 [meeting abstract #919].

#### Sildenafil vs. placebo (3 articles, 8 abstracts)

Boolell, M.; Gepi-Attee, S.; Gingell, C.; Allen, M. UK-92,480, a new oral therapy for erectile dysfunction. A double-blind, placebo controlled crossover study demonstrating dose response with Rigiscan and efficacy with outpatient diary. *Journal of Urology*. 1996; 155(suppl):495A [meeting abstract #739]

Boolell, M.; Gepi-Attee, S.; Gingell, J. C., and Allen, M. J. Sildenafil, a novel effective oral therapy for male erectile dysfunction. *British Journal of Urology*. 1996 Aug; 78(2):257-61.

Derry, F.; Gardner, B. P.; Glass, C.; Fraser, M.; Dinsmore, W. W.; Muirhead, G.; Maytom, M. C.; Orr, M. Sildenafil (Viagra™): a double-blind, placebo-controlled, single-dose, two-way crossover study in men with erectile dysfunction caused by traumatic spinal cord injury. *Journal of Urology*. 1997;157(suppl):181 [meeting abstract #702]

Eardley, I.; Brook, J.; Yates, P. K.; Wulff, M. B.; Boolell, M. Sildenafil (Viagra™), a novel oral treatment with rapid onset of action for penile erectile dysfunction. *British Journal of Urology*. 1997; 79(suppl 4):66 [meeting abstract #CP 12]

Eardley, I.; Morgan, R. J.; Dinsmore, W. W.; Pearson, J.; Wulff, M. B.; Boolell, M. UK-92,480, a new oral therapy for erectile dysfunction: a double-blind placebo controlled trial with treatment taken as required. *Journal of Urology*. 1996; 155(suppl):495A [meeting abstract #737]

Gingell, C. J. C.; Jardin, A.; Olsson, A. M.; Dinsmore, W. W.; Osterloh, I. H.; Kirkpatrick, J.; Cuddigan, M. UK-92,480, a new oral therapy for erectile dysfunction: a double-blind placebo controlled once daily dose response study. *Journal of Urology*. 1996; 155(suppl):495A [meeting abstract #738]

Goldstein, I.; Lue, T. F.; Padma-Nathan, H.; Rosen, R. C.; Steers, W. D., and Wicker, P. A. Oral sildenafil in the treatment of erectile dysfunction. Sildenafil Study Group. *New England Journal of Medicine*. 1998 May 1;338(20):1397-404.

Lue, T. F. A study of sildenafil (Viagra™), a new oral agent for the treatment of male erectile dysfunction. *Journal of Urology*. 1997; 157(suppl):181 [meeting abstract #701]

Quirk, F.; Giuliano, F.; Pena, B.; Mishra, A.; Smith, M. D.; Hockey, H. Effect of sildenafil (Viagra™) on quality-of-life parameters in men with broad-spectrum erectile dysfunction. *Journal of Urology*. 1998; 159(suppl):260 [meeting abstract #998]

Rendell, M.S.; Rajfer, J.; Wicker, P.A., and Smith, M.D. Sildenafil for treatment of erectile dysfunction in men with diabetes: a randomized controlled trial. *JAMA*. 1999 Feb 3; 281(5):421-26.

Wagner, G.; Maytom, M.; Smith, M. D. Analysis of efficacy of sildenafil (Viagra™) in the treatment of male erectile dysfunction in elderly patients. *Journal of Urology*. 1998; 159(suppl):239 [meeting abstract #912]

#### **Trazodone vs. placebo (2 articles, 2 abstracts)**

Costabile, R. A. and Spevak, M. Trazodone is not effective therapy for erectile dysfunction: the results of a placebo controlled double blind study. *Journal of Urology*. 1998; 159(suppl):240 [meeting abstract #916]

Kurt, U.; Ozkardes, H.; Altug, U.; Germiyanoglu, C.; Gurdal, M.; and Erol, D. The efficacy of anti-serotonergic agents in the treatment of erectile dysfunction. *Journal of Urology*. 1994 Aug; 152: 407-9.

Meinhardt, W.; Kropman, R. F.; de la Fuente, R. B.; Lycklama a Nijeholt, G. A. B.; and Zwartendijk, J. Trazodone versus placebo for erectile dysfunction, a doubleblind multicentre trial. *Journal of Urology*. 1996; 155(suppl):497A [meeting abstract #745]

Meinhardt, W.; Schmitz, P. I.; Kropman, R. F.; de la Fuente, R. B.; Lycklama a Nijeholt, G. A. B.; and Zwartendijk, J. Trazodone, a double blind trial for treatment of erectile dysfunction. *International Journal of Impotence Research*. 1997 Sep; 9(3):163-5.

#### vs. testosterone vs. hypnosis vs. placebo (1 article)

Aydin, S.; Odabas, O.; Ercan, M.; Kara, H., and Agargun, M. Y. Efficacy of testosterone, trazodone and hypnotic suggestion in the treatment of non-organic male sexual dysfunction. *British Journal of Urology*. 1996 Feb; 77(2):256-60.

#### **Trazodone + yohimbine vs. placebo (1 article)**

Montorsi, F.; Strambi, L. F.; Guazzoni, G.; Galli, L.; Barbieri, L.; Rigatti, P.; Pizzini, G., and Miani, A. Effect of yohimbine-trazodone on psychogenic impotence: a randomized, double-blind, placebo-controlled study. *Urology*. 1994 Nov; 44(5):732-6.

#### **Yohimbine (1 systematic review / meta-analysis)**

Ernst, E. and Pittler, M. H. Yohimbine for erectile dysfunction: a systematic review and meta-analysis of randomized clinical trials. *Journal of Urology*. 1998 Feb; 159:433-36.

#### vs. placebo (8 articles)

Kunelius, P.; Hakkinen, J., and Lukkarinen, O. Is high-dose yohimbine hydrochloride effective in the treatment of mixed-type impotence? A prospective, randomized, controlled double-blind crossover study. *Urology*. 1997 Mar; 49(3):441-4.



Mann, K.; Klingler, T.; Noe, S.; Roschke, J.; Muller, S., and Benkert, O. Effects of yohimbine on sexual experiences and nocturnal penile tumescence and rigidity in erectile dysfunction. *Archives of Sexual Behavior*. 1996 Feb; 25(1):1-16.

Morales, A.; Condra, M.; Owen, J. A.; Surridge, D. H.; Fenemore, J., and Harris, C. Is yohimbine effective in the treatment of organic impotence? *Journal of Urology*. 1987; 137:1168.

Reid, K.; Morales, A.; Harris, C.; Surridge, D. H.; Condra, M.; Owen, J. A., and Fenemore, J. Double-blind trial of yohimbine in treatment of psychogenic impotence? *Lancet*. 1987; 1:421.

Riley, A. J.; Goodman, R.; Kellett, J. M., and Orr, R. Double-blind trial of yohimbine hydrochloride in the treatment of erection inadequacy. *Sexual and Marital Therapy*. 1989; 4:17.

Rowland, D. L.; Kallan, K., and Slob, A. K. Yohimbine, erectile capacity, and sexual response in men. *Archives of Sexual Behavior*. 1997 Feb; 26(1):49-62.

Susset, J. G.; Tessier, C. D.; Wincze, J.; Bansal, S.; Malhotra, C., and Schwacha M. G. Effect of yohimbine hydrochloride on erectile impotence. *Urology*. 1989; 141:1360.

Vogt, H. J.; Brandl, P.; Kockott, G.; Schmitz, J. R.; Wiegand, M. H.; Schadrack, J., and Gierend, M. Double-blind, placebo-controlled safety and efficacy trial with yohimbine hydrochloride in the treatment of nonorganic erectile dysfunction. *International Journal of Impotence Research*. 1997 Sep; 9(3):155-61.

#### **Yohimbine / Isoxsuprine vs. pentoxifylline (1 article)**

Knoll, L. D.; Benson, R. C. Jr; Bilhartz, D. L.; Minich, P. J., and Furlow, W. L. A randomized crossover study using yohimbine and isoxsuprine versus pentoxifylline in the management of vasculogenic impotence [see comments]. *Journal of Urology*. 1996 Jan; 155(1):144-6.

#### **Transdermal (1 article, 1 abstract)**

##### **Aminophylline / Isosorbide dinitrate / Co-dergocrine mesylate**

Gomaa, A.; Shalaby, M.; Osman, M.; Eissa, M.; Eizat, A.; Mahmoud, M. and Mikhail, N. Topical treatment of erectile dysfunction: randomised double blind placebo controlled trial of cream containing aminophylline, isosorbide dinitrate, co-dergocrine mesylate. *BMJ*. 1996 Jun 15;312:1512-15.

Bergamaschi, F.; Ordesi, G.; Corrada, P.; Torelli, T.; Zanitzer, L. and Campo, B. Buflomedil transdermal electromotive administration (EMDA) in vasculogenic impotence: preliminary study. *Journal of Urology*. 1997; 155(suppl):497A [meeting abstract #744].

#### **Injection (9 articles)**

##### **Alprostadil [PGE1] vs. placebo (3 articles)**

Colli, E.; Calabro, A.; Gentile, V.; Mirone, V., and Soli, M. Alprostadil sterile powder formulation for intracavernous treatment of erectile dysfunction. *European Urology*. 1996; 29(1):59-62.

Linnet, O. I. and Ogrinc, F. G. Efficacy and safety of intracavernosal alprostadil in men with erectile dysfunction. The Alprostadil Study Group [see comments]. *New England Journal of Medicine*. 1996 Apr 4; 334(14):873-7.

Vanderschueren, D.; Heyrman, R. M.; Keogh, E. J.; Casey, R. W.; Weiske, W. H.; Ogrinc, F. G., and de Koning Gans, H. J. A study in patients with erectile dysfunction comparing different formulations of prostaglandin E1. Alprostadil Study Group. *Journal of Urology*. 1995 Nov; 154(5):1744-7.

vs. moxisylyte chlorhydrate (1 article)

Buvat, J.; Costa, P.; Morlier, D.; Lecocq, B.; Stegmann, B., and Albrecht, D. Double-blind multicenter study comparing alprostadil alpha-cyclodextrin with moxisylyte chlorhydrate in patients with chronic erectile dysfunction [see comments]. *Journal of Urology*. 1998 Jan; 159(1):116-9.

vs. papaverine/phentolamine (1 article)

Bechara, A.; Casabe, A.; Cheliz, G.; Romano, S.; Rey, H., and Fredotovich, N. Comparative study of papaverine plus phentolamine versus prostaglandin E1 in erectile dysfunction [see comments]. *Journal of Urology*. 1997 Jun; 157(6):2132-4.

vs. PGE1/Lidocaine (1 article)

Kattan, S. Double-blind randomized crossover study comparing intracorporeal prostaglandin E1 with combination of prostaglandin E1 and lidocaine in the treatment of organic impotence. *Urology*. 1995 Jun; 45(6):1032-6.

vs. PGE1/papaverine/phentolamine (1 article)

Bechara, A.; Casabe, A.; Cheliz, G.; Romano, S., and Fredotovich, N. Prostaglandin E1 versus mixture of prostaglandin E1, papaverine and phentolamine in nonresponders to high papaverine plus phentolamine doses [see comments]. *Journal of Urology*. 1996 Mar; 155(3):913-4.

**Prostaglandin E1/Papaverine/Phentolamine vs. Papaverine/Phentolamine (1 article)**

Shenfeld, O.; Hanani, J.; Shalhav, A.; Vardi, Y., and Goldwasser, B. Papaverine-phentolamine and prostaglandin E1 versus papaverine-phentolamine alone for intracorporeal injection therapy: a clinical double-blind study. *Journal of Urology*. 1995 Sep; 154(3):1017-9.

**Prostaglandin E1/Papaverine/Phentolamine/Atropine vs. PPP (1 article)**

Sogari, P. R.; Teloken, C., and Souto, C. A. Atropine role in the pharmacological erection test: study of 228 patients [see comments]. *Journal of Urology*. 1997 Nov; 158(5):1760-3.

**Intraurethral (5 articles, 4 abstracts)**

**Alprostadil vs. placebo (4 articles, 2 abstracts)**

Costabile, R. A.; Govier, F. E.; Ferrigni, R. G.; McVary, K. T.; Shabsigh, R.; Nemo, K. J.; Tam, P. Y.; Spivack, A. P. Efficacy and safety of transurethral alprostadil in patients with erectile dysfunction following radical prostatectomy. *Journal of Urology*. 1997; 157(suppl):364 [meeting abstract #1424]

Costabile, R. A.; Spevak, M.; Fishman, I. J.; Govier, F. E.; Hellstrom, W. J. G.; Shabsigh, R.; Nemo, K. J.; Rapport, J. L.; Tam, P. Y.; Weldon, K. L. M., and Gesundheit, N. Efficacy and safety of transurethral alprostadil in patients with erectile dysfunction following radical prostatectomy. *Journal of Urology*. 1998 Oct; 160:1325-8.

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