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A COST-EFFECTIVENESS ANALYSIS OF TENSION-FREE VAGINAL TAPE PROCEDURE VS. LAPAROSCOPIC MESH COLPOSUSPENSION FOR PRIMARY FEMALE STRESS INCONTINENCE – A RANDOMISED CLINICAL TRIAL

Hypothesis / aims of study

The purpose of the study was to evaluate the cost-effectiveness (c-e) of tension-free vaginal tape procedure (TVT) and laparoscopic mesh colposuspension with staples (LC) for the treatment of primary female stress urinary incontinence (SUI).

Study design, materials and methods

During the study period (April 1999 and April 2001) the cost data of the two procedures was collected from one of the central hospitals participating in the study. All costs are expressed in Euros (€). A multi-centre randomised clinical trial (4 university teaching hospitals, 2 central hospitals), which was originally planned to compare the two procedures in terms of clinical efficacy and complications, produced the data of 121 patients which were operated due to SUI. SUI was confirmed with urodynamics before entering into the study. The patients were randomly allocated in two treatment groups: 1. TVT group (n=70) and 2. LC group (n=51). A block randomisation was used and the size of the block was 40 patients for each participating centre. The main outcome measures for clinical trial were negative stress test result and negative 48-hour pad test (<8g / 48h). Secondary outcome measures were changes in VAS (0=no bother of SUI; 10=maximal bother of SUI), Urinary Incontinence Severity Score, UISS (a disease specific QoL questionnaire: 0= no impairment of QoL; 20= maximal impairment of QoL) and in King's Health Questionnaire.

Only true costs were calculated and not those charged by the hospital. All additional costs of operations and treatments during a follow-up period of one year were registered and entered to a database. Incremental c-e-ratios were calculated for three parameters: total costs including sick leave, VAS and UISS. To deal with the uncertainty of mean values of point estimates, a bootstrap replica technique was used.

Results

The total procedural costs were €485.4 for TVT and €461.9 for LC. The average hospital costs were €694.7 for TVT (hospital stay 0.7 days) and €1000.1 for LC (hospital stay 1.8 days). The need for sick leave was 15 days in the TVT group and 24 days in the LC group.

Incremental c-e-values are given in Table 1.

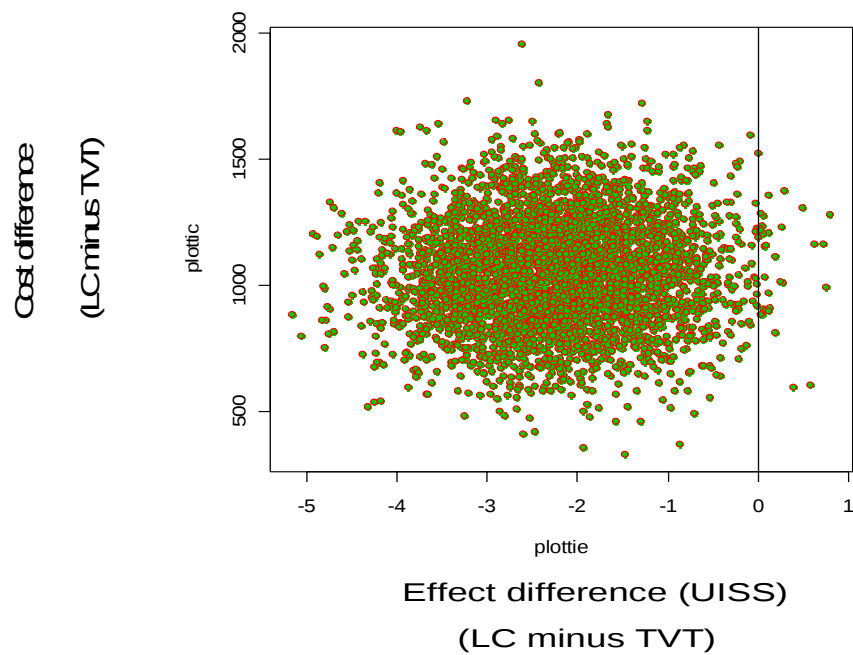
Table 1. Incremental c-e-values for total costs, VAS and UISS – LC minus TVT

	TVT	LC	Incremental value
Total costs (€)	2090	3230	1140
Change in VAS (0-10)	-6.3	-4.4	-1.9
Change in UISS (0-20)	-10.6	-8.6	-2.1

Fig 1 provides a graphical representation as an example of a bootstrap analysis after 4000 replica data for UISS generated from the original data. A simple visual inspection shows that simulated point estimates fall completely over the horizontal axis and almost all of them fall

left of the vertical line on the UISS axis. In other words – LC is more costly to perform and gives poorer outcome in terms of the UISS than the TVT.

Fig 1. Bootstrap replications (n=4000) of mean differences in costs and UISS generated from the trial data



Interpretation of results

LC is more costly to perform than TVT. It also gives poorer subjective outcome measured by VAS and UISS than TVT.

Concluding message

The results of this study suggest that TVT is a cost-effective alternative for LC – at least for one-year – in the treatment for SUI.