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Research Article

Treatment of Male Stress Urinary Incontinence with A Fixed Sling Made of PVDF - 6-Year Follow-Up Data

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Abstract

Fixed slings represent an attractive option for the surgical treatment of male stress urinary incontinence. However, controversy remains regarding the safety and performance of slings in the long run. The present study retrospectively analyzes data from 73 patients that received a fixed sling made of polyvinylidene fluoride (PVDF). After a median follow-up of 72.6 months, 74 % of patients reported treatment success, defined as a pad usage of 0-1 pads/day. Apart from one case of short-term pain, there were no intra-operative and post-operative complications recorded during the follow-up period. The present data add to the growing body of evidence showing that PVDF slings represent a safe and effective treatment option for male stress urinary incontinence.

Introduction

Stress urinary incontinence is a common and bothersome condition for men who have undergone radical prostatectomy. Studies suggest that between 1 and 40 % of patients complain of persistent urinary incontinence following radical prostatectomy [1-5], with significant impact on their quality of life and well-being. If conservative treatment and drug therapy for incontinence fail, international guidelines recommend surgical intervention [6,7]. A registry study with more than 16,000 patients has shown that 6 % of men treated with radical prostatectomy underwent at least one surgical procedure for treating incontinence [8]. These surgical procedures included bulking agents, slings and artificial urinary sphincters. Fiveteen percent of men undergoing surgery received several types of surgical interventions [8]. The guidelines of the European Association of Urology recommend offering fixed slings or artificial urinary sphincters to patients suffering from stress urinary incontinence after prostatectomy [6]. In contrast, bulking agents are advised only if temporary relief of incontinence symptoms is sought [6]. The guidelines caution that artificial urinary sphincters are associated with a higher rate of complications than sling placement [6,7]. Indeed, the rate of reoperations due to complications after artificial sphincter implantation is reported to be around 30 % [9-11]. In comparison, reoperations due to complications are significantly lower after implantation of fixed slings, typically between 0-5 % [12-16]. In terms of continence rates, improvement rates and overall satisfaction, sling and artificial urinary sphincter treatment have been reported to be comparable [17,18] (however, see [19]). Thus, fixed slings represent an attractive treatment choice for patients and physicians.

Despite the wide acceptance of slings, concerns have been raised about their safety and performance due to a general lack of long-term follow-up data beyond 3 years [19]. In addition, the use of mesh has sparked controversies in recent years. The debate has focused in particular on prolapse repair in women [20-22], but has also spilled over to synthetic slings for the treatment of female stress urinary incontinence [23]. To date, most research on mesh materials has centered on polypropylene, but other alternatives exist as well. Polyvinylidene fluoride (PVDF) has initially been used as suture material in cardiac surgery [24, 25] and has been introduced as a mesh material in 2002 [26]. Compared to polypropylene, PVDF meshes have been shown to display improved biocompatibility and biostability in animal studies [26-29]. A recent randomized controlled trial comparing polypropylene to PVDF slings for treating female stress urinary incontinence reported fewer side effects in patients treated with PVDF slings [30]. For male slings, the use of PVDF is less well documented. To date, only one study has examined the outcome of PVDF male sling in 31 patients with a follow-up of about 20 months [31].

The present study analyzes data from 73 patients that received a PVDF sling (DynaMesh®-PRM, FEG Textiltechnik Aachen, Germany) for the treatment of post-prostatectomy stress urinary incontinence. The goal of this retrospective cohort study is to evaluate the long-term safety and performance of the device.

Methods

Between July 2011 and November 2019, male sling surgeries for urinary stress incontinence were performed using DynaMesh®-PRM (FEG Textiltechnik Aachen, Germany) at IRCCS Ospedale Sacro Cuore Don Calabria in Negrar (Verona), Italy. The data were collected consecutively and retrospectively. Study inclusion criteria were that patients were male, full age and sui juris, received a diagnosis of stress or mixed urinary incontinence and signed a written consent for processing their data. In total, 73 patients were included in the study. Patients underwent a physical exam, urodynamic testing and a test for remaining sphincter function. All surgeries were performed with the transobturator outside-in technique. The sling was fixed to the bulbus with sutures and the sling ends were tunneled and sutured. Concurrent surgeries were not performed. For follow-up, the patients were contacted by phone between October 2019 and September 2020. Cure was defined as zero pad usage and improvement was defined as a reduction in pad usage (pad usage: 1 pad/day). Failure was defined as the same number of pads or more pads were used compared to before the surgery. The data was analyzed using Microsoft Excel (Microsoft, Redmond, WA, USA) and XLSTAT (Addinsoft, New York, USA). The study received ethical approval by the Ethical Committee for Clinical Experimentation of the province Verona and Rovigo, Italy (Comitato Etico per le Sperimentazioni Cliniche delle province di Verona e Rovigo (Prot. Negrar 2022-E)).

Results

Patients

All of the patients that underwent surgery were also available for a follow-up interview (n = 73). The median follow-up time was 72.6 months (average: 65 months; range: 2-107 months; Figure 1). Patient characteristics are detailed in Table 1. On average, patients were 69.4 years old with a BMI of 26.4. All of the patients had undergone prostatectomy. Almost 18 % of the patients previously received radiation therapy and 10 % received prior incontinence treatments. All patients suffered from stress or mixed urinary incontinence, which was moderate or severe in most patients (93 %).

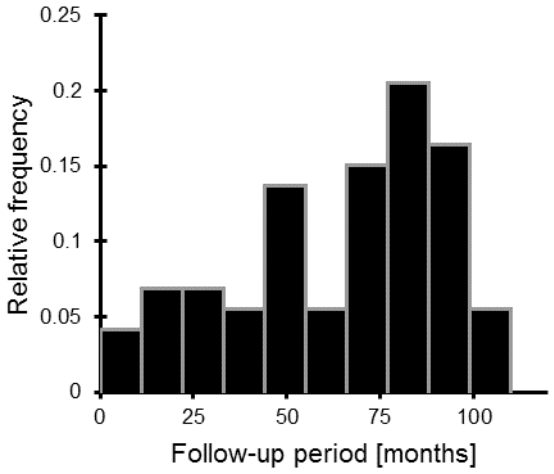

Figure 1: Histogram of follow-up intervals in the patient population (n = 73).

average age	69.4 years	
average BMI	26.4	
previous prostatectomy	73/73 (100 %)	
previous radiation therapy	13/73 (17.8 %)	
previous incontinence therapy	7/73 (9.6 %)	
type of incontinence	stress: mixed: urge:	55/73 (75.3 %) 18/73 (24.7 %) 0/73 (0 %)
level of incontinence	mild: moderate: severe:	5/73 (6.8 %) 34/73 (46.6 %) 34/73 (46.6 %)
neurological symptoms	1/73 (1.4 %)	
residual sphincter function	72/73 (98.6 %)	

Table 1: Patient characteristics.

Safety Parameters

There were no intraoperative complications, such as hemorrhages (defined as > 200 ml blood loss) or lesions to surrounding structures (Table 2). Post-operative complications

were evaluated until the last follow-up time point. Out of all the parameters that were assessed, only one complication occurred, which was a case of post-operative pain that was treated with an anti-inflammatory agent. Other than that, there were no post-operative complications recorded (for a complete list, see Table 2).

intraoperative complications	**total number of complications:**	**0/73 (0 %)**
	- hemorrhage (> 200 ml)	0/73 (0 %)
	- organ lesion	0/73 (0 %)
	- other complications	0/73 (0 %)
postoperative complications	**total number of complications**:	**1/73 (1.4 %)**
	- hematoma	0/73 (0 %)
	- seroma	0/73 (0 %)
	- hematuria	0/73 (0 %)
	- wound infection	0/73 (0 %)
	- tape infection	0/73 (0 %)
	- urethral atrophy	0/73 (0 %)
	- urethral erosion	0/73 (0 %)
	- urethral diverticulum	0/73 (0 %)
	- fistula formation	0/73 (0 %)
	- tape dislocation	0/73 (0 %)
	- voiding dysfunction	0/73 (0 %)
	- urinary tract infection / cystitis	0/73 (0 %)
	- de novo urge incontinence	0/73 (0 %)
	- perineal numbness	0/73 (0 %)
	- de novo sexual difficulties	0/73 (0 %)
	- post-op pain (< 3 months)	1/73 (1.4 %)*
	- chronic pain (> 3 months)	0/73 (0 %)
	- mesh-related complications	0/73 (0 %)
	- other complications	0/73 (0 %)

Table 2: Complete list of intra-operative and post-operative complications. *Perineal pain treated with anti-inflammatory drugs.

incontinence status at follow-up	cured (0 pads/day):	37/73 (50.7 %)
	improved (1 pad/ day):	17/73 (23.3 %)
	same/worse:	19/73 (26.0 %)
re-operation for incontinence	1/73 (1.4 %)	

Table 3: Surgical outcome.

Performance Parameters

After a median follow-up of 6 years, 50.7 % of patients reported to be cured, which was defined as 0 pads used per day. Another 23.3. % of patients used one pad per day, which was considered an improvement relative to the condition before surgical treatment. Thus, a total of 74 % of patients were cured or improved after receiving a PVDF sling for treating stress urinary incontinence. In contrast, 26 % reported no improvement, however none of the patients indicated that the situation was worse than before undergoing surgery. Only one patient (1.4 %) was reoperated due to recurrent incontinence.

Discussion

The results of the study show that PVDF slings offer a safe and effective treatment for male post-prostatectomy stress urinary incontinence. After a median follow-up of 6 years, three quarters of study participants reported a pad usage of 0-1 pads/day, which can be interpreted as treatment success. The results are superior to other reports in the literature: Kretschmer and colleagues [18] reviewed the performance of fixed polypropylene slings and found that 710/1262 patients (56 %) of the patients in the included studies reported treatment cure, which was defined as 0-1 pads/day in most studies (10 out of 14 data sets). Another 235/1262 (19 %) patients reported improvement, for which the definition was less clear (usually denoting a reduction in pad usage by > 50 %). The weighted average follow-up for the included studies on fixed slings was 37 months. For patients treated with an artificial urinary sphincter, Kretschmer and colleagues reported 848/1424 (60 %) patients to be cured, defined as 0-1 pads/day in most studies (7 out of 11 data sets). In this case, the weighted average follow-up was 5 years. With respect to safety, only one complication was reported in the present study, which was short-term pain that resolved after anti-inflammatory treatment. There were no reoperations due to complications. This result is in line with a low rate (0-5 %) of reoperations due to complications reported in the literature on fixed polypropylene slings [12-16]. In contrast, around 30 % of patients that received an artificial urinary sphincter undergo surgery again, mostly due to mechanical failure of the device [9-11].

The present study adds to the growing body of literature showing that PVDF is a safe and effective sling material in pelvic floor surgery [30-34]. Importantly, the study provides long-term data that is critical for the evaluation of patient safety and device performance in the long run. One limitation of the present data set is that it has been collected retrospectively, thus it is prone to selection bias in the sample recruitment. Indeed, previous studies have pointed out that patient selection is key to treatment success [35,36]. The present study is based on consecutive patient sampling and thus represents “real-world” data. Despite the promising results, the findings should be further corroborated by future studies using prospective and/or randomized designs.

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