2. METHODS

Table S.1: Level of Evidence (LE)*

LE	Type of Evidence
1a	Evidence obtained from meta-analysis of randomised trials.
1b	Evidence obtained from at least one randomised trial.
2a	Evidence obtained from one well-designed controlled study without randomization.
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study.
3	Evidence obtained from well-designed non-experimental studies, such as comparative or correlation studies and case reports.
4	Evidence obtained from expert committee reports or options or clinical experience of respected authorities.

**Modified from [1].*

Table S.2: Grade of Recommendation (GR)*

GR	Recommendations
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial.
B	Based on well-conducted clinical studies, but without randomised clinical trials.
C	Made despite the absence of directly applicable clinical studies of good quality.

**Modified from [1].*

3C.2 Pharmacological management

Table S.3: Key pharmacokinetic properties and standard doses of α_1-blockers licensed in Europe for treating symptoms of BPH

Drug	t_{max} (hours)	$t_{½}$ (hours)	Recommended daily dose (mg)
Alfuzosin IR	1.5	4-6	3 x 2.5
Alfuzosin SR	3	8	2 x 5
Alfuzosin XL	9	11	1 x 10
Doxazosin IR	2-3	20	1 x 2-8
Doxazosin GITS	8-12	20	1 x 4-8
Silodosin	2.5	11-18	1 x 4-8
Tamsulosin MR	6	10-13	1 x 0.4
Tamsulosin OCAS	4-6	14-15	1 x 0.4
Terazosin	1-2	8-14	1 x 5-10

t_{max} = time to maximum plasma concentration; $t_{½}$ = elimination half-life; IR = immediate release; SR = sustained release; GITS = gastrointestinal therapeutic system; MR = modified-release; OCAS = oral-controlled absorption system.

Table S.4: 5α-reductase inhibitors licensed in Europe for treating benign prostatic enlargement (BPE) due to BPH; key pharmacokinetic properties and standard doses

Drug	t_{max} (hours)	$t_{½}$	Recommended daily dose (mg)
Dutasteride	1-3	3-5 weeks	1 x 0.5
Finasteride	2	6-8 hours	1 x 5

t_{max} = time to maximum plasma concentration; $t_{½}$ = elimination half-life.

Table S.5: Antimuscarinic drugs licensed in Europe for treating overactive bladder/storage symptoms; key pharmacokinetic properties and standard doses

Drug	T_{max} [h]	$T_{½}$ [h]	Recommended daily dose [mg]
Darifenacin ER[a]	7	12	1 x 7.5-15
Fesoterodine[a,b]	5	7	1 x 4-8
Oxybutynin IR	1	2-5[c]	2-3 x 5
Oxybutynin ER	4-6	13	1 x 5-30
Propiverine IR	2	14-22	2 x 15
Propiverine ER	10	20	1 x 30
Solifenacin	3-8	45-68	1 x 5-10
Tolterodine IR[a]	1-2	2	2 x 2
Tolterodine ER[a]	4	7-10	1 x 4
Trospium IR	5	18	2 x 20
Trospium ER	5	36	1 x 60

t_{max} = time to maximum plasma concentration; $t_{½}$ = elimination half-life; ER = extended release (in some countries some manufacturers may have assigned different designators to the ER formulation); IR = immediate release.

[a]higher exposure can occur in CYP 2D6 poor metabolisers;

[b]only the active metabolite 5-hydroxy-methyl-tolterodine is detectable in blood after oral administration of fesoterodine;

[c]$t_{½}$ is age-dependent, values taken from [2].

Notes: the gel and patch formulations of oxybutynin have not been included in this table; detailed information on other pharmacokinetic parameters and their alteration in renal or hepatic impairment on drug metabolism and pharmacokinetic drug-drug interactions has been summarised [3]; all data refer to drug use in adults; where applicable, pharmacokinetic properties may differ in paediatric populations.

3C.2.5 ***Plant extracts - phytotherapy***

3C.2.5.2 Efficacy

Analysis of each drug class:

Cucurbita pepo: Only one trial has evaluated the efficacy of pumpkin seed extract (Prosta Fink™ forte) in patients with BPH-LUTS [4]. A total of 476 patients were randomly assigned to placebo or Prostat Fink™ forte. After a follow-up of 12 months, IPSS and daytime voiding frequency were significantly reduced in the pumpkin seed group. However, uroflowmetry parameters (Q_{max}), PVR urine, prostate volume, PSA concentration, nocturia and QoL were not statistically different between the groups.

Hypoxis rooperi: These phytopharmacological extracts contain a mixture of phytosterols bonded with glycosides, of which ß-sitosterol is the most important compound (Harzol™, Azuprostat™). Four randomised, placebo-controlled trials with durations of between 4 - 26 weeks were published and summarised in a Cochrane report [5]. Daily doses of plant extracts ranged from 60 - 195 mg. Two trials evaluated symptoms [6, 7] and all four trials investigated Q_{max} and PVR urine. A meta-analysis calculated weighted mean differences of -4.9 IPSS points, +3.9 mL/s in terms of Q_{max} and -28.6 mL in terms of PVR urine in favour of ß-sitosterol. Prostate size remained unchanged in all trials. No further trials have been carried out since the Cochrane report was published in 2000.

Pygeum africanum: A Cochrane report dealing with the clinical results of *Pygeum africanum* extracts (monoor combination preparations) summarised the results of 18 randomised, placebo-controlled trials [8]. Most trials used the *Pygeum africanum* extract Tadenan™. The meta-analysis comprised 1,562 men, but individual trials were small in size and lasted only between 30 - 122 days. Most trials were performed in the 1970s and 1980s and did not use validated questionnaires such as the IPSS. Men treated with *Pygeum africanum* were twice as likely to report symptom improvement (relative risk [RR] 2.07) than were those treated with placebo. The mean weighted difference of Q_{max} was +2.5 mL/s, and of PVR volume -13.2 mL, in favour of *Pygeum africanum*. No further trials have been published since the Cochrane report in 2002.

Secale cereale: A Cochrane report dealt with the clinical results of the main Secale cereale product Cernilton™. It comprised 444 men who were enrolled in two placebo-controlled and two comparative trials (Tadenan™, Paraprost™) lasting between 12 and 24 weeks [9]. Men treated with Cernilton™ were twice as likely to report a benefit from therapy than those treated with placebo (RR 2.4). However, there were no significant differences between Cernilton™ and placebo with regard to Q_{max}, PVR urine, or prostate volume. No additional placebo-controlled trial with a monopreparation of *Secale cereale* has been published since the Cochrane report in 2000.

Serenoa repens/Sabal serrulata: A recently updated Cochrane report summarised the clinical results of 30 RCTs comprising 5,222 men [10]. Serenoa repens (mainly Permixon™ or Prostaserene™) was compared as a mono- or combination preparation with placebo, other plant extracts (*Pygeum africanum, Urtica dioica*), the 5-ARI finasteride, or the α-blocker tamsulosin. Mean follow-up of these trials varied between 4 - 60 weeks. The Cochrane report concluded that Serenoa repens was not superior to placebo, finasteride, or tamsulosin with regard to IPSS improvement, Q_{max}, or prostate size reduction. Similar levels of IPSS or Q_{max} improvements in trials with finasteride or tamsulosin might be interpreted as treatment equivalence [11]. For nocturia, Serenoa repens was significantly better than placebo (mean weighted difference -0.78).

Urtica dioica: Two trials compared the efficacy of stinging nettle monopreparations with placebo [12, 13]. One trial investigated 246 men with BPH-LUTS over a period of 52 weeks [13]. Only IPSS decreased significantly in the phytotherapy group (Bazoton™ uno), whereas Q_{max} and PVR urine were not statistically different between the groups at the end of the trial. The second trial investigated 620 patients with BPH-LUTS over a period of 26 weeks [12]. IPSS, Q_{max} and PVR urine significantly improved compared with placebo.

Combination preparations: Various trials have been carried out, especially with the extract combination of *Sabal serrulata* and *Urtica dioica* (PRO 160/120, Prostatgutt™ forte). A 24-week placebo-controlled trial demonstrated a significant improvement in IPSS in the phytotherapy arm (-2 IPSS points difference) [14]; Q_{max} reduction was similar in both groups. A 24-week open label extension trial of the same patients, in which all patients were treated with PRO 160/120, showed similar improvements of IPSS at week 48 in both groups (-7 IPSS points). A second trial, in which PRO 160/120 was randomised against finasteride, showed similar results for IPSS and Q_{max} in both groups [15].

*3C.2.6 **Vasopressin analogue – desmopressin***

Table S.6: Antidiuretics licensed in Europe for treating nocturia due to nocturnal polyuria; key pharmacokinetic properties and standard doses

Drug	t_{max} (hours)	$t_{½}$ (hours)	Recommended daily dose before sleeping at night
Desmopressin tablet	1.0–2.0	3.0	1 x 0.1-0.4 mg orally
Desmopressin oral lyophilisate (MELT)	0.5–2.0	2.8	1 x 60-240 µg sublingually
Desmopressin nasal spray	1.0	0.4-4.0	1 x 10-40 µg nasally

t_{max} = time to maximum plasma concentration; $t_{½}$ = elimination half-life.

3C.3.6 ***Emerging operations***

3C.3.6.1.2 Efficacy

Table S.7: Results of intra-prostatic ethanol injections for treating BPH-LUTS or BPO in men refractory to medical treatment or in urinary retention

Trials	Duration (weeks)	Patients (n)	Change in symptoms (IPSS)		Change in Q_{max}		Change in PVR		Change in prostate volume		LE
			Absolute	%	mL/s	%	mL	%	mL	%	
Goya et al. 1999 [16]	12	10	-10.9[a]	-47	+5.1[a]	+64	-79.8[a]	-62	-2.1	-4	3
Savoca et al. 2001 [17]	24	8	-11[a]	-52	+5[a]	+46	-103[a]	-79	n/a	n/a	3
Ditrolio et al. 2002 [18]	52	15	-16.5	-74	+6.2	+109	n/a	n/a	-21.6	-45	3
Plante et al. 2002 [19]	52	5	-9.6[a]	-41	+3.2	+32	-7.6	-6.4	-15.8[a]	-30	2b
Chiang et al. 2003 [20]	12 (24)	11	-9.2[a]	-52	+8.2[a]	+155	-203.2[a]	-88	-2.2	-5	3
Goya et al. 2004 [21]	156	34	-8.7[a]	-40	+4.4[a]	+65	-65[a]	-70	+2.1	+4	3
Grise et al. 2004 [22]	52	115 (94)	-10.3[a]	-50	+3.5[a]	+35	n/a	n/a	-7.4[a]	-16	2b
Mutaguchi et al. 2006 [23][†]	64	16	Spontaneous voiding in 87.5% Mean PVR 60 mL	-19.7[a]	-34	3					
Larson et al. 2006 [24]	52	65	-9.4[a]	-44	+2.8[a]	+33	n/a	n/a	n/a	n/a	3
Plante et al. 2007 [25]*	24	79	-10.6 to -13.4[a]	-47 to -55	+3.2 to +8.1[a]	+37 to +94	-1.2 to -27.3[a]	-1 to -26	-5.6 to -11.2[a]	-13 to -25	2b
Magno et al. 2008 [26]	52	36	-13.3[a]	-47	+9.2[a]	+154	-286.4[a]	-99	-12.7	-19	3
Sakr et al. 2009 [27]	208	35	-12.1[a]	-55	+11[a]	+186	-32.6[a]	-47	-2.8[a]	-5	3

Absolute and relative changes compared with baseline are listed with regard to symptoms (IPSS), maximum urinary flow rate (Q_{max}), post-void residual urine (PVR), and prostate volume.

*[a] = significant compared with baseline (indexed whenever evaluated); [†] = patients with urinary retention; * = three study arms comparing transurethral, transrectal and transperineal injections.*

*3C.3.7 **Minimal invasive simple prostatectomy***

Table S.8: Key studies on laparoscopic and robot-assisted simple prostatectomy. Mean values of variables are provided.

Study	Method	N	Change in IPSS	Change in Q_{max} (ml/s)	PV (mL)	Operative Time (min)	Blood loss (mL)	Catheter time (Days)	Hospital stay (Days)
Asimakopoulos [28]	LSP	626	Range from -10.9 to -23.2	Range from 11.0 to 20.7	107	118	314	5.1	5.0
Vora [29]	RASP	13	-12.9	14.8	NA	179	219	8.8	2.7
Matei [30]	RASP	35	-19.0	12.3	107	186	121	7.4	3.2
John [31]	RASP	13	NA	23*	NA	210	500	6.0	6.0
Uffort [32]	RASP	15	-15.7	NA	71	129	139	4.6	2.5

**Only postoperative Q_{max} was available.*
LSP: laparoscopic simple prostatectomy; PV: prostate volume; RASP: robot-assisted simple prostatectomy

*3C.3.8. **Prostatic Urethral Lift***

Table S.9: Summary of studies on prostatic urethral lift.
Data are shown as mean changes and percent changes (where reported), statistical significant changes are depicted in bold values

Study	n	IPSS / AUASI		IIEF-5 /SHIM		MSHQ-EjD		MSHQ-bother		Q_{max}	
		m(A,B,C)	12 m	m(A,B,C)	12 m	m(A,B,C)	12 m	m(A,B,C)	12 m	m(A,B,C)	12 m
Chin [33]	64	- 9.4A (-42%)	- 10.4 (-46%)	1.6C (9%)	1.8 (10%)	1.7C (16%)	0.2 (2%)	- 0.8C (-51%)	- 0.7 (-48%)	3.8A (45%)	2.6 (32%)
McNicholas [34]	120	- 8.2A (-36%)	- 12.3 (-52%)	NA	NA	NA	NA	NA	NA	3.7A (38%)	4.0 (51%)
Roehr-born [35]	206	- 4.1A (-17%)	- 10.8 (-49%)	*0.1D (0.8%)	NA	*2.2D (25%)	NA	*-0.8D (-33.3%)	NA	4.4D (64%)	4.0 (59%)
Woo [36]	19	- 8.1A (-37%)	- 8.6 (-39%)	NA	NA	NA	NA	NA	NA	2.4A (32%)	2.5 (34%)
Woo [37]	64	- 14.1C (-62%)	- 10.4 (-46%)	1.6C (9%)	1.7 (10%)	1.7C (16%)	0.2 (2%)	- 0.8C (-51%)	- 0.7 (-48%)	n	N

IPSS=International Prostate Symptom Score; AUASI=American Urological Association Symptom Index; IIEF-5=International Index of Erectile Function; SHIM= Sexual Health Inventory for Men; MSHQ-EjD=Male Sexual Health Questionnaire-Ejaculatory Dysfunction; MSHQ-bother=Male Sexual Health Questionnaire-Bother; Q_{max}=peak urinary flow rate [mL/sec]; NA=not available; m=months; A=0.5, B=1, C=1.5, D=3
**= no significant difference compared to sham*

3C.3.9. ***Patient selection***

Table S.10: Speed of onset and influence on basic parameters with conservative, medical or surgical treatment modalities for the management of non-neurogenic male LUTS

Treatment	Speed of Onset	LUTS (IPSS)	Uroflowmetry (Q_{max})	Prostate size	PVR	Disease progression
Conservative and drug treatments						
Watchful waiting, behavioural treatment	months	+ (-1.3 to -5.7 points)	-	-	-	?
α_1-adrenoceptor antagonists	days	++ (-31 to -48.2%)	++ (+1.4 to +3.2 ml/s)	-	- / + (-17 to -39%)	+++ (symptoms)
5α-reductase inhibitors	months	+ (-13.3 to -38.6%)	++ (+1.4 to +2.2 ml/s)	+ - ++ (-15 to -28%)	-	+++ (retention)
Muscarinic receptor antagonists	weeks	++ (storage symptoms)	- (-35.3 to -54%)	-	+ (0 to +49ml)	?
PDE5Is (tadalafil)	days	++ (-17 to -37%)	- / +	-	- / + (+9 to -19 ml)	?
α1-adrenoceptor antagonists + 5α-reductase inhibitors	days	++ (-38 to -49.7%)	++ (+2.3 to 3.8 ml/s)	+ - ++ (-11.9 to -27.3%)	- / +	+++ (symptoms + retention)
α1-adrenoceptor antagonists + muscarinic receptor antagonists	days	++ (-31.8 to -66.4%)	++	-		?
Surgical treatments	After catheter removal					
TURP–TUIP	hours	++++ (-63 to -88%)	++++ (+6.9 to 22.9 ml/s)	+++	++++	++++
Open prostatectomy	hours	++++ (-62 to -86%)	++++ (+7.0 to +21.4 ml/s)	++++ (-88%)	++++ (-86 to -98%)	++++
TUMT	weeks	+++ (-40 to -87%)	+++ (+2.4 to 8.4 ml/s)	++ (-8.1 to 33.0%)	++ (-34 to -84.1%)	+++
TUNA™	weeks	+++ (-45 to -56%)	+++ (+4.7 to 6.5 ml/s)	++	+ (-20 ml or -22%)	++
HoLEP/HoLRP	hours	++++ (-66 to -92%)	++++ (+10.9 to 23.0 ml/s)	++++ (-34 to -54%)	++++ (-68 to -98%)	++++
KTP/Greenlight	days	+++ (-31 to -75%)	+++ (+4.7 to 14.9 ml/s)	+++ (-44 to -63%)	+++ (-57 to -91%)	+++
Diode laser	hours	+++ (-55 to -84.3%)	+++ (+5.1 to 13.7 ml/s)	+++ (-30.3 to -58.1%) PSA based reduction	+++ (-58.1 to -87.7%)	+++

Thulium LaserThuVaP, ThuVaRP, and ThuVEP	hours	+++ (-63 to 85.4%)	+++ (+12.8 to 18.7 ml/s)	+++ (-35.7 to -88%) PSA based reduction	+++ (-72.4 to -94.4%)	+++
Prostate stents	hours	++ (-10 to -19 points)	++ (+3 to 13.1 ml/s)	-	+++	?

- no influence; + mild influence; ++ moderate influence; +++ strong influence; ++++ very strong influence; ? unknown

BTX: Botulinum Toxin; HoLEP: Holmium Laser Enucleation of the Prostate; HoLRP: Holmium Laser Resection of the Prostate; IPSS: International Prostate Symptom Score; KTP: K+-titanyl-phosphate, "greenlight" laser vaporization; LUTS: Lower Urinary Tract Symptoms; PDE5I: phosphodiesterase 5 inhibitor; PVR: Post-Void Residual urine; ThuVaP: Tm:YAG vaporization of the prostate; ThuVaRP: Tm:YAG vaporesection; ThuVEP:Tm:YAG vapoenucleation; TUMT: Transurethral Microwave Therapy; TUNA™: Transurethral Needle Ablation; TUIP: Transurethral Incision of the Prostate; TURP: Transurethral Resection of the Prostate.

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