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META-ANALYSIS OF THE OUTCOMES OF TENSION FREE VAGINAL TAPE VS. TRANSOBTURATOR TAPE PROCEDURES IN RANDOMIZED CONTROLLED TRIALS

Hypothesis / aims of study
The aim of this study is to report on a meta-analysis incorporating the most recent evidence from randomized controlled trials on the cure rates, complications and quality of life measures of tension free vaginal tape versus transobturator tape procedures for stress urinary incontinence in females

Study design, materials and methods
Eligible studies were selected through an electronic search of Pubmed, Ovid medline, Embase, Cochrane Collaboration, Web of science and the MetaRegister of controlled trials databases from 1996 to December 2009. A manual search of citation lists and bibliographies of articles, as well as abstracts from international meetings (2007-2009) including the International Continence Society, International Urogynecology Association and the American Urogynecology Society was performed. Two investigators independently reviewed all studies to assess methodological quality and inclusion criteria. Lead authors of selected studies and abstracts were contacted to clarify randomization or to identify unpublished research.
Eligible studies were 1) Randomized controlled trials comparing tension free vaginal retropubic and transobturator tape procedures, 2) At least one objective or subjective outcome measure described 3) Type of incontinence described, 4) Minimum 12 month follow-up data available, 5) Published as an article or abstract 6) Original data only, 7) Tension-free vaginal tape with or without concomitant pelvic surgery. A fixed effect model will be used to calculate summary relative risk estimates and 95 CI. Study criteria excluded non-randomized or quazi-randomized trials as well as non-English studies.

Results
This meta-analysis was carried out according to a predetermined protocol following the recommendations of the quality of reporting meta-analysis (QUOROM) statement.
Following a complete search, 49 papers were deemed eligible for complete review, of which 14 were included in the analysis. Ten studies were excluded for lack of 1 year data, 23 for non- or quazi randomization and 2 for duplicate data. Two of 9 abstracts met inclusion criteria and had sufficient data to analyze. Descriptive analysis will be used for population characteristics including the influence of age, parity, body mass index, menopausal status, concomitant pelvic surgery, indication for incontinence surgery, pre-operative assessment of incontinence and pre- and post-operative Quality of Life measures. Incontinence surgery outcomes measures will be described using a fixed effect model.These include: Objective measures (the cough test, 1 hour pad test, voiding diary or urodynamic investigation) and subjective measures (patient reporting at interview or symptom questionnaires). Changes in Quality of life measures pre- and post-operatively, extracted from UDI-6 and II Q-7 questionnaires will also be plotted. Post-operative complications including mesh erosion rates, pelvic pain and voiding dysfunction will also be compared with a fixed effect model.

Interpretation of results
Results will be presented at the meeting using Forest Plots to describe the relative risk ratios.

Concluding message
Tension-free vaginal tapes are the first line treatment for female stress urinary incontinence.
It is important to gather the best evidence to make appropriate clinical decisions. A meta-analysis is able to provide this evidence. As new studies are conducted, it adds to a growing body of evidence about the merits of the tension free vaginal tape and the transobturator tape.

Specify source of funding or grant	**None**
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	**Meta-analysis of controlled trials**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**it was a meta-analysis and the Declaration is not applicable**
Was informed consent obtained from the patients?	**No**