Faculty of Public Health
Of the Royal Colleges of Physicians of the United Kingdom
Working to improve the public's health

OSPHE 046

New medical procedure: Extracorporeal shockwave therapy for tennis elbow

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CANDIDATE PACK

OSPHE 046

Candidate task

You are a public health trainee in the local organisation that funds primary and secondary health care.

You are to meet a PALS representative[1] from the local commissioning body. The PALS officer is representing a concerned patient, whose GP is not permitted to refer him/her for NHS funded extracorporeal shockwave treatment for tennis elbow. The treatment is offered at a local private sports injury clinic but is not available in local NHS hospitals. The purpose of your meeting is to explain to the PALS officer why the local health funding body is unwilling to fund extracorporeal shockwave treatment for tennis elbow outside the NHS.

You have 8 minutes to prepare for the meeting with the PALS officer. The meeting will also last 8 minutes.

Outline of the situation

Your locality has agreed with the local GPs that treatments that are not supported for routine use by The UK National Institute for Health and Clinical Excellence (NIHCE)[2] will not be considered for funding in the private sector.

The patient in question has tennis elbow and attends the local private sports-injury clinic. The clinic have suggested extracorporeal shockwave treatment and he/she has come back to the GP asking if this can be funded by the NHS because there are no NHS facilities. The GP has tried to explain the policy but the patient is very unhappy about this and wants the PALS officer to approach "the person in charge" of this policy as they believe they should be treated as a special case.

Using the material in the briefing pack and your own experience, prepare for an 8 minute meeting with the PALS officer so they can liaise with the patient and explain the local policy. You do not need to use any visual aids at the meeting but can make notes in you briefing pack.

[1]PALS: Patient Advisory and Liaison Service. English NHS service available in each NHS Trust to assist patients with queries about NHS services and care, including signposting for concerns and/or complaints. Mainly staffed by experienced NHS employees – usually non-clinicians.

[2]National body of clinical experts responsible for assessing the effectiveness of medical technologies. In England this is called the National Institute of Health and Clinical Excellence (NIHCE) and in Scotland the Scottish Medicines Consortium (SMC). The guidance issued by these bodies is used to plan and fund largely new and expensive technologies within the healthcare system.

Candidate guidance

During the meeting you should lead the discussion and explain the following to the PALS officer:

- Explain that, in the NHS new treatments are evaluated by NIHCE before they are taken up in regular practice.
- Explain that NIHCE has reviewed this procedure and that its use is not supported as a routine to be funded by the NHS.
- Explain why this decision has been made for extracorporeal shockwave treatment for tennis elbow.
- Explain what the placebo response is and why it may produce positive results in some studies.
- Describe what treatments are known to be effective or likely to be effective for tennis elbow.

Resources available

- OSPHE tennis enclosure 1 NIHCE Guidance on Extracorporeal shockwave therapies for refractory tendinopathies (plantar fasciitis and tennis elbow) November 2005.
- OSPHE tennis enclosure 2 Extract from Clinical Evidence website about effective treatments for tennis elbow 2003.

At the station

You will be greeted by a marker examiner who will take your candidate number and name, and then hand over to the actor by saying:

"This is the PALS officer. They will now start the station".

OSPHE 046

Candidate Briefing Pack

OSPHE tennis Enclosure 1

National Institute for Health and Clinical Excellence November 2005 guidance (extract). Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow)

1. Guidance

1.1 Current evidence on extracorporeal shockwave therapy for refractory tendinopathies (specifically tennis elbow and plantar fasciitis) suggests that there are no major safety concerns. Evidence on efficacy is conflicting, and suggests that the procedure produces little benefit apart from a placebo response in some patients. Therefore, current evidence on efficacy does not appear adequate to support its use without special arrangements for consent, and for audit or research.

1.2 Clinicians wishing to undertake extracorporeal shockwave therapy for refractory tendinopathies should take the following actions.

- Inform the clinical governance leads in their trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's *Information for the public* is recommended.
- Audit and review clinical outcomes of all patients having extracorporeal shockwave therapy for refractory tendinopathies. The Institute may review the procedure upon publication of further evidence.

2. The procedure

2.1 Indications

2.1.1 Tendinopathy is a collective term describing a chronic condition in which a tendon is affected by a series of microscopic tears at its junction with bone. The condition heals very slowly. Endinopathy can affect many different tendons and results from either injury or overuse. Symptoms include pain, tenderness, weakness and stiffness.

2.1.2 Plantar fasciitis (which affects the sole of the foot and the heel) and tennis elbow are particularly common types of tendinopathy.

2.1.3 Conservative treatments include rest, application of ice, orthotic devices, physiotherapy, analgesics and injection of corticosteroids. Surgery to release the tendon from the bone is an option in patients with refractory symptoms.

2.2 Outline of the procedure

2.2.1 Extracorporeal shockwaves are high-pressure, low-frequency sound waves, generated by a device outside the body and applied to the affected tissue in a site-specific manner. Ultrasound guidance may be used to assist with the positioning of the device. The procedure can be performed with or without sedation.

2.2.2 The mechanism by which extracorporeal shockwave therapy might have an effect on musculoskeletal conditions is not well defined.

2.3 Efficacy

2.3.1 Six randomised controlled trials compared extracorporeal shockwave therapy with a placebo, and five of the six studies reported some efficacy data. The studies reported a variety of outcome measures and used different criteria to define a successful outcome.

2.3.2 In one study of 293 patients, 45% (65/144) of patients treated with extracorporeal shockwave therapy had a successful outcome at 12 months compared with 18% (25/141) of patients who had placebo treatment ($p = 0.002$). A study of 150 patients reported that 56% (41/73) of patients given active treatment had a clinically successful outcome at 3 months, compared with 45% (33/73) of control patients ($p = 0.19$). By contrast, two studies of 272 patients and 166 patients reported no clinically relevant difference between the active treatment groups and control groups at 12 months and 12 weeks respectively. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors stated that there was some uncertainty about the efficacy, and that there may be a placebo effect associated with this procedure.

2.4 Safety

2.4.1 One study was specifically designed to look at side effects of shockwave therapy. The most common complication was reddening of the skin, which occurred after 21% (84/399) of treatment sessions. Pain and bruising occurred in 5% (19/399 and 18/399, respectively) of treatments. Less common complications included swelling, migraine, syncope, nausea and dizziness.

2.4.2 The most common complication reported in the remaining five studies was pain during and after the procedure, which affected between 1% (1/81) and 72% (55/76) of patients. Other complications included bruising, numbness, reddening of the skin, local swelling, rash and neuralgia. For more details, refer to the Sources of evidence.

2.4.3 The Specialist Advisors expressed concern about the possibility of tendon rupture, particularly of the Achilles tendon. They also listed bone necrosis, haematoma and pain as potential adverse events.

2.5 Other comments

2.5.1 It was noted that some studies included patients who had had treatment shortly after onset of symptoms. Tendinopathies often improve spontaneously and so beneficial effects may have been over-reported.

OSPHE tennis Enclosure 2

Extract from Clinical Evidence Search date April 2003
http://www.clinicalevidence.com/ceweb/conditions/msd/1117/1117.jsp
Musculoskeletal disorders: Tennis elbow Interventions

We have searched the evidence for systematic answers to the clinical questions and have then categorised each treatment or intervention according to its harms and benefits in those situations.

Treatments

Beneficial - Topical non-steroidal anti-inflammatory drugs for short term pain relief.
Likely to be beneficial - Oral non-steroidal anti-inflammatory drugs for short term pain relief.

Evidence about non-steroidal anti-inflammatory drugs

One systematic review has found that topical non-steroidal anti-inflammatory drugs improve symptoms in the short term compared with placebo. Minor adverse effects have been reported. The review found limited evidence that oral non-steroidal anti-inflammatory drugs improved symptoms in the short term compared with placebo, although we also found limited evidence that it was less effective than corticosteroid injection in the short term. We found insufficient evidence to assess the longer term effects of non-steroidal anti-inflammatory drugs compared with placebo, although one RCT found that oral non-steroidal anti-inflammatory drugs were more effective than corticosteroid injections in the long term. We found no RCTs comparing oral versus topical non-steroidal anti-inflammatory drugs.

Trade off between benefits and harms - Corticosteroid injections.

Unknown effectiveness - Acupuncture, exercise and mobilisation, non-steroidal anti-inflammatory drugs for longer term pain relief, Orthoses (braces), Surgery.

Unlikely to be beneficial - Extracorporeal shockwave therapy.

Evidence about extracorporeal shockwave therapy

One systematic review and one subsequent RCT found no significant difference in symptoms between extracorporeal shockwave therapy and sham treatment in 3 months.

OSPHE 046

New medical procedure: Extracorporeal shockwave treatment for tennis elbow

MAIN MARKER EXAMINER PACK

OSPHE 046

Examiner situation

The candidate has been told that they should lead the discussion. The examiner should introduce the candidate to all present before asking the candidate to go in-role as the representative of the local public health department. The candidate has been told that no visual aids are needed for the meeting but that they may make notes in their candidate pack. The candidate has been asked to close the interview but the main examiner should intervene to bring the meeting to a close at the end of the OSPHE station if needed.

OSPHE 046

Examiner Answer guidance

The marking guide is shown below.

Areas that the candidate has been asked to cover:

1) Explain that, in the NHS new treatments are evaluated by NIHCE before they are taken up in regular practice.

2) Explain that the UK National Institute for Health and Clinical Excellence (NIHCE) has reviewed this procedure and that its use is not supported as a routine to be funded by the NHS.
The NIHCE guidance shows that evidence on efficacy is conflicting and suggests the procedure produces little benefit apart from a placebo response in some patients. Therefore current evidence on efficacy does not appear to support its use without special arrangements for consent and for audit and research.

3) Explain why this decision has been made for extracorporeal shockwave treatment for tennis elbow.
Four studies with over 100 patients and controls and 3-12 months follow-up are quoted. Two showed significant benefit for the treatment and the other two showed no benefit. The specialist advisors stated that there was some uncertainty about the efficacy, and that there may be a placebo effect associated with this procedure (more information in the briefing pack).

4) Explain what the placebo response is and why it may produce positive results in some studies.

5) Describe what treatments are known to be effective or likely to be effective for tennis elbow.
"Clinical evidence" suggests that topical non-steroidal anti-inflammatory drugs are beneficial for short term pain relief. Oral non-steroidal anti-inflammatory drugs for short term pain relief are likely to be beneficial (more information in the briefing pack).

Examiner briefing pack (these will be inserted by the Faculty office)

Candidate pack, Actor briefing pack.

OSPHE 046

Marking Guide for Examiners

1. Has the candidate appropriately demonstrated presenting skills in a typical public health setting (presenting to a person or audience)?

Avoids jargon. Is clear. Appropriate language for the audience. Maintains eye contact. Appropriate manner and non-verbal communication for the situation. Shows empathy.

2. Has the candidate appropriately demonstrated listening skills in a typical public health setting (listening and responding appropriately)?

Ensures actor's questions are answered appropriately. Answers totality of the question. Manner of response appropriate. Candidate empathises with the PALS officer's account of the patient's situation, including ascertaining the need to find out what other treatments have been tried.

3. Has the candidate demonstrated ascertainment of key public health facts from the material provided and used it appropriately?

Candidate summarises the role of NIHCE in the introduction of new technologies, explains why new treatments need to be subject to systematic analysis, including randomised controlled trials before they should be adopted into routine practice.

4. Has the candidate given a balanced view and/or explained appropriately key public health concepts in a public health setting?

Candidate gives a clear explanation of the placebo effect and how it may affect the results of clinical trials. The candidate is supportive of the GP's actions in this case. Candidate interprets and balances evidence from the effectiveness of different treatments to help the PALS officer guide the patient in deciding what is best.

5. Has the candidate demonstrated sensitivity in handling uncertainty, the unexpected, conflict and/or responding to challenging questions?

Non-confrontational. Ensures a balanced view. The candidate picks up that the patient does not realise that topical NSAIDs can be effective.

OSPHE 046

New medical procedure: Extracorporeal shockwave treatment for tennis elbow

ACTOR BRIEFING PACK

OSPHE 046

Station background

The briefing papers comprise an extract from the UK National Institute for Health and Clinical Excellence (NIHCE) guidance on extracorporeal shockwave therapies for tennis elbow and an extract from the "Clinical Evidence" website which reviews what is known to be effective to treat common conditions. Tennis elbow is a painful condition of the outside of the elbow region where the muscles of the forearm join the bottom of the bone of the upper arm (the humerus). It is mainly caused by overuse of the wrist. It is difficult to treat and although relatively harmless, can be painful and disabling. Untreated it can continue for months or even years, but only a limited number of current medical treatments appear to affect the natural course of the condition.

Actor Brief

The marking examiner will introduce you. The candidate will be asked to start the OSPHE. If the candidate has not finished the meeting in time, the marking examiner is responsible for terminating the OSPHE.

You are playing the role of a PALS officer. These staff members within the NHS advise and help patients, and seek explanations from health professionals, especially in situations where direct contact between patient and professionals may be threatening or difficult. Usually the PALS officers do not particularly advocate on a patient's behalf. However, on this occasion, the patient in question is a very keen tennis player, just on the edge of selection for the "county team" for their age group. They do not want to have to miss tennis because of very painful tennis elbow that has developed this season. They visited a local private sports injury clinic where they were told that extracorporeal shockwave therapy for tennis elbow is the "latest thing" - very effective, fast and without side effects. The patient's GP says that the NHS cannot pay for the treatment in the private sector. All he has offered is anti-inflammatory cream, which the patient feels is a derisory response to a painful condition. The patient has said that they have no faith in treatments that are administered as "creams", and cannot afford to pay for the therapy themselves and the patient feels that the NHS should pay for it at the private hospital. You (as the PALS officer) once suffered from this condition, in similar circumstances, but at a time when little was available to help. You have some sympathy with the position of the patient and so your stance is more strongly to advocate for the patient than you would usually. You remain within professional boundaries and do not get cross or lose control at any time.

You should start the station by saying:

"Thanks for coming in. As you know, our patient is very concerned about not getting this treatment. Please could you summarise the situation for me".

The following questions should guide candidate through the required areas they have been asked to cover if they do not volunteer the responses.

"Could you describe what this 'NIHCE' decision means?"

"The patient knows several of his colleagues who have had this treatment and they say it is brilliant – why would that be?"

"The GP says that they can only provide this skin gel. The patient has tried that for over a month and it has had no effect. Surely we could make an exception here?"

Any 'No Go' areas

The candidate has not been asked to talk about side effects of extracorporeal shockwave treatment or other therapies for tennis elbow, although these are mentioned in the NIHCE guidance.

There are no specific failure criteria but the candidate should maintain a professional attitude with the PALS officer at all times.

Level of conflict

Medium. Push hard for a sensible explanation of the alternatives and how you can progress this seemingly blocked situation.

Areas the candidate has been asked explain

- In the NHS new treatments are evaluated by NIHCE before they are taken up in regular practice.
- The UK NIHCE has reviewed this procedure and recommended that its use is not supported as a routine to be funded by the NHS.
- The candidate should explain why this decision has been made for extracorporeal shockwave treatment for tennis elbow.
- The candidate should explain what the placebo response is and why it may produce positive results in some studies.
- The candidate should describe what treatments are known to be effective or likely to be effective for tennis elbow.