

rinised to an APTT ratio of 5, the other underwent resection of a large bladder tumour extending into the prostate. In the group with INR <1.5 the mean resected weight was 38g (range 6-76g), the mean decrease in haemoglobin concentration was 2.0g/dL (range 0.3-5.3g/dL), the number patients transfused was 0 and the mean stay length was 7 days (range 3-20 days). In the group with INR >1.5 the mean resected weight was 31g (range 1-140g), the mean decrease in haemoglobin was 2.3 g/dL (range 0.6-6.1g/dL), the number of patients transfused was 5 (mean 2 units) and the mean stay length was 8 days (range 5-18 days). One patient with INR <1.5 suffered a post operative PE.

**Conclusions:** In patients at high risk of thromboembolic complications, TURP maybe performed safely in patients with INR >1.5, if the patient and surgeon accept the increased risk of transfusion.

**Abstract Withdrawn**

**MP-20.16**

**Safety and tolerability of dutasteride, tamsulosin and a combination of dutasteride and tamsulosin: Two-year results from the Combination of Avodart® and Tamsulosin (CombAT) study**

Roehrborn R<sup>1</sup>, Siami P<sup>2</sup>, Barkin J<sup>3</sup>, Damião R<sup>4</sup>, Montorsi F<sup>5</sup> on behalf of the CombAT Study Group

<sup>1</sup>Department of Urology, UT Southwestern Medical Center, Dallas, Texas, USA;

<sup>2</sup>Welborn Clinic, Evansville, Indiana,

USA; <sup>3</sup>The Female/Male Health Center, Toronto, Ontario, Canada; <sup>4</sup>Serviço de Urologia, Hospital Universitário Pedro Ernesto - UERJ, Rio de Janeiro, Brazil; <sup>5</sup>Department of Urology, Università Vita Salute San Raffaele, Milan, Italy

**Objectives:** The ongoing CombAT study is investigating whether combination therapy with dutasteride and tamsulosin is more effective than either monotherapy alone for improvement of symptoms and long-term clinical outcomes of AUR and BPH-related prostatic surgery in a population of men aged ≥50 years with moderate-to-severe BPH symptoms and prostatic enlargement. Results of pre-planned 2-year interim safety and tolerability analyses are reported.

**Materials and Methods:** The study is a multicenter, randomised, double-blind, parallel-group study. Eligible subjects were men aged ≥50 years with a clinical diagnosis of BPH, an IPSS ≥12 points, a prostate volume ≥30 cc by TRUS, a total serum PSA 1.5-10 ng/mL, and a Qmax >5 mL/sec and ≤15 mL/sec with a minimum voided volume ≥125 mL. Subjects were randomised after a 4-week placebo run-in period to dutasteride 0.5 mg, tamsulosin 0.4 mg, or the combination once daily for 4 years. Adverse events and vital signs were recorded at every 3-month visit; PSA and laboratory tests at screening and annually. TRUS-guided prostate biopsies were conducted at the investigators' discretion.

**Results:** A similar proportion of patients in each treatment group reported adverse events (Table). No statistically sig-

nificant differences were observed for combination *versus* either monotherapy in clinical laboratory or vital sign thresholds, or DRE changes. Prostate cancer was reported in 21, 11 and 26 men in the combination, dutasteride and tamsulosin groups. PSA decreased by a median of 56.0% and 55.0% from baseline in the combination and dutasteride groups, and increased in the tamsulosin group by 12.1%.

**Conclusions:** The profile of events for combination therapy was consistent with those reported for monotherapies. Drug-related events were more common with combination therapy than monotherapies. Both tamsulosin and dutasteride have different effects on ejaculatory function: this may explain the more than additive rate observed. Rates of withdrawal due to adverse events were low in all groups.

**MP-20.17**

**Trends in LUTS BPH management: is real life a mirror of PLESS and MTOPS? Are older men disadvantaged?**

Graham J, Hehir M, Riddle K, Crispin V, Paterson MA

Urology Department, Forth Valley Prostate Research Group, Falkirk and District Royal Infirmary, Falkirk, Scotland

**Introduction:** The population of older folk in many societies is increasing. In Scotland between 2004 and 2031, the population of men aged 75 and over is set to rise by 75% and those aged 64-75 by 39%. More men will conse-

Table 1. MP-20.16

	Combination (n=1610)	Dutasteride (n=1623)	Tamsulosin (n=1611)
Any adverse event	65%	64%*	63%*
Any serious adverse event	12%	12%*	13%*
Any drug-related adverse event	24%	18%†	16%†
Any serious drug-related adverse event	<1%	<1%	<1%
Any adverse event leading to study withdrawal	10%	8%*	9%*
Any drug-related adverse event leading to study withdrawal	5%	3%	3%
<b>Drug-related adverse events occurring in ≥1% subjects within any treatment group</b>			
Erectile dysfunction	7.4%	6.0%	3.8%
Retrograde ejaculation	4.2%	0.6%	1.1%
Altered (decreased) libido	3.4%	2.8%	1.7%
Ejaculation failure	2.4%	0.5%	0.8%
Semen volume decreased	1.8%	0.3%	0.8%
Loss of libido	1.7%	1.3%	0.9%
Dizziness	1.6%	0.7%	1.7%
Breast enlargement	1.4%	1.8%	0.8%
Nipple pain	1.2%	0.6%	0.3%
Breast tenderness	1.0%	1.0%	0.3%

\*p=n.s. *versus* combination; †p<0.001 *versus* combination.