Palliative care in stroke

Palliative care aims to improve the outcome of patients, especially in life threatening conditions. This is usually provided through prevention and relieving of suffering by a holistic approach; considering the physical, psychosocial and spiritual modes of treatment. The chronic diseases are insidious in onset and are preventable; they contribute to a high mortality and morbidity in the developed world.[1] In this two part review, we look at palliative care in stroke.

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Chronic diseases represent the modern epidemic, where treatment options are exhausted and patients pass from the chronic illness phase to the terminal stage. There is evidence to support the notion that these patients require a palliative approach, even though they have non-malignant conditions.[2,3]

The emerging evidence suggests many health issues of the non-malignant condition are the same as those experienced by cancer patients towards the end of their life.[4] Palliative care has become important in the care of chronic illness in the last decades.[5] There are similarities between the palliative care needs of patients with chronic illness and cancer patients such as physical symptoms, psychological and spiritual needs.[6] However, there are some distinct differences as well. The trajectory of chronic illness is prolonged, compared to a cancer patient although they may have the same palliative care needs.[7]

Chronic illnesses typically affect the physical and psychosocial wellbeing of a patient at an earlier stage than to cancer patients. This leads to the progressive deterioration in their health and wellbeing until the end of their life.[8]

Generally, it is difficult to switch from therapeutic treatment to palliative treatment in a chronic disorder management. This may be due to the diagnostic uncertainty and unpredictable prognosis for the individual patients, the lack of right exposure, training among health workers and limited resources.

Patients with non-malignant conditions have frequent episodes of illness requiring hospitalisation, but the bulk of their care can be provided at home. The integration of service need is important to provide optimal care to these patients.[9] Once the therapeutic option is exhausted in a chronic illness, the clinician should discuss a palliative and supportive care approach at an earlier stage in a concerned fashion so that patients are aware about the outcomes and can plan their life accordingly. The specialist care should be structured around the needs and problems of the patient.

Even dying patients need improved symptom control; better nursing care and open communication about death and dying.[10-12] In 1992, an expert report recommended palliative care should be available to all patients who need it, irrespective of the diagnosis. Only 4% of the patients with non-malignant conditions were admitted for the first time to a hospice or a specialist palliative care unit in 1994–95 despite the fact that these units claimed they would accept referral for these patients.[13,14] Patients with non-malignant conditions are older and also have different dependency patterns.[10] Many of these terminally ill patients are too ill to participate in any type of research or they are still having active treatment, so are excluded from research.[15]

Stroke

Stroke is a major health problem worldwide and has a huge impact on a patient's life. It affects approximately 160,000 people in England every year, causing high mortality and morbidity. It is the third most common cause of death in the UK, with 26,400 people dying each year and costing the NHS approximately £2.8 billion.

Box 1: Complications of stroke.

Pain
- Aspiration pneumonia
- Incontinence of urine/bowel
- Pressure sore
- Loss of mobility/Contracture
- Recurrent fall

Psychological
- Depression
- Dementia
- Lack of emotional support

Social
- Dependent on daily activities
- Lack of financial support

Impact on family and carer
- Job issues for informal carer
- Loss of income
- Physical strain
- Psychological vulnerability
- Limited social life
- Reduced happiness.

Around one third of patients die in the first month after a stroke and most within the first 10 days.[16] The cerebrovascular diseases account for 12% of all deaths.[17] The relative risk of death after a stroke compared to the general population is about 20 times for those over 60 years and doubles for patients over 70 years.[18]

Australian studies have reported that five years after a stroke, 40% of patients were still alive, with half of these disabled or dependent.[19] The literature on prevention, treatment and rehabilitation exists, but little evidence is available about the role of palliative care in dying stroke patients. We know that in developed countries with ageing populations,[20] the incidence of stroke will increase in direct proportion to the age and the majority of the patients affected are above 65 years. It is a prime cause of disability, leading to a permanent residual deficit, which affects them physically and psychologically, leading to a major impact on both the family and society.

It is estimated that approximately 40% of patients with stroke do not fully recover and many are transferred to care homes permanently. Once stroke develops they require complex care as complications can lead to long-term disability (Box 1). Thus, regular input is required from a multidisciplinary team so that the appropriate care can be provided to the patient.

Palliative care and stroke

The awareness about palliative care in stroke is very limited amongst clinicians. Recently "National Clinical Guidelines for Stroke" recommended that all patients with stroke should have accessibility to palliative care if needed and health workers involved in this care should undergo necessary training.

The provisions of palliative care for stroke patients are complex, and require an appropriate input from the clinicians. It helps to understand the psychological and spiritual wellbeing of the patient rather then only physical needs. It is necessary that we assess those interventions, which help in supportive and palliative care provision, so that if the need arises they can be implemented. The palliative care provision to stroke patients should give a clinical benefit in all aspects and be cost effective.

The NHS End of Life Care Programme (2005) is aimed at improving end of life care to all patients irrespective of their diagnosis. This is to help those with advanced, progressive and incurable conditions to live as well as possible until they die. It identifies the needs of both the patient and family and ensures that these needs are met throughout the last phase of the patient's life and into bereavement. The Programme rolled out a few initiatives to improve end of life care (Box 2).

The Gold Standards Framework supports the complete evaluation of palliative care in the community, to provide the appropriate care in a home set up.

The Liverpool Care Pathway (LCP) provides the guidelines to deal with terminally ill patients in an acute set up in a generic way. The LCP is a multiprofessional document that provides excellent care during the dying phase. It helps in providing guidance on the different aspects of care required including comfort measures, anticipatory prescribing of medication, discontinuation of inappropriate interventions, psychological and spiritual support. It also focuses on bereavement and support to the family members.

The Preferred Place of Care tool is a patient held document with the aim of improving services and giving patient's choice as to where they receive their care.[21]

The burden of stroke in an acute setting

A number of studies have tried to identify the total number of patients who are likely to die and then to identify how many patients may have had a stroke. However,

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Presentation: Epilim 200 Enteric Coated and Epilim 500 Enteric Coated: Enteric coated tablets containing 200mg, and 500 mg sodium valproate, respectively. Epilim Crushable tablets containing 100 mg sodium valproate. Epilim Syrup and Epilim Liquid (sugar free) both containing 200 mg sodium valproate per 5 ml. Epilim Chrono 200, Epilim Chrono 300, and Epilim Chrono 500: Controlled release tablets containing a mixture of sodium valproate and valproic acid equivalent to 200 mg, 300 mg and 500 mg sodium valproate respectively. Epilim Chronosphere MR 50mg, Chronosphere MR 100mg, Chronosphere MR 250mg, Chronosphere MR 500mg, Chronosphere MR 750mg, and Chronosphere MR 1000mg: modified-release granules containing a mixture of sodium valproate and valproic acid equivalent to 50mg, 100mg, 250mg, 500 mg, and 750mg of sodium valproate respectively. Epilim Intravenous: 400mg sodium valproate freeze-dried powder per vial.

Indications: All types of epilepsy. Epilim IV - the treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.

Dosage and administration: ***Adults:*** titrate at three day intervals until seizure control is achieved. Initially 600 mg/day increasing in steps of 200 mg to a maximum dose of 2500 mg/day (in the case of Chronospheres to the nearest whole 50mg sachet). ***Children over 20 kg:*** initially 400 mg/day increasing in steps to a maximum dose of 35mg/kg/day (in the case of Chronospheres to the nearest whole 50mg sachet). ***Children under 20 kg:*** initially 20 mg/kg/day - the dose may be increased in severe cases provided that plasma levels are monitored; above 40mg/kg/day chemistry and haematology should be monitored. Epilim Chrono should not be used in this group of patients, due to the tablet size and need for dose titration. ***Epilim Chrono and Chronosphere*** may be given once or twice daily. All other formulations should be given twice daily. ***Epilim Chronosphere*** should be sprinkled on a small amount of soft food or in drinks, which should be cold or at room temperature. The granules should not be crushed or chewed. If preferred the granules can be poured directly into the mouth and washed down with a cold drink. ***Epilim IV*** - Patients already satisfactorily treated with Epilim may be continued at their current dosage using continuous or repeated infusion. Other patients may be given a slow intravenous injection over 3-5 minutes, usually 400-800mg depending on body weight (up to 10mg/kg) followed by continuous or repeated infusion up to a maximum of 2500mg/day. Epilim IV should be replaced by oral Epilim therapy as soon as practicable. ***Combination therapy:*** When starting Epilim in patients already on other anticonvulsants, these should be tapered slowly; initiation of Epilim therapy should then be gradual, with target dose being reached after about 2 weeks. Adjust dose in renal impairment. ***Renal insufficiency*** it may be necessary to decrease the dosage.

Contraindications: Active liver disease, family or personal history of severe liver dysfunction, especially drug related, porphyria, hypersensitivity to valproate.

Special warnings and precautions: ***Discontinuing Epilim:*** discontinuation should normally only be done under the supervision of a specialist in a gradual manner. ***Liver dysfunction:*** Severe liver damage, including hepatic failure sometimes resulting in fatalities, has been very rarely reported. Experience in epilepsy has indicated that patients most at risk, especially in cases of multiple anticonvulsant therapy, are infants and in particular young children under the age of 3 years and those with severe seizure disorders, organic brain disease, and (or) congenital metabolic or degenerative disease associated with mental retardation. The concomitant use of salicylates should be avoided in children under 3 years. Monotherapy is recommended in children under the age of 3 years. In most cases, such liver damage occurred during the first 6 months of therapy, the period of maximum risk being 2-12 weeks. Liver function should be measured before therapy and then periodically monitored during the first 6 months of therapy. ***Pancreatitis:*** Pancreatitis, which may be severe and result in fatalities, has been very rarely reported. Patients experiencing nausea, vomiting or acute abdominal pain should have a prompt medical evaluation (including measurement of serum amylase). ***Women of childbearing potential:*** This medicine should not be used in women of child-bearing potential unless clearly necessary. This assessment is to be made before Epilim is prescribed for the first time, or when a woman of child bearing potential treated with Epilim plans a pregnancy. Women of child-bearing potential must use effective contraception during treatment. ***Suicidal ideation and behaviour:*** Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. ***Carbapenem agents:*** The concomitant use of valproate and carbapenem agents is not recommended. ***Haematological:*** Blood tests are recommended prior to initiation of therapy or before surgery, and in case of spontaneous bruising or bleeding ***Renal insufficiency:*** In patients with renal insufficiency, it may be necessary to decrease dosage. As monitoring of plasma concentrations may be misleading, dosage should be adjusted according to clinical monitoring ***Systemic lupus erythematosus:*** The benefit of Epilim should be weighed against its potential risk in patients with systemic lupus erythematosus ***Hyperammonaemia:*** When a urea cycle enzymatic deficiency is suspected, metabolic investigations should be performed prior to treatment because of the risk of hyperammonaemia with Epilim. ***Weight gain:*** Patients should be warned of the risk of weight gain at the initiation of therapy and appropriate strategies should be adopted to minimise it. ***Pregnancy:*** Women of childbearing potential should not be started on Epilim without specialist neurological advice. Adequate counselling should be made available to all pregnant women with epilepsy of childbearing potential regarding the risks associated with pregnancy because of the potential teratogenic risk to the foetus. ***Diabetic patients:*** Epilim is eliminated mainly through the kidneys, partly in the form of ketone bodies; this may give false positives in the urine testing of possible diabetics. ***Alcohol:*** Alcohol intake is not recommended during treatment with valproate.

Interactions which effect valproate levels: ***Interactions which decrease valproate levels:*** antiepileptics with enzyme inducing effect (including phenytoin, phenobarbital, carbamazepine), mefloquine, chloroquine, rifampicin and carbapenem antibiotics (such as imipenem, panipenem and meropenem). ***Interactions which increase valproate levels:*** Highly protein bound agents (e.g. aspirin), felbamate, cimetidine or erythromycin.

Pregnancy & Lactation
Pregnancy: In humans available data suggest an increased incidence of minor or major malformations including neural tube defects, cranio-facial defects, malformations of the limbs, cardiovascular malformations, hypospadias and multiple anomalies involving various body systems in offspring born to mothers with epilepsy treated with valproate. The data suggest that the use of valproate is associated with a greater risk of certain types of these malformations (in particular neural tube defects) than some other anti-epileptic drugs. Data have suggested an association between in-utero exposure to valproate and the risk of developmental delay (frequently associated with dysmorphic features), particularly of verbal IQ. However, the interpretation of the observed findings in offspring born to mothers with epilepsy treated with sodium valproate remains uncertain, in the view of possible confounding factors such as low maternal IQ, genetic, social, environmental factors and poor maternal seizure control during pregnancy. Both valproate monotherapy and valproate as part of polytherapy are associated with abnormal pregnancy outcome. Available data suggest that antiepileptic polytherapy including valproate is associated with a higher risk of abnormal pregnancy outcome than valproate monotherapy. Autism spectrum disorders have also been reported in children exposed to valproate in utero. The following recommendations should be taken into consideration: This medicine should not be used during pregnancy and in women of child-bearing potential unless clearly necessary (i.e. in situations where other treatments are ineffective or not tolerated). This assessment is to be made before Epilim is prescribed for the first time, or when a woman of child bearing potential treated with Epilim plans a pregnancy. Women of child-bearing potential must use effective contraception during treatment. Women of child-bearing potential should be informed of the risks and benefits of the use of Epilim during pregnancy. If a woman plans a pregnancy or becomes pregnant, Epilim therapy should be reassessed whatever the indication: In epilepsy, valproate therapy should not be discontinued without reassessment of the benefit/risk. If further to a careful evaluation of the risks and benefits, Epilim treatment is to be continued during pregnancy, it is recommended to use Epilim in divided doses over the day at the lowest effective dose. The use of a prolonged release formulation may be preferable to any other treatment form. In addition, if appropriate, folate supplementation should be started before pregnancy at relevant dosage (5mg daily) as it may minimise the risk of neural tube defects. Specialised prenatal monitoring should be instituted in order to detect the possible occurrence of neural tube defects or other malformations. ***Lactation:*** Although there appears to be no contra-indication to breastfeeding, physicians are advised that in any individual case, consideration should be given to the safety profile of Epilim, specifically haematological disorders.

Please refer to the SPC for further information and recommendations

Undesirable effects: ***Congenital and familial/genetic disorders:*** Malformations most frequently encountered are cleft lip and cardiovascular malformations. ***Hepato-biliary disorders:*** rare cases of liver injury. Increased liver enzymes are common, particularly early in treatment, and may be transient ***Gastrointestinal disorders:*** (nausea, gastralgia, diarrhoea) frequently occur at the start of treatment, but they usually disappear after a few days without discontinuing treatment. Very rare cases of pancreatitis, sometimes lethal, have been reported ***Nervous system disorders:*** Sedation has been reported occasionally, usually when in combination with other anticonvulsants. Rare cases of lethargy occasionally progressing to stupor, sometimes with associated hallucinations or convulsions have been reported. Encephalopathy and coma have very rarely been observed. These cases have often been associated with too high a starting dose or too rapid a dose escalation or concomitant use of other anticonvulsants. They have usually been reversible on withdrawal of treatment or reduction of dosage. Very rare cases of extrapyramidal symptoms which may not be reversible including reversible parkinsonism, or reversible dementia associated with reversible cerebral atrophy have been reported. Dose-related ataxia and fine postural tremor have occasionally been reported. An increase in alertness may occur and occasionally aggression, hyperactivity and behavioural deterioration have been reported. Confusion has been reported. ***Metabolic disorders:*** Cases of isolated and moderate hyperammonaemia without change in liver function tests may occur frequently are usually transient and should not cause treatment discontinuation. However, they may present clinically as vomiting, ataxia, and increasing clouding of consciousness. Should these symptoms occur Epilim should be discontinued. Very rare cases of hyponatraemia have been reported. Syndrome of inappropriate secretion of ADH (SIADH). Hyperammonaemia associated with neurological symptoms has also been reported. ***Blood and lymphatic system disorders:*** Frequent occurrence of thrombocytopenia, rare cases of anaemia, leucopenia or pancytopenia. The blood picture returned to normal when the drug was discontinued. Bone marrow failure, including pure red cell aplasia, Agranulocytosis. Isolated findings of a reduction in blood fibrinogen and/or an increase in prothrombin time have been reported, usually without associated clinical signs and particularly with high doses. Spontaneous bruising or bleeding is an indication for withdrawal of medication pending investigations. ***Skin and subcutaneous tissue disorders:*** Rash rarely occurs with Epilim. In very rare cases toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme have been reported. Transient hair loss, which may sometimes be dose-related, has often been reported. ***Reproductive system and breast disorders:*** Amenorrhoea and dysmenorrhoea have been reported. Very rarely gynaecomastia has occurred. Male infertility. ***Vascular disorders:*** The occurrence of vasculitis has occasionally been reported. ***Ear disorders:*** Hearing loss, either reversible or irreversible has been reported rarely. ***Renal and urinary disorders:*** There have been isolated reports of a reversible Fanconi's syndrome (a defect in proximal renal tubular function giving rise to glycosuria, amino aciduria, phosphaturia, and uricosuria), but the mode of action is as yet unclear. Very rare cases of enuresis have been reported. ***Immune system disorders:*** Angioedema, Drug Rash with Eosinophilia, Systemic Symptoms (DRESS) syndrome and allergic reactions (ranging from rash to hypersensitivity reactions) have been reported.

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Further information: Epilim is hygroscopic - keep tablets in blister pack until use and avoid cutting blister strips. Epilim Liquid should not be diluted.

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Epilim Liquid	11723/0024	300ml	£7.78
Epilim Chrono 200	04425/0307	100 tablets	£11.65
Epilim Chrono 300	04425/0308	100 tablets	£17.47
Epilim Chrono 500	04425/0309	100 tablets	£29.10
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Epilim Chronosphere MR 100mg	04425/0312	30 sachets	£30.00
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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk.

Adverse events should also be reported to the sanofi-aventis drug safety department on 01483 505515.

Box 2: Issues during the last year of life

Physical health
- Pain
- Urinary incontinence
- Infection

Psychological
- Cognition
- Depression
- Loneliness

Social care
- Housebound
- Dependent on living by carers

Spiritual

these studies didn't provide the extent of palliative care required as more detailed information was unavailable. The King's College Hospital London Palliative Care Team conducted a case notes review of a set of 553 patients in an acute hospital over three days in 1998.[22] Sixty-four (12%) patients had advanced disease, which was no longer amenable to curative treatment and five patients had the main diagnosis of cerebrovascular disease. A similar study was also conducted in one of the acute hospitals in Sheffield. Case notes of 452 inpatients on a given day were reviewed. Ninety-nine (23%) patients were considered by staff to have palliative care needs, out of which six patients had a stroke. Similar studies have also been conducted worldwide.[23-25] The overall impression is that palliative care provision for stroke patients needs to be set up, so that the optimal care for dying patients can be provided.

Informal carers

The majority of stroke survivors are provided help in the form of physical and emotional support, mainly by close family members. These carers, commonly known as informal carers are not paid but are valuable resources. As a health resource, informal carers play an important role in the successful rehabilitation outcome in stroke survivors.[26] Patients who are poorly supported by family members have psychological problems leading to poorer outcomes.[3,27]

An extensive review on informal carers was conducted in 1999 to identify all the studies considering the impact of a stroke, the factors which help in caring

for a stroke survivor and the health service provision.[28] They could identify 29 studies exclusively on stroke carers. Review studies mainly looked at the psychological impact of caring for the stroke, using the concept of psychological morbidity and a carer burden.[29,30]

The results of this showed that the presence of behaviour, incontinence and cognitive abnormalities in stroke patients, predict carers' emotional dysfunction. The carers' physical health, psychological state and relationship with the stroke survivor prior to the stroke may determine the carers' psychological state post stroke. These studies have established that caring for a stroke patient has a detrimental effect on the physical and social health of the carer. They also highlighted the fact that the use of positive coping techniques contributed to a better psychological outcome.

In a retrospective survey Regional Study of Care for the Dying (RSCD), data was collected by taking information from a randomly selected sample of people who died in 1990.[10] This was from 20 self-selected English health districts that were in the national sample in terms of socio-demographic characteristics and healthcare provision. The respondents included 111 people with the majority of them being informal carers. Of the informants, 20% were spouses, 48% relatives, 20% officials and 11% friends or neighbours.

Two fifths of stroke patients who died needed more help with personal care, a quarter needed more help with domestic chores and a third needed more financial help. Stroke patients living in the community require more help with domestic chores, especially for personal care. Informal carers required better support, especially covering the psychological aspects. Informal carers experienced moderate restrictions in their activities. Two thirds of carers felt that their roles had an adverse impact on their lives.[31] The data also suggested that spouses found caring less rewarding than other respondents. This could be due to the fact that spouses have lost their social companion, particularly if stroke had led to communication and cognition deficit. Thus, improved support for informal carers is required and further research is necessary to identify and evaluate effective ways of providing appropriate support in the community.

The integration of the health and social services is necessary to avoid stroke patients and their families being adversely affected by boundary disputes where neither service takes responsibility for meeting the patients' needs.

The above study was not randomly selected, but the population covered had a similar health service provision, demographic spread and death rate.[5] A further disadvantage of the retrospective approach is that unless patients die from disease, it is difficult to link the study population with any group of patients who can be identified prospectively. The sample size of the study was small and conducted in England only.

Conclusion

Like any other chronic illness, it is difficult to pinpoint an accurate prognosis in stroke. The expertise in palliative care is mainly cancer based and modifying the principles so that it can be provided to stroke patients in an effective and realistic way is a big challenge.

Conflict of interest: none declared

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