Biological Treatment of Individuals with Paraphilias and/or Sexual Disorders

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Outline

- Suggest relevant literature
- Review evidence base for biological treatment
- Present details of best studies
- Present information on current treatment
- Case report
- Ethical considerations
- Future directions
Background

- Employed by the New York State Office of Mental Health (NYS OMH) to consult on the treatment of sexual offenders x 20 years
- Developed anti-androgen protocol and informed consents for OMH to be used for Sexual Offender Management and Treatment Act (SOMTA)
- Completing small research project on medication outcome and acceptance in sample of individuals treated for paraphilias and hypersexual disorders
- Unsuccessfully pursued funding for 20 years for pharmacological studies
Literature


Limited Evidence Base

- Kenworthy et al. in Psychological interventions for those who have sexually offended or are at risk of offending (Review), (which included drug studies for comparison) consulting for the Cochrane Database of Systematic Reviews, 2003, found only 9 randomized controlled studies.

- Contrast with randomized, controlled studies for depression, schizophrenia, where easily 20 or 30 or more exist for various compounds.

- Contrast with, for instance, recently published APA Practice Guidelines for the Treatment of Patients with Substance Use Disorder, Second Edition, 2006, representing past 10 years where there are 1789 references.

- CRISP
Limited Evidence Base

- In United States, National Institute of Health (NIH) has not wanted to fund anything to do with criminal behavior
- National Institute of Justice (NIJ) has not felt capable of funding biological studies
- Drug companies do not want to be associated with deviant sexual behavior
- For instance with SRIs, targets would be to reduce sexual interest, arousal, and activity
- Not commercially viable
- Problems with randomized controlled design where an outcome measure would involve victimization of another
- Criminal populations or “deviant” populations not welcome in many medical center
Biological Treatment

- Androgen Reduction Therapy (ART)
  - Castration
  - Estrogen
  - Progesterone
  - Cyproterone acetate
  - Gonadotropin releasing hormone agonists
- Serotonin Reuptake Inhibitors (SRI)
- Other Agents
Androgen Reduction Treatment (ART)- Animal Studies

- Castration of rats
  - Loss of sex drive & mating behavior
  - Restore with testosterone
- Rats, dogs, other species
  - Castration results in reduction of ejaculation, intromission, mounting in males
Androgen Reduction Treatment (ART) - Primates

- Dixson (1998) *Primate Sexuality*
  - Chemical or physical castration in primates
  - Studied in 6 species
  - Attenuated sexual functioning uniformly demonstrated
  - Reversible with testosterone
- Castration of adult male rhesus monkeys
  - 2-4 weeks decreased frequency of ejaculation, intromission, mounting
  - Marked individual variability; 5 of 10 intromission at one year
- Loy (1971) reported function in castrated rhesus 7 years later
Androgen Reduction Treatment (ART)-Kinsey

- Kinsey (1953)
  - Reviewed literature
  - Large variability in effects of procedure
  - One male studied married and normally sexually active 30 years after castration
  - At 50 years of age 7% of males impotent and sexually unresponsive
  - Concluded that castration would not necessarily protect the public
Androgen Reduction Treatment (ART)-Human Studies

- 17 Studies identified
- Czechoslovakia, Denmark, Germany, The Netherlands, Norway, Sweden, Switzerland, Sweden, and the United States
- Many problems: issues with consent, design, follow-up
- Suggest substantial effect: Langeluddeke in Germany; 1036 vs. 685; 6 weeks to 20 yrs; recidivism 2.3% compared with 39.1%
- In the United States, 9 states allow it currently; effectively it cannot be done without some patient acquiescence, if not consent
- Texas has done this to three inmates; 10 year follow-up
- Very popular among politicians
- Doesn’t solve any problems—can’t forget about sex offenders who have been treated with castration
Androgen Reduction Treatment (ART)-Estrogen

- The first study was published in 1949 by Golla & Hodge in the Lancet; used after physical castration for cancer therapy
- 13 patients
- Reduced testosterone through negative feedback effect
- Further studies by Whittaker (1959) and Bancroft et al. (1974)
- Numerous side effects
  - Nausea
  - Weight gain
  - Feminization
  - Breast cancer
  - Cardiovascular and cerebrovascular ischemic disease
  - Thromboembolism
- Thibault et al. WFSPB report (2010) stated frankly “They must not be used in sex offenders or subjects with paraphilia (No level of evidence and major side effects)”
Androgen Reduction Treatment (ART)-

- Medroxyprogesterone acetate (MPA) is a progesterone derivative which acts like testosterone
- exerts negative feedback on the hypothalamo-pituitary axis, resulting in decreases in both GnRH and LH release
- induces testosterone-alpha-reductase, which accelerates testosterone metabolism and clearance
- increases testosterone binding to testosterone hormone-binding globulin (TeBG), which reduces availability of free testosterone
- may also bind to androgen receptors
- currently used as contraceptive, for endometriosis, or breast cancer
- available as intra muscular depot preparation (150 or 400 mg/ml) (300-500 mg/wk) or per os (2.5, 5 or 10 mg) (50-100 mg/day)
Androgen Reduction Treatment (ART)- Progesterone

- First report of efficacy in reducing sexual drive in healthy males was by Hell et al. (1958)
- Money (1968) reported its first use in case report of one paraphilia
- More than 600 cases including 12 case reports on 23 subjects and 13 open or controlled studies (including 3 double-blind cross-over studies)
  - 100 men accused of sexual assault and referred to a forensic clinic
  - 48 completed assessment
  - 18 agreed to participate in drug trial
  - Only 11 completed 3 month course of MPA or placebo therapy
Androgen Reduction Treatment (ART)-Progesterone

- Adverse effects included weight gain, headache, nausea, asthenia, gynecomastia, lethargy, insomnia, leg cramps, increased blood pressure, diabetes, gallstones, Cushing Syndrome, thromboembolism, pulmonary embolism

- Led Thibault et al. WFSPB report (2010) to say that the benefit/risk ration did not favor use of MPA, which “was abandoned in Europe”

- Still used in United States and Canada; quite inexpensive

- The Oregon depo-Provera Program; Maletsky, Tolan, McFarland (2006)

- State law providing for the evaluation of all individuals convicted of sex offense before release into community

  - 5 year follow-up; 275 men evaluated for ART
    - 79 evaluated, recommended and received-0% sexual recidivism
    - 55 evaluated, recommended and did not receive-18% sexual recidivism
    - 141 evaluated, not recommended-14% sexual recidivism
Androgen Reduction Treatment (ART)-
Cyproterone Acetate (CPA)

- Synthetic steroid, similar to progesterone, acts both as progesterone and antiandrogen
- Direct CPA binding to all androgen receptors (including brain receptors) blocks intracellular testosterone uptake and metabolism
- CPA is a competitive inhibitor of testosterone and DHT at androgen receptor sites
- It inhibits GnRh secretion and decreases GnRh and LH release
- It is used predominantly in Canada, but also the Middle East and Europe and is registered in more than 20 countries for the moderation of sexual drive in adult men with sexual deviation as well as for inoperable prostate cancer, precocious puberty, or hirsutism
- can be given by injection 100 mg/ml, 200-400 mg weekly or every 2 weeks, or as tablets, 50 to 100 mg, 50-200 mg/day
- It is not available in the United States (which was erroneously reported in the WFSBP guidelines)
Androgen Reduction Treatment (ART)-Cyproterone Acetate (CPA)

- First report of CPA in sex offenders was in Germany (Laschet and Laschet (1967, 1971) in an open study
- 1 case report of a female with compulsive masturbation and sexual aggression and 9 case reports of 14 other patients
- 10 open and double- or single-blind cross over studies of 900 male subjects; 20% of cases pedophilic
- WFSPB concluded that most of these studies were not well controlled, some biases were observed (small sample size, short duration of follow-up, cross-over studies, and retrospective studies)
- Overall WFSPB put CPA into a level C category, where “there is minimal research-based evidence to support this recommendation.”
- Additionally, some severe side effects were observed with CPA, including depression, hot flashes, leg cramps, hypogonadism, bone mineral loss, thrombo-embolism, hypertension, kidney dysfunction, pituitary dysfunction, hepatocellular damage, including fatal hepatic necrosis (rare)
Androgen Reduction Treatment (ART)-
Gonadotropin Releasing Hormone (GnRH) Analogues

- WFSPBP noted that “MPA and CPA have shown inconsistent results in the treatment of sex offenders.” GnRH analogues alternatives
- Widely used and indicated for treatment of prostate cancer, endometriosis, premature onset of puberty, and some other cancers
- GnRH agonist treatment has essentially replaced castration, estrogen, progesterone treatment for prostate cancer
- They are analogues of GnRH, a decapeptide, with substitution at the 6 position
- They act at level of pituitary to stimulate LH release initially, which results in transient increase in serum testosterone (flare)
- After initial stimulation, continuous administration obliterates cyclical nature of release and results in desensitization of GnRH receptors, resulting in decrease in LH (and FSH) and secondarily testosterone to castrate levels within 1 to 2 weeks (WFSPBP says 2 to 4, but it is faster)
- Normals report decreased sexual desire; GnRH intracerebrally suppresses aggression in male rate
Table 55–3

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<td>Deslorelin</td>
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Abbreviations: N-EtNH₂, N-ethylamide; tBu, t butyl; d-Nal (2), 6-[3-(2-naphthalenyl)-d-alanine]; ImBzl, imidobenzyl.

Source: Conn and Crowley, 1991. Used with permission.
Androgen Reduction Treatment (ART)-
Gonadotropin Releasing Hormone (GnRH) Analogues

- Three analogues of GnRH available
  - Triptorelin (3.75 mg/1 month; 11.25 mg/3 month); recently approved in Europe for treatment of “extreme sexual deviation” in males
  - Leuprorelin (3.75 mg/1 month; 11.25 mg/3 month)
  - Goserelin (3.6 mg/1 month; 10.8 mg/3 month)
- In treating cancer patients, there was an initial increase in testosterone, there was often a “tumor flare” with increase in tumor markers
- Counteracted by peripheral testosterone blockers, such as flutamide or bicalutamide, oral nonsteroidal antiandrogen which compete with androgen receptors
- Given for a month; risky side effects
- Initially used in studies with individuals with paraphilias; not recommended by some authorities; but WFSBP guidelines suggest androgen blockade
Androgen Reduction Treatment (ART)-
Gonadotropin Releasing Hormone (GnRH) Anologues--Studies

- Uncontrolled observational study, prospective
- 30 men, mean age 32 years
- Severe long-standing paraphilia (25 with pedophilia and 5 with other paraphilias)
- 3.75 mg of triptorelin and supportive psychotherapy for 8 to 42 months
- Intensity of Sexual Desire and Symptoms Scale; a further iteration of the Bancroft Sexual Interest and Activity Scale
- All men had decrease in deviant sexual fantasies
- No one reoffended while on medication; several when off
- Now expanded to 100 men over 15 years (2010)
### Frequency of sexual thoughts

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Please indicate how often you find yourself thinking sexy thoughts by marking the above line in the appropriate place. Mark between numbers if this seems indicated.

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### Sexual Activity Scale

How many times has masturbation or any overt sexual act resulted in orgasm over the past seven days?

Indicate number: _______
Androgen Reduction Treatment (ART)-
Gonadotropin Releasing Hormone (GnRH)
Analogues—Intensity of Sexual Desire and
Symptom Scale-Instructions

“The Intensity of Sexual Desire and Symptoms Scale was used to assess three types of behavior. To assess sexual interest and desire, the men were asked to indicate the nature, intensity, and the frequency of their sexual thoughts and desires in the preceding month (ranging from no sexual thoughts to very frequent sexual thoughts with intense sexual urges). To assess sexual activity, the men were asked about the number of times per week they masturbated, the number of times they engaged in any overt acts that resulted in orgasm, and the nature and number of incidents of abnormal sexual behavior in the previous month. To assess sexual fantasies, the men were asked to imagine their erotic fantasies as vividly (and for as long) as possible and to describe the object of the fantasy (child or adult; female, male, or both), the intensity (ranging from no arousal at all to maximal arousal), and the frequency (per week) during the preceding month. All three types of behavior were rated on an eight-point, scale, and the average of the three scores was used. A score of 1 indicates minimal or no sexual arousal and no deviant sexual fantasies or abnormal sexual behavior, whereas a score of 8 indicates maximal and uncontrollable arousal and abnormal sexual behavior, with all symptoms present.
Androgen Reduction Treatment (ART)-Gonadotropin Releasing Hormone (GnRH) Analogues--Studies

- 23 case reports of efficacy for all three agents
- No randomized controlled studies
- Triptorelin: 2 open prospective studies (41 subjects total) and 2 retrospective (33 subjects)
- Leuprolide: 3 open studies (26 subjects) and 1 retrospective studies (58 subjects)
- Side effects: bone mineral loss: in Rosler’s study of 18 men, who were measured, 11 had decrease in density of femoral neck or lumbar spine; two treated with oral calcium and vitamin D; bisphosphonates used; new cautions
- Other side effects: hot flashes, asthenia, nausea, weight gain (2-13%), transient pain or site reaction, decreased testicular volume, depression, gynecomastia, infertility
- Reversible; safe; only contraindication is allergic reaction
Biological Treatment-Serotonin Reuptake Inhibitors

- Several lines of evidence suggest this
- Animal models show decreased 5HT levels increase sexual appetite and increased reduced them
- SRIs effective in OCD; similarity of some sexual behaviors with OCD; Tourette’s
- Lots of comorbid anxiety and depression
- Side effects of SRIs on sexual function-3-5% in PDR; 50% and higher in other studies
Biological Treatment-Serotonin Reuptake Inhibitors

- Many case reports and series published over past 20 years; Gijs and Gooren (1996)
- No randomized controlled studies of antidepressants
- Health Technology Assessment Program at Birmingham University, UK (2002) conducted systematic review of effectiveness of SRIs for treatment of sex offenders
- 130 studies found; 9 considered acceptable for metaanalysis
- Results favorable: decreased frequency of masturbation and intensity of deviant fantasy
Biological Treatment-Serotonin Reuptake Inhibitors

- Updated literature review in WFSBP
- Only double-blind study was by Wainberg et al. (2006) was dismissed because it “was conducted in males with compulsive behavior and cannot be generalized to sex offenders.”
- However, was an excellent study and very relevant
- “A Double-Blind Study of Citalopram Versus Placebo in the Treatment of Compulsive Sexual Behaviors in Gay and Bisexual Men”
  - 28 men who had sex with men who met threshold for compulsive sexual behavior (CSB) enrolled in 12-week, double-blind trial of citalopram 20-60 mg per day
  - Sexual YBOCS, CGI-CSB, frequency of masturbation/week/hours of pornography/week
  - All favored citalopram group
Biological Treatment-Serotonin Reuptake Inhibitors

- 50-80% response rate is found in these open studies
- Dosage is the same as for other indications
- No dose finding studies
- Nothing to recommend one agent over another
- WFSBP writes “A critical analysis of all studies that involved the use of SSRIs in the treatment of paraphilias concluded that the results of psychotropic drug interventions are not favourable”-i.e. minimal research-based evidence
- Rosler & Witzum (2000) suggested effective only for men with definite OCD
- Wainberg: effect minimal
- My experience: All individuals on ART first treated with SRIs
Biological Treatment
Other Agents

- Lithium carbonate
- Tricyclic antidepressants
- Mirtazapine
- Antipsychotics
- Anticonvulsants
- Naltrexone

- Most case reports with some efficacy; some case series with some efficacy; one early (1975) placebo-controlled cross-over study comparing chlorpromazine plus benperidol and placebo for 12 weeks: no efficacy
- Weakest evidence
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Note: Program data for 2000 is based on unpublished raw data from the 2000 Survey and had previously been rounded to whole numbers.
*The change in the percentage of programs using this medication is significant at $p < .05$.
**The change in the percentage of programs using this medication is significant at $p < .01$.
***The change in the percentage of programs using this medication is significant at $p < .001$. 
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Table 9.6b Canada – Pharmacological sexual arousal control treatments, percentage
“Well, I finally got in touch with my sexuality—it’s disgusting.”
Biological Treatment Recommendations

- WFSBP proposes a 6 level algorithm
- Psychotherapy (cognitive-behavioral therapy); then SSRIs; then low dose ART or SRIs; then increase ARTs and SRIs; then GNRH agonist therapy; with treatment of flare; then add ARTs
- Problem is, lack of research supporting efficacy of this algorhythm and of dosage; seems to go against earlier recommendations
- ATSA guidelines suggest SSRIs, then ART
- New York State Guidelines for patients under SOMTA
Biological Treatment Recommendations

- My recommendations?
- Thorough assessment and risk analysis
- Individual prescription
- Least restrictive alternative; try first with SRIs and then ART
- But, if someone is dangerous or by request, may start ART
- Treatment of flare not necessary
- Careful baseline and follow-up assessment
- Consult PDR or recent drug information at all times
- Case series of 17 patients treated with first SRIs and then ART administered Medication Satisfaction Questionnaire: highly satisfied
- Patients report frustration with SRI treatment; control with ART
Biological Treatment
Case Report

- Eric, now 42
- First patient I treated with GnRH analogues
- Patient of ours for 26 years
- Age 17 referred for treatment of pedophilia
- Hypersexual from young age; at 13 abused younger adoptive brother
- Age 16 hospitalized psychiatrically
- Treated with CBT, discharged after a year
- Reoffended, referred to us at 17, treated with CBT, hospitalized, treated with CBT, discharged at 19, promptly reoffended
- Hospitalized for next 8 years; sued NY for ART
- Started on this at 27; in the community x 15 years on ART
Biological Treatment
Conclusions

- Will continue to see biological treatment used
- Will see better studies
- Critical need for psychometric validation of outcome measures
- Plethysmography is limited
- Some scales exist: Coleman Compulsive Sexual Behavior Inventory; a number of other Hypersexual Scales in process of validation
- Rosler’s Scale, the ISDSS, has no psychometric validation
- Bancroft’s Sexual Interest and Activity Scale also has no validation