Over 90% of male patients (pts) with breast cancer (BC) have a functional estrogen receptor (ER) positive BC. Although tamoxifen, as recommended as standard of care, there is a lack of data regarding efficacy and safety in older men. Endocrine therapy (primary or as alternative) due to small incidence of male BC therapy, strategies are extrapolated from principles established for the treatment of female BC and no prospective randomised studies in male BC pts has been conducted so far. The study is the first prospective, randomized, multicenter trial presenting data on the efficacy and safety of different endocrine treatment options in male BC pts. Materials and Methods

In the phase II trial Male BC (NCT19368247), pts were randomized to receive either tamoxifen 20 mg/day p.o. + GnRH analogue (a) subcutaneous (s.c.) q14m or exemestane 25 mg/day p.o. + GnRH analogue s.c. for 6 months (neo)adjuvant or metastatic therapy (see Figure 1). Primary objective was the 17-estradiol (E2) suppression in the 3 treatment arms after 3 months therapy. Secondary objectives were: decreased estradiol suppression after 6 months, compliance and safety of the three therapies, the level of different steroid hormones (testosterone, 17b-estradiol, DH, SHBG, LH; FSH) after 3 cycles of the study. SHBG level was found to be within 10% in the group B. The study was sponsored and supported by GBG and the Claudia von Schilling Foundation.

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Category</th>
<th>A (tamoxifen)</th>
<th>B (tamoxifen + GnRHa)</th>
<th>C (exemestane)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH</td>
<td>Median</td>
<td>0.4 (0.3)</td>
<td>0.5 (0.4)</td>
<td>0.5 (0.4)</td>
</tr>
<tr>
<td>FSH</td>
<td>Median</td>
<td>3.6 (3.0)</td>
<td>5.2 (3.4)</td>
<td>3.8 (3.4)</td>
</tr>
<tr>
<td>Testosterone</td>
<td>Median</td>
<td>0.8 (0.6)</td>
<td>1.6 (1.0)</td>
<td>0.9 (0.6)</td>
</tr>
</tbody>
</table>

Figure 2: Changes in E2, absolute values between BL + 3 months

Figure 3a: Changes in LH and SHBG, absolute values between BL + 3 months

Conclusions

We describe for the first time hormonal parameters in male BC pts receiving antihormonal therapy in a prospective, randomised setting.

Overall, the results reflect the expected changes of the hormonal parameters. GnRH-a + tamoxifen (arm B) or + exemestane (arm C) led to a comparable reduction in LH/L isolation and LH decrease in arm C, but also significant LH and LH decrease in the GnRH-a group. E2 decrease in arm C and SHBG decreases in arms B and C. Testosterone and SHBG values under therapy are shown in figure 5a.

References

3. Leder B et al., Clin Endocrinol 2006;64:1162–1169.