Unmodified electroconvulsive therapy: a false dilemma

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Abstract

A recent statement commissioned by the Indian Association of Private Psychiatry recommends that unmodified electroconvulsive therapy (ECT) should still be used in some settings in India, invoking the principle of beneficence. This paper critically analyses the IAPP statement in terms of both scientific accuracy and ethical principles. It is found that the statement falls short of the ethical principles of beneficence, non-maleficence and justice. It is the duty of psychiatrists and psychiatric associations to offer the best available care to their patients, both on scientific and ethical grounds.

Introduction

In 2012, a paper entitled "Position statement and guidelines on unmodified electroconvulsive therapy" was published in the April issue of the *Indian Journal of Psychiatry* (1). This statement (henceforth referred to as "the IAPP statement") was commissioned by the Indian Association of Private Psychiatry (IAPP), and was also endorsed by the Indian Association of Biological Psychiatry and the Indian Psychiatric Society (IPS). The latter endorsement is of significance because the IPS is the largest professional body representing psychiatrists in India, and one of its stated objectives is to "promote ethical standards in the practice of psychiatry in India" (2).

The timing of this document was crucial because it closely followed the preparation of the draft version of the Mental Health Care Bill, which banned the practice of unmodified electroconvulsive therapy (ECT) regardless of the circumstances. In opposition to this, the IAPP statement provided a seemingly far-reaching and systematic review of the medical literature pertaining to the practice of unmodified ECT, and concluded that the practice should be continued, both in emergency and non-emergency situations, provided certain criteria were fulfilled (1).

The topic of ECT, and unmodified ECT in particular, has always evoked controversy and strong responses from both its detractors and supporters (3–5). On the face of it, the IAPP statement frames the issue in the form of an ethical conflict, pitting two principal tenets of medical ethics against each other: beneficence and non-maleficence. Its position can be summarised as follows.

1. ECT is an important and life-saving treatment modality in certain serious psychiatric disorders, and is practised all over the world.
2. In contemporary practice, ECT is administered under general anaesthesia and muscle relaxation ("modified ECT") to minimise the risk of muscular and skeletal injuries.
3. In India, however, facilities for anaesthetic evaluation and the administration of anaesthesia may not always be available or affordable (1,5); in such cases, when the patient's life is at risk, unmodified ECT may be better than no treatment at all (5). This is the invocation of the principle of beneficence, ie treatments must be administered for the good of the patient.
4. Recent research has shown that the risk of muscular and skeletal injuries may be overstated (6–8). Thus, unmodified ECT may not be as dangerous as it was once believed to be. The risk of injury can potentially be modified by administering a sedative drug (diazepam) before the procedure, as diazepam acts as a muscle relaxant (1,8). This point is meant to address concerns regarding non-maleficence, by suggesting that unmodified ECT is reasonably safe.
5. Considering the balance between beneficence and an acceptable level of non-maleficence, unmodified ECT should be provided to patients as per point 3 above, as well as in other "non-emergency" conditions (1) in which ECT would be appropriate.

It would seem that the IAPP statement represents a fair and balanced resolution of an ethical dilemma, weighed and analysed in the light of the best scientific evidence. However, this paper will demonstrate that this is not so, and that the IAPP statement's proposal to liberalise the use of unmodified ECT violates not one, but three significant principles of medical ethics.

Before proceeding, however, a historical overview of ECT and the controversies surrounding it is in order.

ECT: a brief history

ECT is not a new treatment in psychiatry, having been practised for over 75 years (9). Though its exact mechanisms of action remain unclear, it involves the induction of a brief seizure by the passage of a direct electric current through the brain. Electric stimulation which is too low to cause a seizure ("sub-shock" or "sub-threshold" stimulation) has no therapeutic effect (10).

ECT is effective in the management of several major mental disorders, including severe depression, mania, acute psychosis,

schizophrenia, and catatonia (10,11). It is also effective in treating neuroleptic malignant syndrome, which is a life-threatening side-effect of antipsychotic drugs (10,11). Though interest in ECT has waned to some extent with the advent of other forms of treatment, particularly medication (12), there is still much active research in the area, particularly in optimising the delivery of treatment and patient outcomes (12,13). Among patients with severe depression, ECT can rapidly reduce the risk of suicide in the short term (14), giving the modality an advantage over antidepressants, which often take weeks to manifest a response.

Initially, ECT was administered in an "unmodified" or "direct" form, which was associated with a significant risk of muscle and bone injuries. This led to the development of modified ECT, in which a patient is given brief general anaesthesia and a short-acting muscle relaxant before the induction of the seizure. With the advent of modified ECT, the unmodified form was gradually phased out, though it is still practised in some parts of the developing world due to economic constraints and lack of proper training (7,15–17). International guidelines on ECT clearly state that the modified form, and not the unmodified one, is to be administered to all patients. The World Health Organization condemns the practice of unmodified ECT (18), something which even the IAPP statement acknowledges (1). In a review specifically addressing the concerns of developing countries, representatives of the World Psychiatric Association have also opposed this practice, stating that the provision of modified ECT "is an ethical obligation on the parts of governments, professional organizations and individual practitioners" (19).

The case for modified ECT

There are at least four reasons to support the practice of modified ECT, three of which are directly related to the key principles of medical ethics.

First, there is the question of efficacy. Psychiatry, like most branches of medicine, has moved towards evidence-based practice, in which evidence from well-designed controlled trials is used to guide treatment. These evidence-based reviews are overwhelmingly based on the results of trials which have used modified ECT (20–22). Thus, when extrapolating from them to clinical practice, the same form of treatment, namely modified ECT, would have to be administered to ensure efficacy, as per evidence-based principles which dictate that clinical treatments must be based on good-quality clinical trials. Though the initial evidence regarding the efficacy of ECT did come from reports on unmodified ECT, the current recommendations and guidelines are based on more recent evidence gathered from the use of modified ECT. This would relate to the principle of beneficence, ie patients should be given those treatments with the best evidence of effectiveness.

The second argument concerns the reason why unmodified ECT was discontinued in the first place, ie the risk of physical injuries, including fractures. This risk is markedly attenuated by the use of modified ECT (10). Though some recent publications have claimed that this risk may have been overstated (6–8,23), I have shown below that these results cannot be taken at face value. If this is so, then the principle of non-maleficence would also apply (a treatment that poses a higher risk of harm should be avoided as far as is possible).

The third argument, which is an extension of the first two, concerns the principle of justice. The mentally ill are already an underserved population in most parts of the world, including India (24). This being the case, the onus is on the medical profession to provide, and advocate for, those treatments that are supported by the best evidence and entail the least risk of harm. Failure to do so would constitute an injustice against patients with serious mental illnesses. In the last section of this paper, I have shown that the neglect of this issue is the principal flaw of the IAPP statement and the arguments used to defend its position.

Finally, a case for modified ECT can be made on the grounds of aesthetics and acceptance by the patient. Unmodified ECT is visually unappealing, and this contributes to the negative portrayal of ECT in the media and popular culture (5,25). As Andrade (5) points out, aesthetic appeal alone cannot be a criterion for choosing a particular treatment, as few medical procedures, particularly surgeries, are aesthetically pleasing. Despite this, the argument is not without value, as the use of modified ECT could help address misconceptions and negative attitudes regarding this form of treatment (25), and increase the patients' level of acceptance of ECT.

Unmodified ECT in India: the first debate

In 1993, Andrade et al (26) published a landmark paper in the *Indian Journal of Psychiatry* that surveyed the practices followed by Indian psychiatrists when administering ECT. The authors noted, with disapproval, that a sizeable proportion of the psychiatrists expressed a preference for unmodified ECT, and were of the opinion that this was a suboptimal practice which had to be replaced by modified ECT in the course of time.

This was soon followed by the publication of Tharyan et al's paper (23), which claimed, on the basis of 10 years of experience, that unmodified ECT was associated with a rate of skeletal complications that was as low as below 1%. This data was derived from patients treated between 1980 and 1990, when unmodified ECT was being practised routinely in India. The authors concluded that, in the absence of trained anaesthetic personnel, the use of unmodified ECT by a trained team was safe and acceptable. They also criticised any move, as in Andrade's paper (26), to recommend modified ECT in "developing countries."

A reply to Tharyan's paper, by Gangadhar and Janakiramaiah (27), offered two valuable criticisms of the original article:

- The paper did not provide enough data to support its contention that "the recommendation to routinely give only modified ECT requires further review;" further data were required on morbidity and acceptability.

- By advocating suboptimal treatment for patients, the authors were tacitly accepting injustice and inequality: in the authors' own words, "Psychiatrists owe it to their patients *to advocate and strive to offer them the best current standards of care, including modified ECT.*" (Emphasis added.)

Thus, Gangadhar and Janakiramaiah invoke all three principles alluded to above. They point out that there is insufficient evidence to make clear decisions on either beneficence or non-maleficence, and invoke the principle of justice when stating that mental health professionals should advocate for their patients, and not for potentially inferior forms of treatment.

As a curious footnote to this first debate, it must be noted that Andrade also published a critique of the Tharyan et al paper (28), in which he highlighted two further issues: the safety concern with regard to silent, "subclinical" spinal fractures, and the questionable clinical significance of the adverse events reported among their patients who had received modified ECT.

The second debate

The second discussion regarding unmodified ECT took place in the pages of *Issues in Medical Ethics,* in the wake of a public petition from a non-governmental organisation, Saarthak, which sought to curtail the use of ECT in India. In particular, the petition sought a ban on the practice of unmodified ECT, which it considered unethical. In response to this, Andrade (3) made a cautious retreat from his previous position, suggesting that unmodified ECT still had a place in India for various reasons, including the high cost of modified ECT and the dearth of trained anaesthesia personnel. This drew a strong reply from the Centre for Advocacy in Mental Health (4), and the original author (5), in turn, replied to clarify his position. In this second paper, the following arguments were offered for the continuation of unmodified ECT.

- In a stuporous or suicidal patient, the administration of unmodified ECT can be life-saving in the event of an anaesthetist not being available.
- In small cities, where anaesthetists struggle with large caseloads, there may be unacceptable delays in the administration of modified ECT, causing weeks or months of suffering to patients.
- In a study conducted by Andrade et al (29), the risk of musculoskeletal injuries in patients receiving unmodified ECT was low.

These arguments are addressed in the next section of this paper.

Problems with the evidence regarding the safety of unmodified ECT

The paper most cited in support of unmodified ECT, because of the large numbers involved, is the 1993 study of Tharyan et al (23) The earlier critiques of this paper on scientific and ethical grounds (4,27,28) have been reviewed above. An additional point which is pertinent, also raised by Waikar et al (4), is that the "trained team" used to restrain the patient during the seizure consisted of four orderlies, three nurses and two postgraduate psychiatry trainees. While this may represent an economic advantage over the use of an anaesthetist, it is doubtful if trained manpower on this scale could be ensured in a small town or a private clinic.

A detailed search of the MEDLINE database for articles on unmodified ECT, published between 1993 and the current date, yielded only four studies of possible relevance. These will be considered individually. Several other papers, which consisted mainly of survey data or patient chart reviews (15–17), are not reviewed here as no useful conclusions can be drawn from them due to their study design.

1. There are two studies from Nigeria, both with a naturalistic design (6,7). Neither study compared modified and unmodified ECT, or unmodified ECT with drug therapy. In both studies, the rates of muscle pain were high (17%–31%), though it was stated that this symptom resolved quickly and the treatments were generally accepted well by the patients (7).

2. Two papers from a municipal hospital in Mumbai describe the use of unmodified ECT. One of these involved the administration of diazepam to patients before the procedure (8). Neither study compared unmodified and modified ECT, and one reported the incidence of back pain to be 52%, the pain being severe in 14% of patients.

These results, taken by themselves, hardly justify the IAPP statement's advocacy of unmodified ECT. All four studies have serious methodological limitations. The most important of these are the small sample sizes and the absence of a control group, which prevents any valid comparison with modified ECT. Moreover, some of these studies suffer from serious ethical flaws, as described below.

- The paper on benzodiazepine-modified ECT (8) included patients as young as 11 years of age. Given the necessity of observing a high degree of caution when using ECT in very young patients, and the insistence of international guidelines (30) on the use of modified ECT in this population, the inclusion of such patients in a potentially dangerous protocol is unacceptable.
- The first Mumbai study (29) states that "unmodified ECT was the norm" in the hospital where the study was conducted because the hospital was understaffed. That this should happen in a large metropolitan city (as opposed to the small towns alluded to in the IAPP statement) is difficult to believe. Moreover, convenience should not be an excuse for dispensing with important aspects of treatment.
- There is a well-documented tendency towards publication bias in all interventional studies in psychiatry, particularly those involving biological treatments. Given this, even if serious adverse events had occurred, it is unlikely that they would have been published. Indeed, the publication of such events would probably render the authors liable to prosecution.

- Three of the studies cited in the IAPP statement in support of unmodified ECT (8,23,29) have been authored or co-authored by members of the IAPP task force. Given the controversial nature of the treatment being considered, there are sufficient grounds to consider this a conflict of interest.

Though the survey- and chart-based data are not reviewed in detail here, it may be noted that they are subject to the same caveats. Therefore, contrary to the position taken in the IAPP statement, there is insufficient scientific evidence to state that unmodified ECT is both safe and effective.

Problems with the IAPP statement

Besides the evident problems with the evidence base that the statement rests upon, there are difficulties with the document itself. These are as follows.

1. Even if we assume that the studies of Tharyan (23) and Andrade (8, 29) are free of the scientific and ethical flaws listed above and were conducted under "ideal" conditions, in hospitals with trained personnel, can a small psychiatric clinic - in a remote area that will face difficulties in obtaining anaesthetic support - ensure the availability of nine trained men and women (23) to restrain a patient? Would doctors in such a clinic feel confident about administering intravenous diazepam (8), especially given the risks of respiratory depression with this drug? If not, then we would expect a far higher rate of complications in such settings than in the "idealised" world of the studies quoted above.

2. Even if we permit the use of unmodified ECT in dire emergencies, the wording of the statement on the non-emergency use of this treatment (1) is ambiguous and lends itself to misinterpretation. Physicians' individual views of what constitutes "a strong indication" are bound to vary and there is scope for abuse (4). Though the IAPP statement must be commended for stating that convenience is not an indication for unmodified ECT, it fails to provide adequate checks and balances to ensure a correct interpretation of this clause. In a setting of limited resources, it is unlikely that the long list of precautions prescribed by the statement will be followed.

3. The clause on "dire emergencies" (1) is fallacious. A single unmodified ECT is not, in itself, "life-saving" in the way that an emergency surgery is. In most mental disorders, several sessions of ECT are often required to obtain a significant response. In some conditions, such as catatonia, drug treatment with lorazepam, which is cheap and easily available, is recommended before trying ECT. Similarly, though the anti-suicidal effect of ECT is fairly well established, it should not be overstated (14,31). Therefore, a restriction or ban on unmodified ECT would not lead to widespread adverse consequences, as claimed by its proponents.

4. The commissioning of these guidelines by the IAPP at this point in time, with the threat of the Mental Health Care Bill looming ahead, is a cause for concern. Why do "private" psychiatrists need a separate organisation to represent them and commission such guidelines when the membership of the IPS is open to all psychiatrists in India? What were the IAPP's motives in commissioning these guidelines at this moment, and why did the IPS endorse them?

Conclusion

If one weighs the evidence carefully, one finds that the picture regarding unmodified ECT is not as clear as the IAPP statement claims, both with regard to beneficence (effectiveness) and non-maleficence (safety). Despite the statement's attempt to provide a balanced overview, there are omissions and distortions in key areas that undermine its validity.

Moreover, in an age in which cutting-edge research on modified ECT and other modes of brain stimulation is being conducted even in government hospitals in India (32, 33), why should professional bodies continue to insist on a treatment that is suboptimal? Instead of advocating unmodified ECT, why does the IPS, which openly states its commitment to "promote ethical standards in the practice of psychiatry in India," not work towards greater collaboration with anaesthetists, the setting up of modified ECT facilities in rural and semi-urban areas, or the training of psychiatrists in basic anaesthesia and life support skills? The failure to do so amounts to injustice, which is a violation of another basic ethical principle. The IAPP statement does not deal fairly with the mentally ill on any of the three grounds of beneficence, non-maleficence and justice, and its harmful consequences are likely to outweigh any benefits in the long run. The words of Gangadhar and Janakiramaiah, though written 19 years ago, are still relevant: "We owe it to our patients to advocate and strive to offer them the best current standards of care, including modified ECT."

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A degree in bioethics: an "introspective" analysis from Pakistan

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Abstract

The success of degree-level bioethics programmes, a recent development across the world, is generally evaluated on the basis of their quantifiable impact; for instance, the number of publications graduates produce. The author conducted a study of Pakistani graduates who had pursued a higher qualification in bioethics, and on the basis of the respondents' written and verbal narratives, this paper presents an analysis of their perceptions of the internal impact of bioethics degree programmes. Using these narratives, the paper also analyses the reactions of their colleagues to their new qualification.

The respondents reported significant changes in their thinking and actions following their education in bioethics. They exhibited more empathy towards their patients and research subjects, and became better "listeners". They also reported changes in practices, the most significant being the discontinuation of the linkages they had established with pharmaceutical firms to seek support, because of concerns related to conflict of interest. Although some respondents believed that their new qualification was generally welcomed by their colleagues, who considered them as ethics resources, others reported that their colleagues harboured unreasonable and impractical expectations from them, and that these were impossible to fulfil. They also got the feeling of being ostracised and regarded as "ethics watchdogs". Whereas the internalisation of bioethics is an encouraging finding in this cohort, the mixed reception that bioethics and those involved in it received indicates a lack of understanding of the field and is a source of concern.

Introduction

The emergence of formal bioethics education programmes which offer graduate-level education in bioethics and award diplomas, degrees and fellowships is a relatively new phenomenon around the world. The aims and objectives listed on the websites of prominent programmes offering such education generally mention the acquisition of scholarly and procedural skills related to bioethics as the main goal. These programmes, which use different pedagogies, ranging from entirely full-time to part-time, fully online or a hybrid mix of strategies, are geared towards equipping their alumni to teach, conduct research and provide bioethics-related services.