



Evaluation of surgical approaches for vesicovaginal fistulae repair: the case for transvaginal repair as the gold standard

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Abstract

Introduction and hypothesis To highlight the success rates of two approaches of transvaginal vs. transabdominal closures for the vesicovaginal fistula (VVF) repair and to investigate the patient, fistula, and surgical factors relevant to surgical characteristics and successful outcomes.

Methods Retrospective analysis of 66 consecutive patients who underwent VVF repair between 2005 and 2020. Fistula profile, operative data, and postoperative outcomes were analyzed. Primary outcome was success rate with regard to surgical approach. Secondary outcomes were to compare patients' and surgical characteristics with regard to surgical approach and correlate these characteristics relevant to surgical outcomes.

Results A total of 66 women with a median age of 47 (27–82) years were included. Most (93.9%) of the VVFs were secondary to gynecological procedures. Thirteen (19.7%) patients had previous VVF repair. The median time from onset of leakage to surgical repair was 120 days. Forty-nine patients underwent transvaginal repair, whereas 17 (25.7%) women had abdominal repair. The success rates of transvaginal and abdominal techniques were 98% and 82%, respectively. Transvaginal approach had a significantly shorter operative time, less intraoperative blood loss, reduced hospital stay, and lower complication rates ($p < 0.005$). Age and time to surgery were positively and significantly correlated with surgical time [r (p value): 0.392 (0.003), (0.0386 (0.01))] and estimated blood loss [0.388 (0.002 and 0.410 (0.001)], respectively.

Conclusion Transvaginal repair of VVF is a technically feasible and successful approach with significantly better operative parameters and lower complications. Despite varied etiology and different surgical approach, age and time to surgery are the main factors that correlate with operative time and blood loss.

Keywords Outcomes · Repair · Vesicovaginal fistula

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Introduction

Genitourinary fistula is a devastating global health condition with an estimated pooled prevalence of 3 million women worldwide [1]. Vesicovaginal fistula (VVF) remains the most common type of fistulae in the genitourinary tract. While in the developing countries VVFs commonly stem from poor obstetric care, the etiology varies in the industrialized world, with the majority being secondary to gynecological or pelvic procedures [2]. Although the prevalence of urogenital fistulae is less when compared to other chronic health conditions, the sequelae of VVFs are detrimental on voiding and sexual function as well as physical and psychosocial wellbeing of the patients [3, 4].

It follows that successful repair of VVF can lead to potentially life-changing improvement in lower urinary tract function and health-related quality of life (HRQoL) [5]. The

majority of VVFs require surgical repair, which may be performed vaginally, abdominally, or laparoscopically. The transvaginal approach (TV) is generally preferred because of its minimally invasive nature and reduced morbidity allowing a quicker recovery [6]. Surgical approach is generally determined by complexity of the fistula and surgeons' preference [7]. In the vast majority of VVF cases, surgical repair is feasible via the transvaginal approach [4]. The abdominal approach may still be indicated in cases of an inaccessible vaginal vault or when concomitant abdominal surgery is required [2, 8].

Despite the significance of surgical treatment for VVF, the evidence for endorsing the use of either approach remains inconclusive. While the current literature is flooded with comparative studies and case series often evaluating the success and functional outcomes after surgical closure, many of the patient and surgical factors relevant to successful repair are largely unknown. There is some limited literature examining the success rates of abdominal versus vaginal approaches for VVF repairs in well-resourced countries, and the vast majority of studies in North America lacked information on fistula and operative characteristics which may influence surgical approach and hence outcomes. Furthermore, only few studies have analyzed patient characteristics or operative factors and correlate only with risk of postoperative complications [4, 9, 10]. This study aims to highlight the success rates of two approaches of transvaginal vs. transabdominal closures for the vesicovaginal fistula (VVF) repair and to investigate the patient, fistula, and surgical factors relevant to surgical characteristics and outcomes.

Materials and methods

Data source and patient selection

We conducted a retrospective cohort study of women aged ≥ 18 years diagnosed with VVF who underwent surgical repair at our tertiary care center in Alberta, Canada, between January 2005 and May 2020. The study cohort was populated using the Discharge Abstract Database for the Calgary health region for all procedures for VVF repair via either abdominal or vaginal approach. Hospital records were reviewed retrospectively on consecutive patients operated on for VVF. Patients without a valid Alberta provincial healthcare number were excluded. No records were missing covariate data. The women included had confirmed vesicovaginal fistula of variable etiology and had undergone surgical closure with or without failed previous repairs. Patients with persistent incontinence secondary to suspected or confirmed sphincter insufficiency or small bladder, concomitant urogenital fistulae (e.g., urethrovaginal fistula, ureteric fistula, and uterovesical fistulae), and incomplete data were excluded. The study was

approved by the Conjoint Health Research Ethics Board at the University of Calgary.

Patient and operative characteristics

Medical record data were reviewed on (1) clinical evaluation and demographics, (2) fistula profile including etiology, history of radiation or previous attempts of repair, size, and site confirmed on imaging (computerized tomography urogram) and/or cystoscopy and vaginal examination, (3) surgical approach (TV or TA) and concomitant procedures, (4) operative data including surgical time, estimated blood loss (EBL), length of hospital stay, and (5) intra- and perioperative complications. We also reviewed the follow-up time and complications. Comorbidities at index surgery were scored using the American Society of Anesthesiologists physical status classification system (ASA) [11].

For comparison between abdominal and vaginal approaches, demographic characteristics, operative factors, surgical approach, and post-surgical outcomes were analyzed. A successful outcome is defined as anatomical closure of the fistulae and absence of residual leakage on cystogram findings and clinical evaluation at 90 days after discharge. Anatomic success was defined as absence of urinary leakage due to the surgical closure of the fistula as reported on cystogram prior to catheter removal following surgery. We reserve the definition of success until the latest clinic follow-up at 3-month postoperative visit. We utilized terminology for 'failed repair' 'when there is need for a repeat procedure.' Postoperative complications are ileus, de novo SUI, overactive bladder symptoms, leakage, de novo pelvic pain, bladder spasms, vaginal bleeding, infection, and failure. The most frequent intraoperative complications reported are bowel, ureteral, or nerve injury.

Surgical procedure

VVF closure and another concomitant procedure, such as ureteral reimplantation, was performed by two experienced urology surgeons (KC and CB) using established surgical techniques of their expertise. Surgical approach was dictated at surgeon expertise based on number and location of the fistula, appropriate fistula tract access, and involvement of other surrounding structures. The TV was attempted whenever feasible, and either a Martius or peritoneal flap was harvested as an interposition graft where possible. For the TV fistula repair, the patient was placed in the lithotomy position. Both ureteric orifices were calibrated using 6-F ureteric catheters to avoid inadvertent injury. A Foley catheter was introduced to the bladder, and the ureteric catheters were secured to the Foley with steri-strips. A 12–14-F Foley catheter was inserted through the fistula, and the balloon was inflated with 10 ml saline. To bring the fistula into view and ease dissection, gentle traction was applied on the Foley catheter during

dissection, and usually long instruments were used through transvaginal repair. The vaginal mucosa circumferentially around the fistula was infiltrated with dilute lidocaine with epinephrine. A circumscribing incision was made sharply around the fistula with a surrounding margin of 1.0–2.0 cm. Anterior and posterior flaps were raised with sharp and blunt dissection until the fistula's tract was fully exposed. No attempts were made to excise the tract. Dissection was carried out widely in all directions to expose the anterior vaginal wall and to isolate the vascularized peritoneal flap with preperitoneal fat. The fistula site was closed longitudinally with interrupted 4–0 Monocryl sutures. Dilute methylene blue was instilled to the bladder to demonstrate water-tight closure. Mobilized pubocervical fascia on each side was brought together over the fistula site and sutured using interrupted mattress sutures of 3–0 Monocryl. This provided a nice second layer of closure. Then, the pedicle flap was mobilized up and across the fistula closure, tacking it down to the pubocervical fascia well beyond the fistula site with interrupted 3–0 Monocryl sutures. This flap acted as an interposing third layer between the bladder and the vagina. Finally, posterior vaginal mucosa was trimmed and advanced up across the repair site and closed to the anterior flap with running interlocking 2–0 Vicryl suture. Open abdominal repair was considered in the following circumstances: potential associated ureteric injury or adhesions, the fistula approaching the ureteric orifice, multiple fistulae, and inaccessible vagina vault. An interposition flap using either omentum or peritoneum was mobilized to the pelvis as supportive graft between closure layers. As a standard practice, single dose of prophylactic antibiotic was administered to all patients with negative urine culture. Intraoperative evaluation includes EBL and operative time by both an anesthesiologist and a clinical nurse. Surgery-specific intraoperative complications were also recorded for the entire cohort. Early postoperative complications were defined as those that occurred < 1 month postoperatively; late post-operative complications occurred between 1 and 3 months from date of surgery. Minor complications were defined by Clavien grade 1.

Postoperative follow-up

Patients who underwent a TV repair were discharged within 24 h, abdominal repairs within 3 days. Prior to Foley catheter removal fluoroscopic or CT cystogram was performed to ascertain tissue integrity and exclude contrast extravasation, with urethral catheter reinserted if urinary leakage was present. Subsequent follow-up visits were done at 1 month, 3 months, and yearly thereafter if indicated. All of the postoperative complications were documented, the latter at 30 and 90 days. Complications were classified based on the Clavien classification system [12]. Subjective assessment of the success using validated questionnaires was not available for all

subjects given the variability in practice patterns and level of patient compliance with questionnaire completion.

Statistical analysis

Data are presented as frequency (percentage) for categorical variables and mean \pm SD or median (IQR) for numerical variables when normally or not normally distributed, respectively. Data were extracted from patients' files, coded on Excel sheets, and then transferred and analyzed using IBM SPSS Statistics version 23.0 (IBM Co., Armonk, NY, USA). Comparisons between TA and TV approaches were performed by independent *n*-test (or Mann-Whitney as a non-parametric alternative test for not normally distributed variables). Chi-square test was used to compare categorical variables between the two groups. *P* values reflect two-tailed tests, and the difference was considered significant when $p < 0.05$. Pearson correlations between patients' characteristics and surgery outcomes are presented as correlation coefficient, *r* (*p* value or correlation significance). As the success rate was high for both surgical approaches, we did not conduct multiple regression analysis (model fitness could not be achieved).

Results

Retrospective chart review identified 66 women who underwent primary or recurrent VVF repair at our tertiary care center during the 15-year study period. The surgeon proceeded with a transvaginal approach for 49 patients and transabdominal approach for 17 cases. Demographic characteristics and etiologies are presented in Table 1. There were no statistically significant differences in demographic variables between the TA and TA groups. The median age (range) was 47 (27–82) years. Most (93.9%) of the VVFs were caused by pelvic surgery, and 97% of those operations were gynecological procedures ($n = 60$). A history of pelvic radiation was present for 3.0% ($n = 2$) patients. The median available follow-up time was 60 (IQR = 69.5) months. The median time for all comers from onset of leakage to surgical repair was 120 days (IQR = 148). For 80.3% of the patients, this was their first VVF repair (Table 1).

Overall success rates were (93.6%) with no statistically significant difference found between groups (TA = 82%, TV = 98%). Surgery and fistula characteristics are subcategorized by surgical approach (Table 2). Surgery characteristics were not normally distributed; therefore, data were analyzed using nonparametric statistics and are presented with medians and IQR. The duration of surgery was significantly ($p < 0.05$) shorter for the TV approach compared to the TA approach (98 [35] vs. 160 [120] min). Similarly, the EBL for the TV approach cases was significantly less with EBL median 50 ml [21.3] compared with 250 ml [375] for the TA approach

Table 1 Demographic information categorized by surgical approach

	All VVF (<i>n</i> =66)	TA approach (<i>n</i> =17)	TV approach (<i>n</i> =49)
Demographic characteristics ^a			
Age (years), median [IQR]	47 [9.8]	46 [16]	47 [9]
BMI, mean±SD	29±7.3	27.2±7.8	29.6±7.1
Cigarette smoking status (%)	12 (18.2)	1 (5.9)	11 (23.4)
ASA classification (%)			
Grade I	29 (43.9)	7 (43.8)	22 (45.8)
Grade II	33 (50)	8 (50)	25 (52.1)
Grade III	2 (3)	1 (6.3)	1 (2.1)
VVF etiology (%)			
Malignancy	3 (4.5)	1 (5.8)	2 (4.1)
Pelvic surgery	62 (93.9)	16 (94.1)	46 (94)
Obstetric	1 (1.5)	0	1 (2.0)
History of pelvic radiation (%)	2 (3.0)	1 (5.8)	1 (2.0)
Previous fistula repair	13 (19.7)	3 (17.6)	10 (20.4)
Onset of leakage to time of repair (days), median [IQR]	120 [148]	75 [225]	120 [130]

^aNo significant differences were found between transabdominal and transvaginal approaches and patients' demographics using independent *t*-test or Mann-Whitney-U or chi-square test. TA; transabdominal, TV; transvaginal. Data are presented as median (Q1–Q3) for variables not normally distributed, mean (SD) for normally distributed variables, and frequency (%) for the rest

($p < 0.005$). Patients who had a TV approach had a significantly ($p < 0.005$) shorter postoperative admission to hospital than the TA approach patients (1 day [1] vs. 7 days [3]). Descriptive statistics represented in Table 2 outline the fistula characteristics. For the total sample population, 56.1% ($n = 37$) of the fistulas were located near the bladder trigone. Fistulas ranged in size from < 1.5 cm (small) to > 3 cm (large) in both surgical approach groups although most (62.1%) were small fistulas in the cohort overall. Various tissues were used for interposition or flaps. A suprapubic catheter (SPC) was more often placed during the TA cases than the TV repairs (64.7% vs. 6.3%). Intra- and postoperative complications (early and late) occurred significantly ($p < 0.05$) more often in the TA approach group (see Table 3). Intraoperative complications were mainly confined to those having TA repair. Bowel abrasion occurred in three patients. The three serosal tear injuries were recognized intraoperatively and were repaired immediately. Hemorrhage not necessitating blood transfusion occurred in two cases in the TA group. Hematuria through ureteric stent was observed intraoperatively in one patient within the TV group, who was managed conservatively with no evidence of ureteric injury or obstruction. In the postoperative period, complications occurred in 11 (16.7%) of patients. The most common complication among the entire cohort was overactive bladder symptoms (5.7%, $n = 5$). Other minor postoperative complications were observed in the form of ileus (3%), pelvic pain (3%), urinary tract infection (1.5%), and bladder spasms (1.5%). All were managed conservatively. No major complications were

met during the procedure in either group as defined by Clavien class 2 or greater. Failures of all three primary repairs were treated with a second repair. One patient treated with TA approach was reported as secondary failure and subsequently managed with SPC.

Age and time to surgery were positively and significantly correlated with surgical time [r (p value): 0.392 (0.003), (0.0386 (0.01)] and estimated blood loss [0.388 (0.002 and 0.410 (0.001)], respectively (Table 4).

Discussion

Successful repair of VVF is achievable by the transvaginal route in the majority of cases [4, 13, 14]. Using the database from a large urban center, the vast majority of our cohort underwent a repair by means of vaginal surgical approach. We found that transvaginal repair of VVF is a technically feasible approach with a high success rate and low morbidity. In comparison, the overall success rate between the two approaches did not reach statistical significance. However, vaginal repair offers certain advantages as demonstrated by a shorter operative time, shorter hospital stay, and reduced blood loss and intra- and postoperative complications compared to the TA approach for both gynecological and obstetric fistulae. In addition, we noted that age and time to surgery are the main factors that correlate with operative time and blood loss.

Table 2 Surgery and fistula characteristics

	All VVF (n=66)	TA approach (n=17)	TV approach (n=49)
Surgery characteristics, median [IQR]			
Operative time (min)*	104 [63.8]	160 [120]	98 [35]
Estimated blood loss (ml)**	50 [150]	250 [375]	50 [21.3]
Length of hospital stay (days)**	2 [3.75]	7 [3]	1 [1]
Fistula characteristics, n (%)			
Fistula site [#]			
Base	9 (13.6)	6 (37.5)	3 (6.1)
Posterior wall	7 (10.6)	4 (25)	3 (6.1)
Around trigone	37 (56.1)	4 (25)	33 (67.3)
Dome	1 (1.5)	1 (6.3)	0
Midline	11 (16.7)	1 (6.3)	10 (20.4)
Fistula size [Goh's classification]			
< 1.5 cm (small)	41 (62.1)	9 (52.9)	32 (66.7)
1.5–3 cm (medium)	19 (28.8)	6 (35.3)	13 (27.1)
> 3 cm (large)	5 (7.6)	2 (11.8)	3 (6.3)
Tissue interposition [#]			
Martius flap	7 (10.6)	0	7 (14.3)
Peritoneal flap	44 (66.7)	3 (17.6)	41 (83.7)
Omentum	10 (15.2)	10 (58.8)	0
None	5 (7.6)	4 (23.5)	1 (2.0)
Fistula tract excision [#]			
Concomitant surgery	17 (25.7)	8 (47.1)	9 (18.4)
Ureteral reimplantation	3 (4.5)	3 (17.6)	0
Ureterolysis, stent	1 (1.5)	1 (5.9)	0
Ureterolysis, excision keloid scar	2 (3.0)	2 (11.8)	0
Closure of vaginal vault	2 (3.0)	2 (11.8)	0
TVT mesh removal (eroded)	2 (3.0)	0	2 (4.1)
Enterocoele/rectocoele repair	5 (7.5)	0	5 (10.2)
Excision endometrioma	1 (1.5)	0	1 (2.0)
Ureteric stent/s insertion	1 (1.5)	0	1 (2.0)
Suprapubic catheter [#]	14 (21.2)	11 (64.7)	3 (6.3)

* $p < 0.05$, ** $p < 0.005$ indicating a significant difference between TA and TV approaches (Mann-Whitney test)

[#] $p < 0.05$ indicating a significant difference between the two approaches (chi-square test)

In the present study we reported our experience of 66 women with VVF of varying etiologies collected over a 15-year period. The overall success rate of VVF repair for the entire cohort was nearly 94% over a mean follow-up period of 2 years, similar to other series reported in the literature [15]. We found that TV approach was associated with less intra- and postoperative morbidity compared to TA technique, as demonstrated by shorter operative time and blood loss as well as need for SPC, postoperative hospitalization, and complications. In more detail, transvaginal approach was associated with a significantly lower incidence of overactive bladder symptoms and observed in about 4% of patients versus 18% with the TA approach. Moreover, none of 49 patients within the TV group developed UTI, bladder spasms, or chronic

pelvic pain. There were no major intraoperative complications reported with TV repair. The major intraoperative complications that were evaluated were bowel, ureteric, or nerve injury.

The majority of cases of VVF in this series were secondary to pelvic surgery; gynecological procedures in particular led to 91% of the VVFs in this group. Similar findings were reported by Lee et al. and Luo et al. with 88% and 94.5%, respectively, for VVFs in WRC caused by surgical misadventures in the pelvis [16, 17]. The most frequent location for the VVF was in the trigone area of the bladder, corresponding to the majority etiology.

It is important to note that although we reported a higher success rate with TV repair, there was no significant difference in success rate relevant to the route of VVF surgical

Table 3 Results and complications

	All VVF (n=66)	TA approach (n=17)	TV approach (n=49)
Outcome			
Success rate	62 (93.9)	14 (82.4)	48 (98)
Failure	4 (6.1)	3 (17.6)	1 (2.0)
Follow-up study, n (%)			
Cystogram	46 (69.7)	12 (70.6)	34 (69.4)
CT cystogram	17 (25.7)	3 (17.6)	14 (31.1)
Cystoscopy	3 (4.5)	2 (11.7)	1 (2.0)
Interval of cystogram from index surgery (days), mean±SD	18.4±6.1	19.3±6.2	18.2±6.0
Cystogram outcome (leak), n (%)	4 (6.1)	2 (11.8)	2 (4.1)
Intraoperative complications [#] , n (%)	6 (9.1)	5 (29.4)	1 (2.1)
Postoperative complications [#] , n (%)			
Early complications [#]	5 (7.6)	5 (29.4)	0
Late complications [#]	6 (9.1)	4 (28.6)	2 (4.1)
Major complications ^a	0	0	0
Minor complications	11 (16.7)	9 (53)	2 (4.1)
Overactive bladder symptoms	5 (7.6)	3 (17.7)	2 (4.1)
Chronic pelvic pain	2 (3.0)	2 (11.8)	0
Urinary tract infection	1 (1.5)	1 (5.9)	0
Bladder spasms	1 (1.5)	1 (5.9)	0
Postoperative ileus	2 (3.0)	2 (11.8)	0

* $p < 0.05$, ** $p < 0.005$ indicating a significant difference between TA and TV approaches (Mann-Whitney test)

[#] $p < 0.05$ indicating a significant difference between the two approaches (chi-square test)

^a Defined as Clavien class 2 or greater

repair. Our results confirm that the TV approach has distinct advantages compared with the TA approach. Most importantly, for the patient, the TV approach was significantly associated with less intraoperative blood loss and lower complication rates at all points from intra- to late postoperative. Furthermore, the TV group had significantly shorter hospitalization stay after surgery (median 1 day vs. 1 week with TA), and the vast majority did not require a SPC. It follows that these quicker and less morbid repairs also benefit the surgeon and the health care system, especially in a publicly funded setting. The authors conclude that in all but the most rare cases where additional abdominal procedures are required, a TV approach should be offered. In our institution, outside of those rare circumstances a TA approach has not been undertaken since (2005), and fistula location or vaginal access has not prevented successful repair in any case.

Debate is ongoing regarding optimal timing for VVF repair [18]. Regardless of surgical approach, the average timing for repair in our cohort is 120 [IQR = 148] days, with the view of minimizing distress to the patient and promoting fistulae maturation; to optimize the surgical outcomes we continue to endorse repair between 6 and 12 weeks from the initial causative surgery but understand that opinions vary on this. Currently, there is no universally agreed upon definition of early versus late intervention. This seems to support the argument that repair should take place at least a few weeks after leakage begins to allow necrotic tissue to slough away, while catheterization promotes maturation of the fistulous tract which in turn facilitates surgical repair. On the contrary, waiting too long may increase the complexity of the surgery. Regardless of surgical approach, age and time to surgery are the main factors that correlate with operative time and blood loss. This finding highlights the impact of aging and poorly

Table 4 Correlation between surgery characteristics and patients' demographics

	Age <i>r</i> (p value)	BMI <i>r</i> (p value)	Time to surgery <i>r</i> (p value)
Operative time (minutes)	0.393 (0.003)	−0.03 (0.84)	0.386 (0.01)
Estimated blood loss (ml)	0.388 (0.002)	−0.295 (0.024)	0.410 (0.001)

Pearson correlation, *r* (correlation coefficient)

estrogenized, atrophic tissues across various surgical domains and potentially postoperative outcomes [19].

Only a few patients in this series had a previous failed repair. Other authors have purported that the best rates of success are with the first repair, and stepwise decreases in success are seen with subsequent surgeries [20]. The results of this study showed that success rates for patients who underwent a repeat repair were still convincing. Similarly, results in contemporary published series also did not find any impact of success rates if the patient had had a previous repair [15, 16].

Our study does have several limitations. As with all single-center surgical series, the generalizability to other hospital settings and health systems may be questioned. There were no differences between the TV and TA approach groups for demographic characteristics, which lends validity to our comparative findings. Different findings could be found at centers with patients dissimilar to those in this study, such as older patients or other body habitus. However, as this database describes a long series and our center has a large catchment area, this limitation may be mitigated. Other limitations include those inherent to retrospective nature of this study and likely our small cohort number, which lacks the statistical power to detect significant differences between groups. We also lacked information on functional and patient-reported outcomes, such as quality of life and urinary and sexual function before and after surgery.

Conclusions

Transvaginal repair of VVF is a technically feasible and successful approach with significantly better operative parameters and lower complications rates. Abdominal surgical approach is a safe alternative with a comparable success rate, but with longer hospital stay and higher incidence of complications. Despite varied etiology and different surgical approaches, age and time to surgery are the main factors that correlate with operative time and blood loss.

Authors' contributions Shamout S: Project development, Data Collection, Data analysis, Manuscript writing/editing. Anderson K: Management data analysis, Manuscript writing. Baverstock R: Management data analysis, Manuscript writing/editing. Carlson K: Project development, Data collection, Manuscript writing/editing.

Declarations

Disclosure/Conflict of interest • None of the authors of this paper has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of the paper.

• We specifically state that “No Competing Interests are at stake and there is No Conflict of Interest” with other people or organizations that could inappropriately influence or bias the content of the paper.

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