'VAGINAL REJUVENATION' AND THE REGULATION OF NEW TECHNOLOGIES: CONTROLS ARE STILL LACKING

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A tour of the stands at the 41st International Urogynaecology Association (IUGA) Annual Meeting in August 2016 revealed a growing number of companies with machines aimed at 'vaginal rejuvenation', an industry-driven misnomer, with promises of tightening of the vagina (for laxity primarily caused by childbirth) and improved sexual satisfaction. A review of the literature regarding the use of energy-based devices, including CO_2-based or erbium:Yttrium-aluminum-garnet (Er:YAG) lasers and radiofrequency-based devices, for the treatment of vaginal rejuvenation, reveal the procedures to be easily performed in the outpatient setting, generally tolerable to the patient, and easy to do. However, most of the studies performed to date are pilot studies with low patient numbers and short follow-up, indicating that both efficacy and safety are yet to be established.[1-4] Moreover, there remain many questions that have yet to be answered, including the possibility of energy transmitted as heat affecting adjacent tissues (such as the cervix, rectum, and bladder) as well as the potential for neoplastic lesions, vulvar dermatoses, and the long-term effects of possible scarring on future obstetric outcome.

It remains unclear as to how online content influences women's consideration and acceptance of female genital cosmetic surgery. Further research is needed into the role the internet plays in its promotion and normalisation, and the consequent effect on patient demand.[5] What is it that drives patients to seek such treatment? Is it the woman herself who seeks better sexual fulfilment or her partner? What is the psychological background of such behaviour? These issues warrant further investigation.

Of greater concern is the fact that there appears to be little worldwide regulation in the sale and use of such devices, with no apparent requirement for the organisation and collection of data in the form of databases or registries. This at least could be used to collect evidence of efficacy and long-term outcomes and to monitor the safety of the devices. These devices are available and have been used by a variety of practitioners including general gynaecologists, urogynaecologists, dermatologists, and plastic surgeons, further complicating matters.

The US Food and Drug Administration (FDA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK regulate the use of medical devices. These regulatory bodies must act in an efficient and timely manner such that patients are not deprived of beneficial innovations, whilst at the same time minimising harm. These bodies have not approved devices for use in this procedure. However, some of the devices used for vaginal rejuvenation have FDA approval for non-genital use. Nonetheless, many sites advertising the procedure misleadingly state that FDA approval has been met. The procedure is also openly advertised without regulation, and is available worldwide.

Although many medical devices for various indications have improved clinical outcomes, not all are beneficial and some have been harmful. Concerns over hip resurfacing techniques and breast implants have raised serious questions about how medical devices are evaluated. Furthermore, it would appear that we have yet to learn the lessons of the vaginal mesh fiasco with industry led introductions of treatments of utero-vaginal prolapse with minimal evidence, and lack of long-term outcomes rather than using a systematic

base of evidence prior to using such products on our unsuspecting and vulnerable patients.[6] The outcome of this has led to a plethora of litigation cases leading the manufacturers to remove their vaginal mesh products from the market.[7] An unfortunate by-product of the vaginal mesh disaster is that evidence-based products such as 'tension-free' vaginal tapes, a treatment for stress urinary incontinence with excellent outcomes and low complication rates, are being unfairly associated with the meshes and mesh kits being used for prolapse treatment, leaving patients with fewer alternative treatments. The Scottish independent review of the use, safety and efficacy of transvaginal mesh implants concluded that robust clinical governance must surround the decision to use the product.[6] It also recommended that the Scottish Government consider alternative methods for the capture of adverse events to further determine the most effective way to ensure complete notification, and that the lack of extended long-term follow-up and related outcome data should be addressed.

The surgical world is a collection of different personalities, some of whom will jump on the latest bandwagon promising innovative new treatments to their patients whilst others at the opposite spectrum wait for an adequate evidence base prior to training and use of new techniques or technologies. What drives this difference in early versus late adopters of new technology? Why are some surgeons much more cautious whilst others will apparently shun the lack of evidence and embrace new treatments? Is it driven by patient demand, financially driven with the promise of increased private income, the desire to use new innovations for the benefit of patients, or inappropriately perceived as being safe? Are patients aware of where their surgeon sits in this debate? More studies are required to investigate the differences between early and late adopters, including surgeon characteristics, their surgical outcomes, complication rates, patient satisfaction surveys, and private practice.

Understanding the considerations that influence physician adoption of new, unproven methodologies is critical to the development of strategies to better align clinical practice with available evidence and to control healthcare costs.[8] Several factors influence this decision, one being physician's peer exposure, since exposure to early or late adopters may influence physician comfort with new innovation.[8]

As a reaction to the analysis of how innovations were taking place in surgery, an expert group was set up within the framework of the Balliol Collaboration to compile recommendations for scientific evaluation of surgical innovations.[9] This group made a series of recommendations including encouragement of the widespread use of prospective databases and registries. Reports of new techniques should be registered as a professional duty, anonymously if necessary, when outcomes are adverse. Protocols for studies should be registered publicly, and randomised trials should be used wherever possible.[9] In the surgical innovation process, registries constitute an important scientific tool that affords insights from the outset and accordingly merits evaluation.[10] This will provide for early identification of any problems or complications on the basis of outcome analysis.

A recent study looking at the regulatory approval of new medical devices suggests that many new devices do receive regulatory approval but often lack clinical trial data supporting their safety and effectiveness.[11] The optimal framework for the regulatory approval of medical innovations remains unclear.[11]

Surgeons should be cautious in the adoption of new technologies. Evidence-based medicine should be used in the decision on when to begin the use of a new methodology and this must only be within the remits of data collection via clinical trials allowing the collection of long-term outcomes of efficacy and safety. Regarding the use of vaginal rejuvenation, the American College of Obstetricians and Gynecologists (ACOG) has stated that these procedures are not medically indicated and the safety and effectiveness has not been demonstrated.[12] This has not precluded its use by gynaecologists or other specialists. Regulation preventing practitioners advertising and offering such interventions to patients outside a trial, for unproven interventions, will help protect patients until safety and efficacy of these devices for use in the vagina is established.

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