SAFETY ALERTS

National Patient Safety Agency: combining stories with statistics to minimise harm

Tara Lamont, John Scarpello

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National Reporting and Learning Service, National Patient Safety Agency, London W1T 5HD
Correspondence to: T Lamont
tara.lamont@npsa.nhs.uk

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In a busy endoscopy clinic, you draw up part of a high strength midazolam ampoule and realise that you have oversedated the patient. The patient has been harmed. What stops you reporting it? What would prevent it from happening again in your trust or elsewhere?

An article about avoiding midazolam overdose is the first in a series of *BMJ* summaries of recommendations to improve patients' safety, based on reports of safety concerns, incident analysis, and other evidence.[1] The midazolam article is from the National Patient Safety Agency (NPSA) in England and Wales, which each week receives reports from healthcare professionals of serious incidents that have the potential for serious harm.[2] This article is a summary of the agency's rapid response report (RRR) on midazolam overdose. RRRs are one-page notices with clear recommendations for actions that will reduce risks to patients, issued to all relevant NHS organisations in England and Wales, from hospitals to primary care organisations (www.nrls.npsa.nhs.uk/resources/type/alerts/).

Previous national safety interventions took time to develop[3] and proved challenging to implement.[4] And so over the past two years, the NPSA has developed RRRs as more timely alerts to staff about new or under-recognised risks. The trigger for an RRR is reported deaths or serious events that may be seen as "one-off" events by local organisations but which at a national level indicate to the agency that system weaknesses exist for which fixes are available that could benefit all trusts. RRRs are issued in England through the Department of Health's central alerting system (https://www.cas.dh.gov.uk), and organisations are required to act on these within a given time (usually six months) and report compliance, which is monitored by regulators. In the case of midazolam overdose, a safer low dose product had become available but was not widely used. Since the agency's RRR was issued, there has been an encouraging twofold to threefold increase in use of safer doses.[1 2]

Some risks highlighted in RRRs have been well publicised—for example, the RRR on strengthening systems for dealing with major haemorrhage (including access to blood and vital equipment) was triggered by the death of a patient after routine laparoscopic cholecystectomy in a stand-alone surgical unit, as featured in a recent BBC *Panorama* programme.[5] In England 95% of trusts now report compliance with actions in this RRR through the central alerting system. But although trusts may have acted to improve systems, individual doctors and nurses may not be aware of RRRs, the evidence of harm from reported incidents, and what can be done by individuals to make practice safer. The new *BMJ* series is aimed at clinicians, highlighting key messages on safer practice.

Box 1 outlines the process for developing rapid response reports and the criteria for prioritising.

The process for generating RRRs[6] is driven by patient safety incidents reported by healthcare staff. This is a voluntary, national reporting system set up in 2003 for the NHS in England and Wales—one of the largest and most comprehensive reporting systems in the world; it has recorded over 3.9 million incidents to date, with encouraging increases in reporting year on year.[8] Staff report incidents through their hospital or primary care organisation so that local action can be taken when needed (for example, supplying missing

Box 1 | Process for developing rapid response reports (RRRs)[6]

- 300 deaths and serious incident reports are reviewed individually each week by clinical staff (these are incidents reported locally by doctors, nurses, and other healthcare professionals) and uploaded to the national database
- After initial screening, the NPSA gathers evidence on selected topics from its wider database (including data on "low or no harm" events and "near miss" incidents), research literature, litigation and coroners' data, and on local investigations by trusts in which serious incidents occurred
- Issues are prioritised using explicit criteria (substantive harm or potential for harm; risk not well known; clear actions to prevent) at a weekly multidisciplinary meeting with clinical and other input, including expertise in human factors[7] and design
- Draft RRRs are drawn up with input from clinicians to identify key actions to reduce risks; the drafts are then issued for comment to external stakeholders and shared with a few hospitals to test the feasibility and impact of recommended actions
- About 10 RRRs are issued each year as one-page notices to the health service through a central system, with required actions for organisations within a deadline

Box 2 | Some risk areas highlighted by rapid response reports (RRRs)*

- Confusion between lipid and non-lipid amphotericin
- Infusions and sampling from arterial lines
- Neurosurgery (burr holes) done on the wrong side
- Insertion of chest drains
- Resuscitation in mental health settings
- Insertion of suprapubic catheters
- Oral products used for bowel cleansing

*See www.nrls.npsa.nhs.uk/resources/type/alerts for all RRRs.

resuscitation equipment). These incidents are automatically uploaded to the NPSA for national learning—over 99% of the agency's incident data come from that route. Healthcare staff, patients, and other members of the public can also report incidents independently through the NPSA website (www.nrls.npsa.nhs.uk/).

Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff (box 1). Important information is often found in the free text—for example, "[Patient] attended ED [emergency department] with haematemesis. Bleeding +++++. Unable to contact any physicians at any site or at home (night-time) to carry out emergency endoscopy. [Patient] bled and died in [the department]."

Although the reporting system is voluntary, with inherent bias and known under-reporting,[9] it at least gives an indication of the scale of the problem, with valuable learning from all harm categories (including important "near miss" events in "no harm" incidents).

To date, we have issued 22 RRRs (box 2). Some are developed very quickly—the RRR on risks to haemodialysis from water supplies contaminated by hydrogen peroxide was issued two weeks after receiving the trigger incident—but most are produced over two to four months.

RRRs focus on fixing systems to reduce harm but also contain reminders for individual clinicians on safer practice. The reports usually reinforce evidence based clinical guidelines developed by others, especially when the agency's data indicate that these are not being followed everywhere. After 44 reported incidents in which patients with glaucoma experienced some loss of vision after delayed follow-up appointments, a RRR reinforced recent NICE guidelines for individual clinicians on the need to adhere to optimal follow-up intervals, as well as identifying system fixes for hospitals to tag patients on their appointment systems.[10]

Early feedback suggests that RRRs have been well received, although more detailed feedback studies are under way. One medical director noted that "the one-page format is good . . . and helpful in alerting staff to safety issues" (unpublished survey of senior NHS managers by the University of York, commissioned by the NPSA, 2008).

Organisations have to report that they have complied with action requests, and these compliance data are monitored by regulators. But as well as using the self reporting data from trusts, the agency looks for evidence of changed practice—for example, by monitoring purchasing trends on low strength midazolam products as recommended in the RRR.[2]

The NPSA national database of patient safety incidents helps to identify risks and weaknesses in the underlying system that may not be apparent locally. But getting to the key issues in such a large database is not easy. The agency's process tries to combine the "power of stories"[11] in the individual incident with evidence from the wider database and elsewhere. Numbers alone will not change clinical practice ("analysing a small number of incidents thoroughly is probably more valuable than a cursory overview of hundreds of incidents"[12]). Without numbers, stories are just anecdotes, but without stories, numbers are just dry statistics.

Behind every RRR is a trigger incident that started the trail. Our thanks to the first busy gastroenterologist who took the time to report an incident of midazolam overdose and helped to prevent other patients being harmed.

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Endpiece

Convalescence

I enjoy convalescence. It is the part that makes the illness worthwhile.

George Bernard Shaw. *Back to Methuselah.* London: Constable, 1921.

Submitted by Sivakumar Sathasivam, consultant neurologist, Walton Centre for Neurology & Neurosurgery, Liverpool

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SAFETY ALERTS

Avoiding midazolam overdose: summary of a safety report from the National Patient Safety Agency

Tara Lamont,[1] Linda Matthew,[1] David Cousins,[1] Jonathan Green[2]

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[1]National Reporting and Learning Service, National Patient Safety Agency, London W1T 5HD
[2]British Society of Gastroenterology (Endoscopy), London NW1 4LB
Correspondence to: T Lamont
tara.lamont@npsa.nhs.uk

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This is the first in a series of *BMJ* summaries of recommendations to improve patients' safety, based on reports of safety concerns, incident analysis, and other evidence. The articles will highlight the risks of incidents that have the potential for serious harm and are not well known, and for which clear preventive actions are available.

To report adverse events to the National Patient Safety Agency, go to www.nrls.npsa.nhs.uk/

Why read this summary?

Midazolam is often used intravenously in single doses of between 0.5 mg and 2.5 mg for conscious sedation of patients for endoscopy or minor surgery as well as for dentistry. Its potential for oversedating patients is well documented by gastroenterologists and others.[1 2] Between November 2004 and November 2008, healthcare staff reported 498 dosing errors for midazolam to the National Patient Safety Agency (NPSA) in England and Wales through the agency's web based surveillance system; in three cases the patient died. Part of an entry in the report from one healthcare professional read: "Patient given intravenous midazolam 7 mg and 5 mg =12 mg by Dr [staff name] and during the procedure (gastroscopy and colonoscopy) then was unrousable. There has been a trend of incidents related to this procedure and this matter has been raised with the unit manager."

This summary is based on the safety report (known as a "rapid response report" or "RRR") from the NPSA on how to prevent overdose of midazolam. The RRR highlights evidence of harm and recommends key actions for staff.

Problems identified by the National Patient Safety Agency

Problems included:

- Drawing up part content of a high strength injection ampoule (10 mg in 2 ml or 10 mg in 5 ml) or giving the whole ampoule by mistake
- Failing to titrate the dose to the needs of the individual patient
- Not understanding the risks of combining midazolam with other drugs, such as opioids
- Wide use of, and possible over-reliance on, the reversing agent, flumazenil—a useful proxy marker of the problems of overdose, whose shorter elimination half-life also raises concerns about possible residual sedation from midazolam.

Safer low dose midazolam ampoules (2 mg in 2 ml and 5 mg in 5 ml) had been available for a couple of years but were not widely used. Higher strength doses were still routinely stocked for general use.

In December 2008 the NPSA issued its RRR on reducing risks of midazolam overdose in adults (NPSA/2008/RRR011, www.nrls.npsa.nhs.uk/resources/?entryid45=59896).

What can we do?

In its 2008 RRR, the NPSA recommended the following key actions.

For clinical areas

Remove high strength midazolam in all but defined areas (such as general anaesthesia, intensive care, and palliative care) and replace with low strength alternatives. Other recommendations include reviewing training needs, identifying a lead (usually an anaesthetist) for sedation policy and auditing use of flumazenil locally.

For individual clinicians

- Routinely use the safer 1 mg/ml strength (in 2 ml or 5 ml ampoules) rather than high strength midazolam in general areas—for example, where outpatient diagnostic procedures are performed
- Do not use part-ampoules or part-phials of high strength midazolam
- Do not rely on flumazenil to reverse oversedation by midazolam—it carries its own risks—but rather aim to prevent oversedation in the first place; however, if you need to use flumazenil, audit its use
- Continue using high strength midazolam for general anaesthesia and intensive care sedation, and for palliative care when syringe drivers are used. In the latter case a formal risk assessment should be undertaken, especially when different strengths of midazolam are stocked for different indications in a single clinical area.

What else do we need to know?

While drawing up this guidance, the agency was aware of wider concerns about training and competences in sedation,[3] the effects of polypharmacy, and sedation processes for children. This RRR also prompted queries from healthcare staff on related issues, such as the rapid tranquillisation of patients in mental health settings.

How will we know when practice has become safer?

NHS purchasing data in England shows an encouraging 22% decrease in average monthly use of high strength midazolam ampoules in the first eight months since the NPSA's rapid response report was issued, compared with average monthly use for 2008 (up to the release of the RRR). During the same period the use of lower strength midazolam doubled for the smaller ampoules (2 mg in 2 ml) and trebled for the larger ones (5 mg in 5 ml).[4]

Use of flumazenil has fluctuated during that time and no discernible trend has emerged yet.[4] The NPSA will continue to monitor the use of flumazenil (although it is difficult to quantify what proportion is used to reverse the effects of midazolam in untitrated overdose).

The NPSA gave organisations until June 2009 to comply with actions recommended in its 2008 RRR. By late October 2009, 74% (248/336) of relevant trusts in England had reported that they had complied with the recommended actions.[5] No further patient deaths caused by midazolam have been reported to the NPSA.

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INTERACTIVE CASE REPORT

A woman with acute myelopathy in pregnancy: case progression

Reinhard Reuß,[1] Paulus S Rommer,[1] Wolfgang Brück,[2] Friedemann Paul,[3 9] Michael Bolz,[4] Sven Jarius,[5] Tobias Boettcher,[6] Annette Großmann,[7] Alexander Bock,[8] Frauke Zipp,[9] Reiner Benecke,[1] Uwe K Zettl[1]

[1]Department of Neurology, University of Rostock, 18147 Rostock, Germany
[2]Institute of Neuropathology, University Medical Center Göttingen, Göttingen, Germany
[3]NeuroCure Clinical Research Center, Charité Universitätsmedizin Berlin, Berlin, Germany
[4]Department of Gynaecology, University of Rostock
[5]Division of Molecular Neuroimmunology, Department of Neurology, University of Heidelberg, Heidelberg, Germany
[6]Neurology Division, Dietrich-Bonhoeffer Klinikum Neubrandenburg, Neubrandenburg, Germany
[7]Department of Radiology, University of Rostock
[8]Neuroradiology Division, Dietrich-Bonhoeffer Klinikum Neubrandenburg
[9]Cecilie-Vogt Clinic for Neurology, Charité-Universitätsmedizin Berlin

Correspondence to: R Reuß
reinhard.reuss@neuro.med.uni-giessen.de

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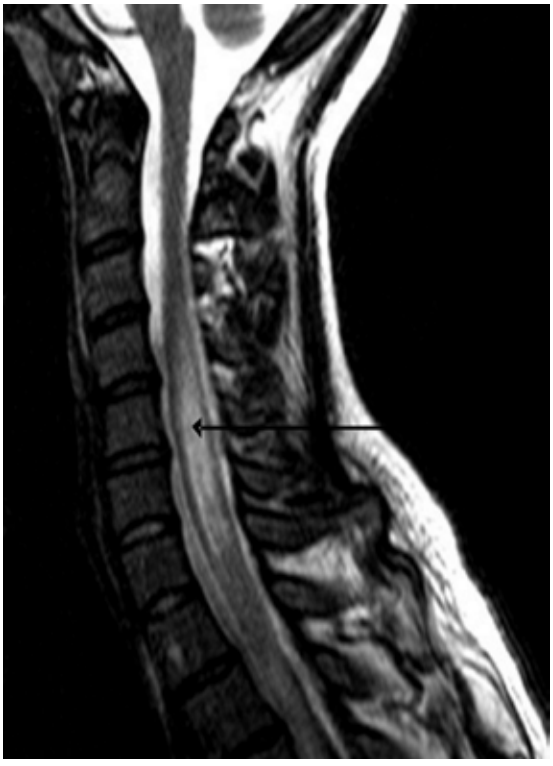
This is the second of a three part case report where we invite readers to take part in considering the diagnosis and management of a real patient using rapid responses on bmj.com. In three weeks' time we will report the outcome and summarise the responses

Last week (*BMJ* 2009;339:b3862) we described the case of Andrea G, who presented with acute transverse myelitis extending over eight segments above T8 and associated with mild lymphogranulocytic cerebral spinal fluid pleocytosis. She had hypotonic paraparesis of the legs accentuated on the left side with increased reflexes. Her dissociated sensory deficit below T8 progressed to a global sensory deficit consistent with incomplete transverse spinal cord syndrome. Acute cord lesions can cause an initial hypotonic weakness with reflexes becoming accentuated later, as seen in this case, or being depressed.

We treated Mrs G with high dose intravenous methylprednisolone pulse therapy, but her clinical condition did not improve. She was also given acyclovir because of the possibility of viral infection. Her urinary tract infection was treated with levofloxacin. Magnetic resonance imaging showed enlargement of her spinal cord lesions over the following days. We therefore decided to perform plasma exchange, which resulted in a slight improvement in the clinical symptoms and no further

Profile and results of other investigations

Test	Result	Normal range
Immunological		
Anti-AQP4 antibody (ratio)	15	<11
Antinuclear antibodies	1:1280	<1:320
Antiscleroderma 70 antibody (U/ml)	1.0	<3.0
Perinuclear antineutrophil cytoplasmic antibodies	1:20	0
Anti-double stranded DNA antibodies (U/ml)	3.9	<35
Antinucleosome antibodies (U/ml)	5.9	<25
Myeloperoxidase antibody (U/ml)	<0.5	<6
Anticardiolipin IgM and IgG (U/ml)	<1.0	<10
Rubella IgG (U/ml)	565	<4
Rubella IgM	Positive	Negative
Rubella enzyme immunoassay (avidity, %)	93	>50
Rubella western blot	E2 positive	E2 negative
Cerebral spinal fluid		
Total cell count (×10⁶/l)	7	<5
Lymphocytes (%)	75	70-85
Monocytes (%)	13	15-30
Segmented granulocytes (%)	12	0
Erythrocytes (×10⁶/l)	0	0
Total protein (mg/l)	397	150-450
Oligoclonal bands	Negative	Negative
Intrathecal IgG synthesis	Negative	Negative
Intrathecal IgM synthesis	Positive	Negative
Intrathecal IgA synthesis	Negative	Negative
Serum and urine		
Serum C reactive protein (mg/l)	12.5	<5
Serum leucocytes (No/l)	15.4×10^9	$4\text{-}9\times10^3$
Urine leucocytes (×10⁶/l)	500	<25



MRI (T2 weighted) showing central symmetric spinal cord lesions (arrow) spanning from C3 to T6 during the first relapse

QUESTIONS

1 What is the diagnostic importance of oligoclonal bands?

2 What are the most effective acute or prophylactic treatments for neurological diseases that are assumed to be antibody mediated?

3 What advice would you give to Mrs G about her present pregnancy and future pregnancies?

Please respond through bmj.com, remembering that the patient is real and that she and her carers will read the response

progression of the lesions. According to the patient, complete clinical remission was achieved by July 2006.

Six months later, in the ninth week of her second pregnancy, Mrs G presented to the neurological emergency room with weakness of both legs. She had severe paraparesis accentuated on the left side with an extensor plantar response on the left and a dissociated sensory deficit of the right leg, which progressed within a few days to paraplegia and severe hypoaesthesia below T7 with an inability to void urine. A gynaecological examination showed no abnormality. Her pregnancy was monitored for four weeks; fetal development was always appropriate to gestational age and the volume of amniotic fluid was normal. Viral and bacterial infections were excluded by extensive testing. The table shows the results of the relevant laboratory tests. Her visual evoked potential was normal. T2 weighted MRI of the spinal cord showed lesions spanning from C3 to T6 (figure).

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EASILY MISSED?

Slipped capital femoral epiphysis

N M P Clarke, Tony Kendrick

Southampton University Hospitals NHS Trust, Southampton General Hospital, Southampton SO16 6YD
Correspondence to: N M P Clarke
ortho@soton.ac.uk

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Slipped capital (or upper) femoral epiphysis occurs during periods of rapid growth in adolescence, when shear forces, particularly in obese children, increase across the proximal femoral growth plate, leading to displacement of the epiphysis. The typical patient is obese. In a recent case study of 54 patients with this condition, all had body mass indexes in the overweight or obese ranges.[1] In boys, accompanying hypogonadism implicates possible endocrine causes.[2] A chronic slip is the most common presentation, with symptoms present for weeks or months as the slip progresses. An acute slip occurs after a traumatic event and prevents weight bearing, whereas in an acute on chronic slip, prodromal symptoms are followed by a sudden exacerbation of pain. The last two types of slip usually present to the emergency department rather than the general practitioner.

CASE SCENARIO

A 13 year old boy visited the general practitioner because of a six week history of intermittent limp and pain in the left lower thigh and knee, which was exacerbated by playing sports. On examination he was overweight, but he had no abnormality in the knee. "Knee strain" was diagnosed, and he was advised to take ibuprofen and abstain from sports. Four weeks later he returned with worsening more persistent pain, now in the thigh as well as the knee. Careful examination of the hip elicited a degree of restriction of flexion and rotation, both internal and external, with 2 cm shortening of the affected leg. Radiography of the left hip showed a slipped capital femoral epiphysis.

Why is it missed?

The indolent nature of the symptoms in a chronic slip and pain referred to the knee often mislead the doctor. Examination of the hip may be overlooked and the diagnosis missed. In a review of 106 patients, those (n=14) who had pain in the knee or distal thigh only were more likely to be misdiagnosed, have unnecessary radiographs, and have more severe slips on confirmation of the diagnosis.[5]

HOW COMMON IS IT?

Incidence is 1-7 per 100 000

It is three times more common in boys than in girls

A bilateral slip occurs in about 20% of cases[3]

Delayed diagnosis is common. One review of 102 patients reported a mean delay of 2.5 months and apparent initial misdiagnosis in 52% of cases[4]

Why does this matter?

Chronic slippage will gradually progress in terms of severity of displacement and deformity, with increasing limb shortening and external rotation, as confirmed by a recent case series.[6] Alternatively, after prodromal symptoms, sudden severe pain may occur with minor trauma such as a fall. This indicates an acute on chronic slip, with major epiphyseal displacement and an increased risk of ischaemic injury and avascular necrosis, which can have devastating consequences. Major surgery may also be needed. Residual deformity causes femoro-acetabular impingement and premature osteoarthritis.[7]

How is it diagnosed?

Clinical features

Any child or adolescent who presents with knee pain must undergo careful examination of the hip. Loss of internal rotation of the leg in flexion, with pain at the extreme of movement, is the key physical sign.

This is a series of occasional articles highlighting conditions that may be commoner than many doctors realise or may be missed at first presentation. The series advisers are Anthony Harnden, university lecturer in general practice, Department of Primary Health Care, University of Oxford, and Richard Lehman, general practitioner, Banbury. If you would like to suggest a topic for this series please email us (easilymissed.bmj@bmjgroup.com)

KEY POINTS

- Knee pain in adolescents should trigger a careful examination of the hip because it may be caused by slipped capital (or upper) femoral epiphysis
- Delayed diagnosis is associated with an increased slip and hence deformity and morbidity
- Radiography in anteroposterior and lateral planes confirms the diagnosis
- Surgical treatment of an early slip leads to an almost normal outcome

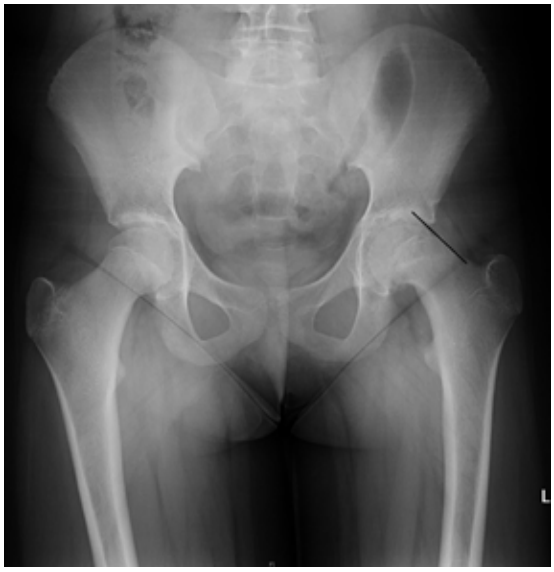

Fig 1 | Anteroposterior radiograph of the hips and pelvis showing a minor left slipped capital femoral epiphysis. Klein's line drawn along the superior femoral neck does not intersect the lateral portion of the epiphysis

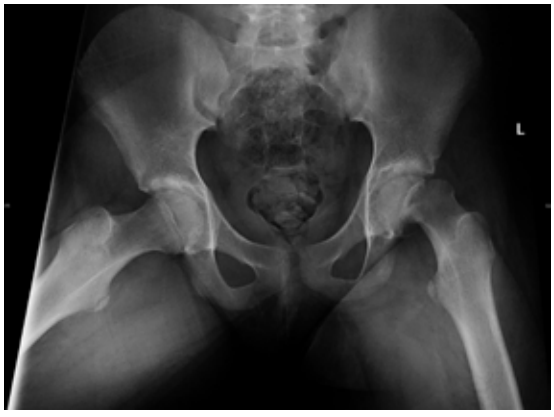

Fig 2 | The same patient two weeks later, after an exacerbation of pain. The radiograph shows increased slip of the left capital femoral epiphysis, with further displacement

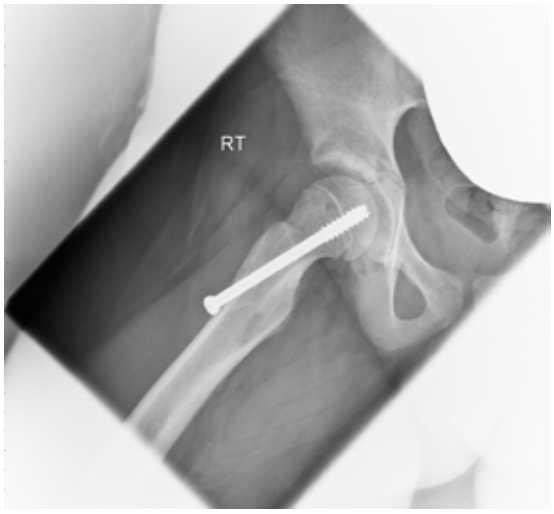

Fig 3 | Screw fixation

Investigations

Anteroposterior and lateral radiographs of both hips on the same film are the primary (and usually the only) imaging needed to diagnose and evaluate the condition. Klein's line drawn parallel to the superior neck on the anteroposterior view will normally intersect the lateral portion of the femoral epiphysis but not if slipped (Trethowan's sign; fig 1).[8] Slipped capital femoral epiphysis must be excluded before investigation for other pathology.

How is it managed?

Once the diagnosis has been confirmed the usual treatment—based on expert consensus and experience—is to admit the patient urgently to hospital and place on bed rest to avoid acute displacement of a chronic slip, which can have a catastrophic affect on prognosis (fig 2).[9] Surgery is needed to stabilise a displaced capital femoral epiphysis and prevent further displacement and increasing deformity. This is achieved by single cannulated screw fixation under image intensifier control (fig 3). The more severe the deformity the more challenging the procedure, necessitating different entry points. Very severe displacement may necessitate femoral neck osteotomy or subsequent salvage procedures for persistent deformity. Remodelling can occur in younger patients.[10] Avascular necrosis and chondrolysis (chemical necrosis of articular cartilage) are the most common complications, the first usually after acute displacement (up to 35% of cases), but both may occur after surgery. Reports of the incidence of chrondrolysis after screw fixation vary, but some are as low as 1.5%.[11]

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10-MINUTE CONSULTATION

Tennis elbow

Christian David Mallen, Linda S Chesterton, Elaine M Hay

Arthritis Research Campaign National Primary Care Centre, Keele University, Keele, Staffordshire ST5 5BG

Correspondence to: C D Mallen
c.d.mallen@cphc.keele.ac.uk

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A 47 year old decorator presents with a two month history of right elbow pain. The pain is worse when he grips a paintbrush or uses a paint roller on the ceiling.

What issues you should cover

Tennis elbow (lateral humeral epicondylitis) is common, peaking at age 35-55 and typically affecting the dominant arm. Men and women are equally affected. It is probably an overload injury related to minor or unrecognised injury (microtrauma). A careful taken history can exclude differential diagnoses, including referred pain and local elbow causes such as olecranon bursitis and osteoarthritis.

Tennis elbow pain is often mild. Episodes typically last six months to two years and usually resolve within 12 months. Acute pain typically lasts 6-12 weeks. Analgesics, such as over the counter paracetamol, co-codamol, or topical non-steroidal anti-inflammatory drugs, provide adequate pain relief for most patients. Injection of corticosteroids (including triamcinolone, methylprednisolone, and hydrocortisone) with local anaesthetic can produce short term pain relief (with mean pain scores (0-100) falling from 60 to 20 over two weeks), but long term effectiveness is less clear. At one year, seven of 10 people who received an injection will be pain free, compared with eight of 10 who did not.

Progressive exercise is beneficial. Splints and orthoses are best used in conjunction with physiotherapy programmes.

USEFUL READING

Arthritis Research Campaign (www.arc.org.uk/arthinfo/patpubs/6044/6044.asp)—Information for patients

Bisset L, Beller E, Jull G, Brooks P, Darnell R, Vicenzino B. Mobilisation with movement and exercise, corticosteroid injection, or wait and see for tennis elbow: randomised trial. *BMJ* 2006;333:939 (doi:10.1136/bmj.38961.584653.AE)

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Smidt N, van der Windt D, Assendelft W, Deville W, Korthals-de Bos I, Bouter L. Corticosteroid injections, physiotherapy, or a wait-and-see policy for lateral epicondylitis: a randomised controlled trial. *Lancet* 2002;359:657-62 (doi:10.1016/S0140-6736(02)07811-X)

What you should do

History

- Ask the patient about the severity of pain and how he has tried to resolve it.
- Ask about the duration of symptoms.
- Take a detailed social and occupational history to determine the cause of the epicondylitis and its effect on his everyday life. Repeated movements of the wrist, especially those associated with resistance (such as backhand tennis stroke) usually make tennis elbow worse. Occupations that involve repetitive turning or lifting at the wrist, such as gardening, keyboard use, plumbing, decorating, and bricklaying, are particularly likely to cause tennis elbow.

Examination and treatment

- Reassure your patient.
- Palpate around the effected elbow joint to identify the area of maximum pain—usually over the common extensor tendon or lateral epicondyle.
- Look for localised pain in the elbow when pressure is applied to the extended wrist (in the "stop traffic" position) or when the patient lifts, grips, or squeezes an object.
- Check whether the patient has paraesthesia or pain above the elbow (rare).
- Diagnose tennis elbow following history and examination. Do not request further investigations.
- Give the patient an information and exercise leaflet.
- Provide practical advice on avoiding aggravating factors, including muscle overload and strong repetitive motion with the elbow extended.
- Inject about 1 ml of corticosteroid-anaesthetic mixture into the site of maximal tenderness until you can feel the periosteum. Spread the injection using a "pepper pot technique" (multiple sites around the epicondyle).
- Demonstrate basic exercises and stretches or prescribe a programme of physiotherapy.
- Prescribe pain relieving drugs.

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