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NATIONAL REGISTRY OF UROGYNECOLOGICAL PROCEDURES INVOLVING IMPLANT DURING YEARS 2007 - 2010

Hypothesis / aims of study

The aim of this project is to report the outcomes of the National Registry of all urogynecological procedures involving implant in our country. We set two main objectives – to map a spectrum of used implants and to study complication rates. [1,2]

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. [3] 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 outcomes of the national registry of the years 2007 – 2010 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

27 centres reported their year 2010 results to our registry. 3086 implants were used – 2409 (i.e. 78%) were intended to treat female stress urinary incontinence and 677 (i.e. 22%) were indicated for the pelvic organ prolapse 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 - 2325 midurethral slings versus 84 periurethral implants (bulking agents) implantations. Midurethral slings were mainly transobturator tapes; retropubic trajectory was used just in 125 cases (i.e. 5,2% of all tapes), transobturator way was chosen in 1929 females (i.e. 80,1%) and 271 patients underwent single incision sling (i.e. 11,3%). In comparison with previous years 2007, 2008 and 2009 this represents a steady rule of transobturator tape trajectory. On the other hand there are some significant changes in popularity of retropubic tape, single incision slings and periurethral implants during these years. Periurethral implants were not virtually used during the years 2007 – 2008 and their popularity arose in years 2009 and 2010 (sharing 3,5% of all anti-incontinence implants in 2010). Both retropubic tapes and single incision slings went through the decrease period followed by comeback. In case of single incision slings this was probably due to the disillusion from the first kind of single incision sling followed by restoration of confidence thanks to the newly designed single incision slings. Details on different kinds of anti-incontinence implants through the years 2007 – 2010 are shown in Table 1.

| Year | Total number of anti-incontinence procedures involving implant | Retropubic midurethral slings | Transobturator midurethral slings | Single incision slings | Periurethral implants (bulking agents) |
|------|--|-------------------------------|-----------------------------------|------------------------|--|
| 2007 | 2232 (100%) | 179 (8,02%) | 1701 (76,21%) | 346 (15,50%) | 6 (0,27%) |
| 2008 | 1536 (100%) | 97 (6,32%) | 1325 (86,26%) | 114 (7,42%) | 7 (0,46%) |
| 2009 | 2033 (100%) | 70 (3,44%) | 1715 (84,36%) | 192 (9,44%) | 56 (2,75%) |
| 2010 | 2409 (100%) | 125 (5,19%) | 1929 (80,07%) | 271 (11,25%) | 84 (3,49%) |

Table 1: Share of different kinds of anti-incontinence implants through the years 2007 – 2010

Pelvic organ prolapse was mainly treated using fixed synthetic meshes during whole period. In 2010 centres reported 672 (i.e. 99,3%) synthetic versus 5 (i.e. 0,7%) biologic meshes; and 578 (i.e. 85,4%) fixed versus 99 (i.e. 14,6%) free meshes. Two main trends in treatment of pelvic organ prolapse with implant were shown in our Registry during the years 2007 – 2010. Firstly, local

loss of interest in biologic grafts was documented; and secondly, comeback of free mesh technique was demonstrated in the year 2010.

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 during the years 2007 - 2010. Declared intra-operative complication rate was around 1% in all the reported years, most often due to excessive bleeding. Early post-operative complications always comprise mainly of delayed spontaneous micturition restoration and urinary tract infections – altogether representing between 2,5% and 5,0% of all cases. Long term post-operative complications were declared in between 3,9% and 6,8% 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.

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