GAVIN PUBLISHERS

Journal of Urology and Renal Diseases

Buttigieg GG. J Urol Ren Dis: JURD-173.

DOI: 10.29011/2575-7903. 000073

Editorial

Urinary Incontinence, Meshes and the Law

George Gregory Buttigieg*

Department of Obstetrics and Gynaecology, Medical School, Mater Dei Hospital, Malta

***Corresponding author:** George Gregory Buttigieg, Department of Obstetrics and Gynaecology, Faculty of Medicine & Surgery, Medical School, Mater Dei Hospital, Malta. Tel: +35623401102; Email: george.g.buttigieg@um.edu.mt

Citation: Buttigieg GG (2018) Urinary Incontinence, Meshes and the Law. J Urol Ren Dis: JURD-173. DOI: 10.29011/2575-7903. 000073

Received Date: 17 December, 2017; **Accepted Date:** 03 January, 2018; **Published Date:** 10 January, 2018

Editorial

The treatment of female urinary incontinence is common ground for gynaecologist and urologist. Those presenting with genuine stress incontinence to the gynaecologist are likely to undergo surgical intervention of one kind of another, and where results are disappointing, urologist referral as "refractory case" is common. The primary intervention by the gynaecologist has over the last 15 to 20 years seen a paradigm shift involving meshes be they applied directly r laparoscopically. This editorial is concerned with the ever-increasing reportage of clinical complications and subsequent medico-legal litigation oriented around the use of such meshes to treat female urinary incontinence.

Whether meshes are applied abdominally or much more commonly vaginally, the immediate post-operative results are often extremely impressive. Unfortunately, the long-term complications have not only made major head-line news but, as expected have often, also led to Court litigation of epidemic proportion. Among these complications we find persistent heavy and untreatable vaginal discharge and/or vaginal bleeding, crippling abdominal pain, local infection, dyspareunia, various types of urinary symptoms and migration of mesh with penetration of bowel and/or bladder. Some of these complications have necessitated further surgery, among other things in an attempt to remove the mesh, not always with satisfactory results.

The introduction of vaginal meshes, essentially took off significantly in the 1990's. Previously, the gynaecologist used the body's own tissues to correct both stress incontinence and utero-vaginal support. The increasing use of meshes was meant to parallel the use of meshes in hernia repairs. One can also understand that the use of a minimally invasive procedure requiring minimal hospitalisation, short anaesthetic period and immediate and impressive continence control made the procedure a most attractive one for surgeons, be they gynaecologists or urologists. Operations, like the Burch colposuspension, previously the golden standard of female GSI corrective surgery, suddenly appeared antediluvian. Naturally, an element of "not falling behind one's peers" can never be separated from the motivating factors.

Between 2008 and 2010, the number of pelvic mesh complaints tripled over the preceding 3 years, in the USA, where over the last 15 years or so, a good 60,000 law suits hit the Courts. Reports of serious complications leading to medical liability suits appeared in many countries. For example, in Scotland, with over 400 cases lodged in the Court of Session, the Scottish NHS is now facing the largest number of simultaneous medical negligence cases in legal history. A huge mass of resultant medico-legal complications still awaits liability judgments. Johnson and Johnson, C.R Bard, American Medical Systems, Boston Scientific and Coloplast have all settled massive amounts of money resulting from such complications. Yet, mesh manufacturers maintain that they released these products into the market with claims that they were a safe and effective treatment for pelvic organ prolapse and stress urinary incontinence. I don't think anyone doubts these intentions. But, facts are as they are. There have also been warning lights since 2008, when the Food and Drug Administration pointed to potential complications. From January 2008 through December 2010, the FDA received 2874 additional reports of complications associated with surgical mesh devices used in pelvic floor repair and to correct stress incontinence, with 1503 reports associated with the former and 1371 associated with the latter. In 2011, the FDA- Medical Device Advisory Committee, concluded that not only is the safety and risk/benefit of such meshes not well established, but that, depending on the specific vaginal location being repaired, no advantage may be garnered over the traditional repair. The last warning, if taken on its own, may be justifiably challenged, on the grounds that advantages of a minimally invasive procedure over say a Burch colposuspension are undeniable, provided that the safety and risk/benefit was acceptable. In 2016, the FDA upped the risk classification from moderate to high risk.

Mesh oriented liability jurisprudence may be extremely challenging. Evaluating liability from medical malpractice involving incompetent surgery versus inherent product defect is only part of this difficulty. Even so, the two elements may not be automatically

mutually exclusive and may certainly co-exist. Thus, it is possible to have both an unsafe product and its insertion being affected by an incompetent surgeon, or indeed, by any surgeon in an incompetent way. Points to evaluate include assessing the extent of pre-patient training and the learning curve of the specific surgeon in question. There is an ocean of difference between a gynaecologist who sub-specialised in uro-gynaecology or a urologist who has inserted a few hundred meshes and a general gynaecologist who is performing his first dozen insertions, after watching one or two cases and a DVD. Even if the element of surgical technical malpractice is eliminated, an inherently problematical mesh may still lead to a ruling of medical liability, especially in the light of the above FDA warnings.

There is another serious and not easily circumvented argument which may, on its own, also lead to medical liability. This is related to the increasing Court weighting allotted to disclosure of medical (in this case pre-operative) information to the patient. This has attained new and almost supreme status along the principle of ever increasing patient autonomy in choosing or accepting medical treatment. The UK Supreme Court ruling in Montgomery) v Lanarkshire Health Board (Respondent) (Scotland) [2015] UKSC 11, has been of landmark importance in this regard. Suffice it to say, that, among other things, this case has eliminated the invocation of the Bolam principle with regard to disclosure of medical information. The Court will no longer ask what would a respected group of peer doctors have done in these circumstances. It is now rather a question of, among many factors "Doctor, did you fully warn your patient about what could go wrong before you inserted the mesh?.