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UPSTREAM tables

Table 1. Key baseline characteristics for the UPSTREAM trial

	n ^a	Urodynamics (n=427) [intervention]	n ^a	Routine care (n=393) [control]
Age(years)	424	67.5 (9.6)	389	67.8 (8.8)
White ethnicity	415	377 (91%)	383	356 (93%)
Comorbidities ^b	420	281 (67%)	383	260 (68%)
Median Q _{max} (IQR), ml/s	402	10.2 (7.4, 15.0)	371	11.0 (7.9, 15.2)
Total IPSS	403	18.5 (6.9)	371	19.4 (7.1)
IPSS QoL	411	4.1 (1.4)	379	4.2 (1.3)
ICIQ Voiding score	394	8.9 (4.0)	370	9.3 (4.4)
ICIQ Incontinence score	395	5.0 (3.4)	369	5.2 (3.3)
ICIQ Daytime frequency (>8)	398	160 (40%)	374	169 (45%)
ICIQ Nocturia (>1)	398	300 (75%)	374	301 (80%)
Erections (reduced or none)	389	277 (71%)	362	275 (76%)
Ejaculation (reduced or none)	383	300 (78%)	359	295 (82%)
Painful ejaculation	359	56 (16%)	343	71 (21%)
Urinary symptoms affect sex life?	378	259 (69%)	358	233 (65%)

Data are mean (SD) or n(%), unless otherwise stated. ^aThe ‘n’ columns are included to signify the denominator which differs from the overall figure due to withdrawals and missing data. ^bAs part of the baseline assessment clinicians were asked if the patient presented with any comorbidity when they were randomised, Additional measures can be found in a previous publication²⁰

Table 2. Primary and sensitivity analysis results for the UPSTREAM trial

	N(U:R) ^a	Urodynamics [intervention]	Routine care [control]	Crude difference in means (95% CI)	Adj. difference in means ^b (95% C.I.)
Primary analysis					
IPSS: Intention to treat ^c	340:329	12.6 (7.9)	13.1 (7.9)	-0.49 (-1.69, 0.70)	-0.33 (-1.47, 0.80)
Sensitivity analyses					
Per protocol ^d	306:305	12.6 (7.8)	12.8 (7.5)	-0.21 (-1.43, 1.00)	-0.10 (-1.25, 1.05)
CACE analysis ^e	330:339			-0.60 (-2.04, 0.85)	-0.39 (-1.70, 0.92)

Data are mean (SD) or n(%), unless otherwise stated. U=Urodynamics, R=Routine care. ^aThe number of men with available 18-month IPSS data. ^bAdjusted for centre and baseline IPSS. ^c12:16 men, in the Urodynamics and Routine care arms, respectively, could not be included in the adjusted analysis due to missing baseline IPSS data. ^dRemoving those who did not comply with their randomised treatment (7:15 excluded from adjusted analysis due to missing baseline IPSS data). ^eNs presented are for as treated groups with unbiased estimates to account for patient crossover using instrumental-variables regression (8:20 excluded from adjusted analysis due to missing baseline IPSS data).

Table 3. Secondary analysis results for the UPSTREAM trial: Surgery rates and Qmax

	n (U:R)	Urodynamics [intervention]	Routine care [control]	Adjusted comparison ^a (95% C.I.)	P value ^a
Surgery for LUTS					
Recommended surgery	397:378	196 (49%)	182 (48%)	1.02 (0.76, 1.38)	0.9
Recommended no surgery		201 (51%)	196 (52%)		
Surgery conducted	408:384	153 (38%)	138 (36%)	1.05 (0.77, 1.43)	0.7
No surgery conducted		255 (63%)	246 (64%)		
Maximum urinary flow rate^b					
Mean Q _{max} (SD) overall, at 18-months ^c	268:270	15.3 (8.3)	15.7 (9.1)	0.14 (-1.33, 1.62)	0.8
Mean Q _{max} (SD), post-surgery for surgery patients ^d	59:59	17.2 (9.3)	18.2 (9.8)	-0.17 (-4.24 to 3.89)	0.9

Data are mean (SD) or n(%), unless otherwise stated. U=Urodynamics, R=Routine care, ^aAppropriate regression models (linear or logistic) adjusted for centre, ^bThese analyses were adjusted for baseline Qmax as well as centre. ^cMissing baseline data led to 18 exclusions from the analysis. ^dMissing baseline data led to 1 exclusion from this analysis.

Table 4. Secondary analysis results for the UPSTREAM trial: Patient reported outcome measures

	n (U:R)	Urodynamics [intervention]	Routine care [control]	Adjusted comparison ^a (95% C.I.)	P value ^a
Urinary symptom patient reported outcomes^b					
IPSS QoL item	343:332	2.7 (1.69)	2.7 (1.64)	-0.07 (-0.32, 0.18)	0.6
ICIQ Voiding score	296:278	6.4 (4.40)	6.2 (4.23)	0.09 (-0.59, 0.77)	0.8
ICIQ Incontinence score	295:282	3.9 (3.07)	4.0 (2.81)	-0.27 (-0.67, 0.13)	0.19
ICIQ Daytime frequency (>8)	297:284	84 (28%)	75 (26%)	1.12 (0.75, 1.67)	0.6
ICIQ Nocturia (>1)	299:282	176 (59%)	189 (67%)	0.66 (0.44, 0.99)	0.042
Sexual symptom patient reported outcomes^c					
Erections (reduced or none)	287:270	206 (72%)	196 (73%)	1.03 (0.63, 1.68)	0.9
Ejaculation (reduced or none)	286:264	244 (85%)	219 (83%)	1.37 (0.82, 2.28)	0.2
Painful ejaculation	255:246	43 (17%)	39 (16%)	1.16 (0.67, 1.98)	0.6
Urinary symptoms affect sex life?	274:266	197 (72%)	179 (67%)	1.28 (0.84, 1.96)	0.3

Data are mean (SD) or n(%), unless otherwise stated. U=Urodynamics, R=Routine care, ^aAppropriate regression models (linear logistic or ordinal logistic) adjusted for centre and the relevant baseline measure, for PROMS and Qmax. Binary PROMS were not adjusted by centre due to perfect prediction, ^bThe numbers refer to the analysable sample for the outcomes of interest at 18-months (missing baseline data led to between 15 and 21 exclusions from the analysis), ^cThe numbers refer to the analysable sample for the outcomes of interest at 18-months (missing baseline data led to between 25 and 41 exclusions from the analysis),