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# Uncritical positive regard? Issues in the efficacy and safety of psychotherapy

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The recent review of the selective serotonin reuptake inhibitors (SSRIs) by the Committee on Safety of Medicines (CSM) and the Food and Drug Administration was occasioned by media concerns about the safety of this class of antidepressant. In much of the prior and subsequent reporting of this issue, two assumptions have consistently been aired. The first is that psychotherapy is equally effective as drugs and the second is that since psychotherapy is not a drug, it is necessarily safer than drug treatments. From these two assumptions emerges a common presumption that psychotherapy should be the preferred approach for many if not most cases of depressive and anxiety disorders. But is this true? And if not, what implications does it have for the management of the new therapists that will soon be employed following the UK government's award of £150 m for psychotherapy services in depression and anxiety? (<http://www.rcpsych.ac.uk/pressparliament/pressreleases2006/pr955.aspx>)

## Are psychotherapies efficacious?

Undoubtedly some psychotherapies have been shown to work in controlled trials but the common supposition (wish?) that they are an effective alternative to drug treatment is not always supported by evidence. One currently contentious area is adolescent depression, where there have been extreme claims made against the safety and efficacy of SSRIs, leading to them being blacklisted by the US authorities. However, what are the alternatives given that three randomised CBT trials have not shown efficacy (Elkin *et al.*, 1989; March *et al.*, 2004; Goodyer *et al.*, 2007)? Also treatment-emergent adverse effects of a self-harm nature similar to those reported with drug treatment have been found (Bridges *et al.*, 2005).

Moreover, few psychotherapy trials have complied with the standard regulations that are required of all drug treatments. These

include double-blinded treatment with random allocation of patients to treatment arms, and blinded rating of outcome and placebo control (Klein, 2000). Even fewer have utilised a full intention-to-treat analysis with sensitivity analysis of imputed missing data that properly accounts for dropouts in trials – indeed the majority of trials in psychotherapy have assessed efficacy only on individuals who have completed the course of therapy (completer analysis). This form of assessment inflates the apparent value of the treatment and gives little indication of its clinical effectiveness or real-world utility, and is not accepted by regulators for the registration of drug treatments in psychiatry.

In anxiety disorders, there are many positive trials of both CBT and exposure therapy but whether any meet the tough criteria that would be required for registration of a drug treatment (i.e. demonstrable efficacy in two independent placebo-controlled studies) is doubtful. Published trials of CBT versus drug treatment and placebo in depression are few but two recent ones have failed to show strong efficacy for the psychotherapy arm (Derubeis *et al.*, 2005; Dimidjian *et al.*, 2006). Furthermore, many psychotherapy trials use patients maintained on waiting lists as controls instead of a placebo treatment. This policy inflates their effect sizes as the waiting list is a much less engaging intervention than the placebo pill plus regular psychiatric assessments that are the bedrock control in drug treatment trials. It is unlikely that drug studies using waiting list controls would be accepted by regulatory authorities.

Moreover, few psychotherapy trials have addressed question of effectiveness in real-world delivery in large multicentre studies as opposed to demonstrating efficacy in a few “expert” sites. It can be argued that a positive aspect of antidepressant therapy is that whatever the quality of the prescribing doctor, the quality of the medication is immutable: this is not the case for psychotherapy. Similar considerations apply to the lack of certainty that psychotherapies work equally well across patients with different IQs, socio-economic sta-

tus, ethnicity or even in those with different primary languages, whereas drug therapy is relatively unaffected by such variables.

## Are psychotherapies safe?

Drug treatments in medicine are subject to very careful scrutiny at all stages from trial design through to post-marketing safety surveillance. Licensing requires proof-of-efficacy in at least two pivotal multi-centre placebo-controlled trials plus (in Europe but not the USA) a long-term efficacy study that is usually of the relapse prevention type. Safety data that range from preclinical toxicology through to human adverse effects are required prior to approval, and monitoring of safety is expected post-marketing. The risk–benefit ratio of a drug is critical in the decision to license and if this is shown to become less favourable than several responses are possible; the license may be revoked – as for example in the case of droperidol – or prescribing restrictions imposed, as with thioridazine.

Psychotherapy is however not subject to such strict regulation – but should it be and should some standard form of adverse effect data collection be implemented? Unfortunately, many psychotherapy trials have not even considered the possibility that their treatment could harm, perhaps because of the assumption (wishful thinking?) by both therapists and the public that as psychotherapy is only talking (with perhaps a little exposure) no possible harm could ensue. Yet all therapists are – or at least should be – aware that therapy can have adverse effects on some patients and a major part of psychotherapy training is how to deal with issues such as counter-transference that can mediate these negative effects (see Spitzer, 1970; Stone, 1971; Crown, 1983; the discussion on the Osheroff case in Klerman, 1991).

There is evidence that psychotherapy can sometimes worsen patient outcome, for example in suicide-attempting patients (Modestin, 1987; Moller, 1992) or those with a predisposition to mania (Kingdon *et al.*, 1986). One form of psychotherapy is exposure therapy, which is based on the premise that worsening of symptoms during exposure is an absolute requirement for subsequent treatment efficacy. When taken to its logical extreme it becomes flooding therapy, which was once popular. The anxiety induced by flooding can be extraordinarily distressing and there are well recognised examples of patients escaping in fear from their treatment and refusing further sessions. David Nutt runs a specialist anxiety disorders clinic in which we have seen a number of patients who could be considered as suffering from a PTSD-like syndrome as a consequence of failed flooding treatment for phobias and OCD.

There have been concerns expressed recently about the observed worsening of symptoms during prolonged exposure psychotherapy for PTSD, which is seen in up to 20% patients early in treatment (Foa *et al.*, 2002). Although this worsening is short-lived and does not appear to affect outcome, it can be very distressing for the patient and has been associated with transient worsening of the illness and suicide attempts. Psychotherapy may continue to be used even it has been shown to be ineffective or even may worsen outcomes (NICE, 2005) when effective drug treatments are available (see BAP guidelines on the treatment of anxiety disorders, Baldwin *et al.*, 2005).

Some effects of psychotherapy can lead to distress to family and others close to the patient. A well recognised example of this is the acquisition of “false memories” usually of abuse by a family member that can seriously disrupt family life and has led to parents being falsely imprisoned. One young adult patient of David Nutt’s with severe OCD was quizzed by a therapist about the possibility that she had suffered sexual abuse by family members. This led to her developing chronic ruminations about the possibility that she might have been abused by her father, even though she knew this had not happened. As a consequence for years she was unable to tolerate being in the same room as him, which markedly exacerbated her problems and caused great distress to the family.

Most people – including many doctors – believe that dependence and withdrawal reactions are unique features of drug treatment. In practice, dependence has always been recognised as such a common occurrence in psychotherapy that sessions are commonly dedicated to preparing the patient for termination of the treatment. Even then, relapse can occur when psychotherapy stops. Sudden abrupt cessation of treatment, as occurs when a therapist is taken ill or leaves the clinic, can precipitate distress that can be as disabling as any drug withdrawal syndrome. Group therapy may be more prone to lead to risks especially when attendance at the group becomes a critical element in the patient’s life. This may lead to the perpetuation of symptoms in order to maintain group attendance and was one reason why some of the early benzodiazepine withdrawal groups failed.

Another proven potential risk of psychotherapeutic treatment is that effective drug treatments are withheld either because the therapist does not believe in their efficacy or because the patients are not introduced to the possibility of their being useful in their condition (Klerman, 1991). This has been highlighted in the last couple of years by the discussion over the safety of antidepressants, especially SSRIs in the treatment of depression in adolescence. Here the lack of efficacy of the SSRIs coupled with an apparent increase in suicidal ideation has led to a widespread concern about the use of drug treatments in all psychiatric conditions in children – not just depression, even though the evidence base in the anxiety disorders is strong (Bridge *et al.*, 2007). It now appears that the apparent increase in suicidal ideation by the antidepressant drugs may have been an artefact in the way the adverse effects were elicited rather than a true pharmacological effect for a similar increase in suicidal ideation has been found during psychotherapy for adolescent depression (Bridge *et al.*, 2005). This study emphasises the fact that very rarely do psychotherapy trials systematically collect adverse effect data, which means that their safety may be significantly overestimated in comparison with drug treatments.

Perhaps the most important aspect of safety relates to abuse of patients by therapists. An anonymous survey of US psychotherapists some years ago revealed a large minority to have had sexual relations with their patients. Gartrell *et al.* (1986) found 7% of male and 3% of female psychiatrists reported sexual contact with patients. More recent data from the USA suggest that those engaged in intense psychotherapy are at higher risk of this behaviour (Morrison *et al.*, 2001). The General Medical Council (GMC) strikes off a small number of psychiatrists each year for inappropriate relations with patients, and many of these are psychotherapists.

Some recent examples suggest such abuse can be with multiple patients over long periods of time, leading to severe psychological consequences and even suicide in the victims (GMC Ker-Haslam report, 2005).

Is it possible to estimate the risk for adverse effects in psychotherapy? Assuming there are 1000 doctors practising psychotherapy in the UK, each with a caseload of 100 patients and the three per year that are struck off are the only ones perpetrating abuse and each abuses only one patient, then this suggests a relative risk of three per 100,000 patient exposures. In drug treatment, a serious adverse effect affecting this percentage of patients would lead to grave regulatory concerns. These figures are a conservative estimate of abuse by medical psychotherapists given only a fraction of perpetrators will be caught and most will abuse more than one patient. Presumably, similar levels of abuse occur with other groups of therapists, perhaps more so, as they are generally less well trained and many are not subject to professional monitoring. The enduring nature of the consequences of abuse perpetrated on the most vulnerable members of society by the professional to whom they have turned for help makes the burden of harm even more considerable.

There is also the issue of therapist safety – giving psychotherapy can be bad for the therapist's mental health. Listening to disclosure of traumas can potentially produce PTSD by proxy (Gersons, 2000) and transference can lead to distress. Some patients can become hostile and threatening, whereas others may develop pathological attachment that can disrupt the life of the therapist and their family through pestering and even stalking.

### Can the safety of psychotherapy be improved?

Taken together, it is clear that psychotherapy is not necessarily always the benign yet efficacious therapy that seems to be generally assumed. Patients should be made aware of the risks as well as the benefits especially now we have a government initiative to improve psychotherapy provision on the NHS. Recently the UK regulators have amended the "yellow card" scheme for drug adverse effects so that patients can use them (CSM 2004). Perhaps a similar scheme should be introduced to require therapists, and allow patients, to report problems with psychotherapy – a "pink card" perhaps? It would seem appropriate that in the UK this be provided by the new Medicines and Healthcare Regulatory Authority (MHRA), which runs the drug adverse effect monitoring schemes.

In addition, therapists need to commit to performance and practise standards and agree to be monitored or audited in terms of these. A psychotherapy standards agency might be required to perform these monitoring processes or it could be carried out as part of professional audit of clinical teams depending on the independence of the practitioners. Only therapists with appropriate training and monitoring should be allowed to practice and if working in the NHS they should be required to only use treatments of proven efficacy. But before all this and before rolling out psychotherapy in place of drug treatment, proper controlled assessments of efficacy and of safety need to be carried out.

As always, the *Journal of Psychopharmacology* welcomes correspondence on this and any other article.

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