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Outpatient periurethral injections of polyacrylamide hydrogel for the treatment of female stress urinary incontinence: effectiveness and safety

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Abstract
Purpose To investigate the effectiveness and safety of periurethral injections (PIs) of polyacrylamide hydrogel (PAHG, Bulkamid®) for the treatment of female stress urinary incontinence (SUI).
Methods This double-centre prospective study included 82 female patients with SUI who were treated with PIs of PAHG between January 2008 and December 2010 in outpatient setting. The International Consultation on Incontinence Questionnaire short form (ICIQ-SF) and the Patient Global Improvement Impression (PGI-I) were used to assess incontinence and patient satisfaction after treatment. The impact of incontinence on quality of life (QoL) was investigated using the Incontinence Impact Questionnaire (IIQ-7).
Results All patients were discharged on the same day of treatment and there was no intraoperative complication. At 1-year follow-up, the efficacy of PIs of PAHG (subjective success rate) was 74.4 %. The subjective responder rate was 86.6 %, 8.5 % of patients had no change and no patient reported worsening of symptoms. The mean number of episodes of urine leakage/24 h and the mean leakage/24 h significantly decreased after treatment. At 1-year follow-up, the IIQ-7 results were significantly improved compared with baseline. 25.6 % of patients had adverse events (mainly urinary tract infections and injection site pain).
Conclusion This study demonstrates that PIs of PAHG are effective and safe and cause significant improvement of the QoL at 1-year follow-up. PIs of PAHG can be safely performed in an ambulatory setting and patients may be discharged on the day of the procedure.

Keywords Bulkamid · Outpatient · Periurethral injections · Polyacrylamide hydrogel · Stress urinary incontinence

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Introduction

The use of bulking agents for periurethral injection (PI) therapy of urinary incontinence (UI) has been introduced since the early twentieth century [1]. It is established that the ideal agent should not be absorbable, toxic, allergenic and it should not cause any immunological, inflammatory and fibrotic reaction; in contrast, it should be durable and of sufficient size to avoid migration. Several materials (such as paraffin, autologous fat, polytetrafluroethylene, ethylene vinyl alcohol, carbon beads, calcium hydroxylapatite, glutaraldehyde cross-linked bovine collagen, porcine dermal implant and hyaluronic acid/dextranomer copolymer) have been used for PIs and some of them were abandoned since they did not correspond to the previously described safety criteria. It was common thinking that the main mechanism of injection therapy in the treatment of UI was related to an obstructive and sealing effect [2]. A more recent study suggested that injection therapy may cause an increasing of the central filler volume and consequently it may increase the power of the urethral sphincter [3]. This explanation justifies the fact that this kind of treatment has

similar cure rates in different subtypes of stress urinary incontinence (SUI) [2]. A recent Cochrane review, including 14 randomised trials investigating the use of injection therapies with bulking agents, concluded that this treatment is safer but less effective than open surgery at 12 months. In particular, the authors stated that since long-term follow up and health economic data are not available, injection therapy cannot be offered as an alternative treatment for patients who can be treated with surgical procedures. In contrast, PI therapy could be considered in women with extensive co-morbidity precluding anaesthesia [4]. In fact, bulking agents are minimally invasive and they can be performed under local anaesthesia in ambulatory setting.

This study aims to investigate the effectiveness and safety of PIs of polyacrylamide hydrogel (PAHG) for SUI treatment in outpatient setting. Furthermore, the changes in quality of life (QoL) after treatment were evaluated.

Materials and methods

Study population

This double-centre prospective study included female patients who were treated for SUI with PIs of PAHG between January 2008 and December 2010. Inclusion criteria for the study were SUI symptoms persisting for $\geq$12 months, SUI diagnosis confirmed by urodynamic assessment, age $\geq$18 years. Exclusion criteria were overactive bladder syndrome, mixed UI, detrusor overactivity on urodynamic investigation, pelvic organ prolapses $\geq$2 according to the pelvic organ prolapse quantification (POP-Q) system [5], previous surgery for pelvic floor diseases (prolapse/incontinence), autoimmune or connective tissue diseases, multiple sclerosis and pregnancy.

Assessment of symptoms and objectives of the study

Patients underwent pelvic examination, multichannel urodynamic testing, stress cough testing and cotton-swab test (Q-tip test) [6]; prolapse was classified according to the POP-Q system [5].

Patients were followed-up at 1, 3, 6 and 12 months. The urodynamic study was repeated at 1-year follow-up.

The following standardised questionnaires administered in Italian were fulfilled by the patients: the International Consultation on Incontinence Questionnaire short form (ICIQ-SF) [7], the Incontinence Impact Questionnaire (IIQ-7) [8] and the Patient Global Improvement Impression (PGI-I) [9]. The ICIQ-SF and the IIQ-7 were administered at baseline and at 1, 6 and 12 months from surgery. The PGI-I was also answered at 3 months from surgery in order to evaluate whether a second treatment was required. Answers 1 or 2 at the PGI-I questionnaire were considered as subjective success. If patients chose answer 1, 2, or 3 at the PGI-I questionnaire, they were identified as responders, while they were considered non responders if they chose answer 5, 6 and 7 and neutral if they chose answer 4. An objective efficacy assessment comprised also the assessment of the number of incontinence episodes in 24 h and 24 h pad-weighting.

The primary objective of the study was to investigate the safety and efficacy of PIs of PAHG for SUI treatment in outpatient setting. Efficacy of PIs of PAHG was defined as answers 1 or 2 at the PGI-I questionnaire (subjective success) at 1-year follow-up. The secondary objective of the study was to evaluate the changes in QoL of the patients after treatment.

The Ethics Committees of the two hospitals approved the study. Each patient included in the study signed a written consent form.

Surgical technique

Stress urinary incontinence was treated by PIs of PAHG (Bulkamid®, Ethicon Women's Health and Urology, Contura, Denmark). The procedures were performed in an outpatient setting by two expert surgeons (who performed more than 20 procedures before the study).

Polyacrylamide hydrogel is an atoxic and resistant to degradation polymer gel made of 97.5 % nonpyrogenic water and 2.5 % cross-linked. The treatment was performed with patients in the lithotomy position under local anaesthesia (10 ml of 5 % lidocaine). Three deposits of PAHG were injected transurethrally using a 23 G needle in the submucosa at the 3, 6 and 9 o' clock positions, 0.5–1 cm distal to the bladder neck, under cystoscopic control. Once the treatment was completed, the bladder was emptied via the endoscope. Antibiotic treatment (cefuroxime, 1.5 g, i.v.) was administered during the injection. Patients, who were not responder at 3-month follow up, were offered a second injection.

Statistical analysis

The intention-to-treat (ITT) analysis was used for data interpretation. Accordingly to data distribution, the Rank Sum Test was used to compare menopausal state, BMI and age of the patients who reported subjective success and who did not reported subjective success. According to data distribution, the Wilcoxon Signed Rank Test was used to compare the total results obtained administering the questionnaires (ICIQ-SF and IIQ-7) at baseline and at follow-up. Proportions were compared by using the Chi-square test. Data were analysed using the Sigma Stat software

version 3.5 and the SPSS software version 13.0 (SPSS Science, Chicago, IL, USA). $p < 0.05$ was considered statistically significant.

Results

Eighty-two patients treated with PAHG were included in the study. Seventy-seven patients completed the 1-year follow-up. The diagrammatic flow of the participants is given in Fig. 1. Table 1 describes the demographic characteristics of the study population.

The median (range) length of the procedure was 7 (range 5–12) min. The mean (±SD) injected volume of PAHG per procedure was 1.6 ± 0.6 ml. No intraoperative complication was recorded. All patients were discharged from the hospital in the afternoon on the same day of the procedure. No patient required readmission to the hospital. 27 patients (32.9 %) were reinjected. No patient received more than two treatments.

According to the ITT analyses, at 1-year follow-up the efficacy of PIs of PAHG (subjective success rate) was 74.4 % (61 out of 82 patients; 95 % CI 63.6–82.4 %). The subjective responder rate was 86.6 % (71 out of 82 patients; 95 % CI 77.3–93.1 %), seven patients (8.5 %; 95 % CI 3.5–16.8 %) had no change and no patient reported worsening of symptoms.

The percentage of patients who reported subjective success was significantly different in the assessment performed in the four follow up ($p < 0.001$). A significantly higher percentage of patients reported subjective success at 1-month follow-up compared with 3-month follow-up

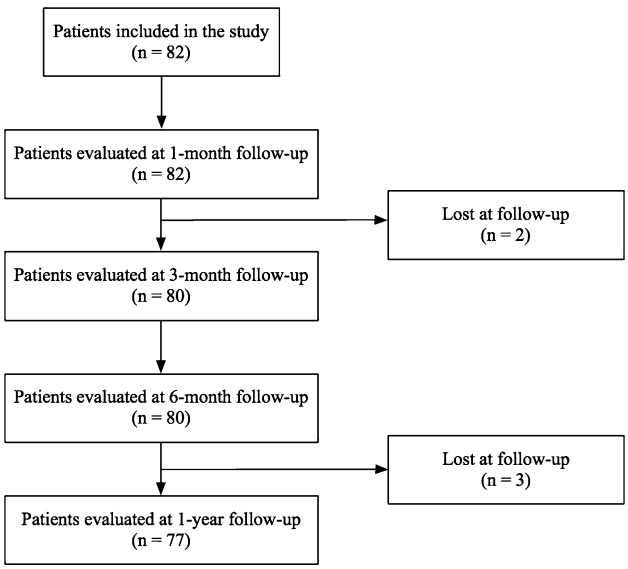

Fig. 1 Flow chart showing women's progress through the study

Table 1 Demographic characteristics of the patients included in the study and reasons for the use of periurethral injections of PAHG

	$n = 82$
Age (years)*	54.3 ± 7.9
BMI (Kg/m^2)*	23.7 ± 1.9
Parity§	2 (0–7)
Menopause (*n*, %)	60 (73.2 %)
Age at menopause (years)*	50.1 ± 1.7
Use of hormonal replacement therapy (*n*, %)	26 (43.3 %)
Smoke (*n*, %)	36 (43.9 %)
Educational status (*n*, %)	
Middle class or less	27 (32.9 %)
High school	43 (52.4 %)
College	12 (14.7 %)

* Mean ± SD

§ Median (range)

($p < 0.001$), 6-month follow-up ($p = 0.010$) and 1-year follow-up ($p = 0.026$; Table 2).

There was no significant difference in BMI between patients who reported and those who did not report subjective success at 1-year follow-up ($p = 0.919$). There was a significant difference in age between patients who reported subjective success and those who did not report subjective success at 1-year follow-up (53.0 ± 6.7 vs. 58.2 ± 9.8 years; $p = 0.043$). There was a non-statistically significant trend towards higher subjective success in patients who were premenopausal than those who were menopausal (90.9 vs. 68.3 %; $p = 0.074$).

At 1-year follow-up, the ICIQ-SF score (4.4 ± 4.9) was lower than at baseline (14.2 ± 3.9; $p < 0.001$). Similarly, at 1-year follow-up, the IIQ-7 results (28.9 ± 8.5) were improved compared with baseline (79.0 ± 10.7; $p < 0.001$; Table 3).

The mean (±SD) number of episodes of urine leakage/24 h decreased after treatment; it was 4.0 ± 1.9 at baseline, 0.5 ± 0.7 at 1 month ($p < 0.001$ vs. baseline), 1.0 ± 0.9 at 3 months ($p < 0.001$ vs. baseline), 0.6 ± 0.7 at 6 months ($p < 0.001$ vs. baseline) and 0.7 ± 0.9 at 1 year ($p < 0.001$ vs. baseline). At 3-month follow-up, the number of episodes of urine leakage/24 h was higher than at 1-month follow-up ($p < 0.001$), 6-month follow-up ($p < 0.001$) and 1-year follow-up ($p = 0.006$) (Fig. 2). The mean leakage/24 h (±SD) decreased after the treatment; it was 42.0 ± 26.4 gr at baseline, 5.8 ± 4.9 gr at 1 month ($p < 0.001$ vs. baseline), 6.3 ± 4.8 gr at 3 months ($p < 0.001$ vs. baseline), 5.4 ± 3.5 gr at 6 months ($p < 0.001$ vs. baseline) and 5.2 ± 2.7 gr at 1 year ($p < 0.001$ vs. baseline). At 3-month follow-up, the mean leakage/24 h was higher than at 6-month follow-up ($p = 0.006$) and 1-year follow-up ($p = 0.007$) (Fig. 3). These findings are consistent with the

Table 2 PGI-I results at baseline and at follow-up; subjective success rate, subjective responder and non responder rate at baseline and at follow-up according to ITT

PGI-I (*n*, %)	1-month follow-up	3-month follow-up	6-month follow-up	1-year follow-up
1. Very much better	29 (35.4 %)	21 (25.6 %)	25 (30.5 %)	21 (25.6 %)
2. Much better	44 (53.7 %)	28 (34.1 %)	34 (41.5 %)	40 (48.8 %)
3. A little better	6 (7.3 %)	14 (17.1 %)	12 (14.6 %)	10 (12.2 %)
4. No change	3 (3.7 %)	15 (18.3 %)	8 (9.8 %)	6 (7.3 %)
5. A little worse	0 (0.0 %)	2 (2.4 %)	1 (1.2 %)	0 (0.0 %)
6. Much worse	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
7. Very much worse	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Lost at follow-up	0 (0.0 %)	2 (2.4 %)	2 (2.4 %)	5 (6.1 %)
Subjective success: 1 + 2	73 (89.0 %)	49 (59.8 %)	59 (72.0 %)	61 (74.4 %)
Responder: 1 + 2 + 3	79 (96.3 %)	63 (76.8 %)	71 (86.6 %)	71 (86.6 %)
Neutral: 4	3 (3.7 %)	15 (18.3 %)	8 (9.8 %)	6 (7.3 %)
Non responder: 5 + 6 + 7	0 (0.0 %)	4 (4.9 %)	3 (3.7 %)	5 (6.1 %)

Table 3 Pre- and post-surgery questionnaires results

	Patients at baseline (n = 82)	Patients at 1-month follow-up (n = 82)	Patients at 3-month follow-up (n = 80)	Patients at 6-month follow-up (n = 80)	Patients at 1-year follow-up (n = 77)
IIQ-7 total score (mean ± SD)	79.0 ± 10.7	26.2 ± 18.8	28.3 ± 18.1	27.0 ± 20.6	28.9 ± 8.5
IIQ-7 p value		$p < 0.001$ (compared with baseline)	$p < 0.001$ (compared with baseline) $p < 0.001$ (compared with 1-month follow-up)	$p < 0.001$ (compared with baseline) $p = 0.285$ (compared with 1-month follow-up) $p = 0.301$ (compared with 3-month follow-up)	$p < 0.001$ (compared with baseline) $p = 0.024$ (compared with 1-month follow-up) $p = 0.190$ (compared with 3-month follow-up) $p = 0.062$ (compared with 6-month follow-up)
ICIQ-SF total score (mean ± SD, n)	14.2 ± 3.9	3.3 ± 3.7	5.7 ± 5.0	4.6 ± 5.4	4.4 ± 4.9
ICIQ-SF p value		$p < 0.001$ (compared with baseline)	$p < 0.001$ (compared with baseline) $p < 0.001$ (compared with 1-month follow-up)	$p < 0.001$ (compared with baseline) $p = 0.015$ (compared with 1-month follow-up) $p < 0.001$ (compared with 3-month follow-up)	$p < 0.001$ (compared with baseline) $p = 0.030$ (compared with 1-month follow-up) $p = 0.033$ (compared with 3-month follow-up) $p = 0.793$ (compared with 6-month follow-up)

fact that the second treatment was performed after the 3-month follow-up.

At the urodynamic study at 1-year follow-up, no alteration of uroflowmetry was observed. The diagnosis of USI was confirmed in the six patients who did not have any change after treatment (answer 4 at the PGI-I questionnaire). One patient who reported subjective success (answer 2 at PGI-I questionnaire) had detrusor overactivity without urgency.

Twenty-one patients (25.6 %) had adverse events (AEs) caused by the procedure. The most common AE was urinary tract infection (UTI), which occurred in eight patients (9.8 %) and was successfully managed with antibiotic therapy. Five patients had injection site pain (6.1 %), which spontaneously resolved within a maximum of 8 days. Two cases of hematuria (2.4 %) were recorded and resolved within 1 day in both patients. Four patients reported de novo urgency (4.8 %). This symptom resolved

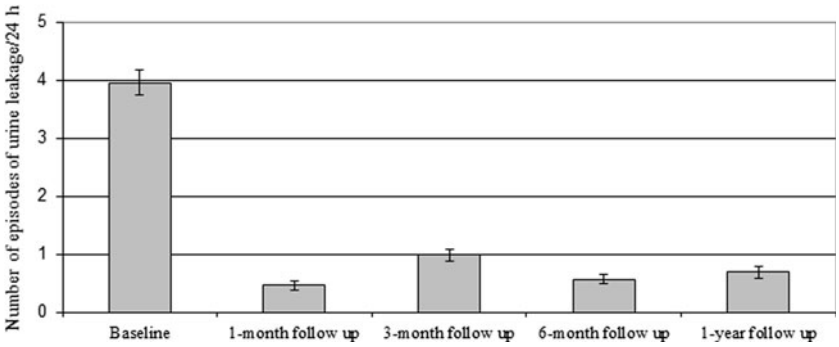

Fig. 2 Number of episodes of urine leakage/24 h at baseline and follow up. Data are presented as mean ± standard error of the mean (SEM)

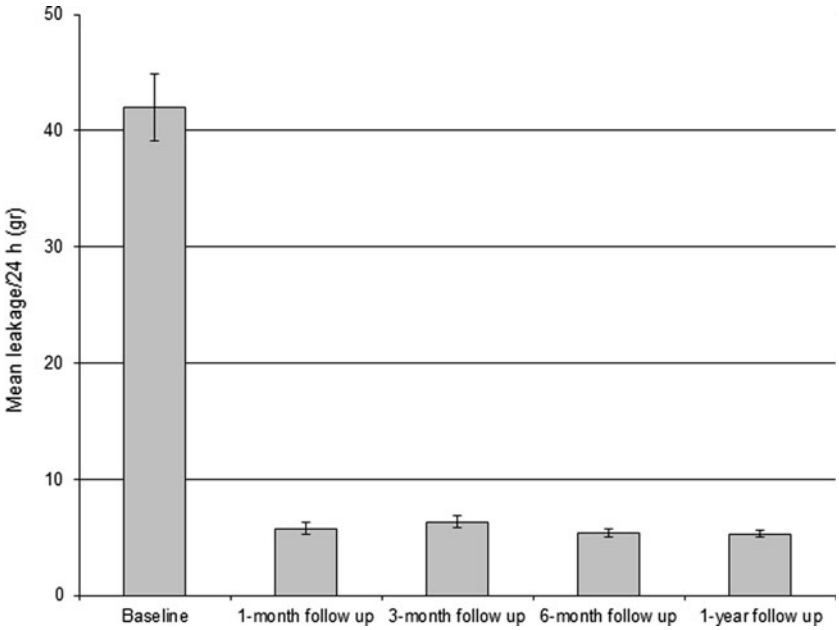

Fig. 3 Leakage/24 h at baseline and follow up. Data are presented as mean ± standard error of the mean (SEM)

in all patients at 3-month follow-up. No patient reported urinary retention or voiding difficulties after surgery.

Discussion

The most updated review on the use of urethral injection therapy for female urinary incontinence stated that the available data provides an unsatisfactory basis to guide clinical practice [4]. Bulking agents therapies are classified as grade of recommendation B against level A for the use of suburethral slings according to the European Association of Urology guidelines on UI [10]. Suburethral slings are considered the gold standard for the non-conservative treatment of SUI showing high and long-term cure rates [11]. Injection therapies are inferior to surgery at 1-year follow-up but display a better safety profile [4]. Other main criticisms on the use of injection therapies include the potential placebo effect (observation of improvement of symptoms after saline injections) [12], the lack of information on long-term efficacy and health economic data. Another critical point is that two or three sessions of injection therapy for a single patient may be required and a satisfactory result is not guaranteed [4]. On the other hand, PIs are minimally invasive procedures and the QoL improvements observed after these procedures are significant and similar to those achieved with surgery [13].

This study confirms the efficacy of PIs of PAHG in the treatment of UI previously reported by other authors [14–17]. At 1-year follow-up, 74.4 % of the patients reported subjective successes, 86.6 % of the patients were responders, 7.6 % were neutral and no patient had worsening of symptoms. The subjective success rate observed in the current study is similar to those reported in previous studies investigating the use of PAHG to treat UI. In a double-centre study, 25 patients (17 with SUI and 8 with mixed urinary incontinence, MUI) were treated with PIs of PAHG. The subjective success was 68.0 % with eight patients who were completely dry and further nine patients who had improvement of symptoms. Unfortunately, this study included both patients with SUI and MUI and, due to the small sample size, no separate analysis of the subjective

success was performed for each type of UI [14]. A multicenter study including 135 patients (67 with SUI and 68 with MUI) was carried out to evaluate safety and efficacy of Bulkamid. The subjective responder rate was 67 % at 12 months and, in particular, it was 70 % among patients with SUI while it was 63 % among patients with MUI [15]. A further analysis of these data demonstrated that the subjective success rate showed a statistically non-significant reduction from 67 % at 12 months to 64 % at 24-month follow-up post PAHG injection [16]. Another recent study included 514 patients treated with four different injection therapies for SUI and MUI; subjective and objective assessments demonstrated improvements without statistical differences in all groups [17].

The percentage of patients who underwent a second injection in the current study was 32.9 %; previous studies reported a percentage of reinjection ranging between 24 and 44 % [14, 15, 18]. Only one study mentioned that a third injection was performed in the 2 % of patients [18].

In the current study, AEs occurred in 25.6 % of the patients but they were not severe (mainly UTI and injection site pain) and they could be managed without readmission of the patients to the hospital. Previous studies reported similar incidence of AEs: UTI (between 7.4 and 40.0 %), urinary retention (between 1.5 and 20.0 %), de novo urgency (8.0 %), de novo urge incontinence (between 1.5 and 8.0 %), injection site pain (3.7 %), haematuria (1.5 %) and nocturia (4.0 %) [14, 15]. However, some cases of severe urinary retention requiring about one week for recovery were previously reported [15]. It is possible that no case of severe urinary retention occurred in our series because the procedures were performed by experienced surgeons.

Previous studies investigating the use of PAHG to treat UI either did not report information on the time of discharge from the hospital [15] or did not usually discharge the patients on the day of surgery [14, 17, 18]. All the patients included in the current study were discharged from the hospital on the same day of the treatment and none of them was readmitted to the hospital.

In the current study, the scores of the IIQ-7 questionnaire showed a significant amelioration of QoL after treatment. Other studies reported a positive impact of PAHG injections on QoL of the patients [14–17]. A study showed that the QoL of the patients assessed through the use of the King's Health Questionnaire, significantly improved in general health perception and in all domains between baseline and 1-year follow-up [14]. QoL of the injected patients, assessed through a visual analogue scale (VAS) score, demonstrated a significant amelioration between baseline and 1-year follow-up and this positive result was maintained at 24-month follow-up [15, 16]. Furthermore, a recent study demonstrates that patients treated by PIs of PAHG have a significant improvement of sexual function and sexual satisfaction [19].

When a physician approaches the management of SUI, the choice of treatment should take in consideration patient's goals and expectations. Patients who seek surgical treatment for SUI mainly wish to obtain amelioration of health related QoL [20–26]. Therefore, the effectiveness of a procedure should be balanced with its invasiveness. PIs are a minimally invasive approach to treat SUI. Therefore, the use of PIs should be taken in consideration as an alternative treatment option particularly in patients who are fragile, in those who have already undergone surgery, in those who do not wish to have surgery, in those who present recurrent SUI or in whom surgical options are restricted (postoperatively, after irradiation) [4, 17, 26–28].

Conclusion

In line with previous investigations, the current study demonstrates that PIs of PAHG are effective and safe, with mild or moderate AEs which are quickly reversible. This study also demonstrates that the PIs of PAHG can be safely performed in an ambulatory setting and that patients may be discharged on the day of the procedure. Furthermore the scores of the IIQ-7 questionnaire show a significant improvement of the QoL at 1-year follow-up. Future studies including large series of patients should investigate the long-term follow-up of patients treated with PIs.

Conflict of interest We have no potential conflict of interest to disclose.

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