COCHRANE CORNER

Pharmacological interventions for those who have sexually offended or are at risk of offending†

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See commentary on pp. 361–365, this issue.

Background

Sexual offending is a serious social and public health problem. Surveys report high levels of psychiatric morbidity in survivors of sexual offences. Biological treatments of sex offenders include anti-libidinal medication: hormonal drugs that have a testosterone-suppressing effect and non-hormonal drugs that affect libido through other mechanisms. The three main classes of testosterone-suppressing drugs in current use are progestogens, anti-androgens and gonadotropin-releasing hormone (GnRH) analogues. Medications that affect libido through other means include antipsychotics and serotonergic antidepressants (SSRIs).

Objectives

To evaluate the effects of pharmacological interventions on target sexual behaviour for people who have been convicted or are at risk of sexual offending.

Search methods

We searched CENTRAL (2014, Issue 7), Ovid MEDLINE, EMBASE, and 15 other databases in July 2014. We also searched two trials registers and requested details of unidentified, unpublished or ongoing studies from investigators and other experts.

Selection criteria

Prospective controlled trials of anti-libidinal medications taken for the purpose of preventing sexual offences, where the comparator group received a placebo, no treatment or 'standard care', including psychological treatment.

Data collection and analysis

Pairs of authors, working independently, selected studies, extracted data and assessed the risk of bias of included studies. We contacted study authors for additional information, including details of methods and outcome data.

Main results

We included seven studies with a total of 138 participants, with data available for 123. Sample sizes ranged from 9 to 37. Judgements for categories of risk of bias varied: concerns were greatest regarding allocation concealment, blinding (masking) of outcome assessors and incomplete outcome data (drop-out rates in the five community-based studies ranged from 3% to 54% and results were usually analysed on a per protocol basis). Participant characteristics were heterogeneous, but the vast majority had convictions for sexual offences, ranging from exhibitionism to rape and child molestation. Six studies examined the effectiveness of three testosterone-suppressing drugs: cyproterone acetate (CPA), ethinyl oestradiol, and medroxyprogesterone acetate (MPA); a seventh evaluated two antipsychotics (benperidol and chlorpromazine). Five studies were placebo-controlled; in two, MPA was administered as an adjunctive treatment to a psychological therapy (assertiveness training or imaginal desensitisation). Meta-analysis was not possible owing to heterogeneity of interventions, comparators, study designs and other issues. The quality of the evidence overall was poor. In addition to methodological issues, much evidence was indirect. Primary outcome: recividism. Two studies reported recidivism rates formally. One trial of intramuscular MPA plus imaginal desensitisation (ID) found no reports of recividism at 2-year follow-up for the intervention group ($n = 10$) *v.* one relapse in the group treated by ID alone). A three-armed trial of oral MPA, alone or in combination with psychological treatment reported a 20% recidivism rate in the combined treatment arm ($n = 15$) and 50% in the psychological treatment only arm ($n = 12$). Notably, all those in the 'oral MPA only' arm ($n = 5$) dropped out immediately, despite treatment being court mandated. Two studies did not report recidivism rates as they both took place in one secure psychiatric facility from which no participant was discharged during the study; another three studies did not appear directly to measure recividism but rather abnormal sexual activity alone. Secondary outcomes: various. Results suggest that the frequency of self-reported deviant sexual fantasies may be reduced by testosterone-suppressing drugs, but not the deviancy itself (three studies). Where measured, hormonal levels, particularly levels of testosterone, tended to correlate with measures of sexual activity and with anxiety (two studies). One study measured anxiety formally; one study measured anger or aggression. Adverse events: Six studies provided information on adverse events. No study tested the effects of testosterone-suppressing drugs beyond 6–8 months and the cross-over design of some studies may obscure matters (given the 'rebound effect' of some hormonal treatments). Considerable weight gain was reported in two trials of oral MPA and CPA. Side-effects of intramuscular MPA led to discontinuation in some after three to five injections (the nature of these side-effects was not described). Notable increases in depression and excess salivation were reported in one trial of oral MPA. The most severe side-effects (extra-pyramidal movement disorders and drowsiness) were reported for the 12 participants in a trial of antipsychotic medication. No deaths or suicide attempts were reported in any study: this is important given the association between antilibidinal hormonal medication and mood changes.

Authors' conclusions

We found only seven small trials (all more than 20 years old) that examined the effects of a limited number of drugs. Investigators reported problems with acceptance and adherence to treatment. We found no studies of the newer drugs currently in use, particularly SSRIs or GnRH analogues. Although there were some encouraging findings, study limitations do not allow firm conclusions to be drawn regarding pharmacological intervention as effective for reducing sexual offending. The tolerability, even of the testosterone-suppressing drugs, was uncertain, given that all studies were small (and therefore underpowered to assess adverse effects) and of limited duration, which is not consistent with current routine clinical practice. Further research is required before it is demonstrated that their administration reduces sexual recidivism and that tolerability is maintained. It is a concern that, despite treatment being mandated in many jurisdictions, evidence for the effectiveness of pharmacological interventions is so sparse and no RCTs appear to have been published in two decades. New studies are therefore needed and should include trials with larger sample sizes, of longer duration, evaluating newer medications, and with results stratified according to category of sexual offenders. It is important that data are collected on the characteristics of those who refuse and those who drop out, as well as those who complete treatment.

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