PREVENTION. CARE. RECOVERY.

Te Kaporeihana Āwhina Hunga Whara

Considered Judgement Form

Meeting date: 25 September 2012

Topic: FertiCare Penile vibrators

Background and Purpose:

Subfertility is widely reported in men with Spinal Cord Injury (SCI), influencing their ability to achieve pregnancy with a fertile partner.

Anejaculation (inability to ejaculate) is commonly found in men with SCI) and is major cause of subfertility (Sonksen et al 2002). The ejaculatory reflex is coordinated in the thoracolumbar area of the spinal cord. The neural pathway for the ejaculatory reflex is via sympathetic fibres arising from T11 to L2 of the spinal cord. Parasympathetic efferent innervation arising from the sacral area of the spinal cord (S2 to S4) is required for the formation of seminal fluid and projectile ejaculation.

It has been suggested that men with a SCI are more likely to have low sperm motility despite having a normal sperm count compared with the general population.

Refinements in techniques to assist ejaculation such as penile vibratory stimulation (PVS) and electroejaculation (EEJ) appear to have been effective in men with a SCI (Sonkenson et al 2002 and Brackett et al 2010).

PVS aims to activate the ejaculatory reflex by placing a vibratory disc against the frenulum of the penis in order to stimulate the penile dorsal nerve. The procedure lasts several minutes, if unsuccessful, stimulation is stopped for 1 to 2 minutes and then recommenced. Almost all of the ejaculations following PVS are antegrade (Sonkensen et al 2002).

A number of brands of medical vibrator are available but the most commonly reported in the literature is FertiCare® (Multicept, Albertlund, Denmark). PVS is generally considered to be a well- tolerated procedure with minimal adverse effects (mainly skin irritation or soreness).

EEJ is conducted with a rectal probe. Although antegrade ejaculation occurs in some men a large proportion will have retrograde ejaculation (in to the bladder) and require bladder catheterisation to retrieve the sperm. EEJ is associated with significant discomfort in men with preserved sensation and due to this spinal or general anaesthesia may be required. PVS is therefore the preferred method.

The purpose of this report is to summarise the evidence for the success of using conservative methods for retrieving sperm of sufficient quality to achieve a pregnancy and live birth for couples where the male partner has a SCI. The report will focus on PVS.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency

Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, l any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence

PVS is generally considered to be a well tolerated procedure with minimal adverse effects (mainly skin irritation or soreness). The intended outcome when using PVS is live birth. As there are many other uncontrollable factors contributing to the success of live birth it is therefore more pertinent to consider ejaculation of good quality sperm as a measure of success as this in turn will provide the opportunity to achieve pregnancy and live birth.

PVS is more effective in achieving ejaculation in men with SCI above level T10. A number of brands of medical vibrator are available but the most commonly reported in the literature is Ferticare. Ferticare has FDA approval.

Thirty-one studies were considered and included for appraisal and data extraction. Within these, there was 1 systematic review of good quality (Brackett et al 1998), 1 prospective randomised controlled trial of mixed quality (Hamid et al 2006), 1 prospective cohort considered to be of mixed quality (Momen et al 2007), retrospective cohort study of mixed quality (Kathiresan 1996), 4 case control studies of mixed quality (Restelli et al 2009, Salsabili et al 2009, Brackett et al 2008 and Qiu et al 2012) and 12 case series studies (evidence at this level is not critically appraised Sonksen et al 2012, Padron et al 1997, Iremashvili et al 2010, Brackett et al 2007).

On balance there is limited evidence of moderate quality reporting on sperm and fertility outcomes. The studies included covered a wide range of SCI from C1 to L5.

PVS was consistently more successful and better tolerated than EEJ. PVS was not found to be successful where the lesion was at T10 or below.

2. Cost

Comment on any economic costs associated with this service, product or procedure

The cost of the ferticare device is NZ$1200

There is no evidence of cost effect for this product, however it is important to consider that the current alternative is IVF which costs approx NZ$12,000 for each round, it can require multiple rounds of IVF for a couple to achieve pregnancy

3. Clinical impact

Comment onl the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

ACC has currently received 1 request to fund this technology. However future requests are anticipated

The evidence suggests that Ferticare PVS provides a safe and effective alternative to IVF in helping men with SCI above the level of T10 produce sperm of high enough quality to achieve pregnancy

4. Equity, Maori Health, Pacific Health, Acceptability

Comment on the extent to which the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome), is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and is consistent with values and expectations of New Zealanders.

There are no equity issues directly associated with the use of this product.

5. Possible Purchasing Options

List the possible purchasing options.

The options are –

1. purchase,
2. don't purchase and,
3. purchase on a case by case basis on the decision of the Corporate Medical Advisor.

6. Evidence Statement

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

There is moderate quality evidence for the effectiveness of PVS for improving sperm motility in men with SCI. The evidence suggests that this treatment is more suitable/effective for men with SCI above T10. There is limited evidence to suggest that this in turn leads to successful pregnancy/live birth in the respective female partner.

7. Purchasing Recommendations

What recommendation(s) does the advisory group draw from this evidence?

Consider purchase for clients with injury above level T10. This must be as a fertility treatment where conception of a child is the intended outcome; as part of a clinically managed treatment plan following professional advice.

As a first step BMA's should request assessment of sperm quality

Can be purchased at recommendation of a urologist; if this is their area of expertise

PGAG Discussions: