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SPECIAL CONTRIBUTION

Creating a gold standard surgical procedure: the development and implementation of TVT

Ulf Ulmsten Memorial Lecture 2014

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The last two decades have witnessed a launch of new surgical procedures, utilizing kits and synthetic materials, at a pace not formerly seen. Some launches have been preceded by thorough clinical documentation and others not. Any innovation, be it a theory or a treatment concept, is only fantasy until it has been tested and clinically documented.

Within the field of surgical management of female stress urinary incontinence the presentation of the mid-urethral theory (a part of the integral theory [1]) implied a paradigm shift of understanding the mechanism of stress incontinence. The theory relied on discoveries and ideas presented between the 1950s and the 1980s by several clinicians such as Axel Ingelman-Sundberg [2], Robert F. Zacharin [3, 4], and Ulf Ulmsten [5–7] just to mention a few. The theory was put into practice by a team led by Professor Ulf Ulmsten by developing a new minimally invasive, ambulatory, standardized surgical procedure to be named the tension-free vaginal tape (TVT) at the time of launch in Europe at the end of 1997 and in the USA at the end of 1998.

Several modifications of a procedure were tested before arriving at the final one, which included the use of a monofilament polypropylene tape with a mesh structure and a pore size of> 75 μm. Once the procedure was finalized, the first prospective clinical trial was conducted at the Department of Obstetrics and Gynecology of the University Hospital of Uppsala, Sweden, the chairman of which was Professor Ulmsten. The trial included 75 primary cases of stress urinary incontinence and were followed for 24 months. The results published in 1996 were very encouraging [8] and prompted further prospective clinical trials conducted in normal clinical settings. At this stage it was decided to follow the same study protocol in all the trials to come.

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The pre- and postoperative evaluations were to include urodynamic testing, a cough stress test, a 24-h pad weighing test, a 2-day voiding diary, residual urine measurement, urine analysis, pelvic examination, and as a quality of life measure a visual analog scale (VAS) on the bother caused by urinary symptoms. It was also decided on the criteria of cure and improvement. To be regarded cured a patient should have a negative stress test and negative pad test, be continent in postoperative urodynamics, and score less than 10 on the VAS, where 0 represents no urinary problems whatsoever and 100 unbearable urinary symptoms. Improvement required a negative stress test, a significant reduction of leakage on the 24-h pad test, and a≥70 % improvement of the individual VAS score. All other cases were regarded as failures.

A multicenter trial including six clinics in Finland and Sweden enrolled 130 primary cases of stress incontinence, who were followed for a minimum of 12 months, showed the same high rate of success as the initial trial. This study was published in 1998 [9], but the results were available to the investigators at the beginning of the year before. The results of trials with a follow-up of 4 years on women suffering from recurrent stress incontinence, intrinsic sphincter deficiency, and mixed urinary incontinence were published in 2001, once again with excellent cure rates [10–12]. Already in the year 2000 5-year follow-up results were available and published in June 2001 showing an overall cure rate of 85 % according to the abovementioned criteria [13] (Table 1). Two independent studies with a 3-year follow-up were published in 1999 [14, 15] revealing the same high success rates as the earlier studies. Today we have the results of a 17-year follow-up period on the performance of the TVT procedure, which shows that no decline in cure rate develops through the years and that no late onset problems occur with the polypropylene tape used in these by now rather elderly women [16].

The most common complication of the traditional incontinence operations has been persistent or recurrent stress incontinence and for the most invasive procedures all the

Table 1 Number of patients, time of follow-up, and cure rate in early clinical trials with the TVT procedure

Patient group		No. of pat.	Follow-up (months)	Cure rate
Primary cases	Ulmsten et al. (1996), first prospective trial	75	24	84 %
Primary cases	Ulmsten et al. (1998), first multicenter trial	131	12	91 %
Unselected patients	Nilsson et al. (2001)	161	24	87 %
Mixed incontinence	Rezapour et al. (2001)	80	48	85 %
ISD cases	Rezapour et al. (2001)	49	48	74 %
Recurrent cases	Kuuva et al. (2003)	51	24	88 %
Primary cases	Nilsson et al. (2001), 5 years follow-up	90	60	85 %

ISD intrinsic sphincter deficiency

complications associated with major surgery. The minimal invasiveness of the TVT procedure and the idea of performing the operation under local anesthesia was aimed at reducing the risk of complications. Utilizing local anesthesia allowed an intraoperative cough stress test to be performed, the purpose of which was explicitly to avoid postoperative voiding problems. Training was thought to be a key to success of performance of the operation and the procedure was therefore carefully standardized to facilitate training.

An excellent opportunity to introduce the TVT procedure in Finland through a systematic training program including all clinics in the country, which performed incontinence surgery, was captured as one of the participants in the clinical development of the TVT operation was responsible for incontinence care in the largest University Hospital in Finland. A representative of every hospital surgically treating stress incontinence was invited to the University Hospital in Helsinki to participate in a training program, which included theoretical training (the importance of focusing on the mid-urethra and not the bladder neck), surgical training, and a follow-up program. Depending upon the earlier experience of the invited surgeons each doctor had to attend two to eight TVT operations, assist in two to four TVT operations, and finally perform two to three TVT operations under supervision. A certificate to perform the TVT operation on their own was awarded to those who successfully participated in the training. A deal with the provider of the TVT kit in Finland was made that only certified surgeons could obtain the TVT kits for clinical use.

Table 2 Rate of complications in a nationwide registry since introduction of the TVT procedure in Finland [17]

Complication	Rate
No. of patients: 1,455	
Bladder perforation	3.7 %
Urethral lesion	0.07 %
Bleeding>200 ml	1.9 %
Retropubic hematoma	1.9 %
Vascular injury	0.07 %
Nerve injury	0.07 %
Bowel injury	0.0 %

The follow-up program included in the training called for registering any kind of intra- or postoperative complications and follow-up visits. This prospective program would thus include the learning curve of every single surgeon performing the TVT procedure. The results of this program were published in 2002. It included all 1,455 TVT procedures performed in the country by the end of 1999. Astonishingly low rates of complications were found, the rate of bladder injury for instance being only 3.8 % [17] (Table 2).

The TVT procedure, being the first minimally invasive surgical operation relying on the mid-urethra theory and utilizing a type 1 synthetic mesh as the tape material, was thoroughly studied and the results were documented before the procedure was offered for common clinical use. The results have furthermore been published in well-renowned peer-reviewed international journals many of them well ahead of launch of the procedure.

Recent history includes the launch and withdrawal of many modifications and copies of the TVT procedure, which shows that any variation of a procedure needs its own thorough clinical testing before it can be accepted for common use. The surprisingly high rates of complications like bladder perforation and postoperative voiding problems seen in more recent reports compared to the rates seen in the initial ones from the Nordic countries emphasizes the need for proper training and adherence to the standardized performance of the operation in order to avoid complications and poorer performance. It is a waste of both public and private resources to launch poorly documented new treatment concepts and it is especially wrong towards the women suffering from stress urinary incontinence to become subjects of experimental efforts without ethical approval and written informed consent.

Conflicts of interest None.

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