

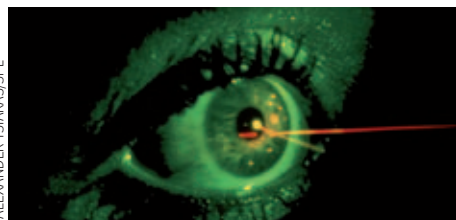


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LETTERS

LASER REFRACTIVE EYE SURGERY

Time for an independent study



ALEXANDER TSIRAS/SPFL

Bastawrous and colleagues raise important issues in their clinical review of laser refractive eye surgery.¹

Radial keratotomy was subject to ongoing independent assessment at nine university hospitals in the United States. They found that it was safe and effective in treating myopia (short sight) but that it often had an ongoing effect, many patients becoming hyperopic (long sighted).² Surgeons learnt to do mini-radial keratotomy and be conservative.

Laser refractive surgery has two clinically significant complications: weakening of the cornea that can lead to keratoconus, and impairment of contrast sensitivity that can affect safe night driving vision. The US Food and Drug administration (FDA) held public hearings about laser refractive eye surgery in April 2008. The complication rate reported varied from 1-2% to 20-30%.

A fully independent study of laser refractive surgery should be conducted as was done for radial keratotomy. Currently, the FDA states that laser eye surgery is for risk takers.³

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Competing interests: None declared.

- 1 Bastawrous A, Silvester A, Batterbury M. Laser refractive eye surgery. *BMJ* 2011;342:d2345. (20 April.)
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Cite this as: *BMJ* 2011;342:d3204

Isotretinoin as contraindication

We wish to raise awareness of a potential hazard of laser refractive surgery and concurrent treatment with isotretinoin, an anti-acne drug.¹ Acne affects 85-90% of the population at some time, and the age of patients affected by acne

overlaps that of patients undergoing laser-assisted in situ keratomileusis (LASIK). Dry eye is a side effect of both LASIK and isotretinoin^{2 3} and can result in serious sequelae such as corneal ulceration, infection, and loss of vision.

Thus, LASIK is contraindicated in patients taking isotretinoin,⁴ but this fact is not well recognised, especially among British dermatologists who prescribe isotretinoin. Previous surveys have highlighted the need to routinely screen for isotretinoin use before approving LASIK and have concluded that patients should wait six months after a course of isotretinoin before having refractive eye surgery.⁵

We recently surveyed the British Association of Dermatologists, and found that 65% did not know whether any of their patients had undergone LASIK while taking isotretinoin, only 30% inquired about recent or forthcoming surgery, and 89% were unaware that isotretinoin may cause ocular problems if a patient had undergone LASIK in the preceding six months.

Patients should avoid isotretinoin six months before or after LASIK treatment. Similarly, LASIK practitioners should check that isotretinoin has not been taken for six months before laser refractive eye surgery.

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- 1 Bastawrous A, Silvester A, Batterbury M. Laser refractive eye surgery. *BMJ* 2011;342:d2345. (20 April.)
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Cite this as: *BMJ* 2011;342:d3353

THE PILL AND THROMBOSIS

Venous thromboembolism is egregiously underestimated

The two papers on oral contraceptives and thrombosis egregiously underestimated the incidence of venous thromboembolism (VTE),

making the results impossible to interpret.^{1 2}

In Jick and Hernandez's report the incidence rates of idiopathic plus non-idiopathic VTE in drospirinone and levonorgestrel users were 5.0 per 10 000 women years (idiopathic cases comprised 61% of total cases) and 2.1 per 10 000 women years, respectively.¹ In Parkin and colleagues' report the corresponding rates of idiopathic VTE were 2.3 and 0.9 per 10 000 women years.² In this second study the combined idiopathic plus non-idiopathic incidence rates cannot be precisely calculated because the non-idiopathic exclusions are only described in the methods, with no numbers given. However, for drospirinone and levonorgestrel users, the combined rates cannot be much more than about 61% higher—about 3.7 and 1.5 per 10 000 women years, respectively.

It is well established that for oral contraceptive users the overall incidence of VTE is 9-10 per 10 000 women years.³ For the reference drug, levonorgestrel, the incidence rates reported by Jick and Hernandez and by Parkin and colleagues were about four and six times too low. Even among the drospirinone users the rates were two to three times too low.

In the US and the UK, the allegation that drospirinone is more thrombogenic than levonorgestrel has been given considerable publicity. The major under-ascertainment of the incidence of VTE in oral contraceptive users, particularly users of levonorgestrel, in these studies makes bias not only possible, but likely.

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Competing interests: SS currently consults, and in the past has consulted, with manufacturers of oral contraceptives, including Bayer Schering, the manufacturer of drospirinone.

- 1 Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirinone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data. *BMJ* 2011;342:d2151. (21 April.)
- 2 Parkin L, Sharples K, Hernandez RK, Jick SS. Risk of venous thromboembolism in users of oral contraceptives containing drospirinone or levonorgestrel: nested case-control study based on UK general practice research database. *BMJ* 2011;342:d2139. (21 April.)
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Study subject to unmeasured confounders and biases

The papers on venous thromboembolism in oral contraceptive users have similar faults to earlier database studies.¹⁻² These include lack of validation of venous thromboembolism (VTE) cases and lack of information on, or control of, important potential confounders such as duration of use, especially short duration use; family history; body mass index (BMI); and smoking.³ Jick and Hernandez's study under-ascertained short duration use of oral contraceptives in cases. Also, women who used drospirenone—which is associated with an increased risk of VTE—were more likely to be short duration users than were users of older drugs. In many areas of the UK the prescription of drospirenone oral contraceptives is restricted because of their higher price. This results in a tendency for women at high risk of VTE to use these pills and may also account for the smaller numbers of drospirenone users and difficulty in finding enough controls. The annual rates of VTE in both studies (which were confined to oral contraceptive users)—1.3 per 10 000—were lower than those found in non-users of oral contraceptives in active surveillance studies,⁴ even when allowing for the restriction to idiopathic cases of VTE. Such major under-ascertainment would increase the likelihood of diagnostic and treatment bias among drospirenone users. In addition, confining studies to “idiopathic VTE” may fail to account for unmeasured confounders and biases and lead to analyses that are not representative of the population of oral contraceptive users at risk of VTE.⁵

The authors state that no evidence exists for non-contraceptive benefits of drospirenone oral contraceptives, even though they are licensed in the US for the treatment of severe premenstrual syndrome and acne.

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Competing interests: AS and DM have received honorariums, conference sponsorship, and consultancy fees from drug companies, including Bayer HealthCare and MSD.

- 1 Parkin L, Sharples K, Hernandez RK, Jick S. Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: nested case-control study based on UK General Practice Research Database. *BMJ* 2011;340:d2139. (21 April.)
- 2 Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data. *BMJ* 2011;340:d2151. (21 April.)
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international workshop held in Berlin, Germany in December 2009. *J Fam Plann Reprod Health Care* 2010;36:117-22.

- 5 Cushman M. Patch instead of pill: a safer menopausal estrogen? *Arterioscler Thromb Vasc Biol* 2010;30:136-7.

Cite this as: *BMJ* 2011;342:d3349

Authors' reply

Shapiro's suggestion that the rates of venous thromboembolism (VTE) in our studies are egregiously low is unfounded.¹ The incidence rates for levonorgestrel users in our study agree with those found in earlier studies of idiopathic VTE in women of childbearing age (including a large World Health Organization hospital based study that prospectively ascertained cases), and the estimates for drospirenone are similar to those found for third generation oral contraceptives.²⁻³ The incidence rate quoted by Shapiro, which came from a consensus statement from a workshop convened by the manufacturers of drospirenone, was based on a study that included women with other causes and risk factors for VTE, so rates would probably be higher.⁴

Although we could not validate VTE cases in the US database we used stringent case inclusion criteria, minimising the chance of including non-cases. Furthermore, any inclusion of non-cases would tend to bias our result towards 1.0 (null finding) and would not explain the increased risk of VTE in users of drospirenone. In the UK study the risk was highest in validated cases, suggesting that had we been able to validate all cases the risk would have been higher than that reported. We did not have difficulty finding controls. The smaller proportion of controls using drospirenone, relative to cases, reflects the association between drospirenone and VTE.

Confounding by family history of VTE is an unlikely explanation for our results.⁵ Even if some preferential prescribing of drospirenone had occurred, the proportion of users is likely to be small because family history is listed as a prescribing precaution. Hence family history would need to carry an improbably high risk to explain a twofold to threefold excess risk in users of drospirenone relative to levonorgestrel. Body mass index (BMI) and smoking status data were not available for the US study. However, in the UK study, adjustment for these factors had little effect on the odds ratios, so the small number of women with missing BMI

and smoking data cannot explain our results. Prescribing restrictions on drospirenone oral contraceptives would also not account for our results because conditions such as premenstrual dysphoric disorder and severe acne are not risk factors for VTE independent of BMI. Allowing for duration of use and calendar time did not alter the odds ratios. We fail to see how the inclusion, rather than exclusion, of non-idiopathic cases would help to “account for unmeasured confounders.”⁵

Finally, the fundamental issue is the need to optimise the benefit to risk profile of drugs. Our studies contribute to emerging evidence that drospirenone oral contraceptives carry a higher risk of VTE than levonorgestrel pills, while systematic reviews have found no convincing evidence that drospirenone confers benefits over and above those of other pills.

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Competing interest: None declared.

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Cite this as: *BMJ* 2011;342:d3347

ACUTE BRONCHOLITIS

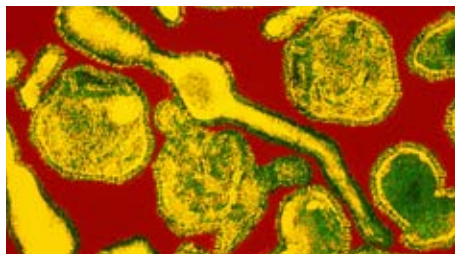
Flawed meta-analysis creates doubt when answers are known

We were disappointed to see a Cochrane review recommend adrenaline and steroids in the outpatient management of bronchiolitis.¹ The results of the meta-analysis reflect selection criteria excluding randomised controlled trials which do not support the author's beliefs rather than the available data.

The stated rationale for excluding studies in which infants have had previous wheezing was to minimise including infants who might later develop asthma (undefined). This is illogical. Firstly, many viruses



CRISTINA PEDRAZZINI/SPL



cause bronchiolitis. Infection does not prevent re-infection and a repeated episode of bronchiolitis. Secondly, studies that have included infants with previous episodes have used this variable and controlled their analyses accordingly.² Thirdly, the correct assignment of the “first episode” depends on accurate parental understanding of wheezing.

Even if excluding infants with recurrent bronchiolitis were valid, individual infants rather than entire studies could have been excluded. Similarly, including only studies with outcomes at days 1 and 7 excludes those with primary outcomes at day 3, and severely limits this meta-analysis.

One excluded study (n=75) shows no significant difference between adrenaline and placebo.³ Another shows a relative risk of 1.18 favouring salbutamol, even after adjustment for recurrent episodes.² This well-designed trial (n=703), dwarfs the six outpatient studies (combined n=295) that were included. The question has been answered: salbutamol is the better bronchodilator.

We also disagree with the assertion: “These two large (steroid) trials . . . provide a strong signal for further synthesis work.”¹ The study of Corneli et al (n=600) shows no benefit from steroids; even their post-hoc subgroup analysis (adjusted for multiple comparisons) was not significant.⁴ It was important to ask if steroids would help. The answer is No.

Many of us have spent years testing these hypotheses. Now we should follow the data rather than insist that there is some subgroup in whom our initial beliefs are correct.

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Competing interests: The authors have conducted original randomised controlled trials and related research in the field.

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4 Corneli HM, Zorc JJ, Mahajan P, Shaw KN, Holubkov R, Reeves SD, et al. A multicenter, randomized, controlled trial of dexamethasone for bronchiolitis. *N Engl J Med* 2007;357:331.

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Authors' reply

Our paper was not a Cochrane review,¹ although it builds on several and adds a network analysis.

To minimise bias we used a predefined protocol developed with physicians and stakeholders which had predefined inclusion criteria for population, interventions, and outcomes.

A priori we decided to focus on first time wheezers. The first episode of wheezing may prove to be the first manifestation of a range of phenotypes with distinct pathological, genetic, viral, or environmental determinants and prognosis.²⁻³ Until valid discriminative tools are available, we need to use simple, clinical variables to stratify this population. To study separately children with first episodes of viral infection, including wheezing,⁴ is clinically relevant with a precedent.⁵

We chose outcomes a priori; all studies that reported at least one of the outcomes were included. Studies that assessed admissions after day 3 were included in the day 7 outcome.

Walsh and colleagues cite one study supporting their beliefs in the superiority of salbutamol.¹ We did not include it because it included recurrent wheezers. To base recommendations on a single trial without considering the totality of evidence when other studies exist is potentially misleading. The study compared salbutamol against another active intervention, but the most recent Cochrane review found no difference in hospital admissions between salbutamol and placebo.⁶

We were motivated by substantial new evidence since earlier reviews. Hence, the volume of research, not the results, motivated our work.

Our analysis excludes a stand alone effect of steroids but suggests some additive effects when combined with adrenaline. We clearly acknowledge the need for further assessment of combination treatment and that there may be a safety issue with high dose steroids.

Substantial variation in the management of bronchiolitis throughout the world shows that answers are not clear. We need to examine existing evidence in an unbiased manner and conduct further rigorous research as needed to guide the management of this complex condition. **Lisa Hartling** assistant professor, Alberta Research Centre for Health Evidence, Department of Pediatrics, University of Alberta, 11402 University Avenue, Edmonton, AB, Canada T6G 2J3
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Competing interests: None declared.

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FUNDING CME

Time for optimism

We thought that the headline on Roehr's article was overly pessimistic.¹ Tabas and colleagues' study showed that most US doctors (83%) believed industry funding should be eliminated from accredited continuing medical education (CME) activities.²

Although only half were willing to sacrifice a free sandwich for this, these views are clearly silly and eminently challengeable among highly paid professionals such as doctors. Never forget that smoking on the ward round used to be socially acceptable.

Together with our colleagues, we recently ran a successful educational conference for trainees in Oxford that was attended by 120 doctors from across the UK.³ We received a little financial support from the university but deliberately sought no commercial sponsorship. Others have demonstrated the feasibility of this approach in a resource poor setting.⁴

We shortly intend to launch a mark, like that of the Fairtrade Foundation, for CME that is independent of industry. If you are interested in this idea please get in touch.

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Competing interests: None declared.

- 1 Roehr B. US doctors are unwilling to pay more to abolish industry funded CME. *BMJ* 2011;342:d2948. (10 May.)
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NEW DEAL ON DISEASE DEFINITION

Diseases: on a continuum rather than discrete entities

Many of the problems associated with the changing definitions of diseases stem from the fact that the great majority of diseases are really pathological

processes that exist on a continuum and are not discrete entities.¹ Apart from single gene disorders, such as Huntington's chorea, there are very few diseases that one either definitely has or has not. Take asthma for example. There is a spectrum of bronchial hyper-reactivity, and all of us will wheeze to a greater or lesser extent depending on the provocation. Our position on this spectrum can fluctuate over time, and whether we are labelled as asthmatic is often an arbitrary decision.

Having a strict, definition based model of disease may be convenient for researchers and those keen to regulate healthcare and performance manage doctors, but it doesn't really reflect how we encounter illness in the real world.

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Competing interests: None declared.

- 1 Moynihan R. A new deal on disease definition. *BMJ* 2011;342:d2548. (3 May.)

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Passion always trumps evidence on objective panels

In an ideal world, everything Moynihan writes about the virtues of objective panels would be manifest.¹ Does no one remember the outcry following the release of the US Preventive Services Task Force 2009 report on breast screening? Or further in the past, the complete rejection of the National Institutes of Health Consensus Conference on Breast Cancer Screening for Women Ages 40-49?

Passion (read vested interests) trumps evidence every time.

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Competing interests: None declared.

- 1 Moynihan R. A new deal on disease definition. *BMJ* 2011;342:d2548. (3 May.)

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RESPONSE

Jack Winkler replies to Joachim von Braun

Von Braun is right: we are into our second food price crisis in four years.¹ Worse, such crises will recur throughout the 21st century as climate change desiccates swathes of the earth, spreading food insecurity.

He proposes a long term programme to cope: improve agriculture, reform trade, increase reserves, control speculation, end export bans, create safety nets, provide preventive healthcare. It would work—on some more blessed planet. But in the venal contemporary world we actually inhabit, full of gross income inequalities, nationalist agricultural subsidies, and inadequately regulated global markets, it is just a laundry list of desiderata.

We are moving in the opposite direction. Consider what has happened in the past two months alone.

- (1) Talks to reform world trade have failed—again. The World Trade Organisation's Doha round is dying, and with it better terms for least developed countries²
- (2) The Organisation for Economic Cooperation and Development (OECD) reported that rich countries have failed to fulfil aid pledges made at Gleneagles, which were partly intended for agriculture³
- (3) The UK and US have flinched at reform of financial markets
- (4) Barclays Capital, the UK's biggest player in commodities, is estimated to make £340m a year dealing in agricultural derivatives⁴
- (5) The G8 is still "considering" international buffer stocks. Von Braun's imaginative proposal for "virtual reserves" languishes
- (6) Glencore, the world's largest commodity trader,

is becoming a public company, so 485 partners will receive windfalls of \$100m each. Commodity trading is indeed profitable

- (7) Glencore's initial public offering document candidly reveals speculative techniques for making it so lucrative.⁵ They include withholding supplies in times of shortage, hoarding them in storage, until the price rises; and diverting scarce supplies to richer countries, which pay higher prices, instead of to poor countries, whose people need them most. Last summer Glencore lobbied Russia to ban wheat exports, thereby raising prices, allowing the company to make a killing.⁶

In his companion podcast, Nabarro articulates the logic behind economists' proposals for solving the problems: "The key requirement is to make certain markets work." Faced with recent failures of the international great and good to achieve that, no politician in a developing country would ever trust global commodity markets to feed the population.

Happily, some are pursuing a different path to food security. Actions include:

- (1) Raising domestic food production to meet a higher percentage of national needs. This is not the economists' bogeyman of self sufficiency but a rational strategy to ensure that people always have at least minimum supplies, so they do not starve when commodity traders hold them to ransom
- (2) Guaranteeing necessary food imports through bilateral trade agreements with supplier countries. This is not the bogeyman of protectionism but a rational response to the inability or unwillingness of rich countries to control the global, multilateral food trading system humanely
- (3) Stopping food exports by local speculators when international prices are rocketing to conserve domestic supplies
- (4) Increasing national and regional food reserves so

that during crises stocks are adequate not only to feed citizens but also to put extra supplies on to the market to defeat speculation. If the World Trade Organisation will not create international reserves, people are creating reserves locally.

- (5) Raising the nutritional quality of the food supply using biofortified seeds for staple crops, whether conventionally bred or nutritionally modified.⁷

The Philippines has already implemented all of these strategies. They offer a better model for future food security than anything the 17 UN organisations concerned with food have yet created.

While economists theorise about markets, international agencies dither, traders speculate, and governments capitulate, pragmatists focus on feeding populations. More people, in more countries, will be healthier as a result.

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Competing interests: The Nutrition Policy Unit is an independent consultancy focused on practical action to improve public health through dietary change. It works primarily with public interest organisations. JTW was professor of nutrition policy at London Metropolitan University until 2010.

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