

Medical malpractice in stress urinary incontinence management: A 30-year legal database review

Nicola B. Lynch^{a,*}, Linhan Xu^a, David Ambinder^a, Rena D. Malik^b

^aUniversity of Maryland School of Medicine, Baltimore, MD, USA; ^bDivision of Urology, Department of Surgery, University of Maryland Medical Center, Baltimore, MD, USA

Abstract

Background: The purpose of this study is to investigate the most common reasons for and judicial outcomes of malpractice claims related to stress urinary incontinence (SUI) management.

Materials and methods: Using the Westlaw database, a search was performed using the terms “medical malpractice” or “negligence” in combination with “stress incontinence” or “stress urinary incontinence” between January 1, 1990 and January 1, 2020. Extracted information included trial date, demographic information, defendant profession, procedure performed, procedure complications, alleged malpractice, trial outcome, and monetary award. Data were analyzed using descriptive statistics.

Results: The Westlaw search yielded 79 case results. Of the cases, 70.4% (n=38/54) had a defense verdict, 22.2% (n=12/54) had a plaintiff verdict, and 7.4% (n=4/54) were settled. The most commonly implicated procedure was mid-urethral sling (63.2%, n=36/57). Among the plaintiffs, 48.4% (n=61/126) claimed negligence in preoperative care, 33.3% (n=42/126) claimed negligence in surgical performance, and 18.3% (n=23/126) claimed negligence in postoperative care. Lack of informed consent was the most common complaint related to negligence in preoperative care (42.6%, n=26/61). The average indemnity payment was \$1,253,644 for preoperative care negligence, \$1,254,491 for surgical performance negligence, and \$2,239,198 for postoperative care negligence. Of the defendants, 63.4% (n=52) were gynecologists and 36.6% (n=30) were urologists.

Conclusions: Negligent preoperative care, with a particular emphasis on failure to obtain informed consent, and negligent surgical performance are the leading causes of malpractice claims during SUI management. Mid-urethral sling was the most commonly litigated procedure. This study highlights key factors to consider in minimizing malpractice risk during SUI management.

Keywords: Litigation; Malpractice; Mid-urethral sling; Stress urinary incontinence; Westlaw legal review

1. Introduction

Medical malpractice plays a significant role in US healthcare spending, accounting for 2.4% of all healthcare expenditure. In 2008, \$55.6 billion was spent on indemnity payments, administrative expenses, and defensive medicine costs related to medical malpractice.^[1] Besides the significant monetary burden associated with medical malpractice, litigation has a significant effect on physician outlook and practice. Physicians involved in malpractice suits are found to have higher rates of burnout and depression, as well as decreased career satisfaction.^[2] The surgical subspecialties, including gynecology and urology, are at particularly high risk for malpractice suits in comparison to other medical specialties. In 2011, gynecology ranked 12th and urology ranked 8th out of 25 specialties in

number of malpractice claims. Gynecologists and urologists have an 8% and 11% chance of being litigated per year, respectively.^[3] For gynecologists and urologists, understanding the causes of medical malpractice and developing solutions to avoid litigation is critical in the current medicolegal environment.

Stress urinary incontinence (SUI) is a highly prevalent urinary condition, with reports estimating up to 49% of women being affected by the condition.^[4,5] SUI significantly affects patients' quality of life, with patients reporting impaired work performance, physical and social functioning, psychologic stress, and sexual dysfunction related to SUI symptoms.^[6] Treatment of SUI primarily involves 1) conservative management with observation, pelvic floor muscle training, and pessary placement; or 2) surgical management with mid-urethral sling (MUS), pubovaginal sling, bulking agent, or Burch colposuspension.^[7] As with any surgical procedure, surgical management of SUI can have associated complications that increase the risk of litigation for the surgeon. The most common complications following SUI surgery include, but are not limited to, bladder injury, urethral injury, urinary retention, urinary frequency, urinary urgency, cystitis, pelvic pain, dyspareunia, mesh erosion, and recurrent SUI.^[8–10]

The purpose of this study is to investigate the most common reasons for and judicial outcomes of malpractice claims related to the management of SUI. We aim to educate physicians on the factors involved in SUI litigation in an effort to decrease the risk of malpractice suits against physicians during SUI management.

* Corresponding Author: Nicola B. Lynch, University of Maryland School of Medicine, 655W. Baltimore Street, Baltimore, MD 21201, USA.
E-mail address: nicola.lynych@som.umaryland.edu (N.B. Lynch).

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2. Material and methods

An advanced search of case and verdict/settlement reports was performed using the Westlaw database (Thomson Reuters, New York, NY). Westlaw is an online legal research service and proprietary database that publishes cases included in the public records of numerous jurisdictions. Westlaw has been validated for use in medicolegal inquires across many medical subspecialties, including urology and gynecology.^[11–18]

The advanced search was performed using the terms “medical malpractice” or “negligence” in combination with “stress incontinence” or “stress urinary incontinence.” Additional search terms such as “mesh,” “midurethral sling,” “pubovaginal sling,” “Burch colposuspension,” “Marshall-Marchetti-Krantz bladder suspension,” “Stamey bladder suspension,” and “bulking agent” were investigated, but ultimately excluded, as they did not produce any new relevant case results as compared to those produced by the original search terms. The search criteria were modified to include all federal and state cases occurring between January 1, 1990 and January 1, 2020. Data extraction occurred during May of 2020 and cases were reviewed by one author (NBL). Institutional review board approval was not required, as Westlaw is a publicly available, online database that does not contain protected patient information.

Data extracted from each case included the date of the trial, patient age, patient sex, defendant profession, type of procedure performed, complications associated with the procedure, alleged malpractice, outcome of the trial, and indemnity payments. Data were analyzed using Excel software with descriptive statistics. Outlier data points were identified using the maximum normed residual test and excluded from final analysis. The threshold of significance was set at a *p*-value of <0.05.

3. Results

The Westlaw database search yielded 963 results. After excluding duplicate and irrelevant cases, 79 unique cases were available for analysis. Irrelevant cases included malpractice cases against product manufacturers and cases unrelated to the management of SUI. Duplicate and irrelevant case number was suspected to be high due to the nonspecific key term search mechanism used by Westlaw.

Of the available cases, there were 24 that documented plaintiff age, with a mean age of 49 years old (range=36–66 years old). All 79 cases listed the plaintiff sex as female. The majority (93.6%) of cases (*n*=50/54) were taken to trial, while 7.4% of cases (*n*=4/54) were settled out of court. Of the cases that went to trial, 70.4% (*n*=38/54) had a defense verdict, while 22.2% (*n*=12/54) had a plaintiff verdict. The average settlement was \$50,000 (*n*=2) and the average verdict award was \$1,595,965 (*n*=11) after excluding one statistically significant \$28,000,000 outlier data point that skewed the data (*p*<0.01).

In numerous cases, plaintiffs made more than one claim against the defendant, resulting in the total number of claims being higher than the total number of cases. The most commonly alleged breach in duty was negligence in preoperative care (48.4%, *n*=61/126). This was followed by negligence in surgical performance (33.3%, *n*=42/126) and negligence in postoperative care (18.3%, *n*=23/126). For claims of negligence in preoperative care, surgical performance, and postoperative care, 26.7% (*n*=8/30), 27.6% (*n*=8/29), and 23.1% (*n*=3/13) of claims were decided in favor of the plaintiff, respectively. The average indemnity payment was \$1,253,644 (*n*=7) for negligence in

preoperative care, \$1,254,491 (*n*=7) for negligence in surgical performance, and \$2,239,198 (*n*=3) for negligence in postoperative care after excluding one statistically significant \$28,000,000 outlier data point that skewed the data (*p*<0.05).

The most common complaint related to preoperative care was lack of informed consent (42.6%, *n*=26/61), followed by inappropriate treatment choice (29.5%, *n*=18/61) and misdiagnosis (19.7%, *n*=12/61). Regarding the information missing from the informed consent process, 72.7% (*n*=16/22) of claims noted that the risks of the procedure were not adequately explained, 22.7% (*n*=5/22) of claims stated that the treatment alternatives were not presented, and 4.5% (*n*=1/22) of claims noted that the procedure was not sufficiently described. For negligence in surgical performance, plaintiffs cited bladder injury (19.0%, *n*=8/42) as the most common cause of malpractice, with urethral injury (14.3%, *n*=6/42) also constituting a common complaint. Negligence in postoperative care was most commonly listed as failure to diagnose/treat postoperative complications (52.2%, *n*=12/23), with plaintiffs also commonly citing failure to refer to a specialist (26.1%, *n*=6/23) as a breach in standard of care (Table 1).

The most common surgical procedure involved in litigation was MUS (63.2%, *n*=36/57), followed by pubovaginal sling (15.8%, *n*=9/57) and Marshall-Marchetti-Krantz (MMK) bladder suspension (10.5%, *n*=6/57). Other procedures involved in litigation included Burch colposuspension, Stamey bladder suspension, and bulking agent (Fig. 1). The type of procedure performed differed across decades, with MMK and Stamey bladder suspensions listed more frequently in the 1990–1999 decade, while MUSs, pubovaginal slings, and Burch colposuspensions performed more frequently in the 2000–2020 decades (Table 2). The most common complications associated with MUS were mesh erosion (18.2%, *n*=6/33) and pelvic pain (18.2%, *n*=6/33) (Fig. 2).

Table 1

Number and percent of malpractice claims related to alleged breaches in duty.

Timing of alleged malpractice	n	%
Negligence in preoperative care	61	–
Lack of informed consent	26	42.6
Inappropriate treatment choice	18	29.5
Misdiagnosis	12	19.7
Improper preoperative work-up	4	6.6
Failure to refer to a specialist	1	1.6
Negligence in surgical performance	42	–
Surgical performance (not otherwise specified)	9	21.4
Bladder injury	8	19.0
Urethral injury	6	14.3
Bowel injury	5	11.9
Ureteral injury	4	9.5
Improper sling placement	4	9.5
Foreign body retainment	2	4.8
Nerve injury	1	2.4
Improper positioning	1	2.4
Excess bulking agent use	1	2.4
Improper positioning	1	2.4
Negligence in postoperative care	23	–
Failure to diagnose/treat postoperative complications	12	52.2
Failure to refer to a specialist	6	26.1
Inappropriate follow-up care	2	8.7
Premature discharge	2	8.7
Premature performance of second surgery	1	4.3

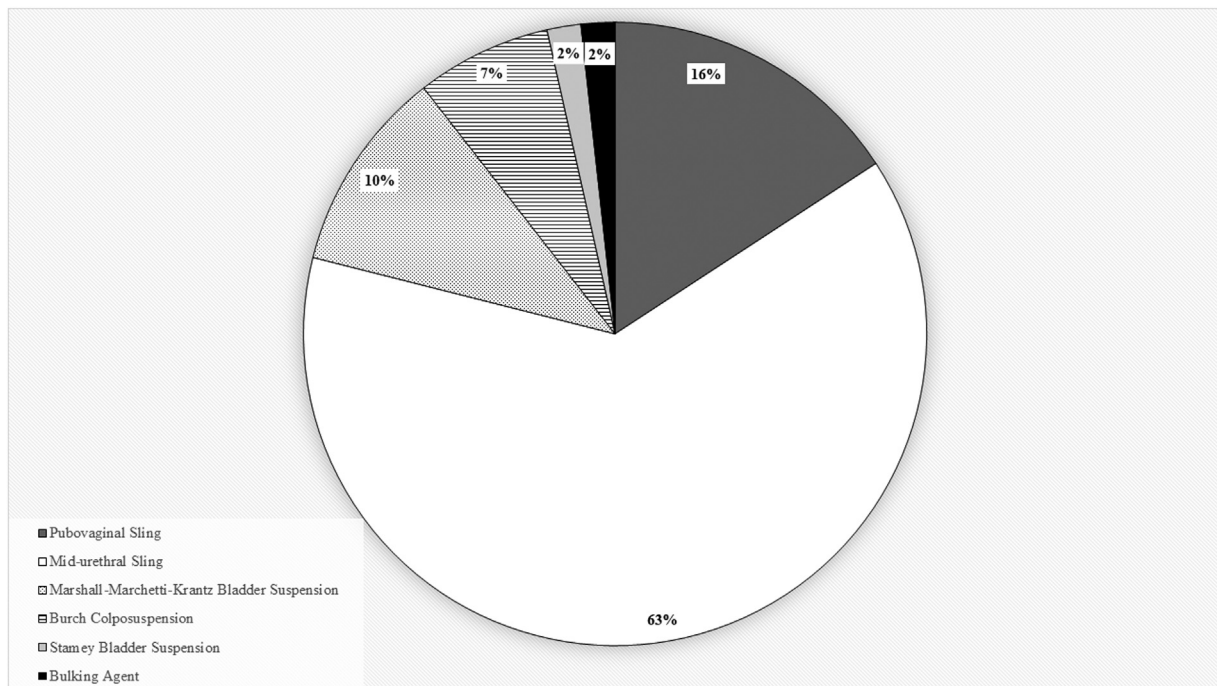


Figure 1. Percent of SUI procedure performed.

The defendant pool consisted gynecologists in 63.6% of cases (n=49/77) and urologists in 36.4% of cases (n=28/77). Of the gynecologists, 73.8% (n=31/42) were generalists while 26.2% (n=11/42) were specialists in Female Pelvic Medicine and Reconstructive Surgery (FPMRS). Of the urologists, 84% (n=21/25) were generalists, 8% (n=2/25) were urologic oncologists, 4% (n=1/25) were specialists in FPMRS, and 4% (n=1/25) were minimally invasive surgeons.

4. Discussion

Medical malpractice is a prevalent and often burdensome issue faced by urologists and gynecologists. Urologists experience an average of 2.1 and gynecologists experience an average of 2.6 lawsuits over the course of their careers.^[19,20] Out of 28 specialties, urology is ranked 12th and gynecology is ranked 2nd

in monetary payments related to malpractice.^[21,22] The indemnity payments of cases awarded in favor of the plaintiff against urologists and gynecologists are significant, with an average award of \$319,062 and \$423,250, respectively.^[21,23] Indemnity payments for urologists are on the rise, with an estimated 191% increase in payment amount per year.^[24] In addition to the significant monetary strain medical malpractice imposes, litigation significantly affects physician outlook on urologic and gynecologic practice. Of urologists, 58% consider referring difficult cases, 60% consider limiting the scope of their practice, 26% consider changing the state in which they practice, and 41% consider leaving medical practice due to fear of litigious repercussions.^[19] Gynecologists report similar fears, with 50% significantly changing their practice, 20% decreasing the number of gynecologic surgical procedures they perform, and 8% halting all performance of major gynecologic surgeries in order to avoid litigation.^[20] The most common reasons for malpractice claims against urologists include postoperative events, intraoperative events, failure to diagnose, medication errors, and foreign body retainment following surgery.^[24] The most common reasons for malpractice claims against gynecologists include improper surgical performance and delay in/failure to treat.^[20] Female Pelvic Medicine and Reconstructive Surgeons receive 10% of total claims against urologists.^[19] Given the substantial medico-legal risk of malpractice for FPMRS, it is pertinent that these physicians be wary of the causes and financial repercussions of litigation in this field. SUI is one of the major urinary conditions managed by FPMRS physicians, and, to the best of our knowledge, this is the first quantitative legal database review investigating litigation related to SUI management. This study provides a cross-sectional analysis of litigious claims related to SUI treatment over the last 30 years.

To establish that medical malpractice has occurred and award a verdict in favor of the plaintiff, 4 distinct criteria must be met. It must be demonstrated by the plaintiff that (a) the physician had a

Table 2

Stress incontinence procedure performed according to decade.

Timing of performed procedure	n	%
1990–1999	6	–
Marshall-Marchetti-Krantz bladder suspension	5	83.3
Stamey bladder suspension	1	16.7
2000–2009	17	–
Pubovaginal sling	7	41.2
Mid-urethral sling	6	35.3
Burch colposuspension	2	11.8
Bulking agent	1	5.9
Marshall-Marchetti-Krantz bladder suspension	1	5.9
2010–2020	33	–
Mid-urethral sling	29	87.9
Pubovaginal sling	2	6.1
Burch colposuspension	2	6.1

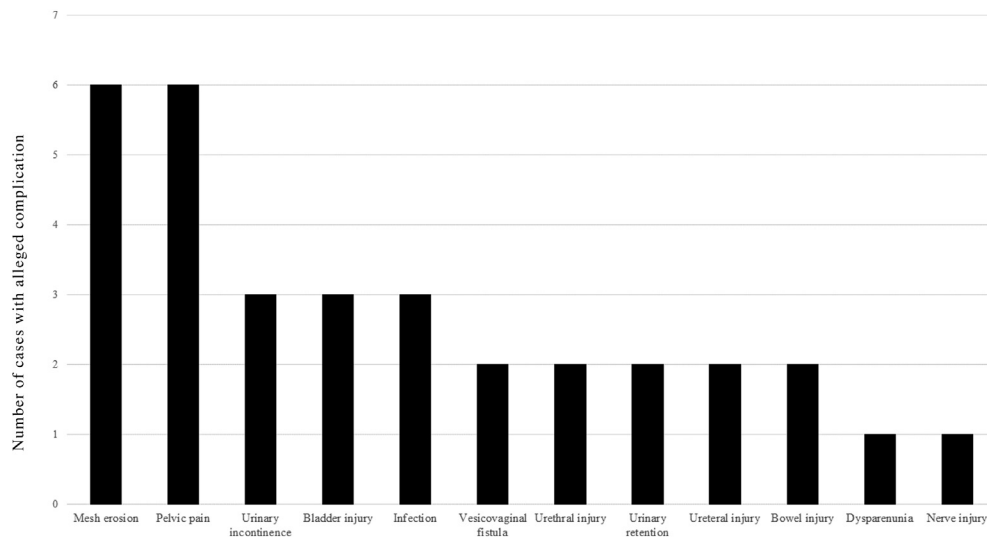


Figure 2. Complications from MUS procedures.

duty to the plaintiff, (b) the physician breached their duty to the plaintiff, (c) the plaintiff suffered damages, and (d) the breach in duty directly caused damages to the plaintiff.^[25] In our study, these criteria were met, and negligence was proven, in 22% of malpractice claims related to SUI management. The most common malpractice claim was negligence in preoperative care (48%), as compared to negligence in surgical performance (33%) and in postoperative care (18%). The percent of claims awarded in favor of the plaintiff were similar across all 3 negligence categories, with 27%, 28%, and 23% of claims awarded for negligence in preoperative care, surgical performance, and postoperative care, respectively. Within the preoperative care claims category, lack of informed consent was cited as the most common breach in duty. With regards to the surgical performance claims category, bladder and urethral injuries were most frequently cited as departures from standard of care. This aligns with other malpractice claims within FPMRS, with both failure to obtain informed consent and surgical negligence cited as the most common reasons for medicolegal claims during non-mesh-related pelvic organ prolapse management.^[18]

The largest indemnity payment during the management of SUI was related to negligence in postoperative care, with an average payment of \$2,239,198 being awarded to the Plaintiff. The average amount awarded was comparatively lower for negligence related to preoperative care and surgical management, with payments of \$1,253,644 and \$1,254,491, respectively. The average indemnity payments in each of these categories were notably higher than those among all urologic and gynecologic claims, with average monetary awards of \$319,062 and \$423,250 respectively cited in medical literature.^[21,23]

Of the analyzed cases, gynecologists were involved in 64% of cases while urologists were involved in 36% of cases. Analyzed according to subspecialty, both the gynecologists and urologists involved in SUI litigation were overwhelmingly generalists, constituting 84% of the gynecologists and 74% of the urologists. Given the relatively low frequency of FPMRS specialists involvement in these SUI litigation cases, the need for either increased FPMRS surgical experience in residency or pursuit of an FPMRS fellowship may be required in order to gain the proper

surgical experience necessary to perform these SUI procedures and avoid litigious claims.

MUS was the most commonly involved SUI procedure in litigation, with 63% of claims involving MUS. This is not surprising, given that the complications and litigation arising from transvaginal mesh products for both pelvic organ prolapse and SUI management have been extensive and at the forefront of the medicolegal system.^[26,27] The most frequently reported complications arising from MUS include bladder injury, urethral injury, bowel injury, mesh erosion, urinary infection, dyspareunia, de novo urgency and urge incontinence, and urinary retention.^[8] In our study, we found similar complications to be prevalent, with mesh erosion and pelvic pain cited most frequently as MUS complications. Despite the prevalence of MUS in medical malpractice litigation, studies have consistently shown that MUS 1) are the most extensively researched procedure for SUI, 2) have a good safety profile, and 3) are highly effective for the treatment of SUI.^[28] In this study, lack of informed consent and surgical performance, with a special emphasis on bladder and urethral injuries, were the leading causes of malpractice claims. Given the unique complications of MUS and associated litigation risk, it is pertinent that urologists and gynecologists engage in a comprehensive discussion with patients prior to surgery, particularly with regards to the risks, benefits, and alternatives to mesh slings. It is additionally important that residency training programs provide appropriate and sufficient training in the placement of sling products to ensure competency and decrease the risk of surgical error.

SUI surgical procedures involved in litigation varied according to decade, with Stamey and MMK bladder suspensions listed more frequently in the 1990–1999 time period, while MUSs, pubovaginal slings, and Burch colposuspensions listed more frequently in the 2000–2020 time period. These findings are as expected, as Stamey and MMK bladder suspension procedures have fallen out of favor in the management of SUI since evidence has emerged that these procedures have decreased long-term efficacy in comparison to the other, more recently developed procedures listed above.^[29]

Aside from the alleged damages claimed by patients, it has been well documented in medical malpractice literature that a large

proportion of filed malpractice suits are attributable to poor patient-provider relationships and communication. In a 1994 JAMA article investigating the relationship between malpractice and doctor-patient relationships, 71% of patients who filed for malpractice reported having a poor relationship with their provider. Among these patients, 32% reported they felt deserted by their physician, 29% reported they felt their views were devalued by their physician, 25% reported their physician delivered information poorly, and 13% reported their physician failed to understand the patients' perspective.^[30] These emotion-laden reasons for filing a lawsuit highlight the need for physicians to establish a compassionate, caring relationships with patients where respect is given for each patient's beliefs and health situation. An open, transparent line of communication must be formed between patient and provider, where information regarding plan of care as well as medical errors can be divulged. When executed successfully, these interpersonal skills can act as a tactic to avoid future involvement in malpractice litigation.

Despite widespread use in medical malpractice research, Westlaw has several limitations that must be considered when using it for medicolegal inquiries. The Westlaw database contains only voluntarily reported cases, meaning it provides a limited sample of all medical malpractice cases. Cases that are settled out of court, dropped, or do not progress to trial are excluded from the database. In addition, Westlaw often omits important medical information, such as the operative note, from its case report. Cases that are published on Westlaw often have incomplete case information present, with some desired medical data points missing. These factors limit the number of malpractice cases that can be analyzed, the amount of data which can be extracted from the cases for analysis, and the conclusions that can be drawn regarding the data. Given the sample size limitations imposed by Westlaw, our study was likely underpowered to detect statistically significant differences between the study groups. In addition, the relevance of the monetary award data is unclear, given that some states have tort reform, meaning the liability payouts are inherently restricted, whereas other states do not. Despite these limitations, Westlaw is the largest publicly available legal database to review malpractice claims and has been used successfully in the past for urology and gynecology litigation research.^[11-18]

5. Conclusions

SUI is a common urinary issue faced by a substantial proportion of the female population and can have a significant effect on patient quality of life. Surgical procedures to manage SUI are commonplace in urologic and gynecologic practice, however, physicians must be wary of the medicolegal repercussions involved in such management. Our study found that urologists and gynecologists managing SUI were most commonly sued for negligent preoperative care, with a particular emphasis on failure to obtain informed consent, and negligent surgical performance. MUS was the most commonly implicated surgical procedure, stressing the need for urologists and gynecologists to obtain a comprehensive informed consent and adequate surgical training in the placement of MUSs. The average indemnity payment was highest when related to negligence in postoperative care, with the average indemnity payments across the 3 negligence categories exceeding the average indemnity payments for all urologic and gynecologic procedures. Urologists and gynecologists must be wary of the heightened medicolegal monetary risk when performing SUI surgeries and take appropriate steps to avoid litigation.

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Statement of ethics

No ethics approval required.

Conflict of interest statement

The authors report no conflicts of interest.

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Author contributions

Nicola B. Lynch: Project development, data collection, data analysis, manuscript writing;

Linh Xu: Project development, data analysis, manuscript writing;

David Ambinder: Project development, manuscript writing;

Rena D. Malik: Project development, manuscript writing.

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