

**A PILOT STUDY COMPARING STANDARD PSYCHOTHERAPY VERSUS
LEUPROLIDE ACETATE WITH STANDARD PSYCHOTHERAPY
FOR SUPPRESSION OF ABERRANT SEXUAL AROUSAL**

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Almost 150,000 confirmed cases of child sexual abuse occurred in the United States in 1993 (Finkelhor 1994). This trauma often results in substantial psychological problems for the victim (Courtois & Watts 1982). Two separate reports of brain imaging studies at the American Psychiatric Association in May 1995 indicated that repeated childhood sexual abuse damages the hippocampus. Most victims exhibit post-traumatic stress disorder (Bower 1995). Studies have shown that high proportions of juvenile offenders, prostitutes, runaways, and adults with sexual dysfunctions were sexually abused as children (Jones et al. 1981, Nakashima 1982, James & Meyerding 1977, Silbert & Pines 1981, McGuire & Wagner 1978). In addition, as many as 40% to 60% of these individuals may become child molesters themselves, thus perpetuating the cycle of abuse (Marshall & Barbaree 1990).

One shocking characteristic of pedophiles is their potential to abuse unbelievably large numbers of children. Typically, these individuals abuse 380 children during their lifetime (Lanning 1987). Given this fact, the potential impact of this project is immense. If combination therapy (LA and psychotherapy) effectively modifies the pedophile's behavior, thousands of victimized children and their families will be saved the anguish of coping with sexual abuse.

In Erie County alone, 100 individuals are currently on probation/parole for sexual crimes and a projected 20-30 child molesters (pedophiles) will be released into the community this year. The criminal justice system has traditionally responded to sex offense-based crime by incarceration, followed by lengthy supervision on parole and probation, or probation alone. The cost of incarceration is approximately \$32,000 per year for five years. Enrollment in a psychotherapy program is often required as a condition of parole, but its degree of success is limited. The reoffense rate for patients treated with psychotherapy alone can reach 24% (Sturgeon and Taylor 1980). The need for an effective, alternative treatment program for sex offenders is imperative.

Testosterone-lowering agents, such as medroxyprogesterone acetate (MPA) and cyproterone acetate (CPA), have been used in the past to treat child molesters. In controlled studies, MPA and CPA have decreased sexual tension, fantasies, preoccupations, and the urgency and frequency of masturbation. MPA therapy requires four injections per month; CPA is oral. Although these agents have resulted in low levels of recidivism among convicted sexual offenders, noncompliance and intolerable, though rare, life-threatening side effects have been reported with CPA and MPA (Bradford 1983). Notable side effects of MPA include weight gain, lethargy, headaches, and leg pain. Of note, the state of California passed a law on August 20,

1996 that requires individuals convicted of sexual offenses to receive treatment with MPA when released from prison. (Currently, MPA is the only drug approved in the United States for testosterone suppression in sex offenders.)

Recently, another category of drugs, the selected serotonin re-uptake inhibitors (SSRI), Prozac, Paxil, and Zoloff, are under consideration for treatment of certain types of pedophilia. Originally used as antidepressants, they may also curb obsessive behaviors and thoughts. Considering these benefits, they may be particularly useful in the regressed pedophile where stress due to feelings of inadequacy and inferiority causes the individual to depart from his normally age-appropriate sexual interests to the less challenging younger subject, causing an impulsive, episodic offense of a child. Sexual dysfunction, decreased libido, and impotence is less than other drugs (5 to 15%) and these may be of use in the married offender where denial of marital sexuality is an issue. A SSRI may be the initial drug of choice in a limited category of patients. The drugs are still under investigation and literature comparing anti-androgens and SSRIs is very scant.

Leuprolide acetate (LA) is one of several recently synthesized agonist analogs of leutenizing hormone/releasing hormone, the hypothalamic factor that stimulates gonadotropin release from the pituitary (Vance and Smith, 1984). This drug is used to treat prostate cancer in men and precocious puberty in children. Decreased or absent libido is frequently reported as a side effect of LA therapy (AHFS 1990). This effect is probably secondary to a primary reduction in LH levels (Vance and Smith, 1984).

The testosterone levels attained with continued administration of LA are lower than those attained with either MPA or CPA. This may result in LA being a more potent inhibitor of sexual arousal compared with other agents. Since LA can be administered every three months by injection, the compliance problems associated with MPA and CPA are negated. Also, because LA exhibits minimal and generally reversible side effects (hot flashes, impotence, low sperm counts) and lowers testosterone below castrate levels, it is potentially superior to the testosterone-suppressing drugs now available.

The chain of events that immediately precedes child molestation begins with the pedophile's exposure to a high risk situation. Although virtually unavoidable, these situations, such as watching a child play, put the pedophile at risk for reoffense. The patient's response to the high risk situation determines the final outcome. When unsuccessful at coping with a high risk situation, the pedophile's typical progression to offense is:

1. an affective response of loneliness or confusion;
2. fantasizing regarding sexual abuse;
3. rationalizing and planning a sexually abusive act; and
4. masturbatory fantasies and reoffense (Pithers et al., 1989)

By suppressing testosterone specifically at the hypothalamic-pituitary level and thereby suppressing aberrant sexual fantasy and arousal, leuprolide acetate may augment psychotherapy and help break the chain (Steps 2 and 4) leading to a reoffense.

Three cases of paraphilia treated with leuprolide acetate have been reported (Dickey, 1992; Rousseau et al., 1990; Cooper & Cernovsky, 1994). One author used LA to treat a patient with multiple paraphilias who had failed to respond to the standard testosterone-suppressing drugs (Dickey, 1992). He found that the patient had a marked decrease in sexual thoughts and activities with no significant side effects.

Rousseau et al. (1990) treated one male exhibitionist with combination LA and flutamide therapy. The frequency of sexual fantasy decreased from 10-20 episodes per week before therapy to 1-2 episodes per week after ten weeks of treatment. Although testosterone was suppressed and exhibitionistic behavior ceased, the patient was able to maintain coital activity. The authors observed fewer side effects with this therapy compared with standard testosterone-suppressing medication.

Cooper and Cernovsky (1994) reported a case in which LA almost totally suppressed self-report and plethysmographic measures of sexual arousal. The subject, a heterosexual child molester, had failed previous treatment with CPA because of an apparent weakening of antilibidinal effects. These authors believed leuprolide acetate may be a superior alternative to both CPA and MPA.

Justine Marut Schober, MD, Principal Investigator, recently treated two young, mentally retarded men with leuprolide acetate (Attachment 1). Both had sexually molested children. One patient, a 16-year-old boy with known epilepsy and mental retardation, was experiencing aggressive sexual episodes associated with uncontrollable epileptic seizure. Many sexual episodes were directed toward two younger sisters. The seriousness of the situation and emotional state of the family prompted immediate intervention in the form of drug therapy.

Other than the initial flare of sexual activity during the first two weeks of therapy, no other sexual episodes have occurred during the 80-month follow-up. The patient has reached adult height and Tanner five development. Bone growth and masculine development are still being monitored. (These did not regress appreciably during therapy.) Severe acne, which was apparent on onset of treatment, cleared almost completely.

The second patient, a 23-year-old retarded man with Tourette's Syndrome, had molested a three-year-old child. He was treated and followed in a manner similar to the first patient. His aberrant sexual behavior also ceased with LA therapy.

The purpose of our research is to compare psychotherapy alone (the current standard treatment) versus psychotherapy augmented with leuprolide acetate for suppression of aberrant sexual arousal in fixated pedophiles. We anticipate that combination therapy (LA and psychotherapy) will be more effective than psychotherapy alone for suppressing aberrant sexual arousal through biochemical reduction of testosterone levels. With combination therapy, patients may then be more amenable to psychotherapy, allowing them to more readily alter their aberrant tendencies.