MAINTENANCE THERAPY FOR HOSPITAL OUT-PATIENTS

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Summary

A study of dosage requirements undertaken among chronic OPD patients found on unnecessarily high drug dosage regimes. Basing on OPD experiences authors discuss long term treatment strategies and strongly advocate low dose intermittent oral therapy.

In keeping with the view of many trans-culturists that there is an ethnic variation in drug response, Chakraborty (1970) had reported low dosage requirement of Bengali patients. In an endeavour to establish the minimum effective dose (ibid) and to set a guideline for out-patient treatment a study was undertaken and briefly reported (Chakraborty et al., 1982). The recent interest in low dose and intermittent neuroleptic treatment has prompted us to update the data and start a new series.

Material and Method

202 patients were selected from all patients receiving treatment at the psychiatric OPD of a large general hospital (where they were thought to be on a high dosage schedule). Selection criteria were- a) at least 3 years duration of drug treatment at this OPD, b) more or less stable condition, c) regularity of attendance.

Besides the usual demographic details, protocols were maintained to record

(a) withdrawal symptoms, (b) subjective distress, (c) prodromal symptoms of relapse, (d) relapse. And the global rating of progress on a 5 point scale from " relapse to stability", assessed from both patients and relative's reports.

At the start of the trial all the patients were clinically examined again to determine whether they did require the amount of psychotropic drugs they were receiving. On the basis of this assessment, drugs were not reduced in 15 patients; in others the drugs were reduced straightaway by half to one fourth of the original dose. The patients were followed-up at weekly interval for 3 months, then at monthly interval for nine months (total one year). Reassurances and psychotherapy

were undertaken for withdrawal symptoms and subjective distress. For prodormal symptoms of relapse drugs were rapidly increased, for full relapse ECT was also given. The aim was to restore the patients atleast to their previous level of functioning or well-being on a lower dosage schedule. Keeping the ethical aspects in mind good care was taken of these patients.

Regression analysis usuing computer was done.

Results

Of the 202 patients full or consistent data could be obtained from 150 patients only. The rest (52) remained as a part of the study but their data was not analysed because of the following reasons - a) remained well without drugs; b) supplemented drugs on their own; c) relatives turned un-cooperative; d) dropped out for long stretches.

Reductions were achieved within the first six weeks, later adjustment were made. Relapses occurred in 12% of the cases, improvements were quick with enhancement of dosage but 1 or 2 ECTs were required in 3 cases. Complaints of distress and withdrawal symptoms came mostly from antidepressive group (which included many obsessionals), these gradually settled with minor adjustments and reassurances. Once stabilised most patients welcomed the lower schedule. The following table sums up the amount of reductions that could be made with success.

Levels of dose reduction achieved

- A. Neuroleptic group Chlorpromazine equivalents mg/day
- B. Anti-depressive group Impiramine mg/day

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Original range of dose	Reduction not tried	Reduction tried	At end of trial			
			Original dose restored	Stabilised at reduction level upto 30% upto 31-45%		Over 45%
A 50 -200	3	27	5	i	2	19
210-400+	5	21	3	5	6	7
		48 (100%)	8 (16.6%)	6(12.5%)	8(16.6%)	26(54.1%)
B 50-150	7	76	10	14	22	30
160-300		11	1	3	1	6
		87 (100%)	11 (12.6%)	17 (19.5%)	23 (26.4 %)	36 (41.3%)

It will be seen that for both the groups. through the whole range, drugs could be reduced by one third to half of the original dose. At the end of the trial majority of the patients were stabilised on 50 mg to 100 mg of chlorpromazine equivalents or 25 mg to 75 mg of imipramine per day. Successful reductions were directly proportional to the initial dose in the case of anti-depressives and to the duration of treatment in the case of neuroleptics. These findings were significant in regression equation (table not given). Anti-cholinergies and diazepams were also drastically reduced and formed part of the study, but that data and other analysis of correlates are omitted here as not being of general relevance. Suffice it to say that maximum resistance and complaints came with the reduction of diazepam; though it was difficult to distinguish the withdrawal effects of diazepam from that of anti-depressives, enhancement of the latter removed many complaints. Elderly ladies on these drugs for years seemed to develop hospital addiction as well many came from long distances by train (free-trippers presumably !). Dyskinesias and other side-effects were not found to be a problem, probably because long-acting drugs and haloperidol were not being used.

Further observations

Following are some observations made during the study taking all aspects of OPD treatment including the new cases into account. References cited indicate support for these impressions. By patients we refer, irrespective of diagnosis, to those fairly recent illness, who had not been exposed to much medications.

- a) Almost 80% of the OPD first attenders respond immediately to treatment. Those who do not make significant recovery within three months are likely to need maintenance treatment. Good responders remain true to form for subsequent relapses.
- b) Patients unused to medication respond to very low doses of drugs. The reverse is also true, previous exposures build up tolerance (unless specially sensitive) calling for high dose.
- c) There is great individual variation in drug response, even 1 mg of trifluperazine or 10 mg show favourable of amitryptiline may response or intolerance. This fact is exemplified by the broad therapeutic range of psychotropic drug, eg. 10 mg to 300 mg of thioridazine etc. (Mc Intyre & Gershon, 1985). We are in broad agreement with low dose treatment policies suggested by Ortiz and Gershon (1986), but the upper limits of neurolepuc drugs in our patients were found to be lower, e.g. chlorpromazine/thioridazine -300 mg or trifluperazine/haloperidol - 30 mg, than that suggested by them (there are rare exceptions; a girl of 22 was once seen receiving daily haloperidol 40 mg and cholorpromazine - 300 mg with anti cholinergic and diazepam. She was also on

parenteral fluphenazine - 25 mg every ten days. She was quiet, but without therapeutic benifit or side -effects!).

- d) Patients are seldom fully compliant, they often adjust doses to suit their individual sense of comfort (Van Putten, 1974). Some patients on neuroleptics will relapse or have exacerbations irrespective of the amount of medication they receive at the time (Johnson, 1985). When a patient does not respond to a drug, higher doses will not help (Ortiz and Gershon, 1986), but a change of drug may do. The transition period may entail polypharmacy, however, initiating treatment with more than one drug of the same group serves no purpose whatsoever.
- e) Classical depression with dejected mood, delusions, psycho-motor retardation etc. are rare in our OPDs, most cases of depression (including that of bipolar disorders) present as a mixed bag of neuroses. Habituation and dependence on anti-depressive drugs occur very easily and quickly. However, though patients welcome drugs that give them sleep, there is a very strong resistance against all drugs, particularly 'sleeping pills'.
- f) Chronic patients many years on medication lose all distinguishing diagnostic features. In such a condition drugs are almost interchangeable, e.g. we found reduction of 50 mg of imipramine bringing on frank schizophrenic relapse, which again responded to imipramine (Hirsch, 1989).

Discussion

The perforce design of the study does not allow us to claim that the dosage requirements of our patients have been established: we found, to achieve that it is necessary to initiate treatment accordingly, which is part of our ongoing project. The dosage arrived at in the present study is, probably similar to what is being currently used at many centres. But our patients had been receiving higher doses, on the average of six years prior to the trial, which was largely unnecessary.

Several surveys of prescribing habits have found that polypharmacy and over-medication are very common as are inappropriate and unnecessary prescriptions (Edwards and Kumar, 1984; Clark & Holden, 1987; Muijen & Silverstone, 1987). The survey by Bagadia and his team (1982) suggest wide variation in

dosage scheduled used by the Indian psychiatrists. Channabasavanna (1988) has recently cautioned against irresponsible drug prescriptions.

It goes without saying over-medication is highly unethical, besides being financially burdensome, it encourages dependence on drugs, and most important, produces introgenic diseases. The alarming increase of the latter has now forced all concerned to recommend smaller doses, 'drug holidays' and 'safer' drugs.

We believe that a cultural factor is operative behind the shifting perspective of drug treatment. Indian medical tradition, which had based itself on subtle clinical signs (now being rediscovered in alternate systems), and incorporated chronobiology in its practice, paid a great deal of attention to dosage of drugs. In ayurveda drugs had to be prepared for each patients individually in the correct dose (matra), excess (matradhykya) was said to increase bodily heat which in turn gave rise to further malfunction. In the early days our allopathic doctors also kept to this tradition. In fact, wherever clinical acumen was the sole standby, patients were given the "correct" dose, and the response and effectiveness created the "ethnic effect" mentioned earlier. However, the Western cultural influence of enthusiastic, over-optimistic, and agressive treatment policies in search of the 'holy grail' of cure (McClelland, 1989) made all to lose sight of the clinical considerations. It could well be that such a war-like attidue towards death and disease is linked to Judeo-Christian philosophies, in contrast to "acceptance" preached by the Eastern ones (Chakraborty, 1967).

These matters are discussed here to emphasize the view that we have to look at our conditions objectively before adopting even the revised orientations and treatment based on experience gained elsewhere.

In India the great majority of mentally ill persons under treatment receive it from hospital out-patients departments. These OPDs are over-crowded and under-staffed (mostly with junior staff at that), the ideal, the expensive and the difficult measures are not within the ambit of the OPDs. Yet this vital sector of our psychiatric services carry heavy responsibilities, because, besides being the

main teaching ground (in-patients facilities being negligible), OPDs in the long run are likely to provide the imprint of what psychiatry is to the population. It has to be remembered 50% of the ever increasing volume of the patients catered for in the OPDs are rural folks from the surrounding areas of urban hospitals (Chakraborty & Sengupta, 1977). Hence it is important to have well thought out policies for OPDs not only for patients regarding treatment but also for trainee psychiatrists regarding their roles and responsibilities.

It is of foremost importance to build a sense of trust and confidence towards the doctors among these out patients. It is equally important not to foster the impression that hospital doctors prescribe high doses of medicines indiscriminately and for indefinite periods. Such measures indicate 'incurability' of mental disorders, which may be belied by the people's own experiences.

We strongly feel that it is not justified to put all patients who receive treatment at the OPDs on long-term maintenance therapy. Patients should be encouraged to attend and follow instructions but the good prognosis patients should be discharged after a period with advice to report if and when prodormal symptoms of relapse appear. Caution is more necessary with anti-depressive drugs as habituation far out-weigh the risk of the odd suicide these may possibly prevent.

These recommendations are justified by the following arguments. Firstly, we found that 60% of those who register at the OPD drop-out after the second visit, it is only a fraction of the total number who ever register become regular or follow insturctions. It is our strong impression that the 'drop-outs' get better, either through self-medication or through social and natural process. So, we contend that only a small proportion of psychotics require long-term medication. Secondly, it has been established that schizophrenia in India carry better prognosis (Verghese et al., 1989); it has also been found that chronicity of all mental disorders treated or untreated among Indians are low (Murphy & Raman, 1971; Chakraborty, 1990).

To return to our recommendation: patients for maintenance therapy can be broadly divided into two groups: those who show a relentlessly downward course or get into unresponsive arrested states and those who frequent relapses. It would have helped matters a great deal if the latter group could be detected at a very early stage. It appears that patients who show quick response with low dosage have better prognosis in the sense that their relapses also show this response. Still, there is no denying that even among these patients, some will gradually become more dysfunctional and have very frequent relapses and may develop strong antipathy towards drugs. We feel, at present there is no other way than trial to detect this pattern of illness.

As an answer to ethical questions about allowing patients to relapse we may restate what is common knowledge that relapses occur frequently with medication, but these may not occur in 5-10 years even without medication, hence benefit of the doubt should go to those who will do well. Verghese and others (1989) have found drug compliance as one of the factors associated with good outcome in Indian patients, but they have also shown that all the significant variables jointly account for only 21.8% of the variations in multiple regression analysis. It is also to be noted that the outcome of schizophrenia is much better in India and Nigeria where care (including drug treatment) is likely to be much less than in Denmark or UK where the outcome has been found to be poor (Sartorious et al., 1977). The factor that Indians have in common with Nigerians may well be social tolerance or abundance of sunlight or low exposure to chemical substances. Whatever may the factors be, endeavour has to be made to preserve and identify this inherent 'immunity'. Hence "prevent relapse at all cost" with costly drugs in ever increasing dosage should not be our aim.

The question of diagnosis has not been brought into the discussion because it is the atypical cases with uncertian diagnosis who have good prognosis and fit in better with our scheme. It is likely that this group is larger than the 'classical' cases. There is no question that clear cut cases of manic-depressive psychosis call for appropriate treatment and preventive measures with lithium and carbamezapine, similarly schizophrenia with distrubing symptoms and bad prognostic signs may require long-acting drugs (an area not

ched by the previous discussions), but where diagnosis cannot be made with certainty, treatment has to be oriented towards the symptoms and the course of the illness.

The training of psychiatrists have been mentioned; targetted treatment as indicated should make them more aware of clinical variations among patients, casual "Repeat All" prescriptions for months on end is a disservice to themselves as well as to the patients. Attempts at prognostication should always be encouraged, these may be just guessing games to start with but may eventually yeild rewards.

Finally, no maintenance therapy is possible without some interaction with patients, in whatever way psychotherapy is imparted this should never be lost sight of.

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