REVIEW

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A literature review comparing the experiences and emergent needs of adult patients with permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs)

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Aims and objectives. This literature review aims to critically appraise any published studies that compare the experiences of patients with permanent pacemakers and those with implantable cardioverter defibrillators. It seeks to identify issues that are similar or unique to one or other group; whether identified needs are being met by current nursing practice and considers how any gaps might be addressed.

Background. Increasing numbers of patients are receiving pacemakers and implantable cardioverter defibrillators (ICDs) as indications for devices continue to expand worldwide. Technical follow-up of such patients is well structured. There is an increasing body of knowledge regarding ICD patients' experiences with promising work testing recovery interventions but less seems to be known about pacemaker patients.

Design. Systematic review.

Methods. Using an integrative approach, electronic searches using comprehensive search terms were supplemented by following reference lists and key journals from 1975–2008.

Conclusion. From the direct comparison studies identified, ICD patients who experience shocks are more likely to report lifestyle limitations than pacemaker patients. However, ICD and pacemaker patients share similar outcomes, with both groups reporting increased anxiety and depression. Whilst experiences of ICD patients have been well reported, experiences of patients receiving pacemakers for any reason and pacemakers or ICDs for heart failure (bi-ventricular devices or cardiac resynchronisation therapy – CRT) remain largely unknown. Although psychosocial interventions are suggested for both groups, these have apparently only been tested and reported for ICD patients.

Relevance to clinical practice. Nurses internationally encounter increasing numbers of patients with pacemakers and ICDs from primary to tertiary clinical care settings, therefore knowledge of patient experiences relating to such devices and their impact is important to inform care planning. Whilst interventions to assist ICD patients are being tested, further research is required regarding the experiences of patients with contemporary pacemakers to inform care planning and potential nursing support interventions.

Key words: implantable cardioverter defibrillators, implanted cardiac devices, nursing interventions, patient experience, permanent pacemakers

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Introduction

With increasingly advanced technology being made available supported by international clinical trials demonstrating efficacy in expanding groups of cardiac patients (Moss *et al.* 1996, 2002, AVID Investigators 1997; Alexander *et al.* 2004; Bristow *et al.* 2004; Bardy *et al.* 2005; Cleland *et al.* 2005, NICE 2006, 2007), numbers of patients receiving permanent pacemaker and implantable cardioverter defibrillator devices are increasing worldwide. Beery *et al.* (2007) report that over 64,000 implantable cardioverter defibrillators (ICDs) and 197,000 permanent pacemakers (PPMs) were implanted in the United States in 2003 alone. The European Heart Rhythm Association Registry data for 2005 suggest rates of between 148,980–253,188 for first pacemaker implants and between 12,236–16,392 for first ICD implants from 2003–2005 across Europe (Ector *et al.* 2007).

PPMs and implantable cardioverter defibrillators (ICDs) can be classed as therapeutic technologies as they interrupt, stimulate, alter and/or regulate body processes (Marden 2005). Contemporary devices consist of a sealed lithium battery and programmable electronic circuitry in a small titanium metal box, usually in combination with at least one and up to three transvenous, endocardial leads. The experiences and needs of patients with pacemakers and ICDs may initially appear to be similar, as both groups have to live with an implanted device and the knowledge that they are, to some extent, dependent on technology. However, the underlying physiological reasons for each device implant are quite varied, with ICDs being provided either following resuscitation from a cardiac arrest or for primary prevention of one, whereas many pacemakers are provided to correct arrhythmias and for relief of rather less life-threatening symptoms such as dizziness, shortness of breath and syncope (Medtronic 2008, Arrhythmia Alliance 2008, National Institute for Health and Clinical Excellence [NICE] 2005, 2006, 2007).

Besides adjusting to having an implanted cardiac device from an aesthetic perspective (Davis *et al.* 2004), both groups must integrate routine technical checks in to their lives and learn to trust the technology. Both groups must cope with having battery generator box changes every few years and may be subject to technology recalls indicating that some or all of their system needs replacing (Medicines and Healthcare products Regulatory Agency 2005, 2006, 2007, Sears & Conti 2006, Hauser *et al.* 2007). Restrictions to activities are similar for both groups in avoiding electromagnetic fields (Prasad & Pennell 2004, Gimel 2008), avoiding contact with sports and understanding precautions regarding mobile phone use (Shan & Ellenbogen 2001). Driving restrictions are not as severe for pacemaker patients as for ICD patients, who face a permanent ban from driving heavy goods or public transport vehicles (DVLA 2008) and up to six months ban from driving standard vehicles, depending on the indication for the ICD (Driver and Vehicle Licensing Agency (DVLA) 2008, Sneed *et al.* 1997). These restrictions for ICD patients have generated quite strong emotions such as anger and frustration (James *et al.* 2001) and nurses caring for them are not well informed about such regulations (Tagney 2004).

Although pacemaker patients are sometimes able to feel their pacing therapy and may be entirely pacemaker dependent to maintain a functional heart beat, they do not have to contend with the high impact defibrillation shocks that many ICD patients feel and this would seem to be the biggest difference in how their experiences of living with an implanted cardiac device differ. However, care for all such device patients is often generic, focusing on technical issues and device follow-up rather than individual patient needs. Whilst some aspects of living with these therapeutic technologies may be similar for both groups, there may be issues that are specific to either pacemaker or ICD patients or to their underlying cardiac condition. Clearly, such information is essential to inform care planning.

As numbers of patients with devices increases and the move for arranging remote technical follow-up from home develops (Lunati *et al.* 2008), it is timely to consider patient's experiences, whether these differ depending on type of device and whether there is unmet need that may benefit from improved nursing support and/or intervention.

Aims

This literature review aims to critically appraise any published studies that compare the experiences of patients with permanent pacemakers and those with implantable cardioverter defibrillators and seeks to identify issues that are similar or unique to one or other group; whether identified needs are being met by current nursing practice and considers how any gaps might be addressed.

Methods

An integrative approach that accommodates the inclusion of studies with different methodologies was chosen to include as many sources of information as possible. Transvenous pacemaker implants were first undertaken in the late 1960s to early 1970s (Fulman 2003), but transvenous ICDs were not developed until late 1980s (Hammill & Stanton 1995). Therefore, a search of available literature was conducted using OVID MEDLINE, CINAHL, EMBASE, BRITISH NURSING INDEX, PSYCINFO and PUBMED electronic databases from 1975–2008. In an attempt to produce a comprehensive review of relevant literature, a wide range of search terms were used, identified from known publications and previous research including pacemaker, permanent pacemaker, implantable cardioverter defibrillator, ICD, implanted devices, transvenous pacemakers, quality of life, patient need, patient experience and psychological implications. Supplementary search terms 'psychological intervention', 'nursing intervention' were subsequently used and, to maintain the integrative approach, additional hand searches were also conducted by following related references from identified studies. Only articles written in English were accepted and articles that focussed on technical device efficacy, implant technique or complications, atrial defibrillators, case reports, book chapters and descriptive clinical reviews were rejected.

Results

Of the initial 472 results obtained, many were irrelevant (e.g. quality of life in cancer patients) and after applying the exclusion criteria above, only three direct comparison studies were found regarding experiences of patients with permanent pacemakers and those with ICDs-Duru et al. (2001), Leosdottir et al. (2006) and Newall et al. (2007). A fourth study reviewing self-reported adjustment experiences of both pacemaker and ICD patients was identified (Beery et al. 2007). Although this study was mainly concerned with evaluating the psychometric properties of the Implanted Device Adjustment Scale and did not set out to compare experiences of patients with pacemakers to those of patients with ICDs, it is included as comparisons and differences were noted. A fifth study 'Measuring patient acceptance of biomedical devices in cardiac patients' (Burns 2004) was excluded as only the abstract of this dissertation was available and patients with atrial defibrillators were included.

From the supplementary search for published papers that outlined possible support interventions with either pacemaker or ICD patient groups, a total of six papers were identified for pacemaker patients and eight for ICD patients. Two of those in the pacemaker search were excluded as they were actually descriptive clinical care papers suggesting the best way to care for patients before and after their pacemaker implant (Stewart and Sheehan 1991, Daberkow 1992). Of the remaining four papers, three are descriptive accounts of nursing support interventions (Hesse 1975, Rossel and Alyn 1977, Torrington *et al.* 1985), one (Schuster *et al.* 1999) was also excluded as it was a pilot study specifically testing the effects of intravenous sedation administration on learning retention after pacemaker implant. Eight studies reporting interventions with ICD patients were identified (Sneed *et al.* 1997, Kohn *et al.* 2000, Carlsson *et al.* 2002, Fitchet *et al.* 2003, Dougherty *et al.* 2005, Davids *et al.* 2005; Sears *et al.* 2007, Smeulders *et al.* 2007). The findings of these intervention studies are considered in the context of current clinical nursing practice.

Comparison studies of patients' experience

Duru et al. (2001) recruited 210 patients, aged 40-70 years, undergoing their first pectoral implantation of a pacemaker (n = 124) or ICD (n = 86) between 1993–1999. Their stated objective was to assess differences in psychosocial adaptation, quality of life and incidence of affective disorders between patients with pacemakers and those with ICDs. Questionnaires were mailed to potential respondents at least six months following implant (3.1 years in the pacemaker group, 2.3 years in the ICD group, which one presumes are 'mean' figures, although this is not stated). No difference was found between patients with pacemakers or ICDs (shock and no shock groups) regarding scores in the Hospital Anxiety and Depression (HAD) scale or Short Form 36 quality of life measurement. However, differences were revealed when asking questions in a specifically designed questionnaire related to technical functions of their device, related information and the need for support. Respondent's answers revealed a significant difference between shocked ICD patients and the other two groups (ICD without shock and pacemaker). Specifically, they reported more limitation in their leisure time activities than patients in the other two groups (p < 0.05) and were particularly concerned about the battery running out (p < 0.05) or about technical failure of their device (p < 0.05). The researchers also reported a greater demand for a support group in the shocked ICD group (42.2%) than in the non-shocked ICD group (20%) or the pacemaker group (19.7%), which was also statistically significant (p < 0.05) (Duru *et al.* 2001). Of concern is that the authors do not cite the untested, un-validated device related questionnaire as one of the limitations of the study, which arguably jeopardises the reliability and validity of the data generated. However, the authors appear to have sufficient confidence in their results to recommend the evaluation of potential benefits of a support group to patients' families as well as to patients themselves.

Leosdottir *et al.* (2006) conducted a study specifically comparing health-related quality of life, hypothesising that ICD patients may have worse quality of life than pacemaker patients. However, they were also assessing various other psychological variables, hence the study is included here. They invited all ICD patients in Iceland in 2002 to participate (44 patients) and a comparison group of randomly selected patients with pacemakers were invited to participate. They assessed all patients using the Beck Anxiety Inventory (BAI), the Beck Depression Inventory (BDI), the General Health Questionnaire (GHQ) and the Icelandic Quality of Life Questionnaire (IQL) and the ICD Psychosocial Index. 41/44 ICD patients chose to participate alongside 61/81 invited pacemaker patients. There were quite wide-ranging differences in time since implant, with ICD recipients having their device for between 11.6–154.9 months and pacemaker recipients from 13.4–290.6 months, yet the authors do not appear to consider this in their limitations or results sections. It seems the questionnaires were administered just once, when patients returned for a planned outpatient clinic appointment a mean time of 28 months following their device implant (range 11.6–154.9 months). This study did not reveal any statistically significant differences between the ICD and pacemaker group in any of the questionnaire scores. Equally, it failed to reveal statistically significant differences between shocked and non-shocked ICD patients. However, numerical differences were identified in responses to some of the questions in the ICD Psychosocial Index such as more fear of death (p = 0.055), more fear of device malfunction (p = 0.084), greater concerns about not being able to work (p = 0.061), more worried about having sex (p = 0.072) and driving (0.080). Although these are not statistically significant, they are similar issues to those identified by Duru et al. (2001). It would have been helpful if the authors could have reviewed results according to length of time since device implant to assess the impact of this additional variable on outcomes measured, as there was such a broad range included. The authors suggest that because individuals are found in both groups who suffer substantially from anxiety or depression, they support recommendations that clinicians should be aware of relevant signs and symptoms, responding to patient's need accordingly. Additionally, they suggest more information prior to implant and improved access to support groups for those in need.

Following on from these two European studies, Newall *et al.* (2007) compared experiences of ICD with pacemaker patients in their cross-sectional study, but interestingly confined the title to 'psychological implications of ICD implant in a New Zealand population'. Patients were randomly selected from pacemaker and ICD follow-up clinics by inviting all device patients to participate in a structured interview following their technical follow-up visit, where a questionnaire adapted from that used by Duru *et al.* (2001) was administered along with the Hospital Anxiety and Depression scale (HADS) and the SF-36 version 2 quality of life measure. The final sample consisted of 46 patients in the ICD group and 49 in the pacemaker group. Those in the ICD

group were significantly younger than those in the pacemaker group (mean age 56.2 years vs. 74.4 years p = 0.05) with increased age positively related to depression scores and inversely related to physical activity in pacemaker patients (i.e. these older patients were less active and more depressed). Regarding the adapted device specific questions, ICD patients thought about their device more frequently than pacemaker patients (16/46 vs. 3/49) and reported taking longer to adjust to their device than pacemaker patients (mean six months vs. mean less than one month). Significant differences were noted between groups regarding need for support groups (25/46 ICD pts [54%] vs. 16/49 PPM pts [32%] p = 0.03) and psychological support (18/46 ICD pts vs. 8/49 PPM pts p = 0.01). The researchers also compared anxiety and depression and mental component quality of life scores with device therapy including number of shocks received and whether these were appropriate or not (seven patients had received appropriate shocks, seven received inappropriate shocks), but found no relationship between any of these variables. The authors suggest that their service helped to ensure low levels of anxiety/depression for the ICD patients, because it consists of a small, consistent, staff group whom the patients get to know and who ensure pre-implant assessment with education at implantation and follow-up. They suggest that the higher levels of depression in the pacemaker group are mainly because of the higher proportion of older, female patients. However, there is no mention of this group being offered pre-implant assessment or education at implant or follow-up, the effects of which might be interesting to observe.

In the only identified American project involving comparison between PPM and ICD patient groups, Beery et al. (2007) conducted a cross-sectional correlational study using self-report data from 174 subjects, partly to provide factor analysis of the Implanted Device Adjustment Scale (IDAS). To support the construct validity of the IDAS, a visual analogue scale (VAS), the Profile of Mood States (POMS) and the SF-36 quality of life measures were used alongside it. The latter two were chosen as they measure components of quality of life (e.g. depression, mental and physical activity and mood) that have theoretical connections to adjustment. A convenience sample of 174 patients was recruited from two large Midwestern cities of North America, including two people with other implanted cardiac devices (e.g. loop recorders) but largely with pacemakers (n = 69, 40%) or ICDs (n = 102, 60%). As with Leosdottir *et al.* (2006), there were considerable differences noted in time since implant amongst the sample population, ranging from 3-252 months. Whilst no differences were noted between ICD and pacemaker patients with regard to total adjustment or other questionnaire scores, ICD patients were more fearful/anxious than those with pacemakers only (p < 0.027) in this subscale. Overall, younger patients (<66 years) in both groups showed statistically significantly more role limitation than older patients (p < 0.013) and had scores indicating more problems with attitude and body awareness (p < 0.01and <0.05 respectively). The authors suggest that older persons may be more accepting of physical limitations as they are more expected with ageing, whereas younger persons may have been limited by not being able to continue working, driving or participating in sports that they had previously enjoyed. The authors conclude that patients who perceived their devices as functioning effectively were better adjusted irrespective of the device (89%), although very few (8%) reported that their devices always worked well. The authors take this to indicate that patients can tolerate some technical malfunctions so long as, overall, they perceive device function to be adequate.

It is beyond the scope of this review to include the numerous studies that explore aspects of general and healthrelated quality of life in the separate groups (see Sears & Conti 2002 for a helpful overview and Groeneveld *et al.* 2007). However, it is perhaps worth noting that many quality of life studies relating to pacemaker patients focus on physical aspects of quality of life, related to the impact of various pacing modes in treating underlying disease processes and providing improvements in distressing symptoms such as dizziness, breathlessness and syncope (see Malm *et al.* 2003 and Van Eck *et al.* 2008 for overview). It seems that very few relate to the more qualitative aspects of learning to accommodate the technology into their lives (Beery *et al.* 2002).

Psychological interventions with pacemaker and ICD patients

Recommendations were made from the comparison studies regarding potential areas for intervention to assist adjustment and recovery following device implant in both pacemaker and ICD patients. However, it seems there are very few published accounts of such interventions and none identified that were applied to both pacemaker and ICD patients.

As identified in the search results, only descriptive accounts of clinical interventions were identified for pacemaker patients as opposed to clinical trials of such interventions and these are briefly outlined here (Hesse 1975, Rossel and Alyn 1977, Torrington *et al.* 1985). Hesse (1975) suggested that patient's misconceptions about their pacemaker and inadequate psychosocial support accounted for adjustment difficulties and describes establishing a Pacemaker Support Programme to provide psychosocial counselling and education about the pacemaker. Rossel and Alyn (1977) suggested that the patient's view of their pacemaker and any associated lifestyle alterations seemed to depend on accuracy of information received regarding what to expect and how to be assured that the device was functioning normally. This was echoed in a later paper by Torrington *et al.* (1985) and may relate to the findings of Schuster *et al.* (1999) who report that, following permanent pacemaker implantation, the amnesic effects of sedation used during the procedure severely impaired a patient's ability to retain information. This issue also applies to ICD patients who may have additional shortterm memory depletion associated with surviving sudden cardiac death events (Doolittle & Sauve 1995).

Entirely in keeping with the fact that their experiences have been more extensively studied (e.g. Dunbar et al. 1993, Dougherty 1994, Fridlund et al. 2000, James et al. 2000, Tagney et al. 2003) and are therefore rather better understood, evidence to support interventions specifically designed to assist recovery of ICD patients is accumulating. Several such studies have been published in recent years (Sneed et al. 1997, Kohn et al. 2000, Carlsson et al. 2002, Fitchet et al. 2003, Dougherty et al. 2005, Davids et al. 2005; Sears et al. 2007, Smeulders et al. 2007). Of these, one describes no obvious benefit from a support group intervention (Sneed et al. 1997), two studies report the benefits of comprehensive cardiac rehabilitation programmes on recovery (Fitchet et al. 2003, Davids et al. 2005), one reports the benefits of a structured nursing telephone intervention (Dougherty et al. 2005), one reports the benefits of a cognitive behavioural therapy based intervention (Kohn et al. 2000), one outlines benefits from a pilot study of a nurse-led education programme (Carlsson et al. 2002), another the feasibility of a nurse and peer-led self-management programme (Smeulders et al. 2007) and one the benefits of a structured psychosocial management programme (Sears et al. 2007). Of note is that five of the eight interventions were developed in North America (Sneed et al. 1997, Kohn et al. 2000, Dougherty et al. 2005, Davids et al. 2005; Sears et al. 2007) with much larger sample populations than the three European studies (Carlsson et al. 2002, Fitchet et al. 2003, Smeulders et al. 2007).

Interestingly, although all except Sneed *et al.* (1997) reported the benefits of the intervention over control groups, none of them appear to have taken any pre-implant, baseline measures and so it is not clear whether some of the benefit is because of psychological state prior to ICD implant. All studies bar one (Davids *et al.* 2005) report using some form of psychological support intervention and several (Kohn *et al.* 2000, Carlsson *et al.* 2002, Dougherty *et al.* 2005, Sears *et al.* 2007, Smeulders *et al.* 2007) report the involvement of

nurses in delivering the intervention. Thompson (2007) makes the very sensible point that training needs are an important consideration in delivering psychological interventions, with some complex interventions requiring acquisition of professional competencies that may be determined through regulatory bodies. These studies were conducted in the USA, where nurse training may include formal education and preparation for delivering complex psychological interventions; however, the specific training of the nurses involved is not stated in the study reports.

Discussion

It is clear that, according to the four comparison studies reviewed, patients with ICDs and pacemakers have very similar experiences around adjusting to technology. The main difference in how they adapt appears to be in relation to receiving shocks. The comparison studies (Duru *et al.* 2001, Leosdottir *et al.* 2006, Beery *et al.* 2007, Newall *et al.* 2007) raised areas to be considered when caring for all patients with a pacemaker or ICD: assessment of patient's understanding of their device and addressing any gaps in knowledge, discussion of any concerns or fears relating to device function or their underlying disease processes, lifestyle ramifications and the implications of their current health situation in relation to their device. However, no published work was identified reporting nursing interventions that applied to both pacemaker and ICD patients.

There appears to be a gap in the recent literature relating to the experiences of pacemaker patients and any psychosocial impact of pacemaker implant. It is perhaps not surprising then that little evidence could be found regarding successful interventions with pacemaker patients. It is also clear that ICD patients have benefited from more extensive research exploring their experiences than pacemaker patients, which appears to have led to the development of promising interventions aimed at assisting adjustment and recovery. Given that the recommendations from the comparison studies were directed at both patient groups, consideration should be given to possible reasons why the needs of pacemaker patients have apparently been marginalised.

In clinical practice, patients with pacemakers may be perceived as requiring less support than those with ICDs, perhaps because their underlying cardiac condition may seem less 'acute' or 'dramatic' compared with the potential for cardiac arrest that indicates the need for an ICD. However, some patients with pacemakers are in fact entirely dependent on their device to maintain a functional heartbeat and could therefore be considered to have equally important support needs.

Organisation of healthcare may also affect how patients are prepared prior to and following device implant as not all countries have nursing involvement in technical device follow-up clinics and involvement in implant procedures may also be limited. This could potentially lead to a lack of knowledge in the nursing teams and reluctance to become involved in information giving, possibly because of fear of being unable to answer questions from patients relating to technical device functions. Additionally, implant procedures are not performed in every hospital that accommodates cardiac patients, which can also perpetuate lack of knowledge and confidence if acceptance of this lack is allowed to persist. Only one study to date has attempted to assess cardiology nurses' knowledge relating to ICDs and their impact on patient's lives (Tagney 2004), and no studies are known that assess nurses' knowledge of pacemakers and their impact to patients. Results from Tagney (2004) suggested that nurses' knowledge in relation to both the technical function and psychological impact of ICDs had previously been assumed in the literature, not assessed and the same may be true of nurses' knowledge in relation to technical function and psychological impact of pacemakers.

Equally, the lack of research around patient experiences and interventions, particularly from Europe, may also reflect a gap in educational preparation of nurses and allied professionals that care for these patient groups. As public expectations for evidence-based care increase, we must consider ways of supporting the development of nursing research expertise to address gaps in knowledge (Priest 2007). Experimental research studies that test an intervention are identified as being especially deficient in cardiovascular nursing, with lack of time, money and competence cited as the main impediments (Fridlund 2007). Although there may be various approaches to support such skills development, Haigh (2008) has recently identified the strength to be captured through clinicians and academics collaborating to ensure rigour is combined with practical application in the creation of clinical knowledge. The development of consultant nurse posts in the UK was an attempt to combine such collaboration in individual roles and may prove a helpful vehicle to enable further research and develop practice in this area.

Future influences

The introduction of biventricular or cardiac resynchronisation therapy (CRT) pacing, with (CRT-D) or without (CRT-P) a defibrillator component, in patients with heart failure has created an additional subgroup of individuals living with quite complex pathophysiology and equally intricate technology (Schiffer *et al.* 2008). Whilst quality of life is being considered in such patients (Mark *et al.* 2008), it is equally essential to capture their subjective experiences to inform the development of appropriate interventions, particularly in those considered to be 'non-responders' to the therapy.

Implications of other future developments such as remote device monitoring (Lunati *et al.* 2008) and increasing numbers of children and young adults with devices must also be considered (Alexander *et al.* 2004, Sears & Conti 2005), as must the needs of device patients and their families when facing death and dying. These may include discussion around issues such as de-activation of shock therapies, informing palliative care teams about the symptom control rather than 'life prolonging' effects of CRT-P and information about the need to explant any devices after death prior to cremation (Goldstein *et al.* 2004, Arrhythmia Alliance 2007, BHF 2007).

Conclusion

Despite recommendations for care interventions made from studies comparing experiences of patients with pacemakers to those with ICDs, it seems that pacemaker patients have been neglected and no evidence was found regarding specific interventions for this group, or joint interventions for both groups. With the recent development of more complex technologies, there is a need for further research exploring patient experiences to inform potential interventions that may assist in adjustment processes. Further investigation is also required to understand any potential barriers to developing nursing research studies with device patients and testing clinical interventions that may enhance adjustment and recovery to ensure that any such potential barriers do not jeopardise appropriate advances in clinical practice.

Contributions

Study design: JT; data collection and analysis: JT and manuscript preparation: JT.

Conflict of interest

No support was received in developing this manuscript in terms of grants, equipment or drugs.

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