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EFFICACY AND SAFETY OF TRANSBTURATOR TAPE (OBTRYX™) IN WOMEN WITH STRESS URINARY INCONTINENCE AND INTRINSIC SPHINCTER DEFICIENCY: RESULTS FROM INTERNATIONAL OBTRYX™ REGISTRY

Hypothesis / aims of study

To date three European registries have been conducted on the standard Tension-free vaginal tape (TVT) procedure for Stress Urinary Incontinence and four on the TOT procedure. The previous registries were national registries and not international as in the TOT - obtryx™ registry. 57 participants from 7 countries (UK, France, Italy, South Africa, Australia, Finland & Spain) contributed to this registry. There is scarce information available on the efficacy of TOT on women with ISD and Non-ISD. Our aim is to compare the efficacy of transobturator tape-TOT (Obtryx™) in the treatment of stress urinary incontinence in women with intrinsic sphincter deficiency (ISD) and non-ISD.

Study design, materials and methods

Two hundred and twenty two women diagnosed with urodynamic stress incontinence were enrolled into this study. Intrinsic Sphincter Deficiency was defined as either a Maximum Urethral Closure Pressure (MUCP) of 20cm H_2O and/or a pressure rise from baseline required to cause incontinence (Valsalva leak point pressure-VLPP) of 60 cm H_2O or less. Based upon the above criteria, 75 women (33.8%) were in the ISD group and 147 (66.2%) were in the Non-ISD group.

Objective healing was defined when physical examination of the patient with the full bladder yielded a negative stress test, while subjective healing was assessed with patient perception of improvement in symptoms (dry, significantly improved, slightly improved, same, worse).The primary outcome was the presence or absence of stress incontinence at 3 months and 12 months postoperatively. Secondary outcomes were the rate of operative complications such as Haemorrhage, perforation of the bladder, urethra, and the vagina.

Results

Table 1. Demography

Variable	Age	BMI
	Mean±SD	Mean±SD
ISD	59.68±11.06	26.22±4.86
Non-ISD	60.8±11.2	26.63±5.11
P value	0.367	0.382

Of the 222 women in this study, 46/147(31%) in Non-ISD group had urgency along with stress urinary incontinence whereas 25/75 (33.3%) in ISD group had urgency along with stress urinary incontinence (p=0.92)

Table 2. Complications

Variable	ISD	Non-ISD	P value
Haemorrhage	3/75 (4%)	8/147 (5.4%)	0.68
Bladder perforation	1/75 (1.3%)	0	0.15
Vaginal perforation	0	2/147 (1.3%)	0.3

Table 3. Objective and subjective cure rates

	At 3 months follow up			At 1 year follow up		
Subgroup	Total	Stress test negative	Subjectively dry or significantly improved	Total	Stress test negative	Subjectively dry or significantly improved
ISD	66	65(98%)	63(95%)	43	40(93%)	40 (93%)
Non-ISD	126	123(97%)	121(96%)	92	84(91%)	84(91%)
P value	<0.05	0.59	0.56	<0.05	0.53	0.53

At 3 month follow up, of the 192/222 (86.4%) women assessed at the clinics, 1/66 (2%) in ISD group had shown stress incontinence at cough stress test on full bladder and in the Non-ISD group 3/126 (2.4%) had SUI (χ^2 =1.13; p= 0.59). At 12 months, 135/222 (61%) completed the followup.43/135 (31.85%) were in ISD group and 92/135 (68.15%) belong to Non ISD group. 8/92 (8.7%) in Non-ISD group had shown SUI and 3/43 (7%) developed SUI (χ^2 = 1.23; p=0.53).

Interpretation of results

In this registry, patients were recruited from seven different countries when compared to the other studies which are essentially single-centre studies (1, 2). In the study 2, of the 138 patients assessed at 6 months with urodynamic studies, 14 of 67 (21%) had urodynamic stress incontinence in the TVT group compared with 32 of 71 (45%) in the transobturator tape group (P=.004), with nine women in the transobturator tape group having repeat sling surgery compared with none in the TVT group. Our study contradicts this and there is no statistical difference in success rate between these two groups. The only limitation in our study is that it is not a randomised trial when compared to the study 2.

Concluding message

From this international registry, the transobturator tape procedure is effective and safe in women with urodynamic stress urinary incontinence with Intrinsic Sphincter Deficiency.

References

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Specify source of funding or grant	**This international Registry is supported by an unconditional education grant from Boston Scientific. Data is blinded to the company.**
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 eithics committee approval because	**It was a multinational registry and in all of these countries, this procedure has been approved.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**