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REGISTER OF UROGYNECOLOGICAL IMPLANTS – A GERMAN INITIATION TRIAL

Hypothesis / aims of study

Although the mesh-assisted repair of POP (pelvic organ prolapse) and/or SUI (stress urinary incontinence) is one of the most commonly performed operations, many aspects of the mesh-application are still under debate or poorly studied. As a reaction to reports on high complications associated with vaginal implantation of alloplastic materials and consecutive flood of law suits in USA, a proper evaluation of indications, mesh materials and risk factors for complications is urgent. A help can be given by the establishment of central registers with the information on implanted and explanted materials and the documentation of the complications.

Our working group present a first consecutive application of a five-step *IDEAL*-method of surgical innovation on mesh development in urogynecology (1). The previous steps of development have been published previously (2,3). The implant register is a consecutive last step of this innovation method and presents a long-term database.

Study design, materials and methods

Based on the successful implementation of surgical hernia registries (*Herniamed,* German quality assurance system and registry for hernia surgery and *EuraHs*, European registry for abdominal wall hernias), a working group was formed to create an online platform for registration and outcome measurement of operations with mesh-application for POP and SUI repair. Development of such a registry involved reaching agreement about clear definitions and classifications on patient variables, surgical procedures and mesh materials used, as well as outcome parameters. The working group comprised of a German expert panel with specific interest in Urogynecology. Over several working group meetings, consensus was reached on ICS-based definitions and parameters for the data to be recorded in the registry.

Results

A set of well-described definitions and complications was made, based on ICS-IUGA standards in terminology and guidelines 2009. Risk factors for recurrences and co-morbidities of patients were listed. Post-operative complications were classified according to existing classifications (ICS-IUGA and Clavien-Dindo). A comprehensive information on management strategies can be provided by the user. Various validated QoL-questionnaires for different symptoms of pelvic floor (incontinence, urge, prolapse, fecal incontinence, constipation, pelvic pain) were integrated. An online platform is created based on the definitions and classifications, which can be used by individual surgeons, teams or for multicentre studies. A website is under construction with easy access to all the definitions, classifications and own statistics and results from the database.

Interpretation of results

An online platform for registration and outcome measurement of mesh application with clear definitions and classifications is offered to the urogynecological community.

Central registers are therefore the future instrument to provide the surgeon in a cost-effective and timely manner with the information for a responsible and individualized preoperative selection of the operation technique and product.

Concluding message

It is hoped that this registry could lead to better evidence-based guidelines for application of meshes for POP and SUI repair based on preoperative evaluation, patient variables, available materials and techniques. A consecutive European register for Urogynecological implants is planned after successful implementation in Germany.

References

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Disclosures

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