Focus

Pelvic floor disorders, internationally shared language, standardized procedures, surgical innovation and clinical evidence

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Language is the specific way of communication among humans; it modifies to suit different needs, in order to follow technologic evolution, customs, habits and life style. It changes through a long process of development along the years. Our children, for example, speak a language different from ours, consisting of mobile SMS or MMS or through internet. These differences may cause problems to communication.

Scientific data, clinical information or medical results should be expressed in a unique way, respecting rules and technical terms, using a language internationally shared and validated.

Misunderstanding can be the result of the absence of a precise language, leading to wrong diagnoses and therapies. A unique terminology is necessary to obtain clinical evidence.

Concerning urinary continence and prolapse, this effort started over twenty years ago, when a group of American urologists and gynaecologists published a study on the standardisation of terminology on Female Pelvic Organ Prolapse and Pelvic Floor Dysfunction.[1]

The reasons for the interest in the international community for a common language in pelvic floor disorders are easily understood. Pelvic floor dysfunctions are nowadays increasingly being correlated with the elderly population over 60, and severely affect the sanitary expenses. DeLancey has stated, "genital prolapse is an epidemic ready to explode". This is why gynaecologists and urologists, industry and politics are so interested in the subject. A bad management will further affect the social costs of the problem. Verifying the efficacy of treatments and comparing the results in patients with genital prolapse and urinary incontinence would reduce health costs, which is particularly needed in a worldwide economic crisis. The International Continence Society (ICS) has produced different attempts to standardise terminology, diagnostic methods and therapies, producing guidelines that are internationally accepted, but not widely used[2].

Christopher Chapple, in an editorial in Neurourology and Urodinamics states[3]: "*I hope you agree that these examples of areas where we need to develop consensus on terminology are important ones and we should all strongly support the efforts of the Standardization Committee, which working through the International Continence Society its sister organizations will continue and progress the debate relating to standardization of terminology related to functional disorders affecting the lower urinary and gastrointestinal tracts*". But nowadays different classifications of prolapse and incontinence are still used whose clinical evidence is far from being "the real" evidence. The existence of a still confounding terminology is witnessed also in another editorial by M. Soligo[4]: "Posterior pelvic floor dysfunction: there is an immediate need to standardize terminology".

The clearest example of the multitude of terms on the pelvic floor is related to the defects of the posterior vaginal wall. The posterior defects are indicated with terms like "rectocele", "posterior vaginal prolapse", "posterior colpocele": are these synonymous or do they refer to different conditions? This language problem is evident on searching in Pubmed: with "posterior colpocele" 5 works can be found; 16 with "descensus of posterior wall", 127 with "posterior vaginal prolapse" and 605 with the keyword "rectocele". Titles are a clear denunciation of the problem. Moreover in three out of five coloproctologic articles "obstructed defecation syndrome" (ODS) is named arbitrarily identifying rectocele and obstructed defecation. ODS is a multifactorial syndrome *sometimes* associated to rectocele, two conditions that might need to be treated in different ways, and the risk of damage is evident when surgery is chosen in a wrong way. Epidemiology predictions on pelvic floor dysfunctions are amazing: the 500.000 surgical procedures/year in the United States will increase from 27% to 31% of the population in 2020, doubling in 2050. The companies are ready to face this increase with new meshes and other devices "ready to use" and easily implantable.

One may suspect that all the difficulties which exist as regards the standardizion of terminology and procedures can be useful for the marketing of medical devices in order to allow anarchic therapeutic paths, with an important potential damage to the patients.

New procedures and prostheses amazingly are sprouting without the support of any scientific evidence, and with no guarantees in case of adverse events, that sometimes are extremely serious.

The lack of control by the scientific societies on these procedures and those who perform them is surprising. Appeals are arising from many authoritative urogynecologists. Donald Ostergard[5] in 2007 wrote in the International Urogynecology Journal: "*New procedures and materials for incontinence and prolapse are proliferating rapidly. Surgical procedures were developed by physicians and carried their names, but over the last 15 years, these procedures are developed by industry and bear the trade names of the companies selling the kits needed to perform them. The Food and Drug Administration approves devices, not procedures, and does not require submission of efficacy or adverse-event data to gain this approval by the 510-K process. Evidence-based medicine is lacking in the performance of these procedures that may be considered experimental by an insurance company or malpractice carrier with denial of payment or coverage. Physicians and hospitals are exposing themselves to financial, legal, and ethical risks when performing or allowing such procedures to be performed. Informed consent from the patient cannot be obtained. We must not confuse medical marketing with evidence-based medicine*". The question of the author is: *what about the future?*

The problem is that industry is making its business, while the role of scientific societies on the control of the procedures with randomized studies is lacking. It is necessary to answer the following question: is the aim of prolapse surgery to reduce the vaginal bulging or rather to restore the pelvic function and improve the quality of life considering the possible complications? The position of some scientific societies is embarrassing, because some of their members perform technical training for surgical procedures, while their role should be the research of clinical evidence. Belonging to a scientific society and working for industry is

contradictory behavior, although is not a crime: it is a clash of interests. The risk is that companies control international societies and this is becoming a legal even more than an ethical problem.

In conclusion surgeons will continue to perform procedures that they feel they are the best for their patients. Industry will continue to develop and promote new materials and devices in the hope of simplifying procedures and improving outcomes, as they realize how big is this market. With time, the available options will only increase. While ideally we would like level one evidence to support what we do, it is unrealistic to expect that this will be available in a timely fashion.

In the meantime, we can only *hope* that surgeons will honestly report their results and complications whatever procedure they are performing. This is the ethical challenge of surgeons.

In 2009 Paulo Palma[6] discussing the ethical challenge of surgical innovation stated: "*How can specialty societies help? Societies should play a major role working on guidelines, defining minimum follow-up before publishing the initial series of patients, selecting acceptable studies, and stimulating publications of data, including complications . These actions would help to improve the standards of surgical innovation*."

Wall and Brown published for the American College of Obstetricians and Gynecologists (ACOG) a study entitled "Commercial pressures and professional ethics: troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapsed"[7] concluding that "*commercial interests are reshaping the practice of gynecological surgery by promoting the use of trochar andmesh surgical kits for the treatment of stress incontinence and pelvic organ prolapse… the ethical implications of changes in surgical practice that are driven by commercial interests are discussed.*

We point out the dangers inherent in the adoption of new procedures without adequate and documented evidence to support their safety and efficacy." The ACOG Practice Bulletins on Pelvic

Organ Prolapse[8] were altered without explanation to downplay the experimental nature of some commercial products. In so doing, ACOG is not meeting its fiduciary responsibilities to patients and is undermining important professional values. The editorial of CA Matthews "The surgical sales representative: examining a new role in urogynecology" gives further light on this matter[9].

We strongly hope that new debates will be opened by the scientific community.

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