**THE TREATMENT OF FEMALE URINARY INCONTINENCE USING IVS TECHNIQUE**

**(INTRA-VAGINAL SLINGPLASTY)**

**DOCTORAL DEGREE THESIS**

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**Objectives:** Evaluation of IVS (Intra-Vaginal Slingplasty) procedure used in the treatment of female urinary incontinence using objective (based on clinical post-operative examination) and subjective criteria (using Quality-of-Life Questionnaire measures) and calculation of patients’ satisfaction level who had undergone such a procedure. This work is a retrospective study analysing and comparing our findings on different levels (efficiency, advantages, disadvantages, complications, etc.) with data from literature.

**Material and Method:** Our study includes 84 patients undergoing IVS procedure during the period of September 2003 - February 2008 in the Gynecological Department of the Regional Clinical Emergency Hospital in Tîrgu-Mureş. The diagnosis was established based on attentive anamnesis, clinical examination and urodynamic exploration used in 27 cases (32%), especially in recurrences or 2nd and 3rd degree of urinary incontinence. The mean age of patients’ was 52 (with limits between 33 and 79). There were 46 cases in menopause period (55%) and 38 cases in genital activity (45%). Most of the patients were multiparous (75%) and had a severe urinary incontinence of 2nd or 3rd degree (83%). The presence of 1st or 2nd degree genital prolaps (with different forms) was present in 58 cases (69%). IVS Technique was associated in 12 cases (14,5%) with other operations, of which 9 simultaneous plastical procedures. There were 20 cases of recurrent urinary incontinence (23,8%). The type of the anesthesia used was the following: 72 epidural anesthesia (85,7%), 8 spinal anesthesia (9,5%), 4 general anesthesia (4,8%). Most of the patients (71 cases - 84,5%) underwent antibiottical prophylactic treatment during and in the post operatory period, for 3 days. Our objective evaluation method is based on clinical examination performed by doctors, establishing a severity scale of incontinence: the complete cure (the success of the operation) was defined by the absence of any urinary leakage evaluated by post-operative examinations or during some efforts; the improvement was defined by the significant reduction of urinary leakages which, by their minimal quantities, made that the patients did not wish for a supplementary therapy; the failure was defined by the presence of an important urinary leakage, in quantities identical or increased than the time prior to the operation. For the subjective evaluation of our results we used the Questionnaires’ method. The questionnaires used in this study represent an original concept including 17 main questions which can be found in most of similar quality-of-life questionnaires used in literature. There are 6 major questions which guide us to the final result of the evaluation. For each patient we calculated a general score: subjectively cured (success), subjectively improved and subjective failure. We also calculated the global subjective success rate which includes the 2 first categories. We compared the subjective results with the objective findings in order to establish the correspondence between the both. We then compared our subjective and objective cure rates with those published in literature. Our results were then compared to the results of other different surgical procedures used in the treatment of stress urinary incontinence, especially Burch operation (by laparotomy or laparoscopy), the sub-urethral plications or other sling procedures. We analysed and compared in detail our results in terms of complications and their occurrence, etiological factors and prophylactic methods and various treatments of these complications.

**Results:** The mean follow-up period was 24,6 months (with limits between 5-58 months). **Subjective results:** the subjective cure rate was 79,8 % (67cases), the subjective improvement rate was 8,3% (7 cases), the global success rate was 88,1% (74 cases). We had 10 cases considered failures which represent a percentage of 11,9 %. **Objective results:** the objective cure rate was 78,6% (66 cases), the improvement rate was 11,9% (10 cases) and the global objective success rate was 90,5% (76 cases). We had 8 cases considered objective failures which represent 9,5%. The total number of complications was 11 cases representing a percentage of 13,09%. Of all these complications, 9 occurred in the first half of 42 patients and the other 2, in the second half of 42 patients. The mean period of keeping the urinary Foley catheter was 1,6 days (39H), with limits between 1 and 14 days. The mean operatory time was 35,6 minutes, with limits between 10 and 95 minutes. The mean hospitalisation time was 5,6 days, with limits between 3 and 16 days. The postoperative urinary bladder rehabilitation was used in 8 cases (9,5%).

**Discussions:** Our global objective results of 90,5% is perfectly similar to those from literature (which vary between 79 and 100%). Our global subjective results of 88,1% are also similar to those from other studies, between 82 and 100% (insignificant differences, p> 0,05). It is worth mentioning that from the total of 44 studies used as terms of comparison, 23 had shorter follow-up periods than our study. In literature there are already studies with 5 years follow-up periods. In general, the short term success rate is between 80 and 90%, and on long terms is of 84,7% (Nilsson). In our study we had 10 cases of subjective failures (11,9%) and 8 cases of objective failures (9,5%). We don’t believe that their cause could be the insufficient pulling force of the extremities of the tape. The comparisons with other techniques used in the treatment of stress urinary incontinence (Burch and other) underline a superior success rate of the IVS procedure, besides other numerous advantages, like: shorter operatory time, shorter hospitalization and convalescence periods, fewer complications and reinventions. **Discussions on the surgical indications:** in the recurrences after surgery incontinence our results are slightly inferior (80-85%) to those of pure stress urinary incontinence (89-94%), but they remain similar to the values from literature. We did not use this technique in the cases of mixt urinary incontinence or ISD (intrinsic sphincter deficiencies). Our results in the cases where the IVS procedure was associated with the cure of genital prolaps (the global success rate of 89%) are almost identical with those cases without simultaneous plastically operations (88%).
In our study we performed 72 satisfactory epidural anesthesia (85.7%). There weren’t any local anesthesia in our study. It seems that the type of anesthesia does not influence the results of this procedure. In elderly patients, we had an objective cure rate of 75% (12 out of 16 cases), slightly inferior to that of under 60 years old patients (79.4% - 54 out of 68 cases). In the obese patients we also obtained good results: in 8 cases the evolution was satisfactory, 7 of them being considered objectively and subjectively cured and 1 who was improved. One of the major factors on which depends the efficacy of the procedure is the surgical experience. We divided our patients in 2 equal subgroups of 45 patients: the 1st subgroup of prior 42 and the 2nd subgroup of the last 42. In the 1st subgroup we had an inferior global objective success rate compared to the 2nd subgroup (83% versus 98%). In the 1st subgroup we had 7 failures and only 1 in the 2nd subgroup (17% vs. 2.4%). Although these values show a real difference, the statistical estimation is irrelevant. We can draw the same conclusions by analyzing the subjective results. The number of complications was also higher in the 1st subgroup (21.4%) compared to the 2nd subgroup (4.8%), but this difference is also statistically irrelevant (p=0.3867). In the 2nd subgroup we had no intraoperative complication. We had 3 bladder perforations which all occurred in the 1st subgroup (the p value could not be calculated because of the 0 value in the 2nd subgroup). In the 2nd subgroup we had a smaller hospitalization time, of less than 4 days (this difference being in this case, significant). The operative time was also inferior in the 2nd subgroup (a mean of 35.3 minutes vs. 36.2 minutes), this difference being irrelevant. In literature most authors treat this matter, stating clearly of the so-called learning curve.

**Complications:** The total number of complications was 11, which are 13%. They all occurred in the 1st 47 cases. The following 37 operated patients did not present any intra- or post-operative complications. Our values are perfectly similar to those from literature, being closer to the most inferior values. The subjective cure rate in the patients with intra- or post operative complications was 36.4%, compared to 86% in the group without complications. These difference is statistically very significant (p = 0.000868). The results are also significant concerning the objective cure rate (36.4% versus 85%) (p=0.001348). **Bladder perforation:** we had 3 bladder perforations (3.6%) out of which 2 were identified during operation. The 3rd case was identified after operation and was considered and included in the subgroup of bladder erosions. In the majority of published studies the bladder perforations did not modify the procedure itself. It does not need to be considered a real bladder wound. Once identified, one has to take out the IVS Tunneller or the tape and to reinsert it using a lateral direction angle and maintaining the tip of the trocar in permanent contact with the posterior face of the pubis. In our study we did not have other intraoperative complications as bleeding by hemorrhagic dissections, major vascular lesions (external iliac vessels, femoral vessels, and epigastric vessels), urethral lesions, intestinal lesions, ilio-pectineal ligament lesions, perforation of parietal peritoneum, vaginal peroration). We had only 1 case of seroma in the Retzius space (1.2%), of 3 cm diameter, which was diagnosed by ultrasounds 3 months after operation and was immediately drained out. We had no case of real parietal hematoma. Our percentage of this complication (1.2%) is perfectly similar to those found in literature. We had 3 cases of vaginal erosion (3.5%) out of which 1 was a double complication (including obstructive syndrome). Our percentage is perfectly similar to those published in literature (varying between 0.3% and 23%) and in this respect we do not consider that the multifilament tape can increase the risks of this complication. It is more likely, in our opinion, a surgical deficiency in the suture of the vagina. We had 1 case (1.2%) of urethral erosion characterized by dysuria, recurrent urinary infections and obstructive syndrome with complete urine retention. Our conduct was a complex one. The urethral erosions are linked to too tight a tape, an abrasive action on the urethral mucosa, by the repetitive erosive effect of the tape. Their reported frequency varies from 0.07% to 4.5%. We had 1 case of bladder erosion (1.2%) in one case of a patient with recurrent 3rd degree stress urinary incontinence, who previously had a vaginal plastic operation with Marion-Kelly sub-urethral plication. The perforation occurred on the left side and was not diagnosed during operation. Due to the early hematuria after operation we performed a cistoscopy which showed the aspect of “transfixiant intravesical tape”. We did a cistoscopic excision of the intravesical portion of the tape and subsequently the immediate evolution was favorable. We had 3 cases of “de novo overactive bladder” (3.5%) which were successfully treated by specific antimuscarinics medicines. Their frequency varies a lot in literature, from 2.3 % up to 25.9%. We had 1 case of subvesical obstruction in which in the 1st step we did an early vaginal relaxation of the tape (the 3rd postoperative day), successfully with reestablishment of the micturition. 6 months after this a vaginal erosion occurred with exteriorization of the tape and we had to practice the resection of this portion, with subsequent favorable evolution. The values in literature regarding this complication vary from 2 to 6%. This is in fact the most frequent post-operative complication of all slings. There is no concern regarding the treatment of the complete obstruction syndrome. There may occur other post operative complications (of which we did not have): chronic urinary infections (0-22%), postoperative pain syndrome (2-5%), suprapubic discomfort (7.5%), minor micturition difficulties, sexual complications (variable frequency).

**Conclusions:** In terms of efficiency we obtained a cure rate, an improvement rate and a global success rate considered satisfactory, perfectly similar to those published in literature. Our results were also competitive in the following cases: recurrent urinary incontinence, patients with genital 1st and 2nd degree of prolapses, obese patients or elderly patients over 60 years of age. Our failure rate was inferior and was statistically correlated with the intra or post-operative complication rate, which suggests that by avoiding these complications one obtains a decrease of the risk of post-operative incontinence recurrence. Most of our operations were performed under loco-regional anesthesia which fully satisfied both the doctor and the patients. The need to acquire a surgical experience with this procedure is a major factor of the success and it plays its part both in the rate of complications as well as in the global success rates of this operation. The mean follow-up period in our study, of 2 years, can be considered satisfactory, even if there are studies of 5 years follow-up, which showed a very small deterioration of success values in time. Even if the IVS Tunneller is distributed in Romania at the price of 376 Euros, its multiple advantages make out of the IVS procedure a technique with very good rate between price and efficiency, superior to that of previous sling or colposuspension techniques by laparotomy or laparoscopy.