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ABSTRACT

Despite the increasing evidence about the inappropriate use of medications by older people, there is very little published evidence about the control and monitoring of neuroleptic drugs used in nursing homes. As others have indicated, this is all the more worrying when set in the context of the paucity of research on nursing home care and the trend to replace registered nurses with untrained care assistants. In the United States, legislation in the form of the Nursing Home Reform Act (OBRA 1987) was introduced, in part, to regulate the prescribing and administration of neuroleptic (antipsychotic) drugs. No such legislation exists in Canada or the United Kingdom. In the case of the latter jurisdiction, the recent Royal Commission on Long-Term Care for older people (The Stationery Office, 1999) has recommended a national care commission to monitor care, and set assessment and quality benchmarks. In Canada this debate has not even begun, and the purpose of this paper is not to ignite controversy, but to raise questions about the use of these drugs with nursing home residents. Voluntary guidelines and education of physicians, nurses and care attendants would be infinitely better than legislation. In the meantime, we need research to address the following questions: For what reasons should these drugs be given to older people? Are these drugs being used appropriately? Is the risk of side-effects too great with these drugs? Are the numbers and type of staff employed in nursing homes adequate/qualified to detect and report side-effects? How well do these drugs manage the behaviours they are given to control? Are they being used as chemical restraints or to make the older person compliant? Are the so-called 'atypical' neuroleptic drugs any better? What we offer in this article is background information that might encourage others to not only review their practice but also to address these questions.

KEY WORDS

neuroleptics  antipsychotic  drug utilisation

older people  long-term care
INTRODUCTION

A recent study by Damestay et al (1999) on 'Prescribing psychotropic medication for elderly patients' once again highlights the vulnerability of older people to over-medication and inappropriate medication. In this context, the use of neuroleptic drugs, also called major tranquilisers, and the newer atypical neuroleptic drugs bear close and renewed scrutiny. The use of neuroleptic drugs, particularly in nursing homes for older people, raises a number of therapeutic and ethical issues.

Other concerns that are starting to surface relate to the restructuring of the healthcare system and budget cuts. In the United Kingdom, frail older patients have been removed from the care of consultant geriatricians as the private nursing home sector has grown, and placed under the care of what Kavanagh and Knapp (1998) call overworked, under-trained and sometimes unenthusiastic general practitioners (cited by Turrell & Castleden, 1999). In addition, the majority of nursing home staff are untrained aides or personal care assistants who, through no fault of their own, lack skill particularly in assessment of older patients' responses to medications and the recognition of side-effects (Kennedy & Mion, 1996). The decision to staff long-term care facilities with largely untrained personnel has much to do with budget considerations. In both the public and private sector, there is a growing belief that care of older people is unskilled work that anyone can provide. Hence, the vulnerability of the older person is increased. While it is true that anyone can give a pill, there is the question of how do we ensure that the response to the medication, good or bad, is accurately observed and reported?

NEUROLEPTIC DRUGS REVISITED

Antipsychotic drugs are often referred to as neuroleptics or 'major tranquilisers' and antischizophrenic agents (Semenchuk, 1997). The common use of the term 'major tranquiliser' has come from the fact that one of the first of these drugs, chlorpromazine, can produce a relaxed state. The label, according to Semenchuk (1997) suggests that all neuroleptic drugs produce this sedative effect, but this is not the case, and haloperidol is one such drug with almost no sedative effect. The term 'neuroleptic' was given to certain antipsychotics because of neurological side-effects such as extrapyramidal symptoms (EPS). The introduction of newer drugs in the United States and Canada, such as Clozapine, Risperidone, Olanzapine and Quetiapine claim to reduce neurological side-effects and are classified as atypical neuroleptic drugs. The point, offered by Semenchuk (1997), is that perhaps these names should not be so interchangeable because of the wide variety of effects.

The most common historical reason for using neuroleptic agents has been for the treatment of schizophrenia. Increasingly, they have been used to treat behavioural disturbances in older people that are considered to be dementia-related, such as verbal or non-verbal agitation, psychosis, wandering, pacing, aggressing and insomnia (Burton et al, 1995). Neuroleptic drugs such as chlorpromazine, mesoridazine (which is not used in the UK market and is an analogue of thioridazine) and thioridazine are considered to be low potency and require a high dosage to initiate an effect. By comparison, the high potency drugs such as haloperidal, trifluoroperoxazine and fluphenazine are given in smaller doses to achieve the desired effect, but their downside is the increased probability of causing extrapyramidal effects such as Parkinsonism, dyskinesia, dystonia, pseudo-parkinsonism and akathisia. Thus it is important to monitor these drugs and start with low dosages as recommended by the Age Concern guidelines (Levenson, 1998) to reduce toxic effects and adverse drug reactions.

SIDE-EFFECTS AND RISK ASSOCIATED WITH NEUROLEPTICS

The major side-effects and risks associated with neuroleptic drug use with older people include sedation, orthostatic hypotension, falls, hip fractures, cardiac complications, cognitive decline, anticholinergic effects and extrapyramidal problems, agranulocytosis, and
neuroleptic malignant syndrome. The side-effects are significant, and according to Tune et al. (1991) surprisingly commonplace.

Sedation and orthostatic hypotension

While neuroleptics vary in the degree to which they cause sedation, sedation is a common side-effect of all neuroleptics, and can occur at twice the rate of placebo (Barnes et al., 1982; Petrie et al., 1982; Levenson, 1998). This drug-induced sedation can make it difficult for older people to get to the toilet, leading to an increase in incontinence (Levenson, 1998; Petrie et al., 1982). Furthermore, orthostatic hypotension is a significant side-effect associated with the use of neuroleptics, particularly the low-potency neuroleptics (Barnes et al., 1982; Keltner & Folks, 1995). Not surprisingly, this combination of sedation and orthostatic hypotension clearly puts the older person at a greater risk for falls and hip fractures.

Falls and hip fractures

Falls, a leading cause of morbidity and mortality in nursing home residents, are more common in nursing home residents receiving neuroleptic medications (Mustard & Mayer, 1997; Thapa et al., 1995). Given this increased risk of falling, it is not surprising to find that current older users of neuroleptic drugs have a twofold increase in the risk of hip fracture (Ray et al., 1987). Thus, the use of neuroleptics to treat older people carries with it potentially high financial, medical and personal costs that may not always be considered when physicians prescribe these drugs.

Cardiac, cognitive and anticholinergic complications

Many neuroleptic drugs, particularly the low-potency neuroleptics, are cardiotoxic and cause numerous cardiac complications (Gomez & Gomez, 1990). In addition, at least one study (McShane et al., 1997) has found that the cognitive decline in older people with dementia receiving neuroleptics was twice that of people with dementia who did not receive them. Furthermore, neuroleptic medications can cause anticholinergic effects, such as constipation, blurred vision and urinary retention, exacerbating many pre-existing medical problems often found in older persons (Lehne & Scott, 1996).

Extrapyramidal side-effects

Perhaps the most distressing and potentially debilitating of all of the side-effects caused by neuroleptics are the extrapyramidal side effects (EPS). EPS is caused by the action of these drugs on dopaminergic activity within the extrapyramidal system that consists of EP tracts, the basal ganglia, the caudate and putamen together with the substantia nigra and is concerned with movements, posture, equilibrium and muscle tone. Extrapyramidal side-effects include: dystonia (spasms or stiffness of the muscles of the eye, neck and back), Parkinsonism (generalised rigidity and tremors similar to Parkinson’s disease), akathisia (restlessness, rocking, pacing and inability to sit still), akinesia (decreased or absent body activity), and tardive dyskinesia (involuntary oral movements such as lip smacking and sucking, jaw movements, ‘fly-catcher’ tongue movements, abnormal movements of the extremities, and difficulty swallowing) (Gomez & Gomez, 1990). With some aspects of EPS, such as Parkinsonism, the side-effect can often be misdiagnosed and mistreated, if treated at all (Avorn et al., 1992; Caligiuri et al., 1998).

While many of the EPS side-effects will disappear when the neuroleptic is discontinued, tardive dyskinesia is in many cases permanent or irreversible, and may become evident only after the medication is withdrawn (Brown & Funk, 1986; Risse et al., 1987). Also, older people are at an increased risk for developing neuroleptic-induced tardive dyskinesia. Even with low doses of typical neuroleptics, the cumulative rates of tardive dyskinesia in older people is as high as 25% after one year, and over 50% after 3 years (Caligiuri et al., 1997; Jeste et al., 1999(a); Jeste et al., 1999(b); Kane & Smith, 1982). As Woerner et al., (1998) have stated:
...tardive dyskinesia rates for patients beginning treatment with conventional antipsychotics in their fifth decade or later are three to five times what has been found for younger patients, despite treatment with lower doses...alternative treatments need to be investigated.

Compounding the problem, nursing staff, who are often in the best position to recognise tardive dyskinesia in its earlier stages, may not be aware of the high risk of tardive dyskinesia linked with neuroleptic use, or how to properly assess for its presence (Bostrom, 1988; Kennedy & Mion, 1996).

Agranulocytosis

Atypical neuroleptic drugs have received a lot of publicity and market promotion because they are considered to be safer with fewer side-effects. According to Breggin (1997) the most publicity has been given to clozapin (Clozaril). But as he points out, This is not a new drug but one that was synthesised in 1960 and caused so many deaths in Europe that by the mid 1970s it was banned in some European countries.' (Breggin, 1997). The reason for the deaths is that the drug causes agranulocytosis, a serious suppression of white blood cell production in the bone marrow, leading to increased susceptibility to infections that are often lethal. Breggin is also very critical of the Federal Drug Agency (FDA) decision to approve the drug in 1990 for use in the USA, and he believes that this is evidence of the growing leniency toward drug companies.

Neuroleptic malignant syndrome

Another extreme disorder that can be caused by these drugs, specifically haloperidol (Haldol) and fluphenazine (Prolinix) is neuroleptic malignant disorder (NMS). It was, according to Breggin (1997), first identified and reported by Delay and Deniker in 1968. However, the drug companies failed to give it formal recognition until they were compelled to do so by the US Federal Drug Agency some 20 years later. The condition of NMS is characterised by severe dyskinesia or akinesia, temperature elevation, tachycardia, blood pressure fluctuations, diaphoresis, dysphagia and urinary incontinence (Coons et al, 1982, cited by Breggin, 1997). The condition of NMS can also be fatal in 20% of cases, and Delay and Deniker warn that at first suspicion, neuroleptic drugs must be stopped immediately and completely. If the patient does survive they are frequently left with permanent dyskinesias and dementia (Breggin, 1997).

According to Pope et al, (1986) the incidence rate for NMS over a 1 year period, in a survey of 500 patients, was 1.4%. The cumulative rate would be much higher, and based on prevalence studies by Addonizio et al (1986) Breggin (1997) believes that NMS, although described as rare, is common or frequent in patients receiving neuroleptic medication. A prevalence rate of 1 in 100 is ‘common' by FDA standards and this makes NMS an extreme risk. Furthermore, Breggin considers that a risk of this size would probably result in most drugs in general medicine being removed from the market.

NEUROLEPTIC DRUG USE IN NURSING HOMES

Staff in nursing homes have traditionally been vigorous dispensers of neuroleptics. The majority of US studies conducted in the 70s and 80s found that approximately 40% of nursing home residents were receiving neuroleptic medications (Avorn et al, 1989; Buck, 1988; Prien et al, 1975; Ray et al, 1980), with some studies finding lower rates of 26% (Beers et al, 1988) and 13% (Gilleard et al, 1983). More recent US studies in the 1990s have found rates of use varying from around 20% (Garrad et al, 1991; Llorente et al, 1998) up to 39.3% (Burton et al, 1995). International studies report varying rates of neuroleptic use in long-term care, ranging from 44% in England (Gilleard et al, 1983), 30.7% in Australia (Snowdon & Vaughan, 1997), 24% in Scotland (McGrath & Jackson, 1996), and 17% in Canada (Earthly et al, 1999).

International comparisons and even intra-national comparisons must be made with caution as individual nursing homes may vary considerably in their use of neuroleptics, depending upon such things as the practice of...
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physicians (Colenda et al, 1996), facility size (Ray et al, 1980), and nursing staff levels (Svarstad & Mount, 1991). Nevertheless, there is increasing evidence of concern, particularly in the United Kingdom, about the use of these drugs in long-term care facilities and the general lack of adequate controls and guidelines (Hughes et al, 1999; Turrell et al, 1999).

Neuroleptic drugs: efficacy and the placebo effect

Given the surprisingly common and significant side-effects of neuroleptic medications, it is important to note that the research-based evidence on the efficacy of these drugs is actually quite low. Despite the widespread use of neuroleptic drugs in older people in long-term care they do not appear to be particularly effective at doing what they are marketed to do, that is, reducing agitation and behavioural disturbances in persons with dementia. In an earlier review of 21 studies on the effectiveness of these drugs in long-term care (Helms, 1985), only 3 met certain conditions for methodological rigour. In two of these studies, the difference in efficacy between neuroleptics and placebo was either unstated, or non-existent. In the third study, the 'therapeutic effect' or the difference in efficacy between antipsychotics (33.5% of patients improving) and placebo (9% of patients improving) was only 24.5%.

In a later review (Schneider et al, 1990), the percentage of dementia patients improving on placebo alone varied anywhere from 0% to 67%. Finally, in a recent meta-analysis of 16 randomised, controlled double-blinded trials on neuroleptic use in dementia-related agitation in long-term care (Lanctot et al, 1998), it was found that on average, the difference between the percentage of patients who improved on neuroleptics (61%) and placebo (34%) was only 26%. It is worth noting that the 26% of subjects who derived a benefit from neuroleptic medication were found to be almost the same percentage (25%) of patients who developed significant side-effects such as EPS, sedation or orthostatic hypotension.

Reviews of efficacy show that the risk to benefit ratio of neuroleptic medications for long-term residents is approximately 1:1. For every resident of long-term care who apparently 'benefits' from these medications, as evidenced by reduced agitation or changes in behaviour, there can be found another resident who has suffered from the negative side-effects. Clearly, it could be argued that in other areas of medicine or long-term care, such a high risk to low benefit ratio would not be acceptable. While efficacy studies inform us that a significant number of long-term residents' behaviour and levels of agitation may improve on neuroleptic medications, the studies also demonstrate that up to 60% of long-term residents' behaviour and agitation will improve on the placebo effect alone (Schneider et al, 1990). Interestingly the 'placebo effect' of neuroleptics is not on the residents themselves, as many of them have dementia and are unable to report on their own agitation or level of 'behavioural disturbance.' It would appear that the placebo effect of neuroleptics is in fact occurring with the nursing staff, who are often the persons responsible for rating the residents' behaviour and agitation in research studies. Much of the reported efficacy of neuroleptics therefore, may in fact be attributed to nursing staff giving long-term care residents medications that they believe are going to work. The apparent powerful 'placebo effect' that medications hold for the nursing staff working in long-term care has enormous ramifications for the care of older people and needs to be more carefully considered and investigated.

LEGISLATION OR THE OPTION OF VOLUNTARY GUIDELINES

In response to an increasing number of scandals, lawsuits and studies reporting inadequate care and ineffective regulation in the US nursing home industry, a new set of federal regulations was mandated by the US Congress in the late 80s. The Omnibus Reconciliations Act of 1987 (OBRA) enacted regulations and reforms that dealt with many aspects of nursing home care, including resident assessment, use of restraints and medication.

The Nursing Home Reform Act, embedded in OBRA, was implemented in October 1990 and required extensive documentation of the prescription of psychotropic drugs. The basic
Ethical issue is that no resident’s drug regimen should include drugs that are not medically necessary (Health Care Financing Administration, 1995). Drugs that are not medically necessary are defined as those used in excessive doses, for too long, without adequate indications, or in the face of adverse consequences. In these cases it is indicated that the dose should be reduced or the drug stopped (Tessier, 1993, cited by Hughes et al, 1999). The Omnibus Reconciliation Act was a noteworthy step, as it was the first time that government legislation specifically mandated an aspect of medical practice in nursing homes (Kane & Garrard, 1994). Hence a physician’s use of medications was now required, by law, to be justified by indications documented in a person’s medical chart (Garrad et al, 1991). Adherence to these regulations is mandatory, and is tied to the accreditation and financial reimbursement of nursing homes.

Following the implementation of the OBRA legislation, two studies reported no significant drop in neuroleptic use associated with the introduction of OBRA regulations in nursing homes (Hawes et al, 1997; Lantz et al, 1996). The study by Lantz and colleagues did not report particularly high rates of neuroleptic use before OBRA regulations. At least four studies, however, have found significant declines in nursing home neuroleptic use after the OBRA regulations, with declines of 26.7% (Shorr et al, 1994), 31% (Semla et al, 1994), 33% (Garrad et al, 1991), and 36% (Rovner et al, 1992). In terms of overall compliance with OBRA neuroleptic use regulations, Llorente et al (1998) found that mean compliance was greater than 70% for appropriate diagnostic indication, recommended dosage limits, and documentation of appropriate target symptoms in eight nursing homes. Altogether, these studies suggest that the OBRA regulations, the legislative approach to reduce and improve neuroleptic usage in nursing homes, has been successful in the US. It would appear, however, that the reduction in neuroleptic drug use has been found not to be due to stopping drugs, but to reducing the number of new users (Shorr et al, 1994, cited by Hughes et al, 1999).

In the United Kingdom, the Royal College of Physicians has called for the development of national guidelines on the administration of drugs in nursing homes and the identification and publication of good clinical and caring practice (Royal College of Physicians, 1997, cited by Hughes et al, 1999). According to Turrell and Castelden (1999), there is very little published evidence about the control and monitoring of medication prescribed for frail residents in nursing homes in the United Kingdom. The same is true of nursing homes in Canada. This is particularly worrying when placed in context of this vulnerable client group and cuts in healthcare budgets that have shifted the bulk of care of residents from registered nurses to untrained care assistants.

Voluntary efforts and the role of education

As Hughes et al (1999) have indicated, the introduction of legislation in the United Kingdom, or a jurisdiction such as Canada to improve the quality of prescribing, is likely to be met with opposition because it will be misinterpreted as an infringement of clinical freedom. Because of this, and the findings of Damestay et al (1999), changing prescribing habits through education - as suggested by Kane and Garrard (1994) - might be the most effective approach.

Voluntary efforts to reform the use of neuroleptics in nursing homes have centered on educational programmes for physicians and nurses. In one study where only physicians were given an educational programme aimed at reducing neuroleptic use, there was no reduction in neuroleptic drug prescribing (Ray et al, 1987). A possible explanation is that close to half of all orders for neuroleptic drugs in nursing homes are written on an ‘as needed’ (pro re nata) basis, where nursing staff use their judgement to decide when neuroleptics shall be given (Kennedy & Mion, 1996; Segal et al, 1990; Beers et al, 1988; Segal et al, 1979). It would appear that educational efforts that include both physicians and nurses have proven to be the most successful. One non-randomised study evaluating the effect of a neuroleptic education programme for physicians and nurses in nursing homes found a 72% decrease in neuroleptic use following the intervention, compared with a 13% decrease in the non-intervention nursing homes (Ray et al, 1992). Other similar, but
randomised interventions have resulted in neuroleptic use reductions of 18% (Avorn et al, 1992), 23% (Meador et al, 1997) and 50% (Rovner et al, 1996). Hence educational interventions in themselves are quite effective in reducing neuroleptic usage in nursing homes, although it is likely that such effects are less enduring than those resulting from legislative reforms, such as OBRA.

CONSEQUENCES OF WITHDRAWING NEUROLEPTICS

Importantly, it appears that the above efforts to reduce use of neuroleptics in nursing homes, through either legislation or education, can often be done safely and without an increase in difficult behaviours. With regards to safety, while one study found a worsening of dyskinetic movements when neuroleptics were withdrawn from nursing home residents with dementia receiving long-term maintenance doses, the withdrawal dyskinesia was usually resolved or diminished after six weeks (Risse et al, 1987). With regard to difficult behaviours, while one study did find that a mandated cessation of neuroleptics in nursing home patients resulted in a 50% increase in behaviour problems (Horwitz et al, 1995), other studies have found no differences in behaviour between nursing home residents who had been withdrawn from these drugs, and those who had not (Bridges-Parlet et al, 1997; Thapa et al, 1994). Thus it appears that the withdrawal of neuroleptics is unlikely to worsen the problems for which they were originally prescribed. For example, McGrath and Jackson (1996) found that 88% of residents receiving neuroleptics in 28 Scottish nursing homes could be deemed to be receiving them inappropriately according to OBRA guidelines. A reasonable conclusion that can be drawn from the existing literature is that more research and controlled trials are needed to demonstrate both the efficacy and long-term safety of these drugs in their use to treat nursing home residents. Furthermore, even residents who may turn out to be poor candidates for a total withdrawal of neuroleptics are probably good candidates for at least a reduction in dose (Meador et al, 1997).

FUTURE RESEARCH

Clearly there is a need for more research on the current use of neuroleptics and this is the basis of a project being undertaken by the authors at the University of Lethbridge. In addition we are collaborating with colleagues in the School of Health Sciences, University of Wales, Swansea and Glan-y-Mor NHS Trust to collect comparative data on neuroleptic drug use. These data will allow us to look at current practice in the context of the American OBRA regulations and the Age Concern voluntary guidelines in the United Kingdom.

RECOMMENDATIONS

The following recommendations are made to minimise the risk associated with neuroleptic drug use and to promote good clinical practice:

1. Before any medication is given to manage behavioural difficulties, attempts must be first made and documented to manage the behaviour with non-pharmacological methods, such as good communication, sensitive nursing care, environmental modifications, and appropriate recreational activities. Nursing home staff must be provided with regular education on such methods.

2. When non-pharmacological approaches have failed and neuroleptics are used, the nursing home facility could adopt guidelines similar to OBRA or the guidelines proposed by the United Kingdom advocacy group, Age Concern (1998).

3. While newer pharmacologic agents, such as Risperidone, Olanzepine, Quetiapine and Trazadone may offer advantages over traditional neuroleptics, their use must be accompanied by a thorough understanding of their side-effects, and an awareness that research evidence for the use of these drugs to treat older people with dementia is small or inconclusive.
4. The key message that must be received by patients, families, administration, physicians and all levels of nursing staff is that many kinds of difficult behaviours in nursing home residents are best dealt with using good social and nursing care and that medications should not be assumed to be the first response to the behavioural problems associated with dementia (Levenson, 1998).

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