

No incision and tension-free vaginal sling for stress urinary incontinence: The role of knotless barbed suture

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A B S T R A C T

Midurethral mesh sling is the most performed incontinence procedure. This hypotheses propose knotless barbed suture could be positioned as a tension-free trans-vaginal sling under the mid-urethra without vaginal incision. Knotless suture sling support and stabilize mid-urethra when intraabdominal pressure increase. This procedure is designed to replace midurethral mesh sling operation, aiming at reducing complications. It is completed in a similar way with retropubic mesh sling procedure, and less invasive. This involve the passage of fine needle from suprapubic skin to midurethral vaginal wall, and knotless suture passing through in fine needle as a U shape. The foundational promises for this hypothesis pertain to two clinical facts: midurethral sling procedure is a gold standard treatment, and the knotless suture offer superior tissue holding or fixation strength originated from the unique barbed design.

Introduction

Stress urinary incontinence (SUI) is a worldwide prevalent disorder characterised by involuntary leakage of urine when intra-abdominal pressure rise due to laughing, coughing, sneezing, lifting or even changing position [1]. It affects about 23% of adult women mean age 56 years, and 8.5%–30.7% have obvious symptom and impaired quality of life [2–4].

During the last 20 years minimally invasive vaginal sling placed under the mid-urethra has become a gold standard surgical procedure for the surgical treatment of SUI [5,6]. Tension free vaginal tape (TVT) is a classical vaginal sling method [7]. Tension free vaginal tape-obturator (TVT-O) and other modified sling procedures have been developed to reduce possibility of complication while aiming at comparable success result [8,9]. All mesh sling procedures have same theoretical basis: stabilizing midurethral when intra-abdominal pressure increase [10]. Midurethral mesh sling has a early and sustained filling with fibrous connective tissue anchoring itself in the tissue and supporting the urethral rested on the sling [11].

Knotless suture offers super holding strength as tissue control device in the open and minimally invasive surgical applications [12,13]. The unique anchor design delivered multiple points of fixation targeted at soft tissue [14]. A broad range of unidirectional and bidirectional knotless suture are available in the clinical practice.

Hypothesis

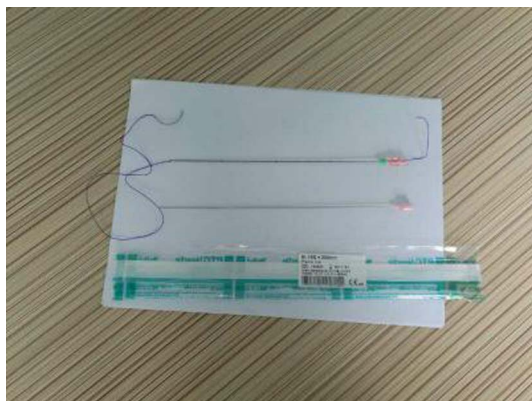
We hypothesize that knotless suture has the same supporting strength with mesh sling used in standard TVT. It keep the urethral shutting down during the intra-abdominal pressure increasing. Knotless suture anchor and fixate itself in soft tissue due to the unique barbed design. They are made to withstand high pull strength to provide strong and secure closure appropriate for high tension area such as fascia. Knotless suture could be placed under the midurethral by fine needle via a retropubic way.

The procedure is designed to be performed in a similar way of TVT. This technique involves several steps. Firstly, a top-to-bottom way of passage of fine needle from suprapubic skin (lateral of mid-line) through retropubic space and the end pelvic fascia to the midurethral vaginal wall. Secondly, the second fine needle pass from suprapubic skin to vaginal wall in same way (symmetrical points). Thirdly, one end (needle cut off) of bidirectional knotless suture pass through in the fine needle from vaginal wall to suprapubic skin (bottom-to-top). Fourthly, the other end of knotless suture pass through the subepithelial vaginal wall with needle (cut off later) to another side of midurethral. Fifthly, the other end of knotless suture (needle cut off) pass in the second fine needle from vaginal wall to suprapubic skin and finish the U turn of sling. Lastly, place the second midurethral knotless suture in the same way. It is emphasized that two points of two fine needles passing through vaginal wall are the same points knotless suture threading in

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and out vaginal wall.



We plan to place two knotless suture under the midurethral in vaginal subepithelial wall. Two U shape midurethral sling anchoring and fixating in the pelvic tissue support the closure of urethral just as the mesh tape in the TVT procedure. This procedure could be finished without skin or vaginal incisions under local anesthesia in the office.

Discussion

Many procedures for the treatment of SUI have been advocated and studied in the past 100 years. The tension-free vaginal tape procedure is the only best studied and documented surgical technology with high success rate and low overall complications [15]. TVT and other midurethral sling procedures using either retropubic or transobturator approach have become the foremost standard in the surgical treatment of SUI [16].

All the midurethral sling success is based on important theoretical evolution described as integral theory and hammock theory resulted from several anatomical studies of urinary incontinence mechanism [10]. Integral theory describe the opposite strength from pelvic muscle stretch vaginal wall against the pubic-urethral ligament, shutting the urethral off from behind [17]. Hammock theory emphasize the importance of support and constriction of urethral in the treatment of SUI. The support is provided by the layers outside the urethra on which it rests, including anterior vaginal wall, pelvic floor muscle and endopelvic fascia [18]. Midurethral sling procedure developed from those theories gain acceptance and popularity. But the complications can't be ignored. The complications are classified as intraoperative (bladder, urethra, viscus and vessel injury), immediate postoperative (voiding problem, groin pain, infection, necrotizing fasciitis), chronic problem (de novo urgency, erosion and extrusion of sling, vaginal sensory loss) [10]. Although transobturator approach designed to reduce retropubic operative complications, mesh associated complications always exist despite of the approach.

Our hypothesis propose a new midurethral sling procedure based on the same theoretical guidance. Instead of usage of synthetic mesh tape, our procedure is designed to place knotless suture under the midurethral in subepithelial vaginal wall. It is tension-free. It provide sustained holding strength originated from anchoring and fixation in the tissue. The procedure has two outstanding characteristics. One is the usage of knotless suture supporting midurethral, the other is free of any skin or vaginal incision. It is less invasive, and economic at the same time.

There are several technique advantages in knotless suture sling procedure. Firstly, less risk of injury of bladder, urethral, vessel in the

Appendixes

Figures of simplified procedure steps:

Step 1 A top-to-bottom way of passage of 2 fine needles from suprapubic skin (lateral of mid-line) through retropubic space and the end pelvic

operation due to fine needle passing through pelvic tissue (considering diameter of the trocar in TVT is 5 mm). Secondly, the absence of vaginal or suprapubic skin incision further reduce the injury of knotless suture sling procedure. Thirdly, free choice of one or two or more sling according to the assessment of urine leakage in the operation or post-operation. As an office service the procedure is convenient to be repeated for more control of incontinence in short time (months) after first attempt. So physician decide whether the second sling needed according to assessment and minimize the risk of voiding dysfunction. Fourthly, there is less risk of sling erosion or extrusion for its well histocompatibility and fine design. Lastly, knotless suture sling is economic compared with mesh sling kit.

Placing one sling (instead of a mesh) might increase the force in the urethra and paraurethral tissue for the reduced surface. Size might be a certain factor resulting sling complication. Risk factors for mesh erosion after vaginal sling for stress urinary incontinence are older age, diabetes mellitus, smoking, length of vaginal incision > 2 cm, recurrent vaginal incision for postoperative complications, and previous vaginal surgery for pelvic organ prolapse or incontinence [20]. Although the size of mesh sling is same, mesh erosion following vaginal sling procedures was found to occur more often after TOT procedures than TVT procedures [20]. The integrity of vaginal wall was emphasized to prevent mesh erosion [21].

Complications of mesh sling procedure such as bladder or vessel injury, voiding dysfunction, groin pain, erosion and extrusion of sling raise concern of United Nation Food and Drug Administration and prompt them to issue a public health notification advising against mesh sling's liberal use [19]. Our hypothesis describe the replacement of mesh sling with knotless suture sling in the midurethral sling procedure. This hypothesis is supported by two important medical facts: knotless suture with great strength of self anchoring and fixation in soft tissue, and sling placed at the level of midurethra approved very successful in management of SUI.

As mentioned above the new sling design has significant advantages comparing with classical mesh sling operation, especially aiming at reducing intraoperative and postoperative complications. The steps of procedure were explained in the figures appended at the end of the paper.

Limitations

Nevertheless no sling procedure or design is completely free of complications considering the blind course of the introducer devices. Postoperation complications of knotless barbed suture in the surgical field have been reported frequently. The increased risk of adhesions and inflammation might be caused by the barbs entrapped in the suture [22]. We designed to cut off some barbs in the middle of bidirectional knotless suture with microsurgery instrument. Suture section without bars reduce possible tissue reaction in the midurethral and vaginal wall. Placing one sling (instead of a mesh) might increase the force in the urethra and paraurethral tissue. We designed to place one more sling in a tension-free way, and might not increase the rate of postoperative complications because of smooth section without barbs. Further experimental animal model is needed to tesify the design mentioned above.

Conflict of interest statement

The authors report no conflict of interest regarding the materials and findings presented.

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