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Update of the Integral Theory and System for Management of Pelvic Floor Dysfunction in Females

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Abstract

Context: The 1990 integral theory (IT) stated that urinary stress and urge symptoms mainly arise (for different reasons) from lax suspensory ligaments, a consequence of altered collagen/elastin. The first surgical application of IT was repair of the pubourethral ligament (PUL), now known as tension-free vaginal tape repair. **Objective:** To update the 1990 IT to the present day (2016).

Evidence acquisition: Published data in peer-reviewed journals concerning IT evolution were evaluated.

Evidence synthesis: In its present form (2016), IT states that pelvic organ prolapse and symptoms of chronic pelvic pain and bladder and bowel dysfunction are mainly caused by laxity in five main suspensory ligaments. The IT explains cure for bladder and bowel dysfunction via the dual function of the ligaments: organ suspension and insertion points for three oppositely acting muscle forces. Lax insertion points weaken muscle forces so they cannot adequately close the urethral or anal tubes (incontinence) or evacuate them (constipation, bladder emptying), or tension the bladder and rectum sufficiently to prevent inappropriate activation of the micturition and defecation reflexes by peripheral stretch receptors (urge incontinence, tenesmus). Up to 80% cure/improvements for the above conditions have been achieved by repair of one or more damaged ligaments via precisely positioned tissue fixation system tapes: "Repair the structure (ligaments) and you will restore the function". Exactly the same operations are performed for patients with major symptoms and minimal prolapse and major prolapse with no symptoms.

Conclusions: This method can reduce costs, improve quality of life for older women, and potentially reduce admissions to nursing homes.

Patient summary: This paper introduces a new way of thinking. Many bladder and bowel symptoms not considered curable via existing methods may be caused by

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loose pelvic ligaments, and thus are potentially curable by reinforcing the ligaments. These symptoms include an inability to hold on to the bladder (urge incontinence), going frequently to pass urine during the day (frequency), getting up at night to pass urine (nocturia), involuntary soiling from the bowel, and chronic pelvic pain. These symptoms are major indications for nursing home admission. In this paper we give examples of cure of these conditions in a group of 70-yr-old Japanese women whose ligaments were strengthened using a tissue fixation system (TFS) in a very minimal way. The TFS involves insertion of a thin (7 mm wide) tape through the ligaments that support the uterus. The tape creates new collagen to strengthen damaged ligaments. The new ligaments act as efficient anchoring points for muscles that open and close the urethra and anus, so these can now function more efficiently. A minimum cure rate of 72% was achieved for all the above symptoms. The method is different from large mesh insertions. Only a thin tape is used to repair damaged ligaments. This method can reduce costs, improve quality of life for older women, and potentially reduce admissions to nursing homes.

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1. Background

The integral theory (IT) of female urinary incontinence [1] is a universal theory of pelvic organ function and dysfunction. It is a different way of thinking, consistent with Thomas Kuhn's description of a theory as "A fundamental change in the basic concepts and experimental practices of a scientific discipline" [2]. In its present form (2016), the IT states

Pelvic organ prolapse, chronic pelvic pain, and bladder and bowel dysfunction are mainly caused by lax suspensory ligaments as a result of altered collagen/elastin.

Repair the structure (ligaments) and you will restore the function.

The IT explains cure of bladder and bowel dysfunction via the dual function of the ligaments: organ suspension and insertion points for three oppositely acting muscle forces. Lax insertion points weaken muscle forces so they cannot close the urethral or anal tubes adequately (incontinence), evacuate them (constipation, bladder emptying), or tension the bladder and rectum sufficiently to prevent inappropriate activation of the micturition and defecation reflexes by peripheral stretch receptors (urge incontinence, tenesmus).

The IT predicts that all these conditions are potentially curable by repair of one or more damaged ligaments. The update has two streams, the IT and surgical practice of the IT, the IT system (ITS). Both are related. Both are critically examined in this update in relation to existing concepts and practice.

2. Methodology

We applied Karl Popper's deductive criteria [3] to the "old" paradigm (existing practices as recommended by learned societies) and the "new" ITS paradigm.

The "old" paradigm is essentially what has been defined, recommended, and practiced by learned societies, in particular the International Continence Society (ICS) [4]. According to this paradigm, bowel, bladder, and pain symptoms are major problems in up to 30% of women. The causation is essentially unknown [5-7]. Other than urinary stress incontinence (USI), such symptoms are not considered surgically curable and are major reasons for patient disability, costs to the community, and admission to nursing homes. Treatment of these conditions is fragmented, reductionist, and discipline-based (Fig. 1), employing muscular rehabilitation, targeting nerve structures and receptors (eg, electrotherapy, drugs, botox, sacral nerve stimulation) and, in extreme cases, surgical interventions such as cystoplasty, graciloplasty, and artificial sphincter insertion.

The "new" paradigm, the IT, began as an Endeavour to create a new operation for repair of USI. On the basis of experimental work in canines, a new surgical principle was established, involving the creation of an artificial neoligament [8,9] via implantation of a tape in the position of the pubourethral ligament (PUL). This principle was applied using a prototype PUL sling [10] for repair of USI and is now known as the midurethral sling or tension-free vaginal tape (TVT), and has become the standard operation to cure USI. Anomalies in the experimental data led to conceptualization of the IT. The core discovery was three oppositely acting directional forces that act against the anterior (pubourethral) and posterior (cardinal/uterosacral) ligaments (Fig. 2):

- To open and close the urethral tube;
- To prevent the stretch receptors activating the micturition reflex to cause urge incontinence and nocturia; and
- To create a "zone of critical elasticity" in the bladder neck area of the vagina that allows separate action of these oppositely acting vector forces.

As originally published in 1990, the IT was a new holistic way of thinking about the pelvic floor in which the ultimate

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