

20kHz TSE pilot study n207 on acute and acute-on-chronic pain

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Macdonald and Coates 1995 observed the higher the frequency, the greater the analgesic effects of TSE. Whereas TSE at frequencies of 2kHz or less fails to relieve acute and acute-on-chronic pain, Macdonald observed there was a tendency for some acute pains caused by conditions such as cancer, myocardial infarction and renal infection to be relieved by TSE performed at a higher frequency: 20kHz.

Patients who did not respond adequately were provided with opioids or other appropriate forms of pain relief in the usual manner. In the case of fractures, it was noted 20kHz TSE tended not to relieve phasic pain. For example, a patient with a fracture might report good relief of the tonic pain at rest; but any attempt at movement produces phasic pain to the usual degree. Severe anxiety also prevented pain relief from TSE.

Macdonald reports an open, pilot study of pain relief reported immediately after 20kHz TSE by consecutive patients suffering acute or acute-on-chronic pains on the following scale: 0, no relief; 100 complete relief. The mean treatment duration was 14.1mins (\pm SEM 0.3). During this time patients were unaware of any sensation from TSE. No side effects were reported. The duration of pain relief however was temporary, four hours or so. As indicated, the patient was admitted to hospital or other forms of pain relief were provided so care could be continued.

Patients numbered 207 (139 females and 68 males). The mean age was 49.8 years (SD 21.3). 164 presented with acute pain of 72hrs duration or less; 43 had acute-on-chronic pain of more than 72 hours.

In this sample (n207), there were five causes of pain: infective, n35; inflammatory, n127; ischaemic, n20; malignant, n21; and neurogenic, n12. Some patients complained of pain with more than one cause: a patient with pleuritic pain, for example, would be regarded as having pain both of infective and inflammatory origin. The diagnoses of the patients studied is detailed on page 3.

Pains were reported in the following four regions of the body: head, neck, upper limbs, n37; chest pain, n45; abdomen, loin, perineum and scrotum, n89; and back and lower limbs, n36. In the case of patients presenting with head, neck, upper chest and limb pains, electrodes were placed on either side of the neck over the transverse processes of C3-C4: for the remainder they were placed over the spinous processes of T1 and T12.

186/207 (89.9%) of patients suffering all types of pain treated by 20kHz TSE derived 50% or more relief. From these figures one can be 95% confident that between 84.9-93.6% of the general population would have a similar degree of relief. However, since this was an open study undertaken in an active practice and consequently with no control group, allowance should be made for placebo responders although the extent of this is not known.

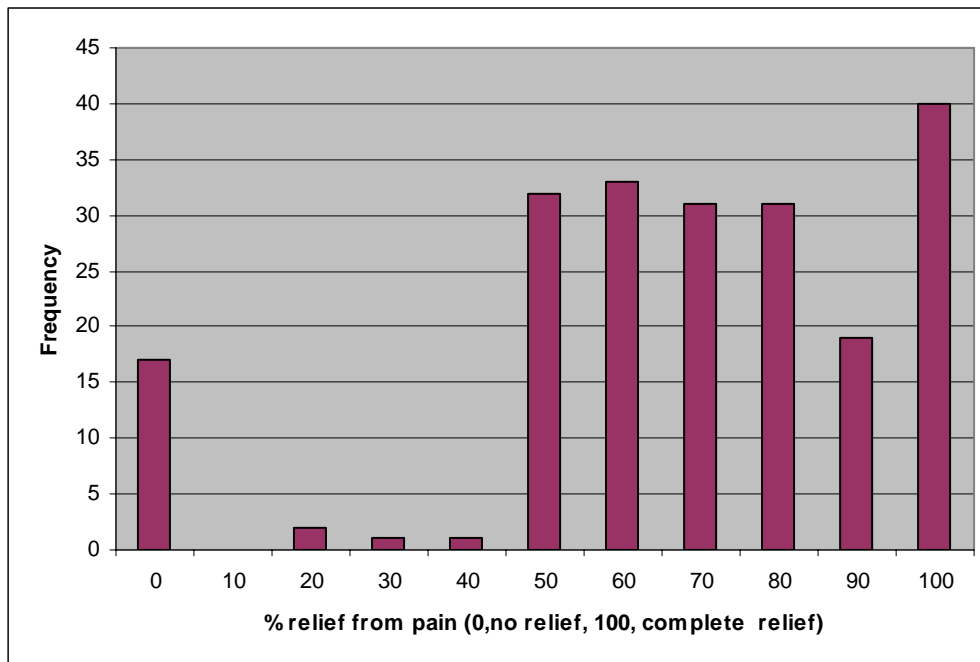
The results are summarised overleaf.

Summarised results of the % relief of various types and locations of pain by 20kHz TSE and the 95% Confidence Limit of percentage relief predicted in the population as a whole.

condition or location	n	those who had 50% or more relief	% who derived 50% or more relief	95% confidence limit: those of the general population deriving 50% or more relief would vary between the percentages of:
ALL RESULTS	207	186	89.9	84.9-93.6
cancer	21	21	100.0	83.9-100
infection	35	30	85.7	69.7-95.2
inflammation	127	119	93.7	88.0-97.2
ischaemia	20	17	85.0	62.1-96.8
neurogenic	12	11	91.7	61.5-99.8
head, neck & upper limbs	37	32	86.5	71.2-95.5
chest pain	45	42	93.3	81.7-98.6
abdomen, loin, perineum, rectum & scrotum	89	81	91.0	85.1-96.0
back & lower limbs	36	32	88.9	73.9-96.9

Frequency distribution of relief (0, no relief; 100, complete relief) of all types of pain n207 treated by 20kHz TSE.

The frequency distribution of relief in all conditions treated by 20kHz is as follows:



Important note: TSE should only be used to treat acute pain under medical supervision where a diagnosis has been made by a health care professional. For this reason, the standard settings of the Acticare TSE device are arranged so that treatment is limited to chronic and acute-on-chronic pains.

Diagnoses of patients suffering acute and acute-on-chronic pain n207 treated by high frequency TSE

Abdominal, loin, perineal, rectal and scrotal pain: anal polyp, strangulated (1); aortic aneurysm (2); appendicitis (2); bladder stone + bladder retention (1); cervical erosion (3); Crohn's disease (1); diverticulitis (1); duodenal ulcer (1); ectopic pregnancy (1); endometriosis (2); gall stones (19); hiatus hernia (1); impacted faeces causing retention of urine (1); large bowel obstruction (2); ovarian cyst (2); pancreatitis (2); pelvic abscess (1); peritonitis following D & C (1); polycystic ovaries (1); post-*puerperal* infection (1); premature labour (2); rectal ulceration (1); renal calculi (2); renal infection (1); scrotal hernia (1); subdiaphragmatic abscess (1); threatened abortion (3); upper intestinal obstruction associated with adhesions (1); ureteric calculus (1); urinary tract infection (14); uterine infection (1).

Anxiety: atypical facial neuralgia (1).

Infection: cellulitis of right thumb and forearm (1); otitis media (2); septicaemia (1); paranasal sinusitis (1); pilonidal sinus (2); septic arthritis of the knee (1); suppurating lower limb ulcer (1); pleurisy (3).

Inflammation: right knee pain following steroid injection (1); gout (1); severe OA (1); rheumatoid arthritis (2); rheumatoid arthritis + polymyalgia rheumatica (1); rheumatoid arthritis causing temporomandibular joint pain (1); OA lumbar spine and hip (1); arc eye (2); deep venous thrombosis (1).

Ischaemia: cardiac: crescendo angina (1); myocardial infarction (8); unstable angina (3); femoral artery: embolism (2); aneurysm (1); gangrene of the 2nd toe (1); peripheral vascular disease affecting both lower limbs (1); strangulated scrotal hernia (1); sickle cell crisis (1); torsion of testicle (1).

Malignant: cancer of lung (1); cancer of the large bowel (2); cancer of maxilla (1); cancer of the oesophagus and inhalation pneumonia (1); cancer of pancreas (3); cancer of the rectum (1); cancer of the sacrum (1); cancer of the tongue (1); sarcoma (1); *metastases:* breast to the jaw (1); breast to liver (1); from breast causing acute abdomen (1); lung to brain (1); lung to cervical spine (1); cervical spine from a sarcoma (1); lung & lumbar spine (1); pleural effusion associated with lymphoma (1); in the pelvis (1); from prostate to spine (1); from rectum (1); in thoracic spine causing compression of spinal cord (1).

Musculoskeletal: abdominal pain - tender oblique muscles associated L4/5, L5/S1 PDI (Prolapsed Disc Injury) (1); back pain associated with numbness of sacrum and left leg (1); low back pain exacerbation (1); C5/6 (PDI) (1); L4/5 PDI + diabetic neuropathy (1); chest wall pain (13); pain in dorsum of right foot (1); headache associated with cervical spondylosis (2); malingering with headache (anxiety) (1); knee pain (1); neck pain (1); thigh pain ? referred from sacroiliac joint (1); sprained sacroiliac joint (1); tender quadratus lumborum (2); torticollis (2); migrainous headache (2); testicle pain referred from T12 (1).

Neurogenic pain: brachial plexopathy (1); brachial plexus avulsion (1); diabetic neuropathy associated with deep ulcer in the heel (1); herpes zoster (3); neuropathy associated with chemotherapy for cancer of the testicle (1); phantom limb (1); Ramsay Hunt syndrome (1); Sudek's atrophy right lower limb (1).

Post-operative pain: angioplasty (1); episiotomy (1); inguinal hernia repair (1); tonsillectomy (1); triple bypass – pain from dissection of internal mammary artery (1); wound infection (1).

Trauma: *fractures* of 2nd-3rd metacarpals (1); 5th MTP joint (1); fracture dislocation of ankle (1); rib (2); thoracic vertebra (3); neck of femur (1); neck of humerus (1); *injury* to chest causing pleural effusion (1) and haemothorax (1); neck (1); forearm and occiput (1); head and coccyx (1); wrists and knees from a fall (1).