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COMPLICATIONS ASSOCIATED WITH TRANS-OBTURATOR SLING PROCEDURES

Hypothesis / aims of study
To determine the number of complications associated with trans-obturator slings as reported to a national database

Study design, materials and methods
We queried the Manufacturer and User Facility Device Experience Database, "MAUDE", a FDA maintained database that collects physician initiated reports of complications associated with medical devices. We used the following terms: "Mentor and ObTape™," "Mentor and sling," "Mentor and tape," "American Medical Systems and Monarc™," "American Medical Systems and sling," "American Medical Systems and tape," "Ethicon/Gynecare and TVT™," "Ethicon/Gynecare and sling," "Ethicon/Gynecare and tape." The TVT™ search was narrowed down to include only the TVT™ obturator system reports by using the catalog number 810081. We then tabulated the results by type of complication, by date of occurrence, and by type of sling (ObTape™ by Mentor, Monarc™ by AMS, and TVT™ Obturator System by Gynecare).

Results
All three trans-obturator systems have been available in the United States since January 2004. Approximately 34,000 trans-obturator sling procedures were performed during this time. Between January, 2004 and December, 2004, 89 reports associated with trans-obturator tapes have been reported to the MAUDE database; 76 with the ObTape™, 6 with the Monarc™, and 7 with the TVT™ Obturator System. Each report was a complication, no device malfunctions were listed.

Eighty-two percent of the complications are either vaginal erosions or site-unspecified erosions. Fourteen of these erosions were associated with infections. One urethral erosion was reported.

Two bleeding complications were reported. One patient had an EBL of 650cc after an uncomplicated pass of the trocar. One patient had oozing during the procedure requiring vaginal packing. Her postoperative hemoglobin decreased from 11.1 g/dl to 6.1 g/dl.

Two cases of postoperative neuropathy were reported. One patient presented with left lateral calf numbness, left foot and posterior thigh numbness and intermittent pain at her 6 week post-operative appointment. These symptoms were controlled with medication. The other patient experienced left leg pain associated with fasciculations and a left sided gait abnormality the presented one week after her surgery. She was diagnosed with an obturator neuropathy and left posterior cutaneous nerve injury by a neurologist. Both patients continued to be symptomatic at the time of the reports.

There were 19 cases of infection. Most of these infections seemed minor; fourteen were associated with mesh erosions. One patient presented on postoperative day #1 with cellulitis at the medial wound site. She was started on intravenous antibiotics but her condition worsened. A CT scan demonstrated an air and fluid pocket in the thigh deep to the abductor muscle. The patient underwent surgical evacuation and removal of the tape. Two abscesses were noted, one extending 15cm down the thigh. Drains were placed and the patient was continued on intravenous antibiotics for 5 additional days and ultimately did well.

Bladder perforation was reported in three patients. One case documented that the bladder perforation occurred with the ObTape™ flat, curved introducer. One case was noted on routine cystoscopy while the other reports did not detail how the diagnosis was made. One case of refractory leg pain was reported. One patient experienced urinary retention after migration of her tape. Two failures were reported. One patient noted that her sling came

loose during intercourse. The second patient felt a pop and then had recurrence of her incontinence.

COMPLICATION	**TVT-Obturator System**	**AMS Monarc**	**Mentor ObTape**
EROSION			
Vaginal	0	3	31
Urethral	1	0	0
Site not specified	0	0	24
EROSION & INFECTION			
Vaginal	0	1	8
Site not specified	0	1	4
INFECTION	1	0	4
EXCESS BLEEDING	1	0	1
NEUROPATHY	2	0	0
BLADDER PERFORATION	1	0	2
PAIN	1	0	0
FAILURE	0	1	1
RETENTION	0	0	1

Interpretation of results

There is scant literature describing trans-obturator tape systems and the associated complications. The trans-obturator tape systems are associated with a low risk of morbidity. Vaginal erosions, extrusions, and wall separations are the most common complication. The TVT™ Obturator System was the only device associated with neuropathy. Bladder perforations were documented: this number likely underestimates the risk of bladder perforation as cystoscopy is not routinely performed with these procedures.

Concluding message

The three commercially available trans-obturator tape systems use different polypropylene meshes and different implantation systems. These differences may affect rates of erosion and the technical difficulty associated with correct mesh placement. There is limited data supporting the use of one mesh over another. These systems should be compared to each other and to traditional procedures to determine their merit. Post-market surveillance is important for safety monitoring of devices. All reports to MAUDE are voluntary so complications are likely underestimated when using this database. Surgeons should be encouraged to report their complications.