REPORT

health technology assessment

ELECTRICAL STIMULATION IN STROKE

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MINISTRY OF HEALTH
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This Health Technology Assessment Report has been prepared from information based on literature reviews and expert opinion. It has been externally reviewed and approved by the Health Technology Assessment Council, Ministry of Health Malaysia. Queries and comments should be directed to"

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EXECUTIVE SUMMARY

1. INTRODUCTION

Stroke is the second leading cause of death globally, and one of most common causes of long-term disability worldwide. Many surviving stroke patients need help in activities of daily living, provided by family members, the health system, or other social institutions.

Stroke disability and outcomes depend on the severity of neurological deficits on presentation. It is estimated that 19% are very severely disabled, 4% severely disabled, 26% moderately disabled, while 41% have minor disability. After complete stroke rehabilitation, 11% of the stroke survivors still have very severe or severe neurological deficits, 11% have moderate disability and 78% have none or only minimal disability.

Shoulder pain is a common complication after a stroke, with about 16 – 72% of patients developing hemiplegic shoulder. There is little or no voluntary movement of the affected upper limbs, and starts usually on the second week after stroke.

To date there is some indication that physiotherapy may be beneficial, especially if the intervention is early. The content of physical therapy may also influence outcome.

2. POLICY QUESTION

Should electrical stimulation be used (singly or in combination with other techniques) in the treatment of stroke patients for improving muscle function, gaining motor function and improving quality of life?

3. SCOPE

- To consider the use of electrical stimulation only for post-stroke rehabilitation
- To include all mode of application/techniques of electrical stimulation
- To consider its use either singly or in combination with other rehabilitation techniques.

4. OBJECTIVE

To determine the safety and effectiveness of using electrical stimulate (ES) in the treatment of stroke patients in improving muscle function, gaining motor function and improving quality of life.

5 RESULTS

There is sufficient evidence that electrical stimulation (ES) is a relatively safe modality, though there is a possibility of triggering epileptic fits with trans-cutaneous electrical nerve stimulation (TENS) in susceptible patients.

For shoulder subluxation and pain, there is sufficient evidence that both TENS and functional electrical stimulation (FES) are effective in promoting improvement in shoulder dysfunction and providing pain relief. There is also sufficient evidence that ES promotes recovery of muscle strength and improves motor function. There is also some evidence to support the effectiveness of the ES combined with other conventional therapies.

There is also some evidence that ES is a relatively low-cost intervention

6. RECOMMENDATION

Electrical stimulation for the treatment of selected stroke patient is safe, low cost, and is advocated for use selectively in the early rehabilitation of stroke patients for the beneficial effect of the hemiplegic shoulder, restoration of motor function and quality of life. However, it is recommended that centers utilizing this modality have trained personnel involved and also involves training care givers utilizing this modality in home rehabilitation programs. Appropriate protocols and monitoring should be developed and utilized, as well as reviewed on a regular basis.

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1. BACKGROUND

In many parts of the world, the proportion of the population surviving until their 50s and 60s is increasing. This trend will have immense effects on the demographic structure of societies in the near future. The global population aged over 65 years is increasing by 9 million a year, and by 2025, it is estimated that there will be more than 800 million people over the age of 65 years in the world. Of these, two thirds will be living in developing countries, e.g. in China alone, there will be more than 180 million people over the age of 65. Increases of up to 300% of the older population are expected in many developing countries within the next 30 years, especially in Latin America and Asia.

Stroke is one of most common causes of death and long-term disability worldwide, being said to be the second leading cause of death globally (CDC, 2004). Two thirds of these deaths occur in people living in developing countries and 40% of the subjects are aged less than 70 years. Thus, while many of these countries are struggling with the consequences and problems of communicable diseases, non-communicable diseases are on the rise. In addition to being a major cause of death, many surviving stroke patients are disabled and need help in activities of daily living, which must be provided by family members, the health system, or other social institutions (WHO, 2002).

2. INTRODUCTION

2.1 Definition

The recommended WHO definition of stroke is “a focal (or at times global) neurological impairment of sudden onset, and lasting more than 24 hours (or leading to death) and of presumed vascular origin” (Hatano, 1976). This definition excludes transient ischaemic attack (defined as focal neurologic symptoms lasting less than 24 hours), sub-dural hemorrhage, epidural hemorrhage, poisoning, and symptoms caused by trauma.

There are three major stroke sub-groups; ischaemic stroke, intra-cerebral hemorrhage, and sub-arachnoid hemorrhage. Each of the types can produce clinical symptoms that fulfill the definition of stroke. However, they differ with respect to survival and long-term disability

2.2 Prevalence and Mortality of Stroke

The prevalence of stroke varies widely, with no consistent trends across countries. Some studies have shown no significant change in stroke incidence over time (Baker & Mullooly, 1997; Ryglewicz et al., 1997; Stegmayr & Asplund, 1996) whereas, others show a decreasing trend (Fogelholm et al., 1997; Tuomilehto et al., 1996), while yet others have shown an increasing incidence (Korv et al., 1996; La Rossa et al., 1993).

It has been estimated that stroke accounted for 5.5 million deaths world wide, equivalent to 9.6% of all deaths in 2001 (WHO, 2002). Although stroke mortality has decreased in most industrialized countries, in some populations, particularly in East Europe, the mortality has increased (Stegmayr & Asplund, 2003). The age standardized, gender specific stroke mortality rate is 44 – 102.6 /100 000 for Japanese and Chinese males, compared with only 19.3 for Australian white males (Zhang et al., 2004). In Malaysia, the cerebro-vascular disease mortality rate is 9.27% and 8.48% in 2000 and 2001 respectively (MOH, 2001).

2.3 Disabilities

Stroke disability and outcomes depend on the severity of neurological deficits on presentation. It has been estimated that 19% are very severely disabled, 4% severely disabled, 26% moderately disabled and 41% have minor disability, while the remaining 10% have no disability. After complete stroke rehabilitation, 11% of the stroke survivors still had very severe or severe neurological deficits, 11% had moderate disability and 78% have no or only minimal disability (Jorgensen et al., 1995). Other studies have found that a large proportion of stroke patients remain moderately or severely disabled (Andrew & Bohannon, 2000; Brown et al., 1999; Bonita & Solomon, 1997; Wade et al., 1983). The magnitude of resultant physical disability is illustrated by the finding that the strength of the lower limbs of patients able to perform voluntary movements early post stroke, may only be 45% of normal at the end of in-patient rehabilitation (Andrew & Bohannon, 2000).

Shoulder pain is a common complication after a cerebro-vascular accident. Studies have shown 16 – 72% of stroke patients develop hemiplegic shoulder pain (Van Ouwenaller, Laplace & Chrantraine, 1986; Hanukah et al., 1984). It may occur in up to 80% of stroke patients who have little or no voluntary movement of the affected upper limbs, and starts usually the second week after stroke, but could start earlier or later (Chantraine et al., 1999)

Hemiplegic shoulder pain has been shown to affect outcome in a negative way (Roy et al., 1995). It interferes with recovery after a stroke, can cause considerable distress and reduced activity, and can markedly hinder rehabilitation (Griffin, 1986; Anderson, 1985). Roy et al (1994) demonstrated that hemiplegic shoulder pain is strongly associated with prolonged hospital stay and poor recovery of arm function in the first 12 weeks after stroke. The cause of hemiplegic shoulder pain has been the subject of considerable controversy. The following processes have all been postulated as causes of painful hemiplegic shoulder - glenohumeral subluxation, spasticity of shoulder muscles, impingement, soft tissue trauma, rotator cuff tears, glenohumeral capsulitis, bicipital tendonitis, and shoulder hand syndrome (Van Ouwenaller, Laplace & Chrantraine, 1986; Van Langenberghe & Hogan, 1986; Hanukah et al., 1984; Rizk et al., 1984; Jensen, 1980; Najenson, Yacubovic & Pikienley, 1971).

24 Treatment

To date there is no evidence that one physiotherapy approach is better than another (Ashburn, Partridge & Souze, 1993; Ernst, 1990). Some studies have indicated that physiotherapy as a whole may be beneficial (Kwakkel et al., 1999; Feys et al., 1998; Dean & Shepgerd, 1997; Ashburn, Partridge & Souze, 1993; Ernst, 1990). Early intervention may be better than late (Cifu & Stewart, 1999), but even late physical therapy may be beneficial (Dean & Shepgerd, 1997; Wade et al., 1992; Yekutiel &

Guttman, 1993). The content of physical therapy may also influence outcome (Parry, Lincoln & Vass, 1999).

3. POLICY QUESTION

Should electrical stimulation be used (singly or in combination with other techniques) in the treatment of stroke patients for improving muscle function, gaining motor function and improving quality of life?

4. SCOPE

- To consider the use of electrical stimulation only for post-stroke rehabilitation
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5. OBJECTIVE

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6 TECHNICAL FEATURES

Electrical neuromuscular stimulation (ES) was first described over 35 years ago (Liberson et al., 1961). Application of an electrical current to the skin stimulates lower motor nerves and muscle fibres resulting in improved contractility and greater muscle bulk (Albert et al., 1984). Decreased spasticity and sensory cortex activation occurs via afferent neuron stimulation, with additional information being provided by the proprioceptive and visual perception of ES induced joint movement (Faghri, 1997; Kumar et al., 1995; Dimitriijevic & Soroker, 1994). Clinical reports have suggested that ES can improve muscle group strength, joint mal-alignment, muscle tone, sensory deficits, pain-free range of passive humeral lateral rotation, as well as self-reported pain intensity (Faghri, 1997; Pandyan et al., 1997; Baker & Parker, 1986; Prade & Tallis, 1995). Most studies of hemiplegic shoulder pain have pursued an analgesic effect through the use of ES to reduce glenohumeral subluxation and obtain better shoulder positioning.

The electrical stimulation system consists of three parts - stimulator unit, electrodes and connecting wires. The electrodes are connected to the stimulator unit by leads that are snapped to the button of the electrode. The electrodes are commercially available, pre-gelled cutaneous electrodes with adhesive sponge backing. The electrical stimulator units are battery-powered and deliver a train of square wave pulses at 33 pps, with a 200-μsec pulse width.

Although ES is frequently administered via two methods, the distinction between them in the clinical setting is unclear. Functional electrical stimulation (FES) causes contraction of muscles in an organized fashion to facilitate the recovery of limb function, reduce spasticity or create better alignment of a joint's articular surface. Trans-cutaneous electrical nerve stimulation (TENS) is often used specifically as an analgesic technique to mask pain by giving lower intensity, higher frequency stimulation to cutaneous peripheral nerves without causing muscle contraction. However, regimens in between FES and TENS have been described, such as “high intensity TENS” (Leandri et al., 1990). The treatment effects of these techniques also overlap e.g. FES has been described as an analgesic (Faghri, 1997), whilst TENS may reduce spasticity and improve function (Potisk, Gregoric & Vodonik, 1995).

6.1 Functional Electrical Stimulation

Functional Electrical Stimulation (FES) is a means of producing useful movement in paralyzed muscles. Electrical impulses are applied using either the skin surface or implanted electrodes and cause muscles to contract in a controlled manor. At the electrode tissue interface, a conversion occurs between the current of electrons passing through the wires and the current of ions moving within the tissue. Then, through this externally applied current, the depolarization of nerve and muscle to threshold is produced by the transport of ions across the tissue membrane. The factors determining whether sufficient current flows to cause an action potential are, impedance of body tissue, electrode size and position, and stimulation parameters.

6.2 Trans-cutaneous Electrical Nerve Stimulation

Trans-cutaneous Electrical Nerve Stimulation (TENS) is a simple, non-invasive analgesic technique that is used for the symptomatic management of acute and non-malignant chronic pain. However, TENS is also used in palliative care to manage pain caused by metastatic bone disease and neoplasm. TENS machines deliver small electrical pulses to the body via electrodes placed on the skin. The stimulation from a TENS machine, which feels like “pin and needles”, affects the way pain signals are sent to the brain. Pain signals reach the brain via sensory nerves and the spinal cord; if these pain signals can be blocked, and then the brain will receive fewer signals from the source of the pain, and will thus feel less pain. TENS machines are thought to work in two ways as follows - when the machine is set on a high pulse rate (90-130Hz) it triggers the ‘pain gate” to close. This is thought to block a pain nerve pathway to the brain. This is the normal method of use. Alternatively, when the machine is set on a low pulse rate (2-5 Hz) it stimulates the body to make its own pain easing chemicals called endorphins. These act a bit like morphine to block pain signals.

These two ways of working tend to reduce different types of pain. High pulse rates tend to ease pain of an acute or superficial nature. The effect can be slow to develop but can last for many hours. Low pulse rates tend to be more effective on chronic deep aching type of pain, but tend not to last as long. Low pulse rates are generally not as comfortable, but the pain relieving effect can be deeper than that produced by higher frequencies. With either high or low frequency TENS is used, once pain is eased, the machine can be disconnected for several hours before it needs to be re-applied. (http://www.patient.co.uk , 26/6/04)

TENS is mainly used for the symptomatic management of acute and non malignant chronic pain. TENS is also used in palliative care to manage pain caused by mestatic bone disease and neoplasm. It is also claimed that TENS has anti-emetic and tissue healing effects although it is used less often for these action.

7. METHODOLOGY

Details of the methodology are as indicated in Appendix 1

8. RESULTS & DISCUSSION

8.1 Safety

The most noted clinical complications include localized inflammation at the electrode site and superficial infection that responds well to topical and oral antibiotic treatment. A study carried out on two long-time users of the system reported that they had no adverse effects to their skeletal system, and the most common problems were daily care of electrodes at exit sites, frequent irritation of the skin around electrodes, and replacement of failed electrodes FES is found to be relatively safe in more than 17 years' use (Agarwal et al., 2003).

In a study comparing stimulation-induced pain during percutaneous (intra-muscular) and transcutaneous neuromuscular electric stimulation for treating shoulder subluxation in hemiplegia, it was found that percutaneous neuromuscular electric stimulation is less painful than trans-cutaneous neuromuscular electric stimulation (Yu et al., 2001).

Rosted (2001) reported in a case study that repetitive epileptic fits was presented in a post-stroke patient after TENS. It seems more likely than not that the TENS triggered the repetitive fits in this patient. Although the risk of this adverse effect seems to be small, it should be borne in mind when TENS is used in a post-stroke patient.

8.2 Effectiveness

8.2.1 Shoulder subluxation and pain

Persistent shoulder pain after stroke that does not respond to simple analgesics should be treated with high intensity TENS or FES (Walsh, 2001).

Trans-cutaneous neuromuscular electric stimulation also decreases shoulder subluxation, but its effect on shoulder pain remains uncertain (Chae & Yu, 2002). Another study also showed that neuromuscular electric stimulation (NES) is beneficial in reducing shoulder subluxation but inconsistent in reducing shoulder pain (Kimberley & Carey, 2002). In a case report of approximately 17 months' post-stroke, where the patient's posterior deltoid, middle deltoid, and supra-spinatus muscles were per-cutaneously implanted with intramuscular electrodes, it was also reported that 6 weeks of NES treatment resulted in marked improvement in shoulder subluxation and pain, and modest improvements in activities of daily living and motor function. The patient remained pain free, but subluxation had recurred. However, the patient was able to volitionally reduce the subluxation by abducting his shoulder one year after the onset of treatment. The patient remained pain free up to 40 months after the initiation of per-cutaneous intramuscular NES treatment (Chae, Yu & Walker, 2001). Another study found that percutaneous NES is feasible for treating shoulder dysfunction in hemiplegia and may reduce shoulder subluxation, reduce pain, improve range of motion, enhance motor recovery, and reduce disability in patients with chronic hemiplegia and shoulder subluxation, but, however, recommends, further investigation (Yu et al., 2001a). In a group of stroke patients, shoulder subluxation was reduced significantly on completion of a six-week NES programme (Baker & Parker, 1986).

Functional electrical stimulation (FES) in patients with shoulder pain and subluxation, applied early after onset of stroke, has shown beneficial positive effects on subluxation, pain and mobility (Vuagnat & Chantraine, 2003). Another study also showed that there is a significant improvement in reducing subluxation as indicated by x-ray, only for a short duration after the first FES treatment. However, it was also found that there is insignificant change of shoulder subluxation for both short and long-duration in the second FES treatment programme (Wang, Chan & Tsai, 2000). Similar results were reported in another study, where the FES patients had significantly more improvement in both pain relief and reduction of subluxation. There was also significant recovery of arm motion (Chantraine et al., 1999). Faghri et al (1994) also found a similar finding, where FES therapy patients showed significant improvements in arm function, electro-myographic activity of the posterior deltoid, range of motion, and reduction in subluxation (as indicated by x-ray).

Clinically and statistically significant improvement in the range of motion and pain has been shown in patients treated with TENS (Shehab & Adham, 2000). There was also significantly less subluxation and pain found after the treatment period, but at the end of the follow-up period there were no significant differences between the groups treated with electrical stimulation or without (Linn, Granat, & Lees 1999). Another study showed that the electrical stimulation therapy of the supra-spinatus and the deltoid muscle is an effective treatment modality for shoulder subluxation and shoulder abduction function in hemiplegic patients (Kobayashi et al., 1999). Leandri et al (1990) showed there is statistically significant improvement in flexion, extension, and abduction and external rotation of shoulder recorded in patients treated with high TENS.

However, one study reported no significant change in pain incidence or change in pain intensity after ES treatment in treatment or control group, but there was a significant treatment effect in favour of ES for improvement in pain-free range of passive humeral lateral rotation. In this study, ES reduced the severity of glenohumeral subluxation but there was no significant effect on upper limb motor recovery or upper limb spasticity (Price & Pandyan, 2001).

A systematic review of the evidence on treating patients with hemiplegic shoulder pain found no definite conclusions could be drawn about the most effective method of treatment, because of the poor quality of the identified studies. However, FES seems to be one of the most promising treatment options (Snels et al., 2002).

8.2.2 Motor function restoration

A review concluded that there is a positive effect of electrical stimulation (ES) on motor control, but no conclusions can be drawn with regards to the effect on functional abilities (de Kroon et al., 2002). A study on ES of the wrist extensors found that it enhances the recovery of isometric wrist extensor strength in hemiparetic stroke patients, with upper-limb disability being reduced after 8 weeks of ES therapy. However, the study could not verify how long the improvements in upper-limb disability are maintained after ES is discontinued (Powell et al., 1999). It has been found in a study on treatment with ES on the posture of the wrist, that there is an improvement in the passive range of extension, although there were no significant changes in the resistance to passive movement. However, these benefits appeared largely to be lost two weeks after ES was discontinued (Pandyan, Granat & Stott, 1997). Baker et al's (1979) study on electrical stimulation of wrist and fingers for hemiplegic patients showed a statistically and clinically significant increase in wrist extension range, with increased extension noted at the metacarpophalangeal and proximal interphalangeal joints. Patients with some voluntary wrist extension before the treatment began were able to increase their extension strength during stimulation. No changes in skin sensation were noted.

It has been suggested that the FES system provides a temporary means of achieving functional activation, and it was found that the percutaneous system has the potential for short-term rehabilitation in individuals with incomplete paraplegia or stroke (Agarwal et al., 2003). A case report found that percutaneous NMES helps modest improvement in activities of daily living and motor function (Chae, Yu & Walker, 2001). A similar study by Yu et al., (2001b) found that percutaneous NMES is feasible for treating shoulder dysfunction in hemiplegia, and it enhances motor recovery and reduces disability in patients with chronic hemiplegic. FES also produced significant improvement in motor recovery as indicated by Fugl-Meyer scores in short-duration hemiplegia, but not in long-duration hemiplegia, with insignificant changes in the second FES treatment programme. It was suggested that patients with hemiplegia of short duration are effectively trained by FES for motor recovery (Wang et al., 2002). An exploratory study of FES in chronic stroke patients found that there were statistically significant differences in motor score and muscle tone before and at the end of treatment. However, the follow-up measurements showed that the effects on motor functions and muscle tone were decreased after completion of therapy, and stratification of the patients in two subgroups indicated that patients with initial high motor scores benefited most during the intervention period (Hendricks et al., 2001). Daly et al., (2000) demonstrated that there were improvements in impairment and disability in active joint movement, coordination, balance, gait and activities of daily living in acute stroke patients using FNS with implanted electrodes (FNS-IM). Another study showed a 20.5% increase in walking speed between the beginning and end of the trial in patients on FES compared to 5.2% in the patient without FES. There was also an improvement in the physiological cost. However there was no improvement in these parameters when the stimulator was not used (Burridge et al., 1997). A case study on 2 subjects using a stimulator on a regular basis showed an increase in walking speed of between 10% and 40% when compared to their baseline measurements (Kenny et al., 2002).

A meta-analysis of randomized controlled trials concluded that FES is a means to promote recovery of muscle strength after stroke. This effect is statistically significant, with a reasonable likelihood of clinical significance as well (Glanz et al., 1996). Another study also indicated that FES may improve motor recovery after stroke (Macdonell et al., 1994). It has been found that the recovery of movement in hemiparetic patients related with functional electrical stimulation is about three times greater, and less dependent upon age, time from lesion, initial value as well as side of lesion (Merletti et al., 1978).

A study with a three-year follow-up on low TENS treatment on post-stroke paretic arm found that motor function of the paretic arm had deteriorated and increase of spasticity was seen in both patients treated with low TENS and those not treated. However, Barthel Activities of Daily Living (ADL) score remained at a similar level in the low TENS group, whereas it showed deterioration in those without treatment (Sonde et al., 2000). A study by Tekeoglu, Adak & Goksoy (1998) on the effect of TENS on ADL index following stroke found that TENS appears to be an effective adjunct in the regaining of motor functions and improving ADL in hemiplegic patients, but the accidental imbalance in severity of disability at entry makes interpretation uncertain. Another study also showed that the use of low TENS significantly increased the motor function, although it did not decrease either pain or spasticity (Sonde et al., 1998). It also been hypothesized that TENS applied to the sural nerve may induce short-term post-stimulation inhibitory effects on the abnormally enhanced stretch reflex activity in spasticity of cerebral origin (Potisk et al., 1995).

A study on a new closed-loop FES system revealed that the mean velocity, cadence, stride length, active ankle motion range, and functional ambulation category improved significantly. However, the differences in the electromyography of the tibialis anterior and the quadriceps muscles between the patient's disabled foot and normal foot were found to be not significant after 12 weeks of training. It is concluded that while this is capable of providing a hemiplegic patient with restoration to regular walking after appropriate gait training, future studies, including a randomized-controlled study, should be implemented to document the efficacy of this system (Chen et al., 2001). Another study found evidence which clearly supports the use of electromyography-triggered neuromuscular electrical stimulation treatment for rehabilitation of wrist and finger extension movements of hemiparetic individual up to one year after stroke. The treatment programme decreased motor dysfunction and improved the motor capabilities in this group of post-stroke individuals (Cauraugh et al., 2000). Another study on FES found a significant improvement in the recovery of arm motion (Chantraine et al., 1999). It was also found that there is a statistically significant improvement noted in all muscle tone/spasticity parameters measured for the upper limb in chronic stable hemiplegia treated with FES (Weingarden et al., 1998).

It has also been shown that NMES can be used to facilitate motor learning in ankle dorsiflexion and wrist extension (Kimberley & Carey, 2002). Chae & Yu’s (2002) study also found that trans-cutaneous NMES facilitates motor recovery. However, its impact on physical disability remains uncertain. Another study revealed that there is a significantly greater gain in Fugl-Meyer score for patients treated with NMES at 4 and 12 weeks after treatment. However, there was no difference in functional independence measure scores from untreated patients at any of the time periods (Chae et al., 1998). The use of multi-channel functional electrical stimulation therapy (MFES) has been demonstrated to produce independent gait in patients during the three weeks of MFES therapy. At 30 months of therapy, the patient was still able to ambulate independently without any significant changes in his gait pattern (Bogataj et al., 1997).

The results of a study suggest that somato-sensory stimulation may be a promising adjuvant to rehabilitation of the motor deficits in stroke patients (Conforto et al., 2002).

Cutaneous stimulation had positive effects in the motor performance, limb sensation and the configuration of SEP of the paretic limb in chronic stroke patients (Peurala et al., 2002).

A study indicated that the surface spinal cord stimulation with middle frequency modulated to low frequency for sensory stimulation on the skin of 12th thoracic and first lumbar area was effective in reducing calf muscle spasticity of hemiplegic patients (Wang, Tsai & Chan 1998).

Winchester et al (1983) in their study on the effects of feedback stimulation training and cyclical electrical stimulation on knee extension in hemiparatic patients found that there was a statistically significant increase in knee extension torque and active synergistic range of motion in the study group. However, no changes were noted in their ability to extend their knees using isolated quadriceps femoris muscle control.

8.2.3 Combination Therapy

A randomized controlled trial investigated the combined use of botulinum neurotoxin type A (BoNTA) and FES, and found evidence of additional benefit (Johnson et al., 2002). Another randomized, double-blind, placebo-controlled trial study carried out on BoNTA and short-term electrical stimulation in the treatment of upper limb flexor spasticity after stroke, found that the placebo-controlled trial favours the concept that electrical stimulation enhances the effectiveness of BoNTA in the treatment of chronic upper limb flexor spasticity after stroke (Hesse, et al., 1998).

A combined therapy biofeedback with FES showed a statistically significant improvement in both knees and ankle minimum flexion angles during swing phase, while velocity of gait, cycle time, and symmetry of stance phases were also improved (Cozen, Pease & Hubbell 1988).

A meta analysis found that when ES was added to conventional therapy, it prevented on average 6.5mm of shoulder subluxation, but only reduced it by 1.9mm compared to conventional therapy alone (Ada & Foongchomcheay, 2002).

8.3. Cost Implications of Electrical Stimulation

A meta-analysis of randomized controlled trials by Glanz et al (1996) concluded that the units that deliver electrostimulation were relatively inexpensive (mean price, $ 1,250), extremely durable and reliable and can be applied by the patient or family member without the ongoing assistance of professional personnel.

Another study found that ES is a relatively low-cost intervention, costing approximately $350 per system with only minor consumables costs (Powell et al., 1999).

9. CONCLUSION

There is sufficient evidence that ES is a relatively safe modality when used by people trained in the modality. Appropriate caution need to be taken with regards to patient with a history of epilepsy.

In term of effectiveness, for shoulder subluxation and pain, there is sufficient evidence that both TENS and FES are effective in promoting improvement in shoulder dysfunction and provide pain relief. With respect to restoration of motor function, there is sufficient evidence that ES promotes recovery of muscle strength and improves motor function, although in some situations, the benefits are not observed on long-term follow-up, or after discontinuation of the ES. There is also some evidence to support the effectiveness of the ES combined with other conventional therapies.

With respect to cost implications, there is some evidence that ES is a relatively low-cost intervention

10. RECOMMENDATION

Electrical stimulation for the treatment of selected stroke patient is safe, low cost, and is advocated for use selectively in the early rehabilitation of stroke patients for the beneficial effect of the hemiplegic shoulder, restoration of motor function and quality of life. However, it is recommended that centers utilizing this modality have trained personnel involved and also involves training care givers utilizing this modality in home rehabilitation programs. Appropriate protocols and monitoring should be developed and utilized, as well as reviewed on a regular basis.

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Appendix 1

METHODOLOGY

Searching was carried out at the following electronic database PUBMED; COCHRANE Database of Systematic Reviews via OVID; INAHTA; OTseeker; Pedro; International Health Technology Assessment Organization Websites; FDA sites; Proquest; Medscape; as well as general search engine of GOOGLE, reference list of all relevant article retrieved were search to identified further studies. The following free text terms were used either singly or in combination.

1 electrical stimulation therapy
2 hemiparasis OR hemiplagia OR stroke OR CVA
3 shoulder
4 arm
5 upper extremity
6 electir* stimulation
7 FES OR TENS OR ES
8 cerebrovasc* OR hemiopar* OR hemipleg*
9 rehabilitation
10 poststroke OR post-stroke
11 shoulder pain
12 wrist pain
13 upper arm
14 shoulder girdle
15 hand
16 wrist
17 cerebrovascular disease

Appendix 2

HTA PROTOCOL

Background
After cerebrovascular accident (stroke), many individuals suffer from motor dysfunction either total paralysis or muscle weakness. This may involve one (mono), two (para or hemi) and sometimes all four (tetra) limbs. Other common conditions associated with it are pain or sub-luxation of the joints or both.

Physiotherapy has been accepted as one of the way to help improve joint stiffness, muscle strength following cerebrovascular event. However, studies have found that electrical stimulation, at low frequency (1.7 Hz), when used on the paretic limb/s has been found to be useful and to help improve the situation. They sometimes used singly or in combination with conventional physiotherapy, acupuncture or botulinum toxin. Electrical stimulation techniques can be applied various ways - surface, percutaneous, transcutaneous, transneuromuscular and intramuscular. Improved functional outcome and quality of life after stroke is one of the important determinants of treatment success.

Policy Question
Should electrical stimulation be used (singly or in combination with other techniques) in the treatment of post stroke patients for improving muscle function, gaining motor function and improving quality of life?

Scope

- To consider the use of electrical stimulation only for post-stroke rehabilitation
- To include all mode of application/techniques of electrical stimulation
- To consider its use either singly or in combination with other rehabilitation techniques.

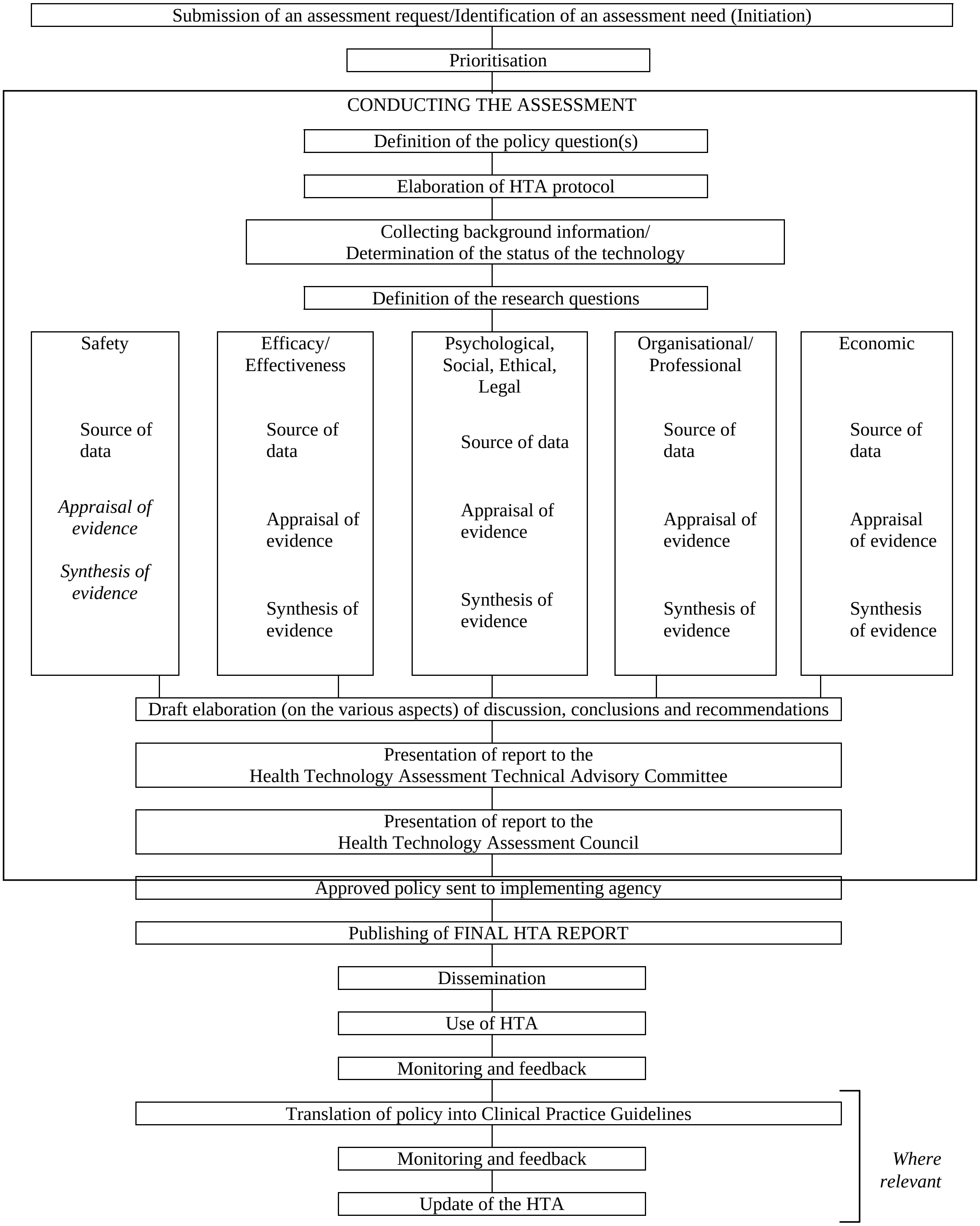
Aspects To Consider

- Effectiveness – all electrical stimulation techniques
- Safety – each mode of application
- Cost implications – cost-benefits or cost-effectiveness of post-stroke case recovered with conventional rehab techniques with/without electrical stimulation techniques
- Ethical issues – to continue/discontinue ES once the functional effect is gained

Objective
To determine the safety, effectiveness, cost implications and ethical considerations of electrical stimulation techniques in rehabilitation of patients with stroke.

Strategy/Assessment Process

I. New HTA



Evidence Table

Safety

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
1	Agarwal S, Kobetic R, Nandurkar S, Marsolais EB. (2003) Functional electrical stimulation for walking in paraplegia: 17-year follow-up of 2 cases. *J Spinal Cord Med.* 26(1), pp 86-91.	Case report -	The most noted clinical complications included localized inflammation at the electrode site and superficial infection that responded well to topical and oral antibiotic treatment. Conclusion: Two long-time users of the system had no adverse effects to their skeletal system. The most common problems were daily care of electrodes at exit sites, frequent irritation of the skin around electrodes, and replacement of failed electrodes.	Poor
2	Yu DT, Chae J, Walker ME, Hart RL, Petroski GF. (2001) Comparing stimulation-induced pain during percutaneous (intramuscular) and transcutaneous neuromuscular electric stimulation for treating shoulder subluxation in hemiplegia. *Arch Phys Med Rehabil.* 82(6), Jun, pp 756-60.	Clinical Trial	Median visual analog scale (VAS) scores for perc-NMES and trans-NMES were 1 and 5.7, respectively (p = .007). Median PRI scores for percutaneous (intramuscular) neuromuscular electric stimulation (perc-NMES) and transcutaneous neuromuscular electric stimulation (trans-NMES) were 7 and 19.5, respectively (p = .018). Nine of the 10 subjects preferred perc-NMES to trans-NMES for treatment. CONCLUSION: Data suggest that perc-NMES is less painful than trans-NMES in the treatment of shoulder subluxation in hemiplegia.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
3	Rosted P (2001) Repetitive epileptic fits--a possible adverse effect after transcutaneous electrical nerve stimulation (TENS) in a post-stroke patient. *Acupunct Med*, 19(1), Jun, pp 46-9.	Case report	A case of repetitive epileptic fits in a post stroke patient after transcutaneous electrical nerve stimulation (TENS) is presented. It seems more likely than not that the TENS triggered the repetitive fits in this patient. Although the risk of this adverse effect seems to be small, it should be borne in mind when TENS is used in a post-stroke patient. Since TENS is now used commonly in post-stroke patients, this problem is worthy of further study.	Poor

EFFECTIVENESS -SHOULDER SUBLUXATION &PAIN

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
1	Wang RY, Chan RC, Tsai MW. (2000) Functional electrical stimulation on chronic and acute hemiplegic shoulder subluxation. *Am J Phys Med Rehabil*. ;79(4), Jul - Aug, pp 385-90; quiz 391-4	Clinical Trial	The experimental subgroup of short duration showed significant improvements in reducing subluxation as indicated by x-ray compared with the control subgroup of short duration after the first FES treatment. The same effect was not shown for the experimental subgroup of long duration. The second FES treatment program only resulted in an insignificant change of shoulder subluxation for both the short- and long-duration subgroups. CONCLUSIONS: The present study suggests that hemiplegic subjects with short post onset duration are effectively trained for shoulder subluxation by the first FES treatment program. The same FES showed not to be effective when applied to the subjects with subluxation of > 1 yr.	Fair

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
2	Ada L, Foongchomcheay A. (2002) Efficacy of electrical stimulation in preventing or reducing subluxation of the shoulder after stroke: a meta-analysis. *Aust J Physiother*., 48(4), pp 257-67.	Meta analysis	when added to conventional therapy, electrical stimulation prevented on average 6.5mm of shoulder subluxation (weighted mean difference, 95% CI 4.4 to 8.6) but only reduced it by 1.9mm (weighted mean difference, 95% CI -2.3 to 6.1) compared with conventional therapy alone. Therefore, evidence supports the use of electrical stimulation early after stroke for the prevention of, but not late after stroke for the reduction of, shoulder subluxation.	Good
3	Chae J, Yu D, Walker M. (2001) Percutaneous, intramuscular neuromuscular electrical stimulation for the treatment of shoulder subluxation and pain in chronic hemiplegia: a case report. *Am J Phys Med Rehabil.* 80(4), Apr, pp 296-301	Case report	At approximately 17 month post-stroke, the patient's posterior deltoid, middle deltoid, and supraspinatus muscles were percutaneously implanted with intramuscular electrodes. After 6 wk of percutaneous, intramuscular NMES treatment, marked improvements in shoulder subluxation and pain, and modest improvements in activities of daily living and motor function were noted. One year after the onset of treatment, the patient remained pain free, but subluxation had recurred. However, the patient was able to volitionally reduce the subluxation by abducting his shoulder. The patient remained pain free for up to 40 mo after the initiation of percutaneous, intramuscular NMES treatment. This case report demonstrates the feasibility of using percutaneous, intramuscular NMES for treating shoulder subluxation and pain in hemiplegia	Poor
4	Yu DT, Chae J, Walker ME, Fang ZP. (2001) Percutaneous intramuscular neuromuscular electric stimulation for the treatment of shoulder subluxation and pain in patients with chronic hemiplegia: a pilot study. *Arch Phys Med Rehabil.* 82(1), Jan, pp 20-5.	N= 8	Subluxation ($p = .0117$), pain ($p = .0115$), shoulder pain-free external rotation ($p < .0001$), and disability ($p = .0044$) improved significantly from T1 to T2. Subluxation ($p = .0066$), pain ($p = .0136$), motor impairment ($p < .0001$), shoulder pain-free external rotation ($p = .0234$), and disability ($p = .0152$) improved significantly from T1 to T3. CONCLUSIONS: Perc-NMES is feasible for treating shoulder dysfunction in hemiplegia and may reduce shoulder subluxation, reduce pain, improve range of motion, enhance motor recovery, and reduce disability in patients with chronic hemiplegia and shoulder subluxation. Further investigation is warranted.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
5	Linn SL, Granat MH, Lees KR. (1999) Prevention of shoulder subluxation after stroke with electrical stimulation. *Stroke*. 30(5), May, pp :963-8.	prospective, randomized controlled study N= 47 patients	The treatment group had significantly less subluxation and pain after the treatment period, but at the end of the follow-up period there were no significant differences between the 2 groups. CONCLUSIONS: Electrical stimulation can prevent shoulder subluxation, but this effect was not maintained after the withdrawal of treatment.	Fair
6	Kobayashi H, Onishi H, Ihashi K, Yagi R, Handa Y. (1999) Reduction in subluxation and improved muscle function of the hemiplegic shoulder joint after therapeutic electrical stimulation. *J Electromyogr Kinesiol*. 9(5), Oct, pp 327-36.	N= 17 patient	After 6 weeks of electrical stimulation of the supraspinatus (S group) and deltoid (D group), a significant ($p<0.05$) reduction in subluxation was observed in both groups when compared to the C group. The maximal force of shoulder abduction showed a tendency to increase in the S group ($p<0.10$). A significant increase in maximal force was also observed in the D group. In most of the TES-treated muscles, the interference pattern of EMG at maximum voluntary contraction increased. The amplitude of the EMG activity of the stimulated muscle also increased. Thus, we concluded that electrical stimulation therapy of the supraspinatus and the deltoid muscle is an effective treatment modality for shoulder subluxation and shoulder abduction function in hemiplegic patients.	Poor
7	Chantraine A, Baribeault A, Uebelhart D, Gremion G. (1999) Shoulder pain and dysfunction in hemiplegia: effects of functional electrical stimulation. *Arch Phys Med Rehabil*. 80(3).Mar, pp 328-31.	Clinical Trial N= 120 patients	The FES group showed significantly more improvement than the control group in both pain relief (80.7% vs. 55.1%, $p<.01$) and reduction of subluxation (78.9% vs. 58.6%, $p<.05$). Furthermore, recovery of arm motion appeared to be significantly improved in the FES group (77.1% vs. 60.3% in the control group, $p<.01$). CONCLUSION: The FES program was significantly effective in reducing the severity of subluxation and pain and possibly may have facilitated recovery of the shoulder function in hemiplegic patients.	Fair

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
8	Price, C., & Pandyan, A. (2001) Electrical stimulation for preventing and treating post-stroke shoulder pain: a systematic Cochrane review *Clinical Rehabilitation* Vol 15, pp 5-19	Systematic Review	There was no significant change in pain incidence (odds ratio (OR) 0.64; 95% CI 0.19-2.14) or change in pain intensity (standardized mean difference (SMD) 0.13; 95% CI -1.0-1.25) after ES treatment compared with control. There was a significant treatment effect in favour of ES for improvement in pain-free range of passive humeral lateral rotation (weighted mean difference (WMD) 9.17; 95% CI 1.43-16.91). In these studies ES reduced the severity of glenohumeral subluxation (SMD -1.13; 95% CI -1.66 to -0.60), but there was no significant effect on upper limb motor recovery (SMD 0.24; 95% CI -0.14-0.62) or upper limb spasticity (WMD 0.05; 95% CI -0.28-0.37). There did not appear to be any negative effects of electrical stimulation at the should	Good
9	Vuagnat H, Chantraine A. (2003) Shoulder pain in hemiplegia revisited: contribution of functional electrical stimulation and other therapies. *J Rehabil Med.* 35(2),Mar, pp 49-54; quiz 56	Review	Functional electrical stimulation in patients with shoulder pain and subluxation, applied early after onset of the stroke, has shown beneficial positive effects on subluxation, pain and mobility. Efforts should therefore be made to better understand the post-stroke shoulder pain in order to provide better outcomes of rehabilitation and thus improve quality of life for patients	Poor
10	Snels I A, Dekker J H, van der Lee J H, Lankhorst G J, Beckerman H, Bouter L M. (2002) Treating patients with hemiplegic shoulder pain *American Jr of Physical Med and Reh*, 81(2), pp 150-160	Systematic review	No definite conclusions can be drawn about the most effective method of treatment because of the poor quality of the identified studies. However, FES and intra-articular triamcinolone acetonide injections seem to be the most promising treatment options.	Good

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
11	Bogataj U, Gros N, Kljajic M, Acimovic-Janezic R. (1997) Enhanced rehabilitation of gait after stroke: a case report of a therapeutic approach using multichannel functional electrical stimulation *IEEE Trans Rehabil Eng*, 5(2), Jun , pp221-32	Case report	An analysis of the measured parameters showed improved performance of the patient during MFES therapy and stagnation or even slight recession during conventional therapy. The patient achieved independent gait during the three weeks of MFES therapy. At 30 months after the beginning of therapy, the patient was still able to ambulate independently without any significant changes in his gait pattern.	Poor
12	Chae J, Yu DT. (2002) Neuromuscular electrical stimulation for motor restoration in hemiparesis. *Top Stroke Rehabil*,8(4), Winter, pp 24-39	Not stated	Transcutaneous NMES also decreases shoulder subluxation, but its effect on shoulder pain remains uncertain	
13	Baker LL, Parker K (1986) Neuromuscular electrical stimulation of the muscles surrounding the shoulder *Physical Therapy* , 66(12), pp 1930-1937	Clinical Trial	In a group of stroke patients, shoulder subluxation was reduced significantly (p less than .05) at the completion of a six-week NMES program. NMES provides the therapist with a powerful new treatment technique to prevent or correct shoulder subluxation, especially in the neurologically involved patient.	Fair

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
14	Walsh K (2001) Management of shoulder pain in patients with stroke *Postgrad Med J.*, 77(912), Oct, pp 645-9	Review	Treatment of shoulder pain after stroke should start with simple analgesics. If shoulder pain persists, treatment should include high intensity transcutaneous electrical nerve stimulation or functional electrical stimulation. Intra-articular steroid injections may be used in resistant cases.	Fair
15	Leandri M, Parodi CI, Corrieri N, Rigardo S (1990) Comparison of TENS treatments in hemiplegic shoulder pain. *Scandinavian Journal of Rehabilitation Medicine* 22(2), pp69-72	Clinical trial (4 week Rx)	Statistically significant improvements for flexion, extension, abduction and external rotation of shoulder were recorded for group treated with high TENS.	Fair
16	Shehab D, Adham N (2000) Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain *Physiotherapy Canada*, 52(3), pp 208-10, 214,	Clinical Trial	A clinically and statistically significant improvement in the range of motion and pain were shown in patients treated with TENS	Fair

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
17	Faghri PD, Rodgers MM, Glaser RM, Bors JG, Ho C, Akuthota P.(1994) The effects of functional electrical stimulation on shoulder subluxation, arm function recovery, and shoulder pain in hemiplegic stroke patients. *Arch Phys Med Rehabil*., 75(1), Jan, pp 73-9.	Randomized control trial N=26 patients	The experimental group received additional FES therapy where two flaccid/paralyzed shoulder muscles (supraspinatus and posterior deltoid) were induced to contract repetitively up to 6 hours a day for 6 weeks. Duration of both the FES session and muscle contraction/relaxation ratio were progressively increased as performance improved. The experimental group showed significant improvements in arm function, electromyographic activity of the posterior deltoid, range of motion, and reduction in subluxation (as indicated by x-ray) compared with the control group. We concluded that the FES program was effective in reducing the severity of shoulder subluxation and pain, and possibly facilitating recovery of arm function.	Good to fair Small sample

MOTOR FUNCTION RESTORATION

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
1	de Kroon JR, van der Lee JH, IJzerman MJ, Lankhorst GJ. (2002) Therapeutic electrical stimulation to improve motor control and functional abilities of the upper extremity after stroke: a systematic review. C*lin Rehabil.* 16(4), Jun, pp 350-60	Meta analysis N= 6 RCT	The present review suggests a positive effect of electrical stimulation on motor control. No conclusions can be drawn with regard to the effect on functional abilities.	Good

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
2	Hendricks HT, IJzerman MJ, de Kroon JR, in 't Groen FA, Zilvold G. (2001) Functional electrical stimulation by means of the 'Ness Handmaster Orthosis' in chronic stroke patients: an exploratory study. *Clin Rehabil.* 15(2), Apr, pp 217-20.	Clinical Trial N= 18 patient (post stroke > 6 months)	The differences in motor score and muscle tone before and at the end of treatment were statistically significant (p = 0.008 and 0.021, respectively). The follow-up measurements showed that the effects on motor functions and muscle tone decreased after therapy completion. Stratification of the patients in two subgroups indicated that patients with initial high motor scores benefited most during the intervention period. CONCLUSION: The present study suggests that Handmaster treatment possesses therapeutic opportunities in chronic stroke patients with spastic paresis of the upper extremity.	Poor
3	Daly JJ, Ruff RL, Haycook K, Strasshofer B, Marsolais EB, Dobos L. (2000) Feasibility of gait training for acute stroke patients using FNS with implanted electrodes. *J Neurol Sci*. 179(S 1-2), Oct 1, pp 103-7.	N= 5 subjects	Post treatment, subjects demonstrated improvements in impairment and disability in active joint movement, coordination, balance, gait and activities of daily living. Considered together with prior research for chronic stroke subjects, this research suggests that FNS-IM can be successfully and efficaciously utilized for gait training for those with acute stroke.	Poor
4	Tekeoglu Y, Adak B, Goksoy T. (1998) Effect of transcutaneous electrical nerve stimulation (TENS) on Barthel Activities of Daily Living (ADL) index score following stroke. *Clin Rehabil.* 12(4), Aug, pp 277-80.	RCT N= 60	TENS appears to be an effective adjunct in the regaining of motor functions and improving ADL in hemiplegic patients, but the accidental imbalance in severity of disability at entry makes interpretation uncertain.	Good

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
5	Wang RY, Tsai MW, Chan RC. (1998) Effects of surface spinal cord stimulation on spasticity and quantitative assessment of muscle tone in hemiplegic patients. *Am J Phys Med Rehabil.* 77(4), Jul - Aug, pp 282-7.	N= 10 patients	results indicate that the surface spinal cord stimulation with middle frequency modulated to low frequency for sensory stimulation on the skin of 12th thoracic and first lumbar area is effective in reducing calf muscle spasticity of hemiplegic patients.	Poor
6	Sonde L, Gip C, Fernaeus SE, Nilsson CG, Viitanen M. (1998) Stimulation with low frequency (1.7 Hz) transcutaneous electric nerve stimulation (low-tens) increases motor function of the post-stroke paretic arm. *Scand J Rehabil Med.* 30(2), Jun, pp 95-9	Clinical Trial N= 44 patients	Results showed that motor function increased significantly in the treatment group, compared to controls. The Low-TENS did not decrease either pain or spasticity. It is concluded that stimulation by means of Low-TENS could be a valuable complement to the usual training of arm and hand function in the rehabilitation of stroke patients.	Fair
7	Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. (1997) The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. *Clin Rehabil.* 11(3), Aug, pp 201-10.	RCT N= 32 patients	Thirty-two subjects completed the trial, 16 in the FES group and 16 in the control group. Mean increase in walking speed between the beginning and end of the trial was 20.5% in the FES group (when the stimulator was used), and 5.2% in the control group. Improvement was also measured in PCI with a reduction of 24.9% in the FES group (when the stimulator was used) and 1% in the control group. No improvement in these parameters was measured in the FES group when the stimulator was not used. CONCLUSION: Walking was statistically significantly improved when the ODFS was worn but no 'carry-over' was measured. Physiotherapy alone, in this group of subjects with established stroke, did not improve walking.	Good to fair Unblinded

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
8	Pandyan AD, Granat MH, Stott DJ. (1997) Effects of electrical stimulation on flexion contractures in the hemiplegic wrist. *Clin Rehabil*. 11(2), May, pp123-30.	Clinical Trial N= 11 patients	Following two weeks treatment with ES the posture of the wrist improved and the passive range of extension increased. However, there were no significant changes in the resistance to passive movement. These benefits appeared largely to be lost two weeks after ES was discontinued. CONCLUSIONS: Short-term ES gives temporary improvements in contractures at the wrist in poststroke hemiplegia.	Poor
9	Glanz M, Klawansky S, Stason W, Berkey C, Chalmers TC. (1996) Functional electrostimulation in poststroke rehabilitation: a meta-analysis of the randomized controlled trials. *Arch Phys Med Rehabil*. 77(6), Jun, pp 549-53.	Meta analysis (literature published from 1978-1992)	Pooling from randomized trials supports FES as promoting recovery of muscle strength after stroke. This effect is statistically significant. There is a reasonable likelihood of clinical significance as well.	Good
10	Potisk KP, Gregoric M, Vodovnik L. (1995) Effects of transcutaneous electrical nerve stimulation (TENS) on spasticity in patients with hemiplegia. *Scand J Rehabil Med*. 27(3), Sep, pp 169-74.	N= 20 patients	The results of the study support the hypothesis that TENS applied to the sural nerve may induce short-term post-stimulation inhibitory effects on the abnormally enhanced stretch reflex activity in spasticity of cerebral origin.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
11	Peurala SH, Pitkänen K, Sivenius J, Tarkka IM. (2002) Cutaneous electrical stimulation may enhance sensorimotor recovery in chronic stroke. *Clin Rehabil*. 16, pp 709-716	Clinical Trial N= 59 patients- F/up: 3 weeks	Modified Motor Assessment Scale ($p < 0.001$), 10-metre walking test ($p < 0.05$), paretic hand function ($p < 0.01$), upper limb skin sensation ($p < 0.01$) and SEP normality classification of paretic upper limb ($p < 0.01$) and paretic lower limb ($p < 0.5$) improved significantly in the treatment group ($n = 51$) after three weeks of stimulation. When active hand treatment and placebo hand treatment were compared, a significant improvement in the sensory and motor function was observed only in the actively treated group. CONCLUSIONS: Cutaneous stimulation had positive effects in the motor performance, limb sensation and the configuration of SEP of the paretic limb in chronic stroke patients.	Fair
12	Sonde L, Kalimo H, Fernaeus SE, Viitanen M. (2000) Low TENS treatment on post-stroke paretic arm: a three-year follow-up. *Clin Rehabil*. 14(1), Feb, pp14-9.	Clinical trial N=28 patients F/up:3 years	Motor function of the paretic arm had deteriorated in both treatment and control groups. Increased spasticity was seen in both groups. ADL score remained at a similar level in the low TENS group, whereas the control group had deteriorated during the same time period. CONCLUSIONS: Low TENS stimulation started 6-12 months after stroke may not have a specific effect on arm motor function years after completion of treatment.	Fair
13	Agarwal S, Kobetic R, Nandurkar S, Marsolais EB. (2003) Functional electrical stimulation for walking in paraplegia: 17-year follow-up of 2 cases. *J Spinal Cord Med*. 26(1), pp 86-91.	Case report -	The coil-wire electrodes, with a survival of 35% after 1 year, to double-helix electrodes improved electrode survival to 80% at 1 year and 48% at 5 years. CONCLUSION: Although the FES system was devised as a temporary means of achieving functional activation until permanent means could be achieved, it was found to be effective and relatively safe for more than 17 years. The percutaneous system has the potential for short-term rehabilitation in individuals with incomplete paraplegia or stroke.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
14	Wang RY, Yang YR, Tsai MW, Wang WT, Chan RC. (2002) Effects of functional electric stimulation on upper limb motor function and shoulder range of motion in hemiplegic patients. *Am J Phys Med Rehabil.* 81(4), Apr, pp 283-90.	Clinical Trial	After the first 6-wk FES therapy, the experimental group of short-duration hemiplegia showed significant improvements in motor recovery as indicated by Fugl-Meyer scores compared with the control group. Such significant improvement did not occur for the experimental group of long-duration hemiplegia. The changes in the second FES treatment program were insignificant. CONCLUSIONS: This study suggests that patients with hemiplegia of short duration are effectively trained by FES for motor recovery.	Fair
15	Chen YL, Li YC, Kuo TS, Lai JS. (2001) The development of a closed-loop controlled functional electrical stimulation (FES) in gait training. *J Med Eng Technol.,* 25(2), Mar-Apr , pp 41-8	Case Report	was revealed that the mean velocity, cadence, stride length, active ankle motion range, and functional ambulation category (FAC) improved significantly from 0.12 +/- 0.07 ms-1, 40.3 +/- 18.3 steps min-1, 0.35 +/- 0.10 m, 15 degrees, level 2 to 0.42 +/- 0.23 ms-1, 68.2 +/- 19.0 steps min-1, 0.70 +/- 0.22 m, 40 degrees, level 4 respectively for the patient. A paired t-test indicated that differences in the electromyography (EMG) of the tibialis anterior and the quadriceps muscles between the patient's disabled (affected side) foot and normal (unaffected side) foot are not significant ($p > 0.05$) after 12 weeks of training. It is concluded that this new closed-loop FES system is capable of providing this hemiplegic patient with restoration to regular walking after appropriate gait training. Future studies, including randomized-controlled study, should be implemented to document the efficacy of this system.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
16	Powell J, Pandyan AD, Granat M, Cameron M, Stott DJ (1999) Electrical stimulation of wrist extensors in post-stroke hemiplegia. *Stroke*. 30(7), July, pp 1384-9.	Clinical Trial	The change in isometric strength of wrist extensors (at an angle of 0 degrees extension) was significantly greater in the ES group than the control group at both 8 and 32 weeks (P=0.004, P=0.014 by Mann Whitney U test). At week 8 the grasp and grip subscores of the ARAT increased significantly in the ES group compared with that in the control group (P=0.013 and P=0.02, respectively); a similar trend was seen for the total ARAT score (P=0.11). In the subgroup of 33 patients with some residual wrist extensor strength at study entry (moment at 0 degrees extension >0), the ARAT total score had increased at week 8 by a mean of 21.1 (SD, 12.7) in the ES group compared with 10.3 (SD, 9.0) in the control group (P=0.024, Mann Whitney U test); however, at 32 weeks the differences between these 2 subgroups were no longer statistically significant. CONCLUSIONS: ES of the wrist extensors enhances the recovery of isometric wrist extensor strength in hemiparetic stroke patients. Upper-limb disability was reduced after 8 weeks of ES therapy, with benefits most apparent in those with some residual motor function at the wrist. However, it is not clear how long the improvements in upper-limb disability are maintained after ES is discontinued.	Fair Small samples size, unblinded
17	Chae J, Bethoux F, Bohinc T, Dobis K, Davis T, Friedl A (1998) Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia *Stroke* 29(5), pg 975 -979	N=64	The treatment subjects and control subjects had comparable baseline characteristic parametric analyses revealed significantly greater gains in Fugl-Meyer score for the treatment group after treatment at 4 weeks after treatment. And at 12 weeks after treatment. Functional independence measure score were not different between groups at any of the time periods. Data suggested that neuromuculars stimulation enhances the upper extremity motor recovery of acute stroke survivor	Fair Small sample size

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
18	Conforto AB, Kaelin-Lang A, Cohen LG (2002) Increase in hand muscle strength in stroke patients after somatosensory stimulation *Ann Neurol* 51(1), Jan, pg. 122-5	Clinical trial	The improvement in muscles strength correlated with stimulus intensity and was identified in the absence of motor training. These results suggests that somatosensory stimulation may be a promising adjuvant to rehabilitation of the motor deficits in stroke patients	Fair
19	Cauraugh J, Light K, Kim S, Thigpen M, Behrman A (2000) Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromusuclar stimulation *Stroke* 31(6), Jun, pg 1360-4	Randomised controlled trial N=11 stroke > or = 1 year	The evidence clearly support the use of electromyography-triggered neuromuscular electrical stimulation treatment to rehabilitation wrist and finger extension movements of hemiparetic individual > or = 1 year after stroke The treatment program decreased motor dysfunction and improved the motor capabilities in this group of poststroke individual	Good Small sample
20	Merletti R, Zalashi F, Latella D, Galli M, Angeli S, Sessa MB (1978) A control study of muscle force recovery in hemiparetic patients during treatment with functional electrical stimulation *Scand J Rehabil Med* 10(3), pg 147-54	Randomised Controlled trial N= 49 F/up: 1 months	The recovery of movement in the stimulated group turned out to be about three time greater than in the control group. And less dependent upon age, time from lesion, initial value. Side of lesion	Good Small sample Short follow up duration

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
21	Kenny L, Bultstra G, Bushman R, Taylor p, Mann G, Hermens H, Holsheimer J, Nene A, Tenniglo M, van der Aa H, Hobby J (2002) An implantable two channel drop foot stimulator" initial clinical resuls *Artif Organs* 26(3) Mar, pg 267-70	Clinical trial N=2	The 2 subject used the stimulator on a regular basis and showed increases in walking speed of between 10% and 40% when compared to their baseline measurements.	Poor
22	Kimberley TJ, Carey JR. (2002) Neuromuscular electrical stimulation in stroke rehabilitation. *Minn Med*,85(4), Apr, pp 34-7.	Not state	NMES can be used to facilitate motor learning in ankle dorsiflexion and wrist extension. Also beneficial in reducing shoulder subluxation but inconsistent in reducing shoulder pain	
23	Weingarden HP, Zeilig G, Heruti R, Shemesh Y, Ohry A, Dar A, Katz D, Nathan R, Smith A. (1998) Hybrid functional electrical stimulation orthosis system for the upper limb: effects on spasticity in chronic stable hemiplegia *Am J Phys Med Rehabil*. -77(4): Jul-Aug, pp 276-81	N=10 F/up: 6 months	A statistically significant improvement was noted in all muscle tone/spasticity parameters measured.	Poor

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
24	Chae J, Yu DT. (2002) Neuromuscular electrical stimulation for motor restoration in hemiparesis. *Top Stroke Rehabil*. 2002 Winter;8(4):24-39	Not stated	Transcutaneous NMES facilitates motor recovery. However, its impact on physical disability remains uncertain.	
25	Baker LL, Yeh C, Wilson D, Waters RL. (1979) Electrical stimulation of wrist and fingers for hemiplegic patients *Phys Ther*.;9(12), Dec, pp 1495-9	N=16	A statistically and clinically significant increase in wrist extension range occurred, increased extension was noted at the metacarpophalangeal and proximal interphalangeal joints of patients , those patients with some voluntary wrist extension before the treatment began were able to increase their extension strength during stimulation. No changes in skin sensation were noted.	Poor
26	Chantraine A, Baribeault A, Uebelhart D, Gremion G (1999) Shoulder pain and dysfunction in hemiplegia: effects of functional electrical stimulation *Arch Phys Med Rehabil*.,80(3), Mar, pp 328-31	Controlled study of 24 months' duration beginning in the first month after onset of stroke.	The group treated with FES showed significantly more improvement than the control group in both pain relief and reduction of subluxation . Furthermore, recovery of arm motion appeared to be significantly improved in the FES group .	Fair

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & Comment
27	Bogataj U, Gros N, Kljajic M, Acimovic-Janezic R. (1997) Enhanced rehabilitation of gait after stroke: a case report of a therapeutic approach using multichannel functional electrical stimulation. IEEE Trans Rehabil Eng.5(2), Jun, pp221-32.	Case Report	An analysis of the measured parameters showed improved performance of the patient during MFES therapy and stagnation or even slight recession during conventional therapy. The patient achieved independent gait during the three weeks of MFES therapy. At 30 months after the beginning of therapy, the patient was still able to ambulate independently without any significant changes in his gait pattern. The accomplishment was mainly attributed to the avoidance of pathological gait pattern development by using MFES assisted gait training and to the high motivation of the patient to walk and exercise during therapy as well as after he was released to go home.	Poor
28	Macdonell RAL, Triggs WJ, Leikauskas J, Bourque M, Robb K, Day BJ, Shahani BT (1994) Functional electrical stimulation to the affected lower limb and recovery after cerebral infarction. *J of Stroke & Cerebrovascular Diseases* ;4(3), pp 155-60	Clinical trial	FES may confer additional benefit in acute stroke rehabilitation.	

COMBINATION THERAPY

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & comment
1	Hesse, S., Reiter, F., Konrad, M., & Jahnke, M. (1998) Botulinum toxin type A and short-term electrical stimulation in the treatment of upper limb flexor spasticity after stroke: a randomized, double-blind, placebo-controlled trial. *Clinical Rehabilitation*, 12, (5), Oct, Pg 381-388	Randomised, placebo trial N= 24	Most improvements were observed in patients of group A. Cleaning the palm ($p = 0.004$) differed across groups. Pairwise comparison for this target variable showed that group A differed from group B and D ($p <0.01$), but not from C. Indicative across-group differences were obtained for elbow spasticity reduction ($p = 0.011$), and improvement of putting the arm through a sleeve ($p = 0.020$). CONCLUSIONS: The placebo-controlled trial favours the concept that electrical stimulation enhances the effectiveness of BtxA in the treatment of chronic upper limb flexor spasticity after stroke.	Good Small sample
2	Johnson CA, Wood DE, Swain ID, Tromans AM, Strike P, Burridge JH (2002) A pilot study to investigate the combined use of botulinum neurotoxin type A and functional electrical stimulation, with physiotherapy in the treatment of spastic dropped foot in subacute stroke *Artuf Organs* 26(3),Mar, pg 263-6	Randomised controlled trial N=21 F/up: 16 weeks	The result was significant upward trend in median walking speed for both group. Trend lines was difference in location There is evidence of an additional, benefit effect of BoNTA and FES.	Good Small sample & short duration follow up

No	Author, Title, Journal	Study Design, Sample Size, Follow up	Characteristic & Outcomes	Grade & comment
3	Cozen CD, Pease WS, Hubbell Sl (1988) Biofeedback and functional electrical stimulation in stroke rehabilitation *Arch Phys Med Rehabil* 69(6), Jun, pg 401-5	Randomised controlled trial N= 36 patients	Combined therapy with biofeedback and FES resulted in improvements in both knees and ankle minimum flexion angles during swing phase that were statistically significant. Velocity of gait, cycle time, and symmetry of stance phases also improved. The length of time elapsed since the stroke did not proved to be a significant factors	Good
4	Winchester P, Montgomery J, Bowman B, Hisiop H (1983) Effects of feedback stimulation training and cyclical electrical stimulation on knee extension in hemiparatic patients *Phys Ther* 63(7), Jul, pg 1096-103	Randomised controlled trial N=40 F/up-4 weeks	Analysis revealed a statistically significant increase increased in knee extension torque and active synergistic range of motion in study group. No change was noted in their ability to extend their knees using isolated quadriceps femoris muscle control.	Good