Title: Vaginal pessaries: Can an educational brochure help patients to better understand their care?

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Brief summary: Happiness, confidence and knowledge about pessaries in women with prolapse improved after distribution of a purposively developed, take-home pessary brochure, regardless of participant age or educational background.

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Keywords: Brochure, confidence, education, happiness, knowledge, prolapse.

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Abstract:

Aims and objectives: Pelvic organ prolapse is a common condition, with reported incidence of up to 50%. We aimed to assess whether written information, in addition to face-to-face consultation, improved happiness with information, confidence to self-manage and prolapse knowledge in women attending a pessary clinic.

Background: Little is known about the effect of adding a written information brochure on clinical outcomes of patients using pessaries.

Design: This prospective study used a pretest posttest method, conducted following Ethical approval.

Methods: Between February and December 2013 all women attending Pessary Clinic were eligible for participation. A questionnaire was developed assessing happiness with information, confidence regarding self-management (using a visual analogue scale, 1-10) and prolapse knowledge (using eight multiple-choice questions). Data were collected in person at baseline prior to distribution of a patient brochure and thereafter by telephone at one-week and three-months. Paired analysis was conducted using the McNemar test and Related Samples Wilcoxon Signed Rank Test for VAS items with $p < .05$ significant.

Results: 60 women were recruited. Fifty-eight completed all questionnaires. Improvement in happiness with information, confidence regarding self-management and knowledge scores occurred at one-week ($p < .05$) and were maintained at three-months ($p < .05$). Changes were unrelated to age ($p > .05$), education level ($p > .05$), first language ($p > .05$) or previous clinic visits ($p > .05$).

Conclusion: A written information brochure, in addition to face-to-face consultation, improves happiness with information, confidence to self-manage and knowledge about pessaries compared to verbal instruction alone and does make patients better able to

understand their care. The written brochure was equally effective in women with low education and advanced age, and occurred regardless of number of clinic visits.

Keywords: Brochure, confidence, education, happiness, knowledge, prolapse, women.

Introduction & hypothesis:

Pelvic organ prolapse (POP) is a common condition in parous women, with a reported incidence of up to 50% (Maher 2013). Whilst many women opt to undergo surgical correction of symptomatic prolapse, many prefer a non-surgical approach (Bugge et al. 2013; Geoffrion et al. 2009; Nemet 2013). Intra-vaginal pessaries are a safe and cost-effective treatment option for conservative management of prolapse and can reduce symptoms by repositioning prolapsed organs to provide anatomical support (Cheon & Maher 2013; Hanson et al. 2006; Maito et al. 2006; McIntosh 2005)(1-4)(1-4)(1-4)(1-4). Their use can give women the choice to defer or even avoid the need for surgical repair (Bugge et al. 2013; Coulter & Ellins 2007; Thakar & Stanton, 2002). Pessaries are regularly used by women who may not choose to have or be fit for surgery, those on surgical waiting lists, those for whom surgery has failed or by those who have not yet completed their families (Maito 2006; Thakar & Stanton 2002).

Patients attending Pessary Clinic (PC) at Mercy Hospital for Women previously received verbal information alone at time of consultation. All women attending the clinic do so due to symptomatic prolapse (grade 2 or 3) requiring management of those symptoms by the use of a vaginal pessary. Clinicians within the clinic identified that there was a consistent lack of knowledge about prolapse and pessary management in the patient group. We hoped that the development and distribution of a condition specific educational brochure would address this situation. The amount of knowledge about prolapse and pessary management that the patient retained following face-to-face consultation was unknown. The provision of appropriately worded, condition specific written materials to patients can improve self-management, health literacy and outcomes by increasing patient knowledge and vigilance (Coulter & Ellins 2007; Ivnik & Jett 2008). With this in mind, a patient information brochure focusing on pessary management was newly developed, aiming to improve happiness with specific information the patient received, confidence to self-manage a pessary, adherence with proposed treatment and knowledge about pessary management. We hypothesized that the addition of a take home information brochure combined with oral information communicated at face-to-face consultation would improve patient happiness with information received, confidence to self-manage the pessary and knowledge about prolapse management compared to oral information alone.

Materials and Methods:

This study used a single-group pretest-posttest quasi experimental method. The brochure is not a stand-alone training method and the experiment was designed to support and reinforce the verbal information provided during a clinical consultation. All patients attending the Pessary Clinic were eligible for inclusion in the study. Nursing staff in the Pessary Clinic were not able to invite every available woman attending the clinic to participate due to the busy nature of the clinic. Women were invited to participate during a routine Pessary Clinic visit according to staff availability, regardless of whether they were patients new to the clinic or they had had a pessary fitted for some time. Patients who could not speak and read English or Greek were excluded, as the brochure was only available to patients in these languages. A new questionnaire was developed to evaluate patient happiness with information received, confidence to self-manage a pessary and knowledge of prolapse and pessary management (Appendix 1). The written brochure was purposively developed for this study. Medical vocabulary was minimized and instructions worded clearly and simply, with a Flesch-Kincaid reading score of less than five (Flesch 1948). The brochure was presented on A4 paper and consisted of two pages of written text and one page containing pictures. The text pages included Pessary Clinic details (opening times, contact details and clinic location), followed by a list of frequently asked questions and answers. These questions related to commonly asked questions and problems seen in the Pessary Clinic. The final page showed pictures of pessary types and provided space for the clinician to personalize the brochure by noting which type and size of pessary the woman was using. The inclusion of key messages and pictures of pessaries provides visual and personalized connection to treatment (Johnson et al. 2008; Palumbo 2000). The brochure was prepared in two languages, English and Greek. As the clinic has a high number of women of Greek ethnicity, the brochure was translated into Greek by a medical translator and given to women in their first language, along with a copy in English. Consultations and follow-up telephone calls for Greek women were conducted using a Greek medical interpreter if required. Questionnaires were completed in person at the initial appointment (pretest) before the new brochure was distributed to each participant and by follow-up telephone interview at one week and three months (posttest).

Demographic data were collected and included age, parity, body mass index (BMI), highest education level achieved (primary, secondary or tertiary), first language, presence of an interpreter, presence of a carer, number of previous visits, PC attendance (months), previous prolapse surgery, menopause status, current sexual activity and vaginal oestrogen use (Table 1). Participants were asked a series of 10 questions at the initial visit (pretest) which formed a baseline, after which the brochure was distributed, and again, by telephone at one week (posttest, one week) and three months (posttest, three months). The follow-up telephone calls followed a prescribed and scripted format. Questions one and two used a visual analogue scale (VAS) to measure responses (0-10, with zero being very

unhappy and 10 being extremely happy). Women were asked (1) How happy are you with the information you have received in the Pessary Clinic? Then, (2) How confident are you to manage your prolapse condition? The remaining eight questions tested knowledge using a multiple-choice format. Each question had five possible answers with one correct and four incorrect (Appendix 1).

Data were entered into Statistical Package for the Social Sciences and analyzed (SPSS v22, SPSS Inc, Armonk, NY, IBM Corp). Descriptive analyses were undertaken with non-parametric tests used for group comparisons. Paired analysis was conducted using the McNemar test for categorical items and Related Samples Wilcoxon Signed Rank Test for VAS and interval items with $p < .05$ significant.

Study approval was obtained from the hospital's Human Research and Ethics Committee. Written information about the study was provided to participants and written consent was obtained from all participants.

Results:

There were 121 eligible women who attended the Pessary Clinic between one and five times during the study period. Of these, 60% of women attending were invited by staff to participate in the study due to staff being unable to approach all of the eligible women during the busy Pessary Clinic. 83% of women approached agreed to participate and 96.6% completed all questionnaires over the study period. Two women withdrew when contacted after one week and their data were not included in the study. Of the 58 remaining women the mean age of participants was 69.3 years (range 29-91). 27.6% of participants were sexually active and 15.5% had previous prolapse surgery. Mean parity was 2.9 (range 1-7) and 87.9% of women were postmenopausal. Mean PC attendance was 22.6 months (range 1-96). Mean previous PC visits was 5.5 (range 1-16). Mean BMI was 28.1 (range 21-44). 43.1% of women attended primary school only, 34.5% attended high school and 22.4% had a tertiary education. 12% of women were accompanied by a carer (Table 1). English was the first language of 70.6% of participants, followed by 15.5% whose first language was Greek. English was a second language for 7% who spoke Italian, 1.7% who spoke Arabic, 1.7% who spoke Maltese, 1.7% who spoke Serbian and 1.7% who spoke Tamil. These women were able to speak and read English and did not require the aid of an interpreter. +

One week after the brochure was given the women were telephoned and all participants were asked if they had read the pessary brochure that they had been given at the pretest personal consultation in the Pessary Clinic. Fifty-one of the 60 women (85%) had done so and one week follow-up questionnaires were completed at this time. Seven (12%)

remaining women who had not yet read the brochure were asked to do so and telephone calls were repeated one week later. At that point all 58 (96.6%) remaining study participants had read the brochure and one week follow-up questionnaires were completed. When asked to rate happiness with information given (using a VAS scale, 0-10), the median initial score was 8.0 (IQR 5.8-10.0). One week after the brochure was distributed the median happiness score had increased to 9.0 (IQR 8.0-10.0; $p=.003$) and at 3 months the median score had further increased to 10.0 (IQR 8.0-10.0; $p=.007$) (Table 2). Confidence to self-manage the prolapse condition initial pretest median score was 6.5 (IQR 4.5-9.0). After one week the median confidence score had increased to 8.0 (IQR 7.0-10.0; $p<.001$) and at 3 months the median confidence score had further improved to 9.0 (IQR 8.0-10.0; $p=.013$).

In regard to knowledge scores, seven of the eight multiple choice knowledge questions had improved scores from baseline. Scores increased from before the brochure was given to the patients in comparison to one week after ($p=.001$) and were maintained (but did not further improve) at three months ($p=.557$). Question eight saw a decline in the correct answer score over the survey period. This question related to increased urinary incontinence, which showed an initial improvement at one week, followed by decreased correct scores at three months compared to initial (pretest score 35 (60%) correct, one week score 41 (71%) correct, and 3 month posttest score of 34 (59%) correct (Table 2). There was no difference according to age at pretest assessment or three month posttest scores for happiness ($p=.50$) confidence ($p=.50$) and knowledge ($p=.90$), with elderly women (≥ 70 years) having no difference in scores than younger participants aged <70 years. Overall the rise in score for happiness, confidence and knowledge was maintained from one week to three months. Though the change in confidence score based on education level was not statistically significant, there was a trend towards increasing confidence based on education ($p=.051$).

Numbers of Greek women in the study group were small ($n=9$). Medical interpreters were used if required. This group was older compared to non-Greek participants though this figure did not reach statistical significance (mean age 75.6 versus 69.3 years; $p=.10$). Education levels among Greek women were lower than non-Greek participants, with eight of the nine Greek women attending primary school only (88.9% versus 34.7%; $p=.003$). At the initial pretest assessment, before the distribution of the pessary brochure, the Greek (as a first language) women's median pretest score for happiness with information was 8 (IQR 4.5-8) compared to the non-Greek group's score of 8 (IQR 6-10; $p=.20$). At the first visit confidence to self-manage in the Greek speaking group had a median score of 5 (IQR 2.5-6.5) compared to the non-Greek group's median score of 7 (IQR 5-7.5; $p=.04$). Median score for knowledge of the pessary and its management in the Greek speaking group was 6 (IQR 4.5-7) compared to the non-Greek group's median score of 7 (IQR 5-7.5; $p=.40$). At

the three months follow-up posttest telephone assessment, median scores had increased significantly to 10 (IQR 8-10) for happiness with information in the non-Greek language group compared to the Greek language group's increased score of 8 (IQR 7.5-9; $p=.03$). Greek speaking women's confidence median scores increased to 8 (IQR 7.5-9) during this period compared to the non-Greek group's score of 9 (IQR 8-10; $p=.07$). Knowledge about prolapse saw no difference between the non-Greek group of women, with a median score of 7 (IQR 7-8) or Greek language score of 6 (IQR 5.5-7.5) at the three months follow-up telephone call ($p=.07$).

Discussion:

Use of written educational material improved across all measured areas in this study, despite a wide diversity of study participants. The term health literacy has been used since the 1970's and its definition has varied in the literature since then (Ivnik & Jett 2008; Sørensen et al. 2012). Protheroe et al. (2009) define health literacy as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in ways that promote and maintain good health'. Health literacy is being identified as important, with patients increasingly expected to be involved in self-care regimens and decision making processes. Elderly patients especially are known to have difficulty recalling verbal information given at time of consultation, potentially contributing to less favorable health outcomes (Anger et al. 2012; Edwards et al. 2012; McCarthy et al. 2012). Palumbo (2000) states that "patient education is vital for successful pessary use". In another study of oral plus written information versus oral alone Johnson describes increased satisfaction and knowledge, brought about by the utilization of standardized information to parents of sick children (Johnson et al. 2008). Similarly Volk et al. (2013), in a pretest, posttest study design of patients with liver cirrhosis found patients had improvements in knowledge scores, regardless of age, etiology, disease severity or time attending clinic following introduction of an educational booklet. Clarke-Moloney et al. (2009) alternatively, in a randomized control trial (oral information versus oral plus written information) found there was no advantage in adding written information to verbal instruction in patients with newly diagnosed leg ulcers, although participant numbers in this study were small with only 20 participants (10 participants in each group).

Generally, written patient instruction is developed aiming to better manage conditions and improve information retention (Coulter & Ellins 2007; Ivnik & Jett 2008; McCarthy et al. 2012). Readability is an important consideration in the development of patient handouts and staff should be aware of the quality and appropriateness of the material that they deliver to their patients to ensure readability of materials is adequate (Fitzmaurice & Adams

2000). Flesch-Kincaid reading scores assess readability and give an overall score, with acceptable scores for patient education materials five or below (Ivnik & Jett 2008). The newly developed pessary brochure has a reading score of 5.0, indicating a reading score suitable for 10-12 year olds (Flesch 1948). Coulter & Ellins (2007) suggests that while written information alone may have little effect, written materials can help when coupled with a personal consultation. Boxell et al. (2012), in a study relating to gynecological cancer education, provided information aimed at patients to improve symptom awareness and help seeking strategies. She recommends that care must be taken not to unduly rely on written brochures. In our study, baseline scores across all areas were high. Over the course of the study one week posttest and three month posttest scores increased, regardless of age, length of time attending the clinic or level of formal education, compared to scores from the pretest personal consultation. Score improvement occurred despite the median number of clinic visits prior to the implementation of the brochure being on average five visits.

Participants involved in the study were of diverse backgrounds. Although Singleton & Krause (2009) suggest this diversity presents a barrier to effective health communication, our results have shown that increased happiness with information provided, confidence to self-manage a pessary and knowledge about prolapse has occurred despite these differences. Richardson et al. (2009) proposes that provision of patient information can empower women to become more involved in decision making regarding pessary management by increasing knowledge and improving confidence. Hawary et al. (2010)(5)(5)(5)(5), in a study of patients attending a urology clinic, suggests that there is a worrying lack of patient knowledge about their condition and recommends that patient education materials and resources be standardized. Low education levels and impaired health literacy present barriers to understanding. Although almost half (43.1%) of this study's participants had a primary school education alone, providing them with appropriately readable and personalized education materials, combined with oral information, made a difference to their happiness, confidence and knowledge in regard to prolapse and pessary management. Chen et al. (2011) describes uptake of health information in regard to heart failure (like prolapse, a chronic condition) and discusses the link between self-confidence and self-management. Increased scores in confidence and happiness are reflected in this study, with increased scores at one week and three months follow-up. In fact, women with higher educational levels also benefitted from the addition of an appropriately written, personalized, condition specific information brochure. Although we were not able to examine the impact of these improvements on patient outcomes, higher knowledge about prolapse, pessary use and potential complications may result in less Emergency Department presentations for non-urgent prolapse management issues.

Strengths and limitations of the study:

There were several strengths to this paper. Firstly, the 60 participants who initially took part did so with a low drop-out rate over the course of the study. Only two women failed to complete all questionnaires. There was wide variation in participant age, education, ethnicity, time spent at the Pessary Clinic and background of women. While it was a non-random sample, it is representative of the day-to-day Pessary Clinic population. There were limitations however, including that invitation of eligible women to participate was sometimes restricted by staffing or time constraints. This was a single center study. The questionnaire and patient brochure have not been assessed in a formal validation process for reliability and validity. The educational intervention and questionnaire may not equate with correct pessary position and effective management of prolapse symptoms. This study's aim and intention was to measure the difference before and after the introduction of an educational brochure. We did not seek to measure whether this altered the symptom outcome for women with prolapse. The authors developed the questionnaire and did not employ focus groups or other methods to develop, test or review the document. Also, the link is unknown between patient happiness with the information given and happiness with the pessary itself. Broad categorization of school achievement was measured but didn't include formal literacy testing to accurately establish participant literacy levels.

Conclusion:

When compared with the normal approach (verbal information only at time of consultation) the addition of a written, condition specific patient information brochure resulted in score improvement. In this study happiness with information provided, confidence to self-manage, and knowledge about prolapse and pessary management scores were high at baseline. The introduction of a pessary information brochure resulted in score improvement across all areas after one week, which was maintained at three months, compared to baseline. There was no difference in the improvement scores related to educational level, number of Pessary Clinic visits, first language or participant age. A written, take-home brochure does benefit women using an intra-vaginal pessary to better understand their care, and does improve happiness with information provided, confidence and knowledge about prolapse and pessary use, compared to verbal information alone. The results of this study are encouraging and point toward adoption of the practice of providing both verbal and written information regarding conservative management of prolapse as routine clinical practice.

What does this article contribute to the wider global clinical community?

Following the completion of our study we have learned that:

- A written information brochure, in addition to face-to-face consultation, improves happiness with information, confidence to self-manage and knowledge about pessaries compared to verbal instruction alone and does make patients better able to understand their care.
- The results of this study are encouraging and point toward adoption of the practice of providing both verbal and written information regarding conservative management of prolapse as routine clinical practice.
- Patient education is important and takes many forms including verbal, written and demonstration.
- Appropriately constructed and developed written patient material can help patients to get the most out of their care.

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Appendix list

Appendix 1: Pessary Clinic Questionnaire

Table list

Table 1: Demographic details

418 **Table 2:** Questionnaire results

419 **Appendix 1: Pessary Clinic Questionnaire**

420 **Question 1- (Visual Analogue Scale)**

421 How happy are you with the information you have received in the Pessary Clinic?

422 0 1 2 3 4 5 6 7 8 9 10

424 **Very unhappy** . **Extremely happy**

425

426 **Question 2- (Visual Analogue Scale)**

427 How confident are you to manage your prolapse condition?

428 0 1 2 3 4 5 6 7 8 9 10

430 **Very unhappy** . **Extremely happy**

431

432 **Question 3- (correct answers are those marked in bold)**

433 What is vaginal prolapse? Please tick the correct answer

- 434 1. ***It is when organs drop from their normal position in the pelvis.***.....☐
- 435 2. It is the cause of urinary leakage.....☐
- 436 3. It is a vaginal infection.....☐
- 437 4. It is an operation.....☐
- 438 5. It only involves the uterus.....☐

439

440 **Question 4-**

441 What does a pessary do? Please tick the correct answer

- 442 1. A pessary is a skin treatment.....☐
- 443 2. ***A pessary helps to keep a prolapse in place.***.....☐
- 444 3. A pessary is a type of surgery.....☐
- 445 4. A pessary is used to treat constipation.....☐
- 446 5. A pessary is a type of prolapse.....☐

447

448 **Question 5-**

449 Your pessary falls out? What should you do? Please tick the correct answer

- 450 1. Call an ambulance..... ☐
- 451 2. ***Wash it, put it into a plastic bag and bring it in next time.***..... ☐
- 452 3. Do nothing..... ☐
- 453 4. Throw it away..... ☐
- 454 5. Visit your physiotherapist..... ☐

455 **Question 6-**

456 How often should you use the vaginal cream or vaginal tablet that your doctor has prescribed?

457 Please circle the correct answer

- 458 1. Weekly..... 2. Monthly..... 3. Daily..... 4. ***Twice weekly***..... 5. Only if I have a problem.....

459

460 **Question 7-**

461 You find that there is a large amount of bleeding from the vagina? What should you do? Please
462 tick the correct answer

- 463 1. Do nothing..... ☐
- 464 2. Have a salt bath..... ☐
- 465 3. ***Come to the Mercy Hospital's Emergency Department.***..... ☐
- 466 4. Wait till morning and see how things are..... ☐
- 467 5. Take two paracetamol tablets..... ☐

468

469 **Question 8-**

470 There is an increase in urinary leakage? What should you do? Please tick the correct answer

- 471 1. Don't worry about it..... ☐
- 472 2. Call your physiotherapist..... ☐
- 473 3. ***Discuss the problem at your next clinic appointment.***..... ☐
- 474 4. Call an ambulance..... ☐
- 475 5. Come to the Emergency Department..... ☐

476

477 **Question 9 –**

478 You have a smelly discharge from the vagina. What should you do? Please tick the correct
479 answer

- 480 1. Do nothing, it will go away by itself..... ☐
- 481 2. Take some Ural or cranberry juice..... ☐
- 482 3. **Ring the Pessary Clinic to make an appointment**..... ☐
- 483 4. Use some perfume or female deodorant to mask the smell..... ☐
- 484 5. Use some cream from the chemist..... ☐
- 485

486 **Question 10-**

487 You think you have a urinary tract infection? What should you do? Please tick the correct answer

- 488 1. Do nothing, it will get better by itself..... ☐
- 489 2. **Contact a health professional (nurse, doctor, hospital)**..... ☐
- 490 3. Use your vaginal cream..... ☐
- 491 4. Contact your physiotherapist..... ☐
- 492 5. Ring a relative or friend..... ☐
- 493

494 **Table 1: Demographic data**

Descriptor	n (%) or mean (95% CI) <i>n</i> = 58	Range	Median (IQR)
Age (years)	69.3 (65.9-72.7)	29-91	69.5 (62.5-80.3)
Parity	2.9 (2.6-3.2)	1-7	3.0 (2.0-3.3)
BMI	28.1 (26.9-29.4)	21.0 – 44.0	27.0 (25.0-31.0)
Education level	25 (43.1)		
Primary school	20 (34.5)		
Secondary school	13 (22.4)		
Tertiary studies			
First language other than English	17 (29.3)		
Interpreter used	11 (19.0)		
Attended with carer	7 (12.1)		
Number of Pessary Clinic visits	5.5 (4.4-6.5)	1-16	4.0 (2.0-8.0)
Length of time at Clinic (months)	22.3 (16.2-28.3)	1-96	11.5 (3.8-36.0)

Prior prolapse surgery	9 (15.5)		
Menopausal	51 (87.9)		
Hormone replacement therapy	50 (86.2)		
Vagifem	10 (17.2)		
Ovestin	40 (69.0)		
Sexually active	16 (27.6)		

Table 2: Questionnaire results

Question	Initial	1 week post-test	3 months post-test
Q1 Happiness with information given			
Mean (95%CI)	7.3 (6.6-8.1)	8.5 (8.1-9.0)	9.0 (8.7-9.4)
Median (IQR)	8.0(5.8-10.0)	9.0 (8.0-10.0)	10.0 (8.0-10.0)
Q2 Level of confidence to self-manage			
Mean (95%CI)	6.2 (5.3-7.0)	8.0 (7.5-8.4)	8.5 (8.1-8.9)
Median (IQR)	6.5 (4.5-9.0)	8.0 (7.0-10.0)	9.0 (8.0-10.0)
Q3 What is vaginal prolapse?	47 (81.0)	51 (87.9)	53 (91.4)
Q4 What does a pessary do?	52 (89.7)	54 (93.1)	56 (96.6)
Q5 Your pessary falls out, what should you do?	41 (70.7)	47 (81.0)	50 (86.2)
Q6 How often should you use your prescribed vaginal oestrogen?	40 (69.0)	48 (82.8)	49 (84.5)
Q7 There is vaginal bleeding, what should you do?	48 (82.8)	47 (81.0)	49 (84.5)
Q8 There is an increase in urinary leakage, what should you do?	35 (60.3)	41 (70.7)	34 (58.6)
Q9 You have a vaginal discharge, what should you do?	41 (70.7)	46 (79.3)	52 (89.7)

Q10 You think you have a urinary tract infection, what should you do?	49 (84.5)	55 (94.8)	54 (93.1)
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