POD-10.09

Modified Balloon-Tamponade of the Cavity of Transvesical Protetectomy: Experience in 2092 Cases

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Introduction and Objectives: Open operation was, and will always be, a good treatment for benign prostatic hyperplasia (BPH). Our objective is to explain why our patients successfully overcame the main hazard of open prostatectomy: which is hemorrhagic complications?
Material and Methods: Study from 1957 to 2006, including 2092 cases of BPH. Presentations: resistant lower urinary tract symptoms(LUTS) and or acute / chronic retention. BPH below 60 grams not included in the study. *Intervention*: Transvesical exposure. Only frank bleeders at prostato-vesical junction controlled. Then we turn the prostatic fossa into a temporarily half-closed cavity with catgut sutures; just to retain balloon in cavity for effective tamponade. Using balloon-tamponade,we get smoothened walls and *instantaneous* hemostasis. Balloon choice is crucial: *it must inflate in a spherical apple-like shape***.** Measurements: Main outcome measure: assessment of intra-and post-operative blood loss.
Outlet complications followed-up as outpatients for one year.
Results: *Instantaneous* hemostasis was achieved once the balloon was inflated a little more than the size of the *sub-vesical* portion of the adenoma. This allowed the whole operation to take less than 60 minutes. Immediate re-operation needed for six cases, (0.3%) in whom the balloon either got ruptured or displaced into bladder. Peri-operative transfusions needed for 24 patients in the whole series, (1.15 %). Sixteen infective secondary hemorrhages around the eleventh day (0.8%). Thirty-five vesical neck contractures, (1.7 %). Twenty-seven urethral strictures and/or meatal stenosis (1.3 %); attributed to long pre-operative catheterization.
Conclusions: Our modification greatly improves the morbidity spectrum of open prostatectomy; making it an excellent option, especially for large adenomas. Open prostatectomy teaching should continue as a mandatory skill. A skill needed in more than 60% of the world, even in developed nations.

POD-10.10

Decreased Efficiency of GreenLight HPS™ Laser Photoselective Vaporization Prostatectomy (PVP) with Long-Term 5α-Reductase Inhibition Therapy: Is It True?

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Introduction and Objectives: 5α-reductase inhibitors reduce angiogenesis in benign prostatic tissue. This has been postulated to affect the efficiency of the potassium-titanyl phosphate (KTP) laser during PVP, which has hemoglobin as its primary chromophore. Whether this effect of 5α-reductase inhibitors applies to GreenLight HPS™ laser PVP is not clear. We evaluate GreenLight HPS" laser PVP as treatment for benign prostatic hyperplasia (BPH) in patients on long-term 5α-reductase inhibitors.
Materials and Methods: We prospectively evaluated our initial GreenLight HPS" laser PVP experience in patients with and without long-term 5α-reductase inhibition. Transurethral PVP was performed using a GreenLight HPS™ side-firing laser system with normal saline irrigant. Voiding trials were performed two hours post surgery; if unable to void, a urethral catheter was replaced. American Urological Association Symptom Score (AUASS), maximum flow rate (Qmax) and post void residual (PVR) were measured preoperatively and at 1, 4, 12, 24 and 52 weeks post surgery. Serum PSA and TRUS were also obtained at the 12 week follow-up interval.
Results: There were 169 consecutive patients identified; 54 were on either finasteride or dutasteride for more than 6 months and 115 were not. Mean prostate volumes were 67±35 and 74±47 mL (p=0.79) and mean PSA values were 2.1±2.3 and 2.7±2.7 ng/ml (p=0.16), respectively. There were no significant differences in the parameters of laser utilization (14±9 and 13±9 minutes, p=0.45) and energy usage (88±63 and 86±57 kJ, p=0.83). All were outpatient procedures with the majority of the patients catheter-free at discharge. All patients were able to discontinue their prostate medications following surgery. The mean rates of prostate vaporization (3.3±2.2 and 3.0±1.4 mL/min, p=0.11; 0.55±0.33 and 0.59±0.71 mL/kJ, p=0.77) and TRUS volume decrease 12 weeks post surgery (54±14 and 51±12 %, p=0.32) were similar between the two groups. AUASS, Qmax and PVR values showed significant improvement within each group ($p<0.05$), but the degree of improvement between the two groups did not show statistical significance.
Conclusion: Our experience suggests that 5α-reductase inhibitors do not have a detrimental effect on the efficiency and efficacy of GreenLight HPS™ laser PVP.

POD-10.11

Long-term Efficacy of Combination Therapy with the Dual 5-α Reductase Inhibitor Dutasteride and the α-Blocker Tamsulosin in the Treatment of Benign Prostatic Hyperplasia: 4-year Results from the Randomized, Double-blind, CombAT Trial

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Introduction and Objectives: Investigate the efficacy and safety of dutasteride/tamsulosin combination *versus* each monotherapy for improving symptoms and clinical outcomes in men with moderate-to-severe BPH.
Materials and Methods: In this 4-year, international, randomized, double-blind, parallel-group study, 4844 men ≥50 years with BPH (IPSS ≥12, total prostate volume [PV] ≥30 cc, serum PSA 1.5-10 ng/mL, Q_{max} 5-15 mL/s) were randomized to receive dutasteride 0.5 mg/day (n=1623), tamsulosin 0.4 mg/day (n=1611), or the combination (n=1610) for 4 years. Safety data and the primary endpoint at 4 years have previously been reported: combination therapy significantly reduced the risk of AUR or BPH-related surgery by 65.8% *versus* tamsulosin, from 11.9% to 4.2%. Here we report the secondary endpoints of change from baseline in IPSS, prostate volume, Q_{max}, BPH impact index (BII) and IPSS question 8, and the proportion of men with symptom improvement ≥3 IPSS points.
Results: At 4 years, mean change from baseline in IPSS, BII and QoL were significantly greater with combination *versus* both monotherapies; mean change in PV and Q_{max} were significantly greater with combination *versus* tamsulosin but not *versus* dutasteride (Table 1).
Conclusion: At 4 years, significantly greater improvements from baseline were observed in IPSS, BII and IPSS Q8 with combination therapy *versus* both monotherapies, and for PV and Q_{max} *versus* tamsulosin. The signifi-

POD-10.11, Table 1. Effect of treatments on secondary endpoints at 48 months (intention-to-treat population, LOCF)

	Dutasteride 0.5 mg + tamsulosin 0.5 mg (n=1610)	Dutasteride 0.5 mg (n=1623)	Tamsulosin 0.5 mg (n=1611)
Symptoms-related endpoints			
Adjusted mean IPSS change from baseline	−6.3	−5.3**	−3.8**
Prostate volume change from baseline, cc (adjusted mean, %)	−13.1 (−27.3%)	−13.7 (−28.0%)	+5.2 (+4.6%)**
Adjusted mean Q_{max} change from baseline, mL/s	2.4	2.0	0.7**
Proportion of men with IPSS change from baseline ≥3 points	71%	66%*	59%
QoL-related endpoints			
Adjusted mean BII change from baseline	−2.2	−1.8**	−1.2**
Adjusted mean IPSS Q8 change from baseline	−1.5	−1.3**	−1.1**

*p<0.04 *vs.* combination therapy; **p<0.001 *vs.* combination therapy; QoL, quality of life.

cant improvement in IPSS score with combination therapy *versus* both monotherapies observed within 1 year was maintained to 4 years, and along with the significant reduction in risk of AUR or BPH-related surgery, provides support for the long-term use of dutasteride and tamsulosin combination therapy in men with moderate or severe BPH and prostatic enlargement.

Podium Session 11: Prostate Cancer, Advanced Disease Wednesday, November 4, 13:30-14:50

POD-11.01

Dose Finding and Safety Analysis of Inecalcitol in Combination with Docetaxel-Prednisone Regimen in Hormone-Refractory Prostate Cancer (HRPC) Patients (PTS)

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Introduction: Inecalcitol is a novel synthetic vitamin D3 analogue with potent antiproliferative effects in human cancer cell lines and a 100-fold lower hypercalcemic activity than calcitriol in animal models.

Materials and Methods: In this study, escalating dosages of inecalcitol was combined to chemotherapy in naive HRPC pts. Safety and efficacy were evaluated in groups of 3-6 patients receiving inecalcitol daily or every other day on a 21-day cycle in combination with docetaxel (75mg/m2 q3w) and oral prednisone (5mg bid). Bisphosphonates were prohibited during the first cycle. Patients received up to six cycles unless unacceptable toxicity or disease progression. Primary endpoint was dose limiting toxicity (DLT) defined as grade 3 hypercalcemia within the first cycle. Calcemia, creatininemia and CBC were assessed weekly; biochemistry, ECG and PSA every 3 weeks. Efficacy endpoint was PSA response defined as ≥30% decline within 3 months.

Results: Five dose levels: 40, 80, 160, 300, 600 μg have been evaluated in 34 pts; 9 pts are still being treated at 600 μg; 25 pts have completed 6 cycles (13 bone metastases; 3 extrasqueletic metastasis, 8 bone and extrasqueletic metastases; 1 PSA-only disease). Median age was 72 years [range, 53-87], median Gleason score (Gs) 7 [36% Gs 10-8, 64% Gs 7-6] and median PSA 41.5 ng/mL [range, 0.9-962.4].No increased calcemia was reported. Most adverse events (AE) were G1-2, asthenia (19pts), constipation (14pts), diarrhea (13pts). G3-4 AEs were neutropenia (11pts) lymphopenia (9pts), asthenia (3pts), arrhythmia (2 pts), general health deterioration (2pts) and diarrhea (1pt). None of these AEs was considered related to inecalcitol. Of the 23 evaluable pts for PSA response, 20 (87%) had ≥30% PSA decline.

Conclusion: Results from this ongoing study show the safe toxicity profile of inecalcitol when given daily in HRPC pts. PSA responses with this combination are encouraging. As DLT was not reached, higher dose of inecalcitol (1000 μg/day) will be further tested.

POD-11.02

Early Versus Delayed Endocrine Treatment of T2-T3 pN1-3 M0 Prostate Cancer Without Local Treatment of the Primary Tumour: Final Results of European Organisation for the Research and Treatment of Cancer Protocol 30846 After 13 Years of Follow-up

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Introduction and Objectives: The timing of endocrine treatment for prostate remains controversial. The issue is addressed in protocol 30846 of the European Organisation for Research and Treatment of Cancer for patients with lymph node positive cancer without local treatment of the primary tumour.

Materials and Methods: 234 patients with histologically proven adenocarcinoma of the prostate (PC) and nodal metastases (pN1-3) were randomized to immediate vs. delayed endocrine treatment (ET) without treatment of the primary tumour. ET consisted of the use of a depot LHRH agonist and one month of an anti androgen or surgical castration. The main endpoint is overall survival. Disease specific survival was evaluated.

Results: All except 3 patients were treated according to allocation by randomization. The median follow-up amounts to 13 years. The median duration of protocol treatment was 2.7 years in the delayed and 3.2 years in the immediate group. At the time of this evaluation 193 patients have died (82.5%) and 59.4% of the deaths are due to PC. The power of the study to show slow non-inferiority of DET according to the original sample size calculation has reached 80%. The intention to treat analysis shows a 22% increase in the hazard of death for those randomized to delayed treatment. The median survival on immediate treatment is 7.6 years (95%