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Testosterone Prescribing in a New Irish Specialist Menopause Clinic

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Abstract

Aim

The primary indication for testosterone therapy in women is hypoactive sexual desire disorder (HSDD). There is currently no licensed testosterone product for women in Ireland. I aimed to evaluate testosterone prescribing based on the 2022 BMS Testosterone Guidelines.

Methods

Patients "ever" prescribed testosterone from April 2021-June 2022 were selected.

Results

277 (11.7%) patients. Mean age 52 +5.96. Testogel was prescribed for 97.8% (271), Androfeme 1.8% (5) and Tostran 2% gel (1). Documented clinical indications were HSDD 73.2% (203), brain fog 18.8% (52), exhaustion 21.6% (60). 79% (219) patients received a HRT trial prior to Testosterone initiation with 54.9% (152) co-prescribed vaginal oestrogen. Total testosterone before treatment 0.47 (FAI = 0.8), 6 weeks on treatment 2.7 (FAI = 3.9), 6 months on treatment 2.7 (FAI = 2.4). 21.3% (59) required dose adjustments. 35% (97) had documented symptom improvement. 9.39% (26) discontinued testosterone. 7.58% (21) reported side-effects.

Discussion

Variable symptom benefit was noted despite an overall increase in testosterone levels compared with baseline. One-fifth of patients required dose reductions. Side-effects were noted infrequently. Highlights the need for a cost-effective female specific product for accurate dose administration.

Methods

I evaluated the use of testosterone in our new clinic (Menopause Health, based in Dalkey, Co. Dublin) with the Guidelines from the Global Consensus Position Statement on the Use of Testosterone Therapy for Women(2) and the BMS Testosterone Guidelines (1). A chart review was done of all patients registered in our clinic. The Socrates report tool was used to generate a list of patients "ever" prescribed testosterone containing products from the opening of the clinic April 2021 to June 2022 when the review was carried out. Patients in the practice are prescribed 1/10th of the standard measured dose of the male HRT product "Testogel", used daily. 4 main outcome measures were looked at from these new guidelines:

1. Indications for testosterone prescribing and products used.
2. Proportion of patients prescribed testosterone that received a trial of HRT initially and were treated for vulvovaginal atrophy.
3. Proportion of patients that had testosterone levels monitored and required dose-adjustments.
4. Proportion of patients reporting benefits/side-effects/discontinued.

Results

Demographics: 11.7% (277) of our total patient cohort of 2377 patients were selected to be or have been prescribed testosterone between April 2021 and June 2022 in the clinic. The mean age of patients audited was 52, with a range of 25-70. 23.8% had a documented significant gynaecological history; POI (4%, 11), early menopause (4.7%, 13), hysterectomy+/- BSO (11.6%, 32), BSO (3.2%, 9), oophorectomy (0.4%,1).

Testosterone Products: Testogel was prescribed for 271 patients (97.8%), Androfeme 5 patients (1.8%) and Tostran 2% gel (1 patient). Product price ranged from approx €12/month (Testogel), €30/month (Androfeme), €90/month (Tostran) in our local Dalkey pharmacy.

Main Outcome Measure 1: The first main outcome measure of the audit looked at the indication for testosterone prescribing. (Figure 1) The primary documented clinical indication for prescribing in the clinic were HSDD (73.2%), brain fog (18.8%) and exhaustion (21.6%) 9.7% were prescribed testosterone for "other" reasons, namely: Low mood, poor concentration, myalgia, cognition, sleep, forgetfulness. There is significant overlap between the groups with 25% of patients having 2 or more symptoms. Indication was not documented in 17.3% of patient files.

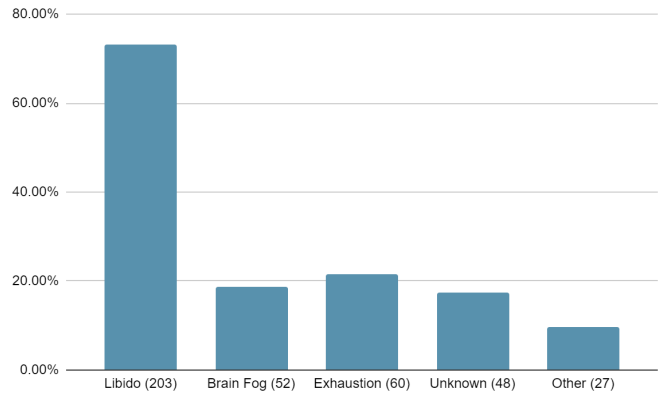

Fig. 1: Indications for Testosterone Prescribing

Main Outcome Measure 2: The second main outcome measure of the audit looked at whether patients received a trial of conventional HRT before testosterone therapy was initiated and whether vulvovaginal atrophy was treated. 79% of patients received a trial of conventional HRT prior to

Testosterone initiation with 54.9% co-prescribed vaginal oestrogen. *16.2% (45) of patients commenced testosterone elsewhere which affects our data.* At the time of the audit almost 80% of patients were taking combined HRT with testosterone. 6.3% of patients were prescribed testosterone on its own with 8.3% taking oestrogen and testosterone only (Fig 2).

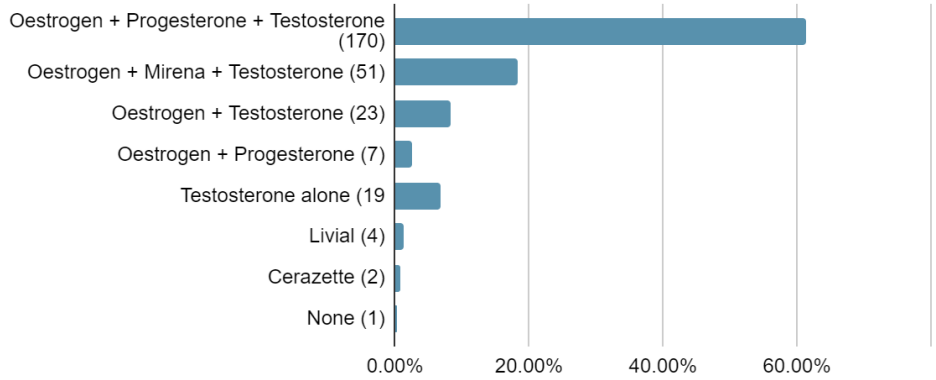

Fig. 2: Medications Prescribed to patients at the time of review

Main Outcome Measure 3: The third main outcome looked at was around the monitoring that was done of total testosterone levels (Table 1). Baseline bloods, 6/52 and then 6 monthly bloods are recommended by the recent BMS guidelines. 19.5% of patients had testosterone levels done before testosterone initiation. 46.9% had bloods done at 6/52 and 22% at 6 months. 84.7% of patients attended for repeat bloods 6/52 after a dose change was recommended. Many patients had not yet reached the 6 week or 6 month treatment duration or unfortunately were lost to follow up and therefore had no bloods done which affects these figures. But overall it was very clear that we were having difficulties getting patients to comply with bloods to allow us to monitor testosterone levels on an ongoing basis.

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	Yes	No	Unknown / too early
Bloods done pre Testosterone therapy (277)	19.49% (59)	64.3% (178)	16.2% (40)
	46.9% (108)	38.3% (88)	14.8% (34)
Bloods done after 6/52 (230)	22% (40)	32% (58)	45.9% (83)
Bloods done at 6/12 (181)	84.7% (50)		
Bloods done 6/52 post dose change (59)			

Table 1: % of patients that attended for recommended blood monitoring

Normal physiological levels for our lab are FAI <5, Total testosterone <2. Baseline total testosterone levels before treatment 0.47 (0.09-1 Range), FAI = 0.8. Total testosterone levels after 6 weeks of testosterone treatment = 2.7 (0.4-11.96 Range), FAI = 3.9. Total testosterone levels 6 months after treatment = 2.7 (1.1-3.39 Range), FAI = 2.4.

		Average	Range	N =
BEFORE	**Total Testosterone**	**0.47**	0.09-1	5
	FAI	0.8	0.09-2.8	54
6/52 AFTER	**Total Testosterone**	**2.7**	0.4-11.96	N = 100
	FAI	3.9	0.4- 16	N = 76

6/12 AFTER	**Total Testosterone**	**2.7**	1.1-3.39	N = 3
	FAI	2.4	0.5- 14	N = 51

Table 2: Total testosterone + FAI levels before and during testosterone treatment

At the time the study was initiated FAI levels were widely used by menopause specialists in Ireland, however, following the BMS 31st Annual scientific conference, which took place June/July 2022, I then changed the focus of my study to reflect best practice. Total testosterone levels were now used within the practice to monitor testosterone treatment and patient safety. FAI is felt not to be a great indicator of what is happening at an intracellular level (3)

Dose adjustments were required in 59 (21.3% of patients). 13.4% (37) reduced to alternate days, 2.5% (7) reduced to 2-3 times a week, 2.5% (7) stopped treatment, reduced to once a week (1), increased dose (2), pt uncontactable (2).

Main Outcome Measure 4:
The final main outcome measure looked at side-effects and treatment discontinuation. Symptom improvement was documented for 97 (35%), with 17.3% finding a "good" improvement and 7.6% noticing a "slight" improvement. No improvement was documented for 10.5% (29) and 65% (180) had no outcome documented. 26 (9.39%) of patients discontinued their medication and 21 (7.58%) reported side-effects (hair excess, worsening of symptoms, joint aches + pains, hair loss, abdominal pains, acne, worried about high-costs).

Discussion

Variable symptom benefit was noted despite an overall increase in FAI levels compared with baseline; 0.47 total testosterone before to 2.7 after. Poor patient compliance with follow up bloods was apparent. Documentation in the clinic needs improvement with consideration for use of symptom scores such as the Female Sexual Function Index. One-fifth of patients required dose reductions but reassuringly side-effects were noted infrequently. This review highlights the need for a cost-effective female specific product for accurate dose administration. Further research in this interesting area is required.

Declarations of Conflict of Interest:
None declared.

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