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ORIGINAL ARTICLE

An Internet-based survey to evaluate the comfort and need for further pubovaginal sling training

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Abstract

Introduction and hypothesis The pubovaginal sling (PVS) dates to the 1940s as an efficacious surgical treatment for stress urinary incontinence (SUI). Recently, it has been replaced by the midurethral sling (MUS). Since 2008, international regulatory agencies increased regulation and issued warnings on vaginal mesh for repair of pelvic organ prolapse (POP), which has led to increased scrutiny of the MUS. Thus, the need for surgical comfort with PVS is resurfacing. We sought to evaluate the surgical practice patterns among international urogynecologists for the treatment of SUI and identify whether a need and interest for more training exists.

Methods We developed a short, Internet-based survey for members of the International Urogynecological Association (IUGA). Descriptive analyses, binomial and multivariate logistic regressions were calculated to determine significant associations.

Results Among 556 members who responded to the survey, 72% did not offer PVS in practice. Among those who did, there was as significant relationship between offering PVS and practicing in the United States, board-certification in urogynecology, PVS exposure in training, increasing number of PVS performed during training, and comfort with PVS. Members interested in further PVS training were younger, less comfortable with PVS, performed fewer PVS, or had no exposure in training.

Conclusion Most IUGA members do not offer PVS in clinical practice. As would be expected, members who performed more PVS in training and were more comfortable with PVS were likely to offer it to patients. Our results highlight a learning gap, especially among younger providers who are not comfortable with PVS and desire further training in this procedure.

Keywords Pubovaginal sling · Autologous fascia sling · Stress urinary incontinence · Midurethral sling · FDA warning

Abbreviations

SUI	Stress urinary incontinence
PVS	Pubovaginal sling
MUS	Midurethral sling
FDA	Food and Drug Administration
TVT	Tension-free vaginal tape
POP	Pelvic organ prolapse
IUGA	International Urogynecological Association
AUGS	American Urogynecologic Society
US	United States
UK	United Kingdom
TGA	Therapeutic Goods Administration
FPMRS	Female Pelvic Medicine and Reconstructive Surgery
SUFU	Society of Urodynamic and Female Pelvic Medicine and Urogenital Reconstruction
AUA	American Urological Association
AGSA	Urogynaecological Society of Australasia

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Introduction

The prevalence of stress urinary incontinence (SUI) in women approaches 50% and can be treated with conservative or surgical management. Primary surgical options include colposuspension, bulking agents, and slings [1]. Over the last two decades, slings have been the mainstay of surgical treatment. The pubovaginal sling (PVS) with autologous (rectus fascia or fascia lata) or cadaveric tissue was first described for the treatment of SUI in the 1940s. It gained popularity in 1978

by McGuire and Lytton due to its high success rate in treating SUI from intrinsic sphincter deficiency [2]. Subsequent publications have established its adequate safety and efficacy. Chaikin et al. reported a 93% SUI cure or at least a 50% improvement at 1 year after placement of an autologous rectus fascia PVS among 251 women [3]. When compared with the Burch colposuspension, the rectus fascia PVS had better efficacy and patient satisfaction at 24 months but slightly higher complication rates, including urinary tract infection (UTI), urge urinary incontinence (UUI), and voiding dysfunction [4]. By the early 1990s, the synthetic midurethral sling (MUS) was being used in Europe and received approval by the United States (US) Food and Drug Administration (FDA) in 1998. It quickly replaced the PVS as the gold standard for treatment of SUI due to its ease of placement [5, 6]. In 2005, a randomized control trial comparing PVS to tension-free vaginal tape (TVT) reported comparable efficacy at 6 months; however, TVT had a sustained advantage of lower morbidity and overall cost [7].

Since 2008, international regulatory bodies, including the FDA, the Therapeutic Goods Administration (TGA), and the European Union Regulatory System, began to investigate vaginal mesh due to reports of serious adverse events. From 2008 to 2016, the FDA issued several public health notifications to classify mesh for transvaginal repair of pelvic organ prolapse (POP) as a high-risk device [8, 9]. Similarly, the European Scientific Commission published a statement in 2015 that recommended limiting the use of vaginal mesh for POP [10]. Most recently, the TGA banned transvaginal mesh for treating POP in November 2017 [11]. With controversy surrounding vaginal mesh, the MUS has subsequently undergone increasing scrutiny. Not surprisingly, patient perception of mesh has been negatively affected by these warnings, which may also translate to the use of mesh for SUI [12]. Furthermore, while strict premarket approval requirements only apply to mesh for POP repair, it could extend to mesh for SUI in the future. For example, the TGA has increased the regulation of minislings, citing "a lack of adequate scientific evidence…to be satisfied that the risks to patients associated with the use of mesh products as single-incision minislings for the treatment of stress urinary incontinence are outweighed by their benefits." [11].

Despite concerns and regulatory changes surrounding synthetic slings, their effect on international practice patterns is poorly understood and varying. Rac et al. retrospectively assessed surgical trends at eight US academic centers for management of SUI from 2007 to 2013 [13]. Two institutions had a statistically significant decrease in the use of synthetic mesh, specifically from 2011 to 2013. An Australian review of Medicare data from 1994 to 2014 showed a peak in MUS operations in 2002, a plateau by 2011, followed by a decline in 2012 [14]. Interestingly, the decline in MUS was not replaced by another incontinence procedure. Both studies concluded that the FDA warnings may have played a role in their findings. Surveys by the International Urogynecologic Association (IUGA) and American Urogynecologic Society (AUGS) have demonstrated a decrease in the use of mesh for POP but no change in the rates of synthetic slings [6, 15]. Alternatively, an analysis of the National Surgical Quality Improvement Program database from 2006 to 2012 showed a rise in MUS procedures.

While PVS is a more technical and morbid procedure than MUS, it lacks the risk associated with mesh [4, 16]. Thus, surgical comfort with PVS is becoming more important in the field of urogynecology. Furthermore, with evidence that FDA warnings may affect patient desire to receive an MUS, there is a need to assess surgeon comfort with other surgical options for the treatment of SUI. We sought to evaluate practice patterns and comfort with the use of PVS among international urogynecologists and identify whether an interest in further training exists.

Materials and methods

This was an observational survey for IUGA members. Participation was anonymous and voluntary. Thus, the study was exempt from Institutional Review Board approval. We developed a short, Internet-based survey using Survey Monkey® to assess: (1) surgical comfort with PVS among urogynecologists, (2) practice patterns, (3) and interest in further training on PVS placement (Fig. 1). US practitioners were further questioned regarding their year of fellowship graduation and board certification status. If a practitioner had exposure to PVS in training, they were asked to identify which types and how many they recall performing. Types of PVS included autologous rectus, autologous fascia lata, and cadaveric fascia. Irrespective of whether a respondent answered yes or no to offering PVS in practice, comfort with PVS was also assessed, from very comfortable, somewhat comfortable, to not comfortable. The survey was tested by the research team and found to take ~5 min to complete.

The survey was approved by the Chair of The Research & Development Committee at IUGA, and then electronically blasted to the full IUGA membership with a short cover letter from the research team. A reminder email was sent 1 week later in hopes of increasing the overall response rate. Descriptive analyses and chi square analyses were performed to determine factors that were significantly associated with offering PVS and requesting additional training in PVS. Factors that were significant on univariate assessment were then evaluated on a multivariate logistic regression model to determine odds ratios (OR) with 95% confidence intervals (CI). Specifically, we sought to identify whether practice location, exposure in training, and number of procedures performed in training affected whether providers offered PVS in their practice and whether it affected their interest in further training. The Statistical Package for Social Sciences (SPSS, version 24) was used for data analysis.

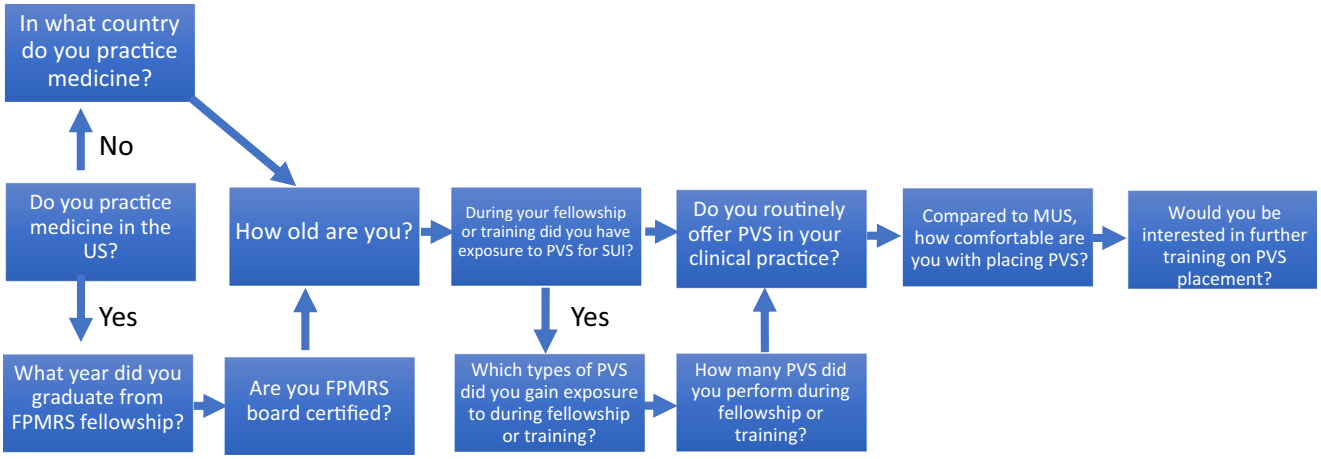

Fig. 1 Internet-based survey using branch logic

Results

Of the 2026 current IUGA members, 556 voluntarily responded to the survey. This was consistent with a 27% response rate with a 7% incomplete response rate (Table 1). The majority (38.6%) of responders were between 51 and 65 years old, with an overall range from 25 to >65 years old. Sixty-five countries were represented, of which the US made up the largest proportion of responders (21%), followed by the United Kingdom (UK) (14%) and Australia (11%) (Table 2). Pubovaginal sling exposure was reported in 51% (276/539) of respondents. Within this group, 81% (223/276) learned placement with a rectus fascia graft, and most saw less than five procedures (34%). Interestingly, those who practice in the US were more likely to have PVS exposure in training. More than half (53%) of respondents were not comfortable with PVS, with only 28% offering PVS in their current practice. Of these 271 members who were not comfortable, 79 (29%) had prior exposure to PVS in training. Additionally, 271 (53%) members were interested in gaining further training in PVS placement and management, of which 119 (43%) had prior exposure to PVS.

On univariate analysis of member characteristics, offering PVS to patients during counseling for SUI was significantly associated with practicing in the US ($p < 0.001$), PVS exposure in training ($p < 0.001$), increasing number of PVS performed during training ($p < 0.05$), and comfort with PVS ($p < 0.001$) (Table 3). However, on multivariate logistic regression, the only factor that remained significant was increasing comfort with PVS. Those who felt very comfortable were eightfold more likely to offer PVS (OR 8.521, 95% CI 3.581–20.274) compared with those who were not comfortable. Similarly, those who were somewhat comfortable were nearly threefold more likely to offer PVS (OR 2.642, 95% CI 1.171–5.964).

Within the subgroup of members who reported interest in further PVS training, decreasing comfort level with PVS, no exposure to PVS in training, and fewer PVS performed in training were associated with desiring additional training on univariate assessment (Table 4). After further multiple logistic regression modeling, being exposed to fewer than five or from five to ten PVS compared with >20 during training and being somewhat comfortable with PVS remained statistically significant (Table 4).

Discussion

To our knowledge, this survey is the first of its kind to specifically evaluate international clinical practice with PVS and assess desire for further training within the FPMRS community. At our institution, we offer MUS and PVS to eligible patients seeking surgical management of SUI, but we surmise that this is not common practice in the FPRMS community. Our study confirms this assumption, with only 28% of participants offering PVS in practice. Additionally, 49% desired additional training in PVS placement.

Our member response rate was consistent with previously published reports based on IUGA membership surveys [6, 17]. Inherent to survey-based studies, our results likely incurred selection and recall bias. While the survey was only offered in English, the largest proportion of the IUGA membership is represented by countries in which the primary or one of the official languages is English. The membership is represented by as many as 92 countries, with the most members coming from the US (12%), the UK (11%), The Netherlands (10%), and Australia (6%). Our responder rate was consistent with this distribution. Another potential weakness is that our survey did not explicitly exclude physicians who do not practice urogynecology. Like the techniques used by Khaja et al. to target the FPMRS audience using survey questions, we asked about graduation from FPRMS fellowship, with the intention to target members practicing urogynecology [18]. Based on questions like: "Do you fit shelf or Gellhorn pessaries?" Khaja reported 1324 members who specialize in urogynecology or gynecology. Based on this

Table 1 Member response to survey questions

Survey question	*N* (%)
Age	554
25–30	5 (1)
31–40	132 (24)
41–50	178 (32)
51–65	215 (39)
>65	24 (4)
Practice in the US	556
Yes	116 (21)
FPMRS board-certified	90 (77)
No	440 (79)
PVS exposure in training	539
Yes	276 (51)
Rectus fascia	223
Fascia lata	91
Cadaver fascia	69
No	263 (49)
Number of PVS in training[a]	273
< 5	95 (34)
5–10	68 (25)
11–20	42 (15)
>20	68 (25)
Comfort with PVS	513
Not comfortable	271 (53)
Somewhat comfortable	127 (25)
Very comfortable	115 (22)
Offer PVS in current practice	513
Yes	144 (28)
No	369 (72)
Interest in further training	513
Yes	271 (53)
No	242 (47)

FPMRS Female Pelvic Medicine and Reconstructive Surgery, *PVS* pubovaginal sling

[a] question only available to responders who answered yes to PVS exposure in training

Table 2 Countries represented by ten or more members

Country	*N* (%)
United States	116 (21)
Other (64)	440 (79)
Argentina	15
Australia	61
Austria	13
Brazil	22
Canada	18
Chile	21
Germany	21
Mexico	11
The Netherlands	34
New Zealand	13
Switzerland	17
United Kingdom	82

denominator, our responder rate of 42% (556/1324) would represent the highest to date. However, if most of our survey responses were from non-FPMRS-trained members, this would lead to a falsely lower number of participants who are knowledgeable in PVS given that exposure to PVS among non-FPMRS physicians is not expected.

As discussed previously, transvaginal mesh for repair of POP and SUI has been under scrutiny since 2008 after serious complications were reported. Subsequently, international regulatory organizations have conducted extensive reviews of the literature and increased monitoring of transvaginal mesh. The FDA asserted that: "the safety and effectiveness of multi-incision slings [for the treatment of stress incontinence] is well established in clinical trials" [19]. In contrast, the TGA removed minislings from the Australian Register of Therapeutic Goods, thus limiting access to MUS for patients [11]. In light of varying regulations, and to address concerns that patients and providers may have regarding the use of slings for treatment of SUI, several urologic societies have published official statements supporting their use. The AUGS and the Society of Urodynamic and Female Pelvic Medicine and Urogenital Reconstruction (SUFU) have stated that they: "support the use of the mid-urethral sling in the surgical management of stress urinary incontinence," while the American Urological Association (AUA) noted that: "extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI [20, 21]." The Urogynaecological Society of Australasia (AGSA) issued a statement that called the decision by the TGA: "disservice to women," and reiterates that the MUS is supported by all pelvic floor societies in Europe, the UK, and the US [22]. Anecdotally in our practice, we have noted that patients remain averse to having mesh placed for any indication.

Mock et al. reported similar counseling to ours: patients are offered PVS and MUS for surgical management of SUI. When offered both procedures, an equal number of participants choose one or the other with similar rates of efficacy and safety [23]. This may suggest that if PVS were readily available, more patients may be interested in this nonsynthetic option. Furthermore, their study had few complications and no difference in treatment efficacy between groups. While they did not specifically evaluate changes in patient preference after the FDA warnings, their practice patterns predate the FDA warnings and only represent one institution, which was US based.

While few studies directly compare MUS and PVS, historically, PVS is felt to have higher rates of urinary retention,

Table 3 Univariate and multivariate analysis for members who offer pubovaginal sling (PVS) in practice

	Univariate		Multivariate	
	OR (95% CI)	*P*-value	OR (95% CI)	P-value
Practice in the US	2.546 (1.63–3.976)	<0.001	1.390 (0.76–2.541)	0.285
PVS exposure in training	2.135 (1.434–3.179)	<0.001	0.802 (0.471–1.364)	0.415
Increasing number of PVS in training				
< 5	Reference		Reference	
5–10	2.037 (1.009–4.114)	0.047	1.368 (0.632–2.962)	0.427
11–20	3.318 (1.518–7.252)	0.003	1.872 (0.774–4.529)	0.164
>20	2.861 (1.43–5.724)	0.003	1.184 (0.533–2.628)	0.678
Increasing comfort with PVS				
Not comfortable	Reference		Reference	
Somewhat comfortable	3.698 (2.157–6.340)	<0.001	2.642 (1.171–5.964)	0.019
Very comfortable	16.262 (9.426–28.054)	<0.001	8.521 (3.581–20.274)	<0.001

urgency, and wound and urinary tract infection, with overall similar objective and subjective cure rates. A recent meta-analysis demonstrated similar rates for UTI (11%, 11%), bladder injury (6%, 4%), and efficacy for MUS and PVS, respectively [24]. Additionally, wound complications were relatively low with PVS (8%). Rates of mesh extrusion for MUS were 7%, a complication that does not exist with PVS. Polypropylene slings have been shown to be 15 times more likely to erode into the urethra and 14 times more likely into the vagina when compared with autologous slings [25]. With this contemporary information, PVS in the treatment of SUI is a reasonable alternative and should be offered to eligible patients.

Even though PVS is a valid, effective, and appropriate procedure for some patients, we show that most providers lack comfort with this procedure and desire additional training. As expected, most such members did not have exposure to PVS in training. Interestingly, close to half of those interested in future training had prior exposure to PVS. Perhaps members with prior PVS exposure feel that future training would act as a refresher course to a procedure they are already familiar with. Additionally, they may be able to better appreciate the benefits and feasibility of PVS having in the past seen first hand its efficacy. Wu et al. surveyed the Nationwide Inpatient Sample from 1998 to 2007 to determine trends in SUI surgery [26]. The total number of surgeries for SUI both increased and changed over this period. In 1998, retropubic suspensions comprised 52.3% of cases, decreasing to 13.8% in 2007. "Other repair of SUI," likely representing MUS, comprised 22.4% in 1998 and 75.2% in 2007. Oliphant et al. surveyed the National Hospital Discharge Survey and found a similar trend [27]. With a drop in retropubic procedures (be it Burch colposuspension or PVS), trainees are less exposed and unable to perform them competently and safely upon graduation [28]. As suggested by Ghoneim and Rizk, cadaveric courses and hands-on experience with mentors are valuable opportunities to gain experience in the surgical technique of PVS [29].

Although PVS has slowly fallen out of favor, we believe there is a resurgence in the pipeline as the controversy with mesh continues to evolve. We do not contend that the minimally invasive nature, high efficacy, and overall low

Table 4 Univariate and multivariate analysis for members interested in further pubovaginal sling (PVS) training

	Univariate		Multivariate	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
No PVS exposure in training	1.877 (1.321–2.667)	<0.001	1.001 (0.156–6.420)	0.999
Number of PVS in training				
< 5	3.692 (1.87–7.292)	<0.001	3.732 (1.821–7.649)	<0.001
5–10	2.747 (1.333–5.662)	0.006	2.577 (1.229–5.402)	0.012
11-20	1.481 (0.645–3.403)	0.354	1.519 (0.652–3.536)	.332
>20	Reference		Reference	
Comfort with PVS				
Not comfortable	1.805 (1.159–2.811)	0.009	0.945 (0.56–1.594)	0.831
Somewhat comfortable	2.310 (1.379–3.869)	0.001	1.876 (1.085–3.243)	0.831
Very comfortable	Reference		Reference	

complication burden of the MUS lends itself as the preferred surgical option for SUI, but the PVS is a necessary tool in a urologist's or urogynecologist's armamentarium for complex patients or for those who do not desire mesh. If providers lack the comfort with this procedure, we may not be providing the complete range of care to our patients.

Our findings highlight the need to revisit PVS in training and provide supplemental training for those who are in current practice.

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Compliance with ethical standards

Conflicts of interest None.

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