We observed that groups who received GAHT were more likely to be diagnosed with chronic pain than those who did not. Cox proportional hazards models revealed a 21.4% (HR 1.214, 95% CI: 1.093, 1.348) increased hazard for TMHT vs TMNI and 14.0% (HR:1.140, 95% CI: 1.009, 1.289) for the TWHT vs TWNI groups. (Table 1, Fig. 1)

Conclusion: Our study indicates a significant association between GAHT and the likelihood of chronic pain diagnosis in transgender individuals, both in patients receiving testosterone and those receiving estrogen. It should be noted that our propensity score matching cannot fully eliminate unmeasured or residual confounding. Additional limitations include potential undercounting of both trans patients and chronic pain due to the lower sensitivity, high specificity ICD-10 codes we chose, and potential access-related disparities in healthcare for transgender populations resulting in undercounting in measured covariates. Further research is required to better understand causal mechanisms and to improve screening and management of chronic pain in trans populations. Our next step will be to further characterize the full range of factors contributing to chronic pain in transgender patients.

SAT-B2-T4: BICALUTAMIDE USE AS ANTIANDROGEN IN TRANS FEMININE ADULTS - A SAFETY PROFILE

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Presented by: Kristen Vierregger

Introduction/Background: Bicalutamide is a non-steroidal anti-androgen (NSAA) approved for use for treatment of metastatic prostate cancer (MPC) by the FDA in 1995. An antagonist at the androgen receptor (AR), it binds to cytosolic ARs, inhibiting androgenic effects in target tissues. Androgen deprivation is a clinical goal in trans feminine (TF) gender-affirming hormone therapy (GAHT), though bicalutamide use has been limited in this clinical setting by lack of data substantiating its safety in this patient population.

In 2019, Neyman et al., reported a small study of TF adolescents (n=23), in which oral bicalutamide 50 mg daily was shown to be safe, effective, and a more affordable option for patients unable to access GnRH agonists for androgen suppression. Citing specific concern for bicalutamide's hepatotoxicity risk, including fulminant liver failure leading to death, and the lack of literature investigating its use in TF patients, the World Professional Association (WPATH) Standards of Care v8 (2022), "do not recommend [bicalutamide's] routine use."

Bicalutamide is currently used off-label to treat other androgen-dependent disorders, with 13 published case reports of its use in male precocious puberty, 7 in hirsutism in cisgender women with PCOS, 4 in female pattern hair loss, and 2 in minoxidil-induced hypertrichosis in female pattern hair loss. Though authors of each of these studies were aware of its hepatotoxic potential, none observed it in their cohorts.

There are 9 published case reports of bicalutamide-induced liver injury since 1995, each occurring within 6 months of starting the drug; 7 patients survived upon drug withdrawal and 2 died. Despite this, bicalutamide is considered "generally safe" by the WHO and remained the standard of care for MPC until it achieved generic status in 2011 and newer generation AAs became available.

Specific Aim: We present our findings to specifically address WPATH's concerns that insufficient data exists to consider bicalutamide's inclusion in TF GAHT. We hope to pool our data with clinics using bicalutamide for TF GAHT to lend power to the study and increase confidence in inclusion/exclusion determination.

Materials and Methods: Approval was obtained from University of California Irvine's IRB for a retrospective chart analysis of the electronic health records from one gender-affirming clinic to compare transaminase levels (AST and ALT) over time in TF patients prescribed oral bicalutamide 25 mg daily as part of TF GAHT from 2016-2022. Data was deidentified and imported into Python for analysis.

Results: We report 231 patients with AST and ALT serum levels taken within 6 months of oral bicalutamide 25 mg daily initiation and at specific intervals thereafter, with 143 followed to 24 months. No elevation in AST or ALT, defined as 3x the laboratory's upper reference limit, were reported in any patient in any interval up to 24 months follow up.

Conclusion: Our results support broader evidence acknowledging bicalutamide-induced liver injury as a rare adverse event — but one that should not preclude its use. With adherence to recommended precautions - careful patient selection, education regarding early signs of liver toxicity, and laboratory monitoring - this clinic's data favorably support bicalutamide's consideration for inclusion in TF GAHT.

SAT-B2-T5: TESTOSTERONE'S IMPACT ON CERVICAL CANCER SCREENING, BY THE NUMBERS

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Presented by: Derek Chen

Introduction/Background: The Papanicolaou (Pap) test, also called cervical cytology, is an effective and widely used screening procedure for detection of cervical cancer (CC). Although CC screening is recommended for all patients with a cervix between the ages of 21-65, current approaches for CC screening have not accounted for the unique circumstances of transgender individuals. Three studies, to date, have found that transgender individuals on testosterone therapy are more likely to have unsatisfactory cervical cytology results due to atrophic changes of the cervix in the setting of suppressed estrogen (a side effect of testosterone therapy). Additional evidence is needed to demonstrate the need for revised guidelines and approaches for CC screening among transgender patients using testosterone for gender affirming therapy.

Specific Aim: To assess the frequency of inadequate and/or atrophic cervical cytology specimens among transgender patients undergoing testosterone therapy and determine the frequency of need for repeated specimen collection to render a cytologic result.

Materials and Methods: Design and Analysis: Retrospective chart review. Number of available Pap results varied by patient, so all Pap results were pooled. Chi-square and t-tests were used to compare results between testosterone-associated Pap specimens (TAPS) and non-testosterone specimens (NTS). Setting: Primary care clinics from the Oregon Health and Science University system. Population: Medical chart reviews of 213 patients identified as transgender patients with a cervix between 2012 and 2019 at one of the primary care clinics. Transgender individuals were identified using sex at birth, legal sex, gender identify, organ inventory, and gender dysphoria diagnostic codes. Outcome Measures: Primary outcome was quality of specimen (transformation zone present, transformation zone absent, atrophic specimen, scant cellularity). Secondary measures include presence of inflammation (yes/no) and Pap results (normal/abnormal). Testosterone therapy status prior to Pap test was noted in chart. CC screening results between January 2012 and December 31 2022 were collected.

Results: Results: 304 unique Paps were included. Average age of patients with TAPS and NTS results was 30 years old. TAPS (n=132) were more likely to lack cells from the cervical transformation zone, demonstrate scant cellularity, or be described as atrophic than NTS (56.1% vs 32.6%; $p<.001$, respectively). Among TAPS 5.3% had scant cellularity and 27.3% had atrophic characteristics; none of the NTS had these characteristics. TAPS were also more likely to show signs of inflammation (12.1% vs 3.5%; $p<.01$), even when atrophic or scant-cellularity specimens were excluded (11.2% vs 3.5% $p<.05$).