NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Evaluation Pathway Programme assessment

Specification for manufacturer/sponsor submission of evidence

March 2010

Addendum to Section B 5 – Clinical effectiveness

Awake use
Clinical experience with oesophageal Doppler monitoring in awake patients

Oesophageal Doppler monitoring is a minimally invasive technology requiring the insertion of an ultrasound probe into the oesophagus of the patient. Use in anaesthetised/fully-sedated patients is well accepted, without reports of serious adverse incidents or discomfiture after use. However in some surgical settings (i.e. orthopaedic procedures) patients can be anaesthetised using regional anaesthesia.

It has been questioned whether use of an ultrasound probe would be tolerated by an awake sedated patient, the central question is whether the patient’s gag reflex would prevent use.

However the insertion of an ultrasound probe is similar to the insertion and use of nasogastric feeding tubes. The main use of a nasogastric tube is for feeding and for administering drugs and other oral agents such as activated charcoal. Insertion rates and tolerability of nasogastric tubes has been well documented.

An oesophageal Doppler ultrasound probe has similar characteristics in terms of diameter and rigidity to that of a nasogastric tube. However the ultrasound probe has a soft flexible tip rather than the stiffer leading edge of the nasogastric tube and thus may pose less risk in this respect. Insertion using local anaesthetic lubricating gel would parallel the technique used for nasogastric tubes.

It is also important to distinguish between placing this probe on an awake patient and placing the probe on an anesthetised patient, who then wakes up with the probe in-situ. Deltex Medical provides a range of probes that were primarily designed for use on the anaesthetised patient, who then post operatively tolerates the probe awake, with only a limited number of reported issues. These primarily relate to when the patient comes around from the anaesthetic and tries to remove the tubes, including the probe from their nose or mouth.

The bigger challenge is to provide a probe that can be placed on a patient who is awake, due to the potential discomfort and issues with patient movement causing interference on the received Doppler signal.

There is 9 years’ experience with the use of oesophageal Doppler probes in awake subjects. A successful design for an awake use oesophageal Doppler probe has three ideal attributes:
1. The probe has sufficient inherent stiffness that it can be easily inserted nasally, without undue manipulation, via the patient’s oropharynx into the oesophagus without coiling on itself.

2. The probe shaft is sufficiently flexible to present minimal pressure on the distal surface of the patient’s oropharynx.

3. The probe shaft transmits torque smoothly to allow easy focusing with minimal manipulation.

A combination of these characteristics is important for patient comfort as such a probe shaft would require minimal manipulation to insert and focus and result in the least amount of pressure on oropharyngeal tissues.

**Design Process**

There have been three periods of experience with Deltex Medical ‘awake patient’ probe designs:

1. Early work with probes designed for anaesthetised patient applications, the EDP90 (Esophageal Doppler Probe USA) and the ODP (Oesophageal Doppler Probe UK). These designs were of identical probe shaft and tip construction.

2. ADPn series (Awake Doppler Probe). The ADP had identical silicone tubing and tip construction but the internal spring was more flexible.

3. I₂n series (Instant Intervention Probe). The I₂n series of probes were of identical silicone tubing and tip construction, but contained a modified spring to provide flexibility equivalent to the ADP, but rotational torque characteristics for focusing equivalent to the EDP90 and ODP probe designs.

**Early experience with EP90 and ODP probes**

Early oesophageal Doppler probes designed for fully anesthetised patients were however stiffer than nasogastric tubes. These early probe designs were not indicated for use with awake patients however there have been reports of successful use in awake patients⁴,⁵.

⁴ Atlas & Mort 2001
⁵ Moppett et al 2002

**Awake Doppler Probe (ADP)**

In 2005 Deltex Medical designed and evaluated oesophageal Doppler probes specifically designed for comfort in patients undergoing surgery with regional anaesthesia and light sedation. These probes known as Awake Doppler Probes (ADP) possessed a finer softer spring within the catheter. This created
a more flexible probe shaft which reduced pressure on the distal surface of the oropharynx and so reduced the gag response. These designs were evaluated and reported on by two groups of clinicians at University College London and Queen’s Medical Centre Nottingham\textsuperscript{3,4}.

The University College workers\textsuperscript{3} reported that:

“In our series, 11 of 15 ADP’s were easily inserted and quick to focus with no associated morbidity. These early positive experiences of both patient and operator suggest that ADP may offer an extended role for monitoring cardiac output in both awake surgical patients and peri critical care”.

The Nottingham group\textsuperscript{4} reported that:

“…nasally inserted TOD probe is well tolerated by the majority of awake subjects, however there is a small group of people in whom it is poorly tolerated despite adequate anaesthesia. It provides consistent cardiac indices over an extended period of time with only slight adjustment of position required.”

**Instant Intervention Probe (I\textsubscript{2}N series)**

The Instant Intervention Probe series I\textsubscript{2}N is the probe design currently provided by Deltex Medical for awake patient applications. Since their launch in 2007 Deltex Medical has delivered 23,406 I\textsubscript{2}N series probes (as at end March 2010).

I\textsubscript{2}N series probes utilises a pitched spring configuration, which combines flexibility and torque transmission characteristics. The ADP device reported to have good comfort performance by Walker et al and English and Moppett contained a fine wire close coiled spring of 1440 coils (ODP spring possessed 720 coils). Whilst the finer wire spring was sufficiently flexible the increased in the number of coils reduced the transmission of torque. This reduction in torque increased the difficulty in rotating the probe to achieve focus. This resulted in increased focusing time and potentially increased manipulation.

The I\textsubscript{2}N series probes contain a spring with 440 coils. This probe shaft design was demonstrated in engineering trials to have a flexibility equivalent to the ADP series but with enhanced rotational torque. The acceptability of the design was tested against the three ideal attributes listed above.

**Insertion success**

Results of 160 insertions into anaesthetised, sedated and fully awake patients were recorded. 106 insertions were in patients under general anesthetic, 31 in
sedated patients and 23 in fully awake patients. Success was considered to be the ability to insert the probe smoothly at the first attempt without undue force or the need to remove and re-insert.

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The I₂n series of probes were shown to insert efficiently with 90% success at the first attempt across all patient anaesthesia groups (re-insertion rates were not recorded). Insertion achieved better than eight of ten first insertions in sedated and awake patients. Whilst some clinicians reported a noticeable difference in 'feel' these results were considered equivalent to experience with the stiffer standard oesophageal Doppler probes.

### I₂n Total Insertion Success

[Graph showing insertion success rates]

#### Focusing

Achieving focus within an acceptable period of time is indicative of the ability to adjust the depth of the probe tip but most importantly the ability to rotate the probe efficiently. Clinicians were asked to record their focusing experiences, in particular the time taken to achieve first focus including the insertion period.

Time and motion studies of standard probes have suggested an average time to establish first focus of three to four minutes. The I₂n series results were
not significantly different to experience with standard probes. 129 of 160 focus events were completed within 5 minutes with 116 focused in less than 3 minutes.

**Awake tolerance**

In an additional study of the tolerance of the probe in awake patients, clinicians reported that 76 of 81 probes were well tolerated by patients in the awake part of their treatment. Some clinicians were reluctant to insert in fully awake patients so the results reflected both patient and clinician reports.

As usage has expanded there have been independent reports of usage. The outreach programme in Colchester uses the I₂n series of probes in fully awake patients to successfully manage fluid status in a general ward situation.

A poster from Sunderland reported on 20 consecutive spinal anaesthetics in fractured neck of femur patients whilst reporting a promising outcome there were limitations with the flexible oesophageal probe in this group of patients. The probe was inserted at the time of positioning for spinal anaesthesia and although easy to insert, significant sedation was required particularly in the patients with dementia. This study highlights issues related to placing this device on the elderly awake patient. Even though the Doppler group of patients had an improved outcomes and shorter lengths of stay compared to the control group, it was noted that the probe had practical limitations which
would restrict its routine use. There was obviously a clear benefit to using this technology, so finding ways around the limitations they observed would seem a sensible approach.

It was also been reported in the British Journal of Hospital Medicine that there is good potential for less invasive monitoring devices to extend into the ICU and wards. In 2007 Usher et al reported that ‘there is increasing evidence to support early and aggressive management of critically ill patients (Rivers et al). Outreach teams are now commonplace on many UK hospital wards, bringing the concept of intensive care to the patient rather than waiting for patients to decompensate and require critical care submission’. ‘Since the newer compliant probes, designed for use in the awake patient have been developed there is increasing potential for extending monitoring in a wide range of clinical settings’.

Summary

Deltex Medical has manufactured and distributed in excess of 23,000 probes designed for awake use. Many such probes are used successfully post operatively, where the probe is inserted under general anaesthetic, but is left in place into the later awake/sedated phase of recovery and in fully awake outreach programme patients. Most reports are that the probe is easy to insert and focus and is well tolerated where the probe is inserted under a reasonable level of sedation initially or where the patients are fully aware of the short period of discomfiture during insertion.

References

   http://www.bjhm.co.uk/downloads/BJHM_68_3_126_130_Doppler.pdf