

Applying evidence to individual patients – is shared decision-making the answer?

Professor Trish Greenhalgh
Taormina, 28th October 2017



The BIG ISSUE in EBM: lack of personalisation

*“[In] EBM, the individuality of patients tends to be devalued, the focus of clinical practice is subtly shifted away from the care of individuals toward the care of populations, and **the complex nature of sound clinical judgement is not fully appreciated.**”*

Mark Tonelli: ‘The philosophical limits of EBM’

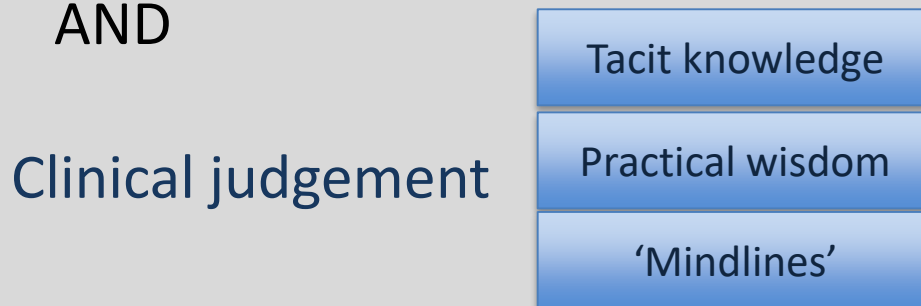
J Eval Clin Pract 1999; 73: 1234



Real EBM = integration of...



AND



AND



Shared decision-making: questionable assumptions

1. The patient wants to share a decision.
2. Sharing the decision will produce individualised care.



Sackett's comment on individualizing care

*“Were the patients in this trial **sufficiently similar** to the patient in front of me (in whatever key respects) that I can apply the findings in this case?”*



Old-fashioned clinical method

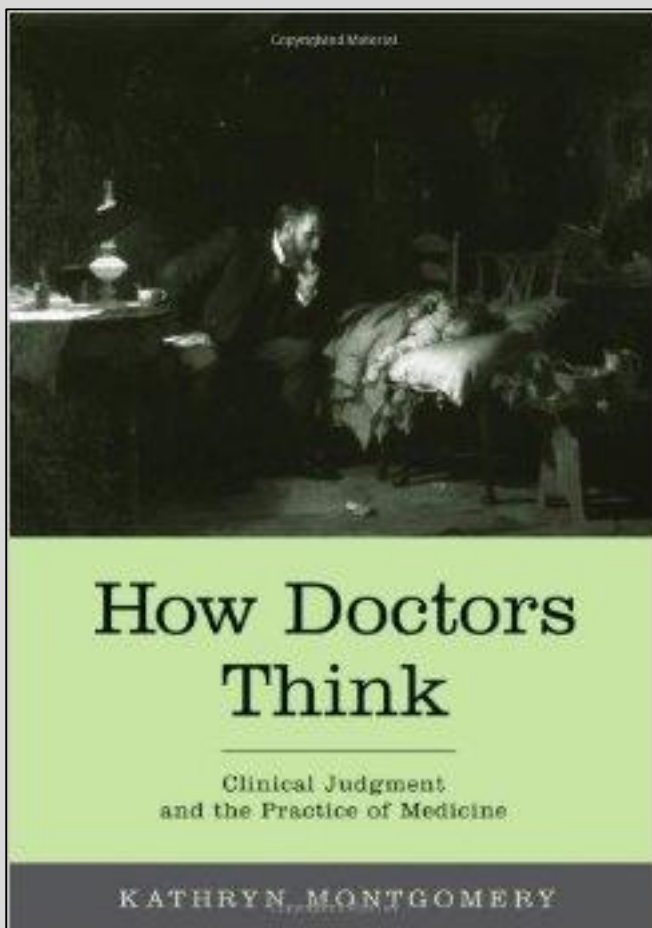
*“**What do I know about this patient:** her history, the examination, test results, how she reacted the last time she took this drug, her beliefs, her family circumstances etc. And given all that, what evidence do I need?”*

This is patient-based evidence.

It's not just 'preferences' or 'values', it's the totality of what's going on with this patient.

We don't use it enough.





Narrative based medicine

Narrative based medicine in an evidence based world

Trisha Greenhalgh

In a widely quoted riposte to critics who accused them of naive empiricism, Sackett and colleagues claimed that “the practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice.”¹ Sackett and colleagues were anxious to acknowledge that there is an art to medicine as well as an objective empirical science but they did not attempt to define or categorise the elusive quality of clinical competence. This article explores the dissonance between the “science” of objective measurement² and the “art” of clinical proficiency and judgment,³⁻⁵ and attempts to integrate these different perspectives on clinical method.

The limits of objectivity in clinical method

Science is concerned with the formulation and attempted falsification of hypotheses using reproduc-

Summary points

Even “evidence based” clinicians uphold the importance of clinical expertise and judgment

Clinical method is an interpretive act which draws on narrative skills to integrate the overlapping stories told by patients, clinicians, and test results

The art of selecting the most appropriate medical maxim for a particular clinical decision is acquired largely through the accumulation of “case expertise” (the stories or “illness scripts” of patients and clinical anecdotes)

The dissonance we experience when trying to apply research findings to the clinical encounter often occurs when we abandon the narrative-interpretive paradigm and try to get by on “evidence” alone



Case example: Patient TG, aged (nearly) 55



Trisha Greenhalgh @trishgreenhalgh
Bad bike smash. In hospital 2 broken arms, on today's 'trauma list'. Thanks to kind bystanders and #NHS. Sorry will be out of action UFN.

RETWEETS 10 FAVORITES 8

9:14 AM - 4 Mar 2014

Reply to @trishgreenhalgh

Vanessa H @HPS_Vanessa · 4 Mar 2014
@trishgreenhalgh !!!! terrifying. Good luck with the healing process.

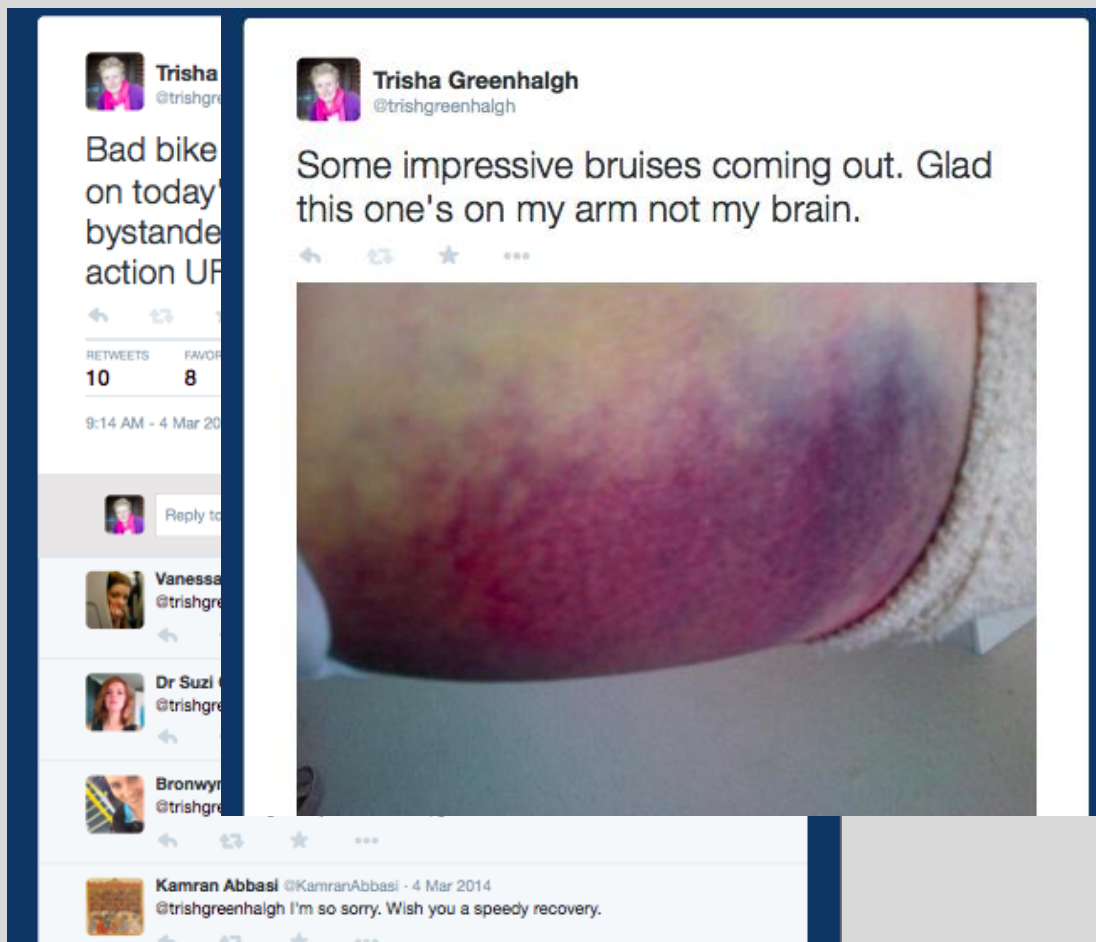
Dr Suzi Gage @soozaphone · 4 Mar 2014
@trishgreenhalgh Oh no! Get well soon, lots of love x

Bronwyn Hemsley @BronwynHemsley · 4 Mar 2014
@trishgreenhalgh sorry to here that :(get mended soon.

Kamran Abbasi @KamranAbbasi · 4 Mar 2014
@trishgreenhalgh I'm so sorry. Wish you a speedy recovery.



Case example: Patient TG, aged (nearly) 55



The image shows a screenshot of a tweet from Trisha Greenhalgh (@trishgreenhalgh) dated 9:14 AM on 4 Mar 2014. The tweet text reads: "Some impressive bruises coming out. Glad this one's on my arm not my brain." Below the text is a photograph of a large, dark purple and red bruise on a person's arm. The tweet has 10 retweets and 8 favorites. Below the tweet, several replies are visible, including one from Vanessa (@trishgre) and another from Dr Suzi (@trishgre). At the bottom, a reply from Kamran Abbasi (@KamranAbbasi) dated 4 Mar 2014 says: "I'm so sorry. Wish you a speedy recovery."



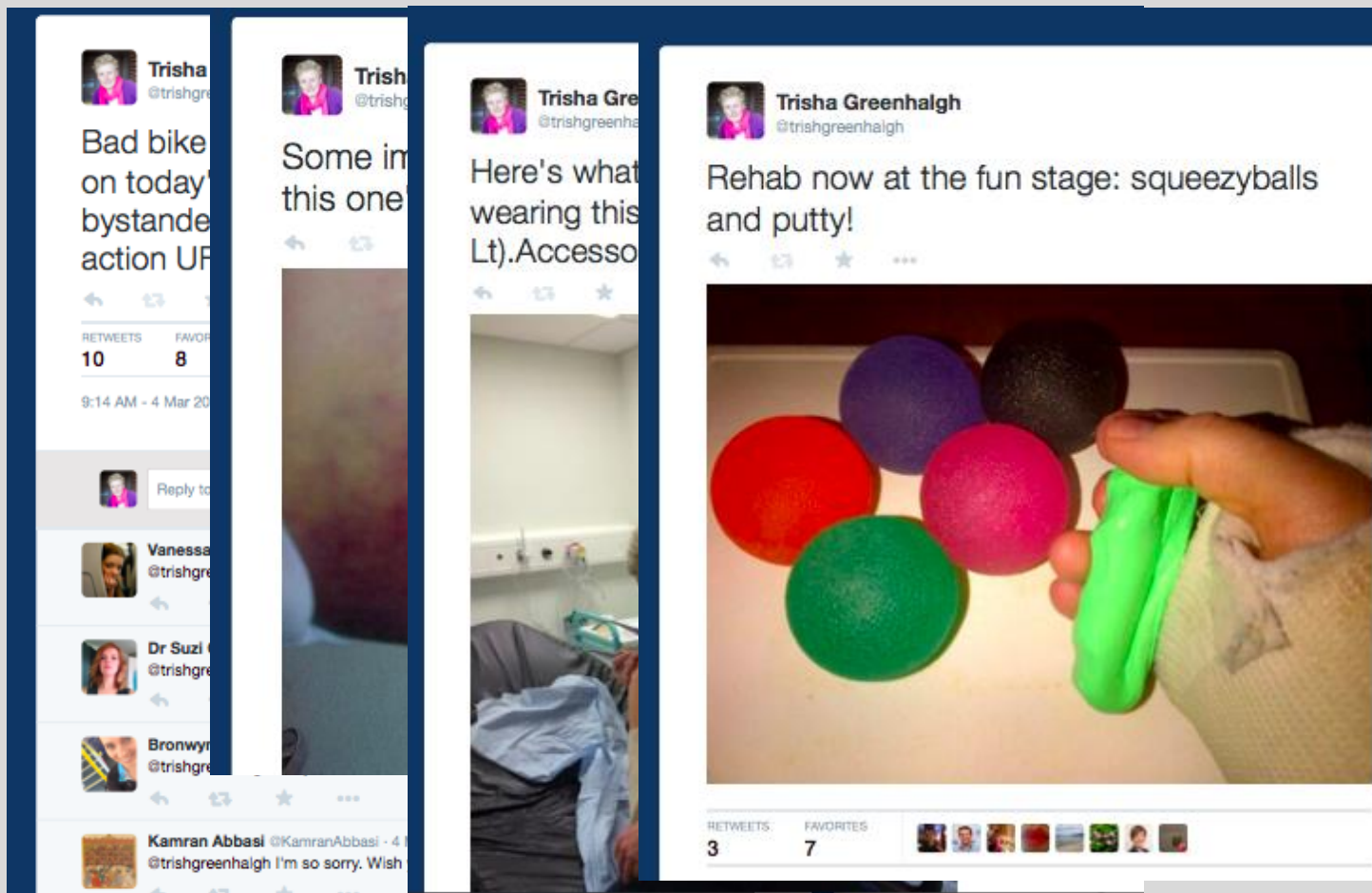
Case example: Patient TG, aged (nearly) 55



The image shows a screenshot of a Twitter thread. The main tweet is from Trisha Greenhalgh (@trishgreenhalgh) and reads: "Here's what the well dressed invalid's wearing this season (collar+cuff Rt, triangular Lt). Accessories by Nurse Julia". Below the text is a photograph of an elderly woman sitting in a wheelchair, wearing a white triangular arm cast on her left arm and a white collar-and-cuff cast on her right arm. A woman in a red uniform, identified as Nurse Julia, is standing behind her, smiling. The thread includes several replies from other users, such as Vanessa (@trishgre), Dr Suzi (@trishgre), Bronwyn (@trishgre), and Kamran Abbasi (@KamranAbbasi), who expresses sympathy for the patient.



Case example: Patient TG, aged (nearly) 55



Trisha Greenhalgh @trishgreenhalgh

Bad bike on today by bystander action UP

RETWEETS 10 FAVORITES 8

9:14 AM - 4 Mar 20

Reply to

Vanessa @trishgre

Dr Suzi @trishgre

Bronwyn @trishgre

Kamran Abbasi @KamranAbbasi · 4
@trishgreenhalgh I'm so sorry. Wish

Trisha Greenhalgh @trishgreenhalgh

Some in this one

Trisha Greenhalgh @trishgreenhalgh

Here's what wearing this Lt).Accesso

Trisha Greenhalgh @trishgreenhalgh

Rehab now at the fun stage: squeezeballs and putty!

RETWEETS 3 FAVORITES 7



Case example: Patient TG, aged (nearly) 55



Trisha Greenhalgh @trishgreenhalgh

Bad bike accident on today by bystander action UP

RETWEETS 10 FAVORITES 8

9:14 AM - 4 Mar 20

Reply to

Vanessa @trishgre

Dr Suzi @trishgre

Bronwyn @trishgre

Kamran Abbasi @KamranAbbasi · 4
@trishgreenhalgh I'm so sorry. Wish

Trisha Greenhalgh @trishgreenhalgh

Some in this one

Trisha Greenhalgh @trishgreenhalgh

Here's what I'm wearing this (Lt).Accesso

Trisha Greenhalgh @trishgreenhalgh

Rehab now a and putty!

RETWEETS 3 FAVORITES 7

Trisha Greenhalgh @trishgreenhalgh

One month after my accident, I'm feeling much better. Thanks all for your support!



Subjective narrative

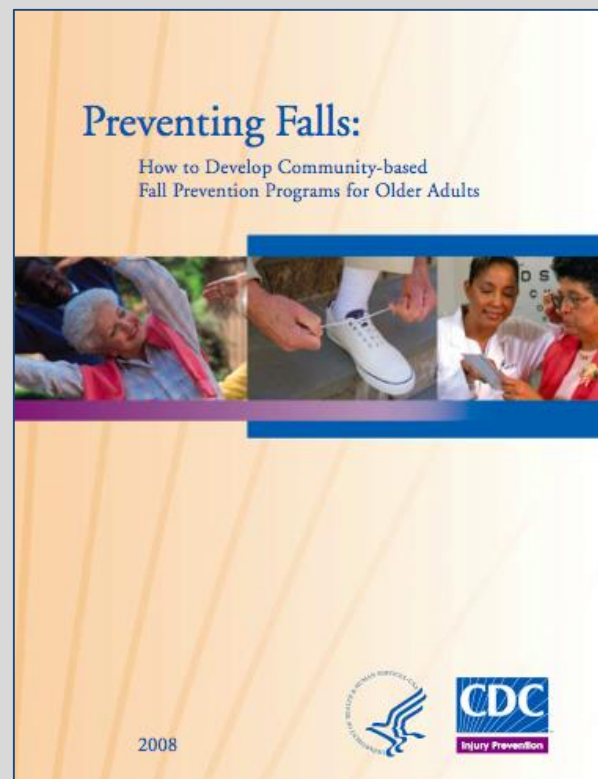
I was riding my racing bike along the towpath. I was going about 20 miles an hour.

Something got caught in my front wheel. The bike somersaulted into the air. I came down heavily on the concrete, landing on my arms and the back of my head.

I was very dazed. Both my arms were deformed and useless. My fingers were numb. My helmet was split.

Objective summary

"55 yr old female
Fell off bike"



Subjective narrative

*I was riding my **racing bike** along the towpath. I was going about **20 miles an hour**.*

*Something got caught in my front wheel. The bike somersaulted into the air. I **came down heavily on the concrete**, landing on my arms and the **back of my head**.*

*I was **very dazed**. Both my arms were deformed and useless. My fingers were numb. **My helmet was split**.*

My Falls-Free Plan

Appendix A - Risk Assessment

Name: _____ Date: _____

As we grow older, gradual health changes and some medications can cause falls, but many falls can be prevented. Use this to learn what to do to stay active, independent, and falls-free.

Check "Yes" if you experience this (even if only sometimes)	No	Yes	What to do if you checked "Yes"
Have you had any falls in the last six months?			<input type="checkbox"/> Talk with your doctor(s) about your falls and/or concerns. <input type="checkbox"/> Show this checklist to your doctor(s) to help understand and treat your risks, and protect yourself from falls.
Do you take four or more prescription or over-the-counter medications daily?			<input type="checkbox"/> Review your medications with your doctor(s) and your pharmacist at each visit, and with each new prescription. <input type="checkbox"/> Ask which of your medications can cause drowsiness, dizziness, or weakness as a side effect. <input type="checkbox"/> Talk with your doctor about anything that could be a medication side effect or interaction.
Do you have any difficulty walking or standing ?			<input type="checkbox"/> Tell your doctor(s) if you have any pain, aching, soreness, stiffness, weakness, swelling, or numbness in your legs or feet— don't ignore these types of health problems. <input type="checkbox"/> Tell your doctor(s) about any difficulty walking to discuss treatment. <input type="checkbox"/> Ask your doctor(s) if physical therapy or treatment by a medical specialist would be helpful to your problem.
Do you use a cane, walker, or crutches , or have to hold onto things when you walk?			<input type="checkbox"/> Ask your doctor for training from a physical therapist to learn what type of device is best for you, and how to safely use it.
Do you have to use your arms to be able to stand up from a chair ?			<input type="checkbox"/> Ask your doctor for a physical therapy referral to learn exercises to strengthen your leg muscles. <input type="checkbox"/> Exercise at least two or three times a week for 30 min.
Do you ever feel unsteady on your feet, weak, or dizzy ?			<input type="checkbox"/> Tell your doctor, and ask if treatment by a specialist or physical therapist would help improve your condition. <input type="checkbox"/> Review all of your medications with your doctor(s) or pharmacist if you notice any of these conditions.
Has it been more than two years since you had an eye exam?			<input type="checkbox"/> Schedule an eye exam every two years to protect your eyesight and your balance.
Has your hearing gotten worse with age, or do your family or friends say you have a hearing problem?			<input type="checkbox"/> Schedule a hearing test every two years. <input type="checkbox"/> If hearing aids are recommended, learn how to use them to help protect and restore your hearing, which helps improve and protect your balance.
Do you usually exercise less than two days a week ? (for 30 minutes total each of the days you exercise)			<input type="checkbox"/> Ask your doctor(s) what types of exercise would be good for improving your strength and balance. <input type="checkbox"/> Find some activities that you enjoy and people to exercise with two or three days/week for 30 min.
Do you drink any alcohol daily?			<input type="checkbox"/> Limit your alcohol to one drink per day to avoid falls.
Do you have more than three chronic health conditions ? (such as heart or lung problems, diabetes, high blood pressure, arthritis, etc. Ask your doctor(s) if you are unsure.)			<input type="checkbox"/> See your doctor(s) as often as recommended to keep your health in good condition. <input type="checkbox"/> Ask your doctor(s) what you should do to stay healthy and active with your health conditions. <input type="checkbox"/> Report any health changes that cause weakness or loss as soon as possible.

The more "Yes" answers you have, the greater your chance of having a fall. **Be aware of what can cause falls and take care of yourself to stay independent and falls-free!**

Case TG: Objective summary

7 operations on arms over 4m
Numb fingers persisted

Reassured "you did break your arms dear"

Reviewed at 6m: wasting of hands, heaviness / clumsiness
/ hyperreflexia in legs

MRI scan "Severe disc prolapse C56 and C67. C6 and C7
vertebrae collapsed".

→ Cervical disc replacement x2



NICE

National Institute for
Health and Care Excellence

Algorithm 3: Selection of adults for imaging of the cervical spine

Adults presenting to the emergency department
who have sustained a head injury.

Are any of the following risk factors present?

GCS < 13 on initial assessment

Intubation

A definitive diagnosis of cervical spine injury is required urgently
(e.g. before surgery)

Other body areas are being scanned for head injury or multi-
region trauma

- The patient is alert and stable, there is a suspicion of cervical spine injury and any of the following are present: age > 65; dangerous mechanism of injury (fall from > 1 metre or 5 stairs, axial load to head [e.g. diving], high speed motor vehicle collision, rollover motor accident, ejection from a motor vehicle, accident involving motorized recreational vehicles, bicycle collision); focal peripheral neurological deficit or paraesthesia in the upper or lower limbs.

Learning point:

It takes judgement to decide which guideline(s) to follow and how

An 'over-55 yr old female with fall' may ALSO be an athlete with a high-impact hyper-flexion injury of the cervical spine





SORTING THINGS OUT

CLASSIFICATION AND ITS CONSEQUENCES

GEOFFREY C. BOWKER AND SUSAN LEIGH STAR

We create classification schemes (e.g. ICD10, the old/frail). Once these become enshrined in guidelines, protocols etc, they ossify and reproduce our assumptions and prejudices (which now appear ‘scientific’).



Self-proclaimed experts in EBM said:

“You didn’t need that operation. RCTs have shown that in cervical disc lesions, surgical groups didn’t do any better than conservatively managed groups.”

They said this **without** taking a full history, **without** asking what the examination or MRI findings were, and **without** acknowledging the inclusion/exclusion criteria for the trials



Self-proclaimed experts in EBM said:

“You didn’t need that operation. RCTs have shown that in cervical disc lesions, surgical groups didn’t do any better than conservatively managed groups.”

They said this **without** taking history, **without** asking what the examinations were, and **without** acknowledging exclusion criteria for the trials

Rubbish EBM



Spine

SPINE Volume 38, Number 20, pp 1715-1722
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RANDOMIZED TRIAL

Surgery *Versus* Nonsurgical Treatment of Cervical Radiculopathy

*A Prospective, Randomized Study Comparing Surgery Plus Physiotherapy With Physiotherapy
Alone With a 2-Year Follow-up*

Markus Engquist, MD,*† Håkan Löfgren, MD, PhD,‡ Birgitta Öberg, PhD, RPT,§ Anders Holtz, MD, PhD,¶
Anneli Peolsson, PhD, RPT,§ Anne Söderlund, PhD, RPT,|| Ludek Vavruch, MD, PhD,‡ and
Bengt Lind, MD, PhD**††



RANDOMIZED TRIAL

Surgery *Versus* Nonsurgical Treatment of Cervical Radiculopathy

A Prospective, Randomized Study Comparing Surgery Plus Physiotherapy With Physiotherapy

Almeida et al. Spine 2013;38:1715-1722

Conclusion. In this prospective, randomized study of patients with cervical radiculopathy, it was shown that surgery with physiotherapy resulted in a more rapid improvement during the first postoperative year, with significantly greater improvement in neck pain and the patient's global assessment than physiotherapy alone, but the differences between the groups decreased after 2 years. Structured physiotherapy should be tried before surgery is chosen.



RANDOMIZED TRIAL

Surgery *Versus* Nonsurgical Treatment of Cervical Radiculopathy

A Prospective, Randomized Study Comparing

At the end of the study, the patients in the surgery group had significantly greater improvement in their global assessment of health than the patients in the physiotherapy group.

Conclusion. In this prospective study of patients with cervical radiculopathy, it was shown that surgery resulted in a more rapid improvement in the patient's global assessment of health over a 1-year period, with significantly greater improvement in the patient's global assessment of health. The differences between the groups were statistically significant. Therefore, surgery should be tried before physiotherapy.

Also, these patients had not previously tried physiotherapy

Exclusion criteria were the following:

1. Obvious myelopathy.
2. Slight, intermittent signs of myelopathy (“mild myelopathy”) but a lack of objective findings.
3. A history of neck distortion (whiplash-associated disorder) or “generalized” muscle pain, for example, fibromyalgia.
4. Need for another type of surgery, for example, vertebral body resection or foraminotomy.
5. Malignancy, inflammatory joint disease, or psychiatric disorder.
6. Difficulty understanding the Swedish language.
7. Concurrent work-disabling disease.



RANDOMIZED TRIAL

Surgery Versus Nonsurgical Treatment of Cervical Radiculopathy

A Prospective, Randomized Study Comparing

...

Conclusion. In this prospective study of patients with cervical radiculopathy, it was shown that surgery resulted in a more rapid improvement in pain over 1 year, with significantly greater improvements in the patient's global assessment of health. The differences between the groups suggest that surgery should be tried before physiotherapy.

Also, these patients had not previously tried physiotherapy

Exclusion criteria were the following:

1. Obvious myelopathy.
2. Slight, intermittent signs of myelopathy but a lack of obvious myelopathy.)
3. A history of neck surgery or "generalized degenerative disease."
4. Need for a major body resection.
5. Malignancy, or a psychiatric disorder.
6. Difficulty understanding Swedish language.
7. Concurrent work-related disease.

.....to use evidence in the manner of the fabled drunkard who searched under the street lamp for his door key because that is where the light was, even though he had dropped the key somewhere else" Grimley Evans



Subjective narrative

Should I take NSAIDs following my cervical spine surgery?

I don't want to bleed

I don't want delayed healing

But I don't want pain either

Objective summary

Patient advised not to take NSAIDs for 1 month following surgery "some evidence of delayed healing of bone repairs, and risk of bleeding is higher in the post-op period"





Trisha Greenhalgh

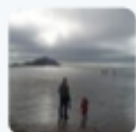
@trishgreenhalgh

Anyone got an evidence base for "don't take NSAIDs when recovering from disc replacement surgery"? Or indeed for the counter-argument?



ben dean @bendean1979 · Feb 17

@ewenharrison @trishgreenhalgh if you're not worried about the evidence for disc replacement, then don't worry about NSAIDs.....



ben dean @bendean1979 · Feb 17

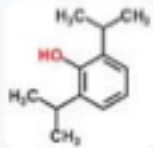
@ewenharrison @trishgreenhalgh think the evidence for harm in terms of slowing healing is weak, effect on healing is pretty small imho





Trisha Greenhalgh
@trishgreenhalgh

Anyone got an evidence base for "don't take NSAIDs when recovering from disc replacement surgery"? Or indeed for the counter-argument?



Journal Club @STHJournalClub · Feb 17

@trishgreenhalgh @traumagasdocol Lumbar discs - yes; ACDFs - not in first 24 h postop. When/if they bleed, airway is often compromised.



ben dean @bendean1979 · Feb 17



Dr Helgi @traumagasdocol · Feb 17

@trishgreenhalgh I routinely prescribe them post-discectomy. Such good painkillers, opioid sparing, get you up and about quickly.



Differential inhibition of fracture healing by non-selective and cyclooxygenase-2 selective non-steroidal anti-inflammatory drugs

Louis C. Gerstenfeld ^a, Mark Thiede ^b, Karen Seibert ^b, Cindy Mielke ^b,
Deborah Phippard ^b, Bohus Svagr ^a, Dennis Cullinane ^a, Thomas A. Einhorn ^{a,*}

^a Department of Orthopaedic Surgery, Orthopaedic Research Laboratory, Boston University Medical Center, Doctors Office Building, Suite 808, 720 Harrison Avenue, Boston, MA 02118, USA

^b Pharmacia Corporation, 700 Chesterfield Parkway, Chesterfield, MO 63198, USA

Abstract

Non-steroidal anti-inflammatory drugs (NSAIDs) specifically inhibit cyclooxygenase (COX) activity and are widely used as anti-arthritics, post-surgical analgesics, and for the relief of acute musculoskeletal pain. Recent studies suggest that non-specific NSAIDs, which inhibit both COX-1 and COX-2 isoforms, delay bone healing. The objectives of this study were 2-fold; first, to measure the relative changes in the normal expression of COX-1 and COX-2 mRNAs over a 42 day period of fracture healing and second, to compare the effects of a commonly used non-specific NSAID, ketorolac, with a COX-2 specific NSAID, Parecoxib (a pro-drug of valdecoxib), on this process. Simple, closed, transverse fractures were generated in femora of male Sprague-Dawley rats weighing approximately 450 g each. Total RNA was prepared from the calluses obtained prior to fracture and at 1, 3, 5, 7, 10, 14, 21, 35 and 42 days post-fracture and levels of COX-1 and COX-2 mRNA were measured using real time PCR. While the relative levels of COX-1 mRNA remained constant over a 21-day period, COX-2 mRNA levels showed peak expression during the first 14 days of healing and returned to basal levels by day 21. Mechanical properties of the calluses were then assessed at 21 and 35 days post-fracture in untreated animals and animals treated with either ketorolac or high or low dose parecoxib. At both 21 and 35 days after fracture, calluses in the group treated with the ketorolac showed a significant reduction in mechanical strength and stiffness when compared with controls ($p < 0.05$). At the 21-day time point, calluses of the parecoxib treated animals showed a lower mean mechanical strength than controls, but the inhibition was not statistically significant. Based on physical analysis of the bones, 3 (25%) of the ketorolac-treated and 1 of 12 (8%) of the high dose parecoxib-treated animals showed failure to unite their fractures by 21 days, while all fractures in both groups showed union by 35 days. Histological analysis at 21 days showed that the calluses in the ketorolac-treated group contained substantial amounts of residual cartilage while neither the control nor the parecoxib-treated



Nonunion of the femoral diaphysis

THE INFLUENCE OF REAMING AND NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

P. V. Giannoudis, D. A. MacDonald, S. J. Matthews, R. M. Smith,
A. J. Furlong, P. De Boer

From St James' University Hospital, Leeds and York District Hospital, York, England

We assessed factors which may affect union in 32 patients with nonunion of a fracture of the diaphysis of the femur and 67 comparable patients whose fracture had united. These included gender, age, smoking habit, the use of non-steroidal anti-inflammatory drugs (NSAIDs) the type of fracture (AO classification), soft-tissue injury (open or closed), the type of nail, the mode of locking, reaming v non-reaming, infection, failure of the implant, distraction at the fracture site, and the time to full weight-bearing. Patients with severe head injuries were excluded. Both groups were comparable with regard to gender, Injury Severity Score and soft-tissue injury.

There was no relationship between the rate of union and the type of implant, mode of locking, reaming, distraction or smoking. There were fewer cases of nonunion in more comminuted fractures (type C) and in patients who were able to bear weight early. **There was a marked association between nonunion and the use of NSAIDs after injury ($p = 0.000001$) and delayed healing was noted in patients who took NSAIDs and**

Locked intramedullary nailing is the treatment of choice for fixation of fractures of the femoral shaft,^{1,2} allowing early mobilisation with reliable healing and few complications. Rates of nonunion of between 1% and 25% have been described.⁴⁻⁹ Curylo and Lindsey¹⁰ reported an increased incidence of nonunion and attributed this to the improved survival of multiply injured patients and current methods of internal fixation.¹⁰ An increase in the rate of nonunion has been reported after the use of thin solid unreamed implants¹¹ and we have previously described a slow healing time when using an unreamed technique.¹²

Other local factors which may predispose to nonunion include the severity of the injury, extensive operative debridement, section of the soft tissues, inadequate stabilisation and distraction of the fracture and general factors such as weight-bearing, infection, smoking, the use of drugs and head injury.¹³⁻¹⁶

We have therefore assessed the influence of the technique of unreamed nailing and the thin solid nail on the rate of nonunion and have also attempted to determine the influence of other factors which may influence it.



Review Article

Do Nonsteroidal Anti-Inflammatory Drugs Affect Bone Healing? A Critical Analysis

Ippokratis Pountos,¹ Theodora Georgouli,¹ Giorgio M. Calori,² and Peter V. Giannoudis^{1,3}

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Nonsteroidal anti-inflammatory drugs (NSAIDs) play an essential part in our approach to control pain in the posttraumatic setting. Over the last decades, several studies suggested that NSAIDs interfere with bone healing while others contradict these findings. Although their analgesic potency is well proven, clinicians remain puzzled over the potential safety issues. We have systematically reviewed the available literature, analyzing and presenting the available *in vitro* animal and clinical studies on this field. Our comprehensive review reveals the great diversity of the presented data in all groups of studies. **Animal and *in vitro* studies present so conflicting data that even studies with identical parameters have opposing results.** Basic science research defining the exact mechanism with which NSAIDs could interfere with bone cells and also the conduction of well-randomized prospective clinical trials are warranted. **In the absence of robust clinical or scientific evidence, clinicians should treat NSAIDs as a risk factor for bone healing impairment, and their administration should be avoided in high-risk patients.**



Reviews on Recent Clinical Trials, 2012, 7, 00-00

Effect of Non-Steroidal Anti-Inflammatory Drugs on Bone Turnover: Evidence-Based Review

Ioannis Konstantinidis^{1*}, Spyridon N. Papageorgiou^{2*}, Athanassios Kyrgidis^{3,4}, Thrasivoulos-George Tzellos⁴ and Dimitrios Kouvelas⁴

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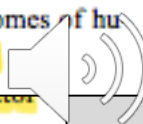
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⁴*Department of Pharmacology & Clinical Pharmacology, School of Medicine, Aristotle University of Thessaloniki, Thessaloniki, Greece*

Abstract: Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently used for acute and chronic pain control and treatment of inflammation, osteoarthritis and rheumatoid arthritis. NSAIDs have been shown to inhibit bone healing in animal studies due to the inhibition of prostaglandin synthesis. However, little evidence exists regarding the effect of NSAID exposure on human bone metabolism. This systematic review summarizes the current literature of randomized controlled trials (RCTs) investigating NSAIDs with bone remodeling-related outcomes in humans. After performing computerized searches in the most widely indexed databases, study selection, data abstraction and risk of bias assessment were conducted in duplicate. The results were controversial regarding the association of NSAID with bone formation or resorption. Increased bone mineral density following NSAID exposure was reported by some studies. Based on the levels of biochemical markers, no effect was seen on bone formation, while some evidence was found for a decreased rate of bone resorption in NSAID patients. Trials investigating the effects of NSAID treatment on bone metabolism outcomes of human patients are limited. Further research is required to confirm or refute the findings of this systematic review.

Clinical trials are warranted. In the absence of robust clinical or scientific evidence, clinicians should treat NSAIDs as a risk factor for bone healing impairment, and their administration should be avoided in high-risk patients.



Subjective narrative

Should I take NSAIDs following my cervical spine surgery?

I don't want to bleed

I don't want delayed healing

But I don't want pain either

Objective evidence

NSAIDs inhibit the same kind of prostaglandins that are involved in bone healing

Animals given NSAIDs showed slower healing of induced fractures

People with delayed healing were more likely to have taken NSAIDs

In RCTs, post-surgical patients had higher incidence of GI bleeding



Subjective narrative

Should I take NSAIDs following my cervical spine surgery?

I don't want to bleed

I don't want delayed healing

But I don't want pain either

Conclusion:

In *this* patient, given the history, clinical picture and equivocal nature of the evidence, the benefit-harm balance is in favour of NSAIDs, especially after the first 24 hours

Individualized evidence about this patient

Ex-elite athlete: years of moderate-dose NSAIDs → no adverse effects

Several stress #s treated with NSAIDs → all healed fine

Adverse reaction to opioids (dose-related itching/vomiting)

“Difficult operation” – surgeon

Currently in considerable pain

BMJ editorial to write this week



The uncontroversial conclusion

Ask yourself:

“Is the management of *this patient* in *these circumstances* an appropriate (‘real’) or inappropriate (‘rubbish’) application of the principles of EBM?”

EBM ‘experts’ should avoid pulling rank on experienced clinicians by citing irrelevant RCTs out of context



The more controversial (and much more interesting) conclusion:

If we practice patient-focused, individualization of the evidence (aka *real EBM*), we will often find that **more research is NOT needed**

Perhaps the uncertainty in science is *inherent*

Perhaps we need to return to old-fashioned clinical method and use EBM *less* comprehensively...



Thank you for your attention

Trish Greenhalgh

Professor of Primary Care Health Sciences

 @trishgreenhalgh

#EBHC2017

