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Urinary stress incontinence

Benefits of using tension-free vaginal tape remain unproved

New minimal access surgical sling procedures such as the tension-free vaginal tape procedure are now being used to treat urinary stress incontinence in women. These procedures use minimal tension—urethral support is perhaps achieved from a tissue reaction to the tape, which produces a collagen scar along the length of the tape and increases support of the bladder when the rectus muscle contracts. The tension-free vaginal tape procedure is often carried out under regional or local anaesthesia. Many women would undoubtedly welcome the choice of a less invasive procedure than open retropubic colposuspension—as long as the minimal procedure cures urinary incontinence and does not result in major complications.

What does the currently available evidence say? Two recent systematic reviews concluded that, although the minimal access surgical sling procedures (and particularly tension-free vaginal tape) may be promising, the quality of the evidence available so far is not conclusive.^{1 2} So far almost all the evidence has come from case series. So the six month results for the first multicentre randomised trial of tension-free vaginal tape have been eagerly awaited,³ since only preliminary results could be included in these systematic reviews.

Ward et al concluded that in their trial tension-free vaginal tape was as effective as colposuspension in treating stress incontinence. Several aspects of the trial, as well as results from other studies of tension-free vaginal tape, indicate that this claim may still be somewhat premature. In the trial, the authors prespecified that a difference of 10% in cure rates between tension-free vaginal tape and colposuspension would be clinically important, but unfortunately they were unable to recruit the required number of 394 patients overall. Ultimately 344 women were randomised, and only 287 completed the urodynamic investigations at six months—156/175 (89%) after tension-free vaginal tape and 131/169 (78%) after colposuspension. Ward et al analysed most of their data on an intention to treat basis, making the assumption that all missing patients were treatment failures. This assumption is questionable, however, and it would have been better also to reanalyse assuming missing patients were treatment successes and then attempt to explain any differences between the sets of results.⁴ Unfortunately, a more correct interpretation (taking into consideration the underpowered study and missing results) is that tension-free vaginal tape may be better, worse, or the same as colposuspension in this study.

Of greater concern, however, may be the biases inherent in this study that seem to favour tension-free vaginal tape. A large number of women who agreed to join the trial seem to have withdrawn when placed in the colposuspension group. Given that the study was performed in the NHS and that tension-free vaginal tape may have been readily available for trials only, it may well be that patients were willing to continue in the trial only if they were allotted to the group treated with the less invasive approach. The report mentions that the women who withdrew from the colposuspension

group before surgery had less severe incontinence. This reinforces the importance of closer analysis of these women in interpreting the results obtained, ideally in a true intention to treat analysis, which requires testing of several assumptions.

Irrespective of these statistical and methodological concerns, women treated with vaginal tape had shorter operating times and reduced hospital stays than women treated with open colposuspension, as would be expected from a less invasive technique. They were also able to return to work and normal activities more rapidly. What remains to be addressed, even if the operations are of equal short term benefit for incontinence, is the issue of long term cure rates. This will require further follow up of patients in both groups. Women will also need to base their decisions on the possibility of complications. The trial showed more intraoperative complications, such as perforation of the bladder, in the vaginal tape group. Postoperative complications, such as infections, were more prevalent in the colposuspension group.

Although this study begins to add evidence from randomised controlled trials, at best we can conclude only that we need further studies with adequate power and long term follow up, whose outcomes are analysed more stringently. The study by Ward et al also shows that, even when resources can be found to start a randomised controlled trial, many factors coincide to make surgical research problematic. It is often difficult to recruit sufficient patients to produce a robust result. Especially in surgery, authors of underpowered trials tend to make unsupported recommendations for changes in practice.⁵ The often unknown motivations of participants who withdraw from trials once they are aware of their treatment allocation and the multiple reasons for becoming lost to later follow up make intention to treat analyses more complex. For surgical randomised controlled trials, issues related to the learning curve and differences in performance between surgeons complicate analysis of results even further.^{6 7}

We must, however, find ways to optimise the ability of randomised controlled trials to answer the questions that they were designed to answer. Funders need to be prepared to fund randomised controlled trials on the basis of realistic recruitment rates, or they may need to provide “top up” or contingency funding so that trials do not remain underpowered. Trialists should also have access to specialised statisticians and methodologists who have the skills to model scenarios, particularly for inputting missing data, such as losses to follow up. The alternative is that we revert to reliance on observations of current practices, where variation in practice might be seen as a large but poorly controlled experiment,⁸ to attempt to make informed choices between treatments. The difficulties experienced with the tension-free vaginal tape trial mean that women needing to choose between minimal access and conventional surgery still do not have enough evidence

to make this decision, even though the difficulties were probably surmountable.

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Competing interests: AMG is a member of a group commissioned by the National Institute for Clinical Excellence to conduct a technology assessment review of tension-free vaginal tape.

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Your career: planning for the unexpected

Come to the BMJ Careers Fair and learn how to think about an unpredictable future

Are you somebody who plans ahead in life? Do you have an idea of what you might be doing in 10 years' time? The training and work of doctors is increasingly controlled. In Britain, for example, specialist training is defined, general training is being defined, and lifelong appraisal and revalidation are being introduced. Everybody will need to have a personal development plan. Doctors might therefore feel that their working life is being planned for them, but these innovations come at a time when the future is highly uncertain. Will the NHS still exist in 10 years' time? What changes will the new genetics and information technology bring? Will Britain be part of the United States of Europe by 2020? What will it be like to practise in a world where many patients with chronic disease are better informed than their doctors? Might another war break out? Might you develop a serious illness? People who want to think ahead need to recognise that the world predictably changes in unpredictable ways. But how can you think about the unpredictable when that seems impossible? Those who would like to learn one approach should read the article by Philip Hadridge and Rhona MacDonald in *BMJ Career Focus*, join a web vote, and come to the BMJ Careers Fair.¹

Successful organisations have always thought about the future, but they learnt years ago that the future was unpredictable and that simply projecting trends forwards led to false conclusions. Planners therefore developed "scenario planning," where instead of predicting one future you imagine several plausible but different futures. One way to do this is by identifying drivers of change—such as new technology—and imagining where these might lead. You then examine your current plans in the light of these possible futures. Plans that will work equally well in several of the worlds are more likely to succeed. You can also reflect on what the imagined worlds have in common and plan accordingly.

The NHS has engaged in scenario planning, imagining one world where people ceased to trust

institutions such as the NHS and another world where people felt so overwhelmed by information that they needed organisations they could trust.² The *BMJ* has used scenario planning to think about the future of medical publishing. In one scenario research is made available through large databases rather than journals. A second scenario describes a world of global, electronic conversation where publication, either paper or electronic, is not important. In a third scenario publishing is controlled largely by huge global organisations—drug companies, technology companies, retailers, or bodies such as the World Bank.

Although it is routine for companies to plan for an unpredictable future, it is rare for individuals. How many doctors think about working in a future that might be very different from now? Not many probably, although the health service in 10 years' time is highly likely to be very different from now. The problem is to know how it will be different. How many doctors think about a future in which they might develop a chronic illness, suffer a serious adverse event, or fall in love with somebody from far away? Again, these things happen commonly but unpredictably. That is why Philip Hadridge, Rhona MacDonald, and others from BMJ Careers have used the ideas behind scenario planning to help doctors plan for an unpredictable future.¹ Why not join in?

Richard Smith *Editor, BMJ*

Competing interests: Richard Smith is the editor of the *BMJ* and chief executive of the BMJ Publishing Group. He is responsible for the financial performance of both and clearly wants the BMJ Careers Fair to go well. He is, however, paid a fixed salary and will not benefit personally from the fair.

The BMJ Careers' National Medical Careers Fair will take place on 29-30 November 2002 at the Business Design Centre, Islington, London. (<http://www.bmjcareers.com/careersfair/>)

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