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NATIONAL REGISTRY OF UROGYNECOLOGICAL PROCEDURES INVOLVING IMPLANT IN THE YEAR 2009

Hypothesis / aims of study

The aim of this project is to report the outcomes of the National Registry of all urogynecological procedures involving implants in our country during the year 2009. We set two main objectives – to map a spectrum of used implants and to study complication rates.

New urogynecological mesh implantation techniques gained very quickly popularity arising probably from an extreme success of Tension Free Vaginal Tape (TVT). Uncontrolled implantation of many different kinds and modifications of original TVT, and moreover, implantation of disparate meshes in order to treat pelvic organ prolapse brings urgent need of feedback. Of course, we accept the significance of randomized controlled trials and other evidence based sources of data but we do think also Registers can bring valuable data due to their completely different point of view and particularly their coverage of near all cases and not only specific cases enrolled into clinical trials.

Study design, materials and methods

Methods are determined by the design of the Registry and correspond to a retrospective registry analysis. We submit the year 2009 outcomes of the national registry established in our 10 million population country. This Registry is designed solely for the field of Urogynecology and is aimed to cover all surgical procedures involving implantation of the artificial material, no matter the indication – both female urinary incontinence and pelvic organ prolapse. Registry was introduced and has been kept by the National Urogynecological Association. Cooperation with the Registry is not mandatory by law in our country but we ask all Centres involved in Urogynecology for cooperation every year.

Results

25 centres reported their year 2009 results to our registry. 2565 implants were used – 2033 (i.e. 79%) were intended to treat female stress urinary incontinence and 532 (i.e. 21%) were indicated for the pelvic organ prolapsed treatment. These numbers represent a considerable proportion of all implants sold in our region – in stress urinary incontinence we seem to cover at least two thirds of all implants and in pelvic organ prolapse treatment it seems to be more than 80%.

Predominant implant for female stress urinary incontinence is midurethral sling - 1977 midurethral slings versus 56 paraurethral bulking agent implantations. Midurethral slings were mainly transobturator tapes; retropubic trajectory was used just in 70 cases (i.e. 3,5% of all tapes), transobturator way was chosen in 1715 females (i.e. 86,7%) and 192 patients underwent single incision sling (i.e. 9,7%). Compared to the year 2008 this represents decrease in retropubic tapes (6,3% of all tapes in the year 2008) and increase in single incision slings (7,4% of all tapes in the year 2008). Pelvic organ prolapse is mainly treated using fixed synthetic meshes – 525 (i.e. 98,7%) synthetic versus 7 (i.e. 1,3%) biologic meshes; and 503 (i.e. 94,6%) fixed versus 27 (i.e. 5,1%) free meshes.

Complication rate reported by cooperating centres is surprisingly low compared to the generally accepted numbers of complication rates but this is fate of all registers. No death was reported in connection with mesh implantation. Declared intra-operative complication rate was below 1%, most often due to excessive bleeding. Early post-operative complications mainly comprise of delayed spontaneous micturition restoration and urinary tract infections – altogether representing 2,5% of all cases. Long term post-operative complications were declared in 5,5% of all operated cases – most commonly reported are failure to treat, vaginal protrusions of mesh and de novo urgencies.

Interpretation of results

Mesh implantation techniques in urogynecology are gaining popularity. Transobturator tape remains local mainstay of urogynecological implants.

Complication rate reported by cooperating centres is considerably low compared to the generally accepted numbers of complication rates but this is a usual bias of all registers, especially in their early years.

Concluding message

We do think Registries are very valuable source of medical knowledge and their sense is undoubted, mainly in the task of newly introduced treatment methods.

Specify source of funding or grant	**Not applicable.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**

This study did not require ethics committee approval because	**This is not study - it is National Registry.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**