MALE FACTOR

Delayed vasectomy success in men with a first postvasectomy semen analysis showing motile sperm

Michel Labrecque, M.D., Ph.D., Karine St-Hilaire, B.Sc., and Lucile Turcot, M.D., Ph.D.

Evaluation Research Unit, Research Center, Hôpital Saint-François d'Assise, Centre Hospitalier Universitaire de Québec (CHUQ), Quebec City, Quebec, Canada

Objective: To determine the frequency of and factors associated with delayed vasectomy success in men with first postvasectomy semen analysis showing motile sperm.

Design: Descriptive study.

Setting: One hospital-based family planning clinic and two private clinics from the Quebec City area, Canada. Patient(s): Three hundred nine men vasectomized between 1990 and 2001 and who had a first semen analysis showing motile sperm.

Intervention(s): None.

Main Outcome Measure(s): Vasectomy success, based on the last available semen analysis—either in the medical record or as requested for the study—and on sterility as established by a telephone-based questionnaire in 2003. Result(s): Among the 309 men, 174 (56.3%, 95% confidence interval 50.7%-61.7%) had delayed vasectomy success. Significant independent factors associated with delayed vasectomy success were lower sperm count in the first postvasectomy semen analysis and shorter interval between vasectomy and first postvasectomy semen analysis.

Conclusion(s): Delayed vasectomy success occurs in more than half of men with a first postvasectomy semen analysis showing motile sperm. The decision to repeat vasectomy should not rely on a single semen analysis showing motile sperm. (Fertil Steril® 2005;83:1435-41. ©2005 by American Society for Reproductive Medicine.)

Key Words: Vasectomy, sterilization, sexual, male, treatment outcome

Vasectomy is a safe and effective method of contraception, but sterility is not obtained immediately after the surgical procedure. Sterility usually is confirmed by the complete disappearance of sperm or by a very low count of nonmotile residual sperm in one or two semen analyses, the first being performed in most cases 8-12 weeks after vasectomy (1, 2).

The presence of motile spermatozoa at the time of the first postvasectomy semen analysis is a source of concern, because it is often considered as a failure of sterilization, indicating the need to repeat the vasectomy. The frequency of vasectomized men with motile sperm at the time of the first postvasectomy semen analysis varies widely according to the occlusion method performed, ranging from 0.3% to 13% (3–6). The most common cause is presumed to be early

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recanalization. Rarely, it might be because of duplication of the vas or to surgical error, such as performing vasectomy twice on the same vas.

On the basis of physiologic studies showing that after vasectomy sperm in the vas deferens are viable for only a few days (7–9), some investigators suggest that the presence of motile sperm in the semen ≥ 3 weeks after vasectomy indicates a recanalization (10, 11). However, in men whose semen analysis showed motile sperm ≥ 8 weeks after vasectomy, the complete disappearance of spermatozoa over subsequent semen analyses done a few weeks or months later has been reported (3-5, 12, 13). An early recanalization taking place during the first few weeks after vasectomy could therefore be transient, occluding spontaneously over the following weeks or months and resulting in delayed vasectomy success. This means that when a first semen analysis performed 8-12 weeks after vasectomy shows motile sperm, it most probably indicates early recanalization but not automatically vasectomy failure.

To our knowledge, there are no studies estimating the frequency of delayed vasectomy success when motile sperm are present at the time of the first semen analysis. The lack

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Reprint requests: Michel Labrecque, M.D., Hôpital Saint-François d'Assise, Unité de Recherche Évaluative, 10 rue de l'Espinay, Quebec City, Quebec G1L 3L5, Canada (FAX: 418-525-4194; E-mail: michel. labrecque@mfa.ulaval.ca).

of a consensus regarding the management of patients with such finding is therefore understandable. According to a survey of British urologists who practice vasectomy, the interval between vasectomy and the decision to repeat the intervention if semen analysis shows motile spermatozoa varies between 2 and 24 months, with an average interval of 6.8 months (14).

The objective of this study was to evaluate the frequency of delayed vasectomy success in men with motile sperm found at the time of a first semen analysis performed 3–26 weeks after the vasectomy and to determine the factors associated with this outcome.

MATERIALS AND METHODS

Between January 1, 1990 and December 31, 2001, 7,456 men had a first vasectomy performed at a family planning clinic of a university hospital and two private clinics in the Quebec City metropolitan area, Canada. All surgeries were performed by the same physician or under his supervision in approximately one third of the surgeries performed at the university hospital. At all three clinics, the vas was isolated out of the scrotum with the no-scalpel technique (15).

Three different occlusion techniques were performed, according to when and where the vasectomy took place. The first technique (n = 4,275), performed at the university hospital until January 1994 and at the private clinics until October 1999, consisted of ligating the vas with metal clips (one on each stump of each vas) and excising an approximately 1-cm segment of the vas between the clips (5, 16). The second technique (n = 576), performed at the university hospital from January 1994 to July 1996, consisted of thermal cautery of 1 cm of the lumen of the prostatic end of the vas, ligation of the prostatic end with one metal clip, excision of a vas segment of approximately 1 cm at the testicular end, and fascial interposition with one metal clip over the testicular end left open (5). The third procedure (n = 2,605), performed at the university hospital starting July 1996 and at the private clinics starting October 1999, consisted of thermal cautery of 1 cm of the lumen of the prostatic end, fascial interposition with one metal clip over the prostatic end, and testicular end left open (16). In addition, excision of a 1-cm segment of the testicular vas was performed along with this last procedure between July 1996 and February 1997 at the university hospital. The first semen analysis was routinely requested 8-12 weeks after vasectomy.

Using the computerized database of medical records maintained in each of the three clinics, we retrospectively selected men who had motile sperm at the time of their first postvasectomy semen analysis, performed between 3 and 26 weeks after vasectomy. Figure 1 illustrates the selection flow chart. The study was approved as a medical audit by the Director of Professional Services at the university hospital, and institutional review board approval was not required.

All patients included in this study—with motile sperm at the time of the first semen analysis—were managed with a

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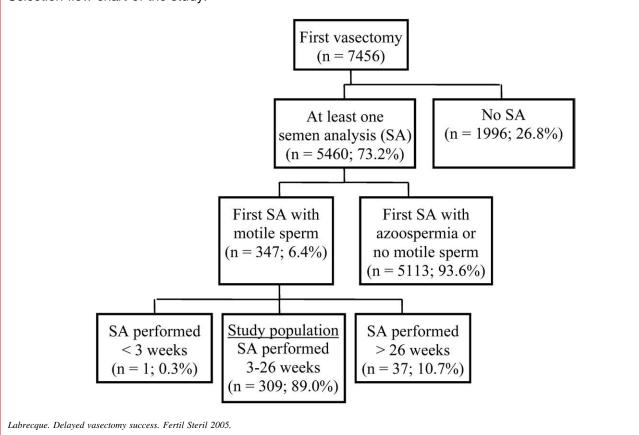
conservative approach. They were requested to submit semen samples every 6 weeks until final vasectomy status was established. Repeat vasectomy was offered only to men with a similar or an increasing number of motile sperm in a subsequent semen analysis or to men with persistence of motile sperm 6 months after vasectomy. This 6-month interval was chosen in 1990 because it was judged to be the maximum period that men were willing to wait before their final postvasectomy fertility status was established. Reasons for repeating vasectomy were verified in the medical record of each man with a repeat vasectomy.

Sociodemographic characteristics, semen analysis results, and information concerning the follow-up of each man were obtained with the computerized database. All data were confirmed with the source medical records. In June and July 2003 all men, except those whose vasectomy already was classified as confirmed failure because of a repeat vasectomy, were phoned to complete a questionnaire inquiring about their fertility status since vasectomy. They also were requested to submit a semen sample for analysis unless they had a semen analysis done during the preceding year, the result of which was retrieved from medical records with their written consent. Several attempts were made to contact each man over the 2-month data collection period. Verbal consent for the telephone questionnaire and a semen sample was obtained. Men who agreed to submit a semen sample were called again if the semen analysis was not performed after 2 weeks. Almost all semen analyses, either in the course of standard care or as requested in the study, were performed by the same tertiary care hospital laboratory according to World Health Organization guidelines, including centrifugation of the sample (17).

Final vasectomy status was defined according to the following criteria: [1] confirmed success: last semen analysis showing azoospermia or $\leq 0.1 \times 10^6$ /mL nonmotile sperm, plus sterility confirmed by questionnaire (the man reported no pregnancy since the vasectomy, was the biologic father of one or more children before the vasectomy, and had unprotected regular intercourse after the vasectomy for ≥ 1 year with the same partner), and none of the failure criteria; [2] probable success: last semen analysis showing azoospermia or $<1 \times 10^{6}$ /mL nonmotile sperm, or sterility confirmed by questionnaire, and none of the failure criteria; [3] confirmed failure: a repeat vasectomy recorded in the database or reported by the man at the time of the questionnaire, or last semen analysis performed ≥ 1 year after vasectomy and showing any number of motile sperm or $\geq 1 \times 10^6/mL$ nonmotile sperm; [4] probable failure: last semen analysis performed before 6 months after the vasectomy and showing an increasing number of motile sperm, or last semen analysis performed 6 months-1 year after the vasectomy and showing any number of motile sperm or $\geq 1 \times 10^6$ /mL nonmotile sperm, or a pregnancy ≥ 3 months after vasectomy as recorded in the database or reported at the time of the questionnaire; [5] indeterminate: success or failure cannot be established according to the preceding criteria. The index

Selection flow chart of the study.

FIGURE 1



(last) semen analysis was either a recent semen analysis performed <1 year before data collection or the last semen analysis retrieved in the medical record when a recent semen analysis was not available and the man did not comply to our request to submit a semen sample in the context of the study. All criteria were established before data collection.

Probability of delayed vasectomy success is presented with 95% confidence interval (CI). Association between delayed vasectomy success and various potential prognostic factors (age at vasectomy, total number of sperm in the first semen analysis, vas occlusion technique performed, and interval between vasectomy and first semen analysis) was determined by logistic regression. Indeterminate cases were assumed to be failures in regression models. A *P* value <.05 was considered as statistically significant. All analyses were performed with commercial software (SAS 8.0; SAS Institute, Cary, NC).

RESULTS

Characteristics of the study population are presented in Table 1. Of the 309 men selected for the study, we intended to contact the 198 who were not already classified as confirmed failures because of a repeat vasectomy according to our records. Of these, 189 (95.5%) completed the questionnaire,

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2 refused, 3 were deceased, and 4 had no contact information available. The final status of these last 9 men was determined according to their medical records. Of the 189 patients who completed the questionnaire, 101 (53.4%) agreed to submit a semen sample for analysis. However, despite a recall only 57 patients (30.2%) finally complied.

Of the 309 men included in the study, 113 (36.6%) had a repeat vasectomy, including 2 identified at the time of the questionnaire and performed by another surgeon. Review of the medical records revealed that vasectomy was repeated for persistence of motile sperm 6 months or more after the vasectomy (n = 62), similar or increasing number of motile sperm found in subsequent semen analysis (n = 50), and persistence of high number of nonmotile sperm (7 × 10⁶/ mL) 7 months after the vasectomy (n = 1). Only 4 (3.5%) men underwent repeat vasectomy with a count of ≤100,000 motile sperm (rare motile sperm) with a range of 19–63 weeks after vasectomy.

The distribution of all 309 men according to their final vasectomy status is presented in Table 2. The frequency of delayed success in men with motile sperm at the time of the first semen analysis was 56.3% (95% CI 50.7%-61.7%), most men being classified as confirmed success.

TABLE 1

Characteristics of the study population (n = 309).

Characteristics			
Mean age at vasectomy (y)	36.3 ± 5.4		
Mean no. of children	2.0 ± 1.0		
Location of the vasectomy			
University hospital	67 (21.7)		
Private clinics	242 (78.3)		
Vas occlusion technique			
Ligation with clips and excision	281 (90.9)		
Cautery and FI on testicular end	19 (6.2)		
Cautery and FI on prostatic end	9 (2.9)		
Mean time between surgery and	6.7 ± 2.4		
data collection (y)			
Total no. of sperm (motile and			
nonmotile) at first SA	77 (04 0)		
$<1 \times 10^{6}$ /mL	77 (24.9)		
1×10^{6} /mL-19 × 10 ⁶ /mL	164 (53.1)		
\geq 20 × 10 ⁶ /mL	68 (22.0)		
Mean time between surgery and first SA (wk)	13.9 ± 4.4		
Mean no. of SA	$\textbf{2.4} \pm \textbf{0.8}$		
Note: Values are either means \pm SD or proportion (%). FI = fascial interposition; SA = semen analysis.			
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According to logistic regression analysis, significant independent factors predictive of delayed vasectomy success were lower sperm count at the time of the first postvasectomy semen analysis and shorter interval between vasectomy and first postvasectomy semen analysis (Table 3). Mathematical modeling did not show significant interaction between these factors. Age and vas occlusion surgical technique were not independently associated with delayed vasectomy success.

In 57 men, we were able to compare the results of the last semen analysis requested as part of standard clinical care with the results of a recent semen analysis, done either as part of this study or <1 year before the study. Of the 42 who had a last standard care semen analysis showing azoospermia, 38 (90.5%) maintained azoospermia in their recent semen analysis, 2 (4.8%) had nonmotile sperm, and 2 (4.8%) had motile sperm (total sperm count of 3.9×10^6 /mL and 0.10×10^6 /mL). These last 2 men had their vasectomy done 10 and 7 years before the study, respectively. Neither reported a pregnancy since the vasectomy, nor had they been using contraception during the last year before the study. Nevertheless, both men were classified as confirmed failure and had a successful repeat vasectomy following these findings.

All four men with a last semen analysis in the medical record showing $< 1 \times 10^{6}$ /mL nonmotile sperm had a recent semen analysis with azoospermia. In the 11 men with a last semen analysis in the medical record showing any number of motile sperm, recent semen analysis showed azoospermia in

TABLE 2			
Distribution of men according to final vasectomy status ($n = 309$).			
Final status	n (%)		
Confirmed success (final SA showing azoospermia or $\leq 0.1 \times 10^6$ /mL nonmotile sperm <i>and</i> sterility confirmed by telephone questionnaire) ^a	129 (41.7)		
Probable success	45 (14.6)		
Final SA showing azoospermia or $<$ 1 $ imes$ 10 ⁶ /mL nonmotile sperm	37 (12.0)		
Sterility confirmed by telephone questionnaire ^a	8 (2.6)		
Indeterminate (failure or success cannot be established according to other criteria)	3 (1.0)		
Probable failure	9 (2.9)		
Final SA performed <6 mo after vasectomy and showing an increasing number of motile sperm	1 (0.3)		
Final SA performed between 6 mo and 1 y after vasectomy and showing any number of motile sperm or $\ge 1 \times 10^6$ /mL nonmotile sperm	6 (1.9)		
Partner pregnant 3 mo or more after the vasectomy	2 (0.6)		
Confirmed failure	123 (39.8		
Repeat vasectomy	113 (36.6		
Final SA performed 1 y or more after vasectomy and showing any number of motile sperm or $\ge 1 \times 10^6$ /mL nonmotile sperm	10 (3.2)		

Note: SA = semen analysis.

^a The man reported no pregnancy reported since vasectomy, was the biological father of one or more children before vasectomy, and had unprotected regular intercourse after vasectomy for at least 1 year with the same partner.

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Association between delayed vasectomy success and potential prognostic factors.

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Factors	Delayed success n (%)	Unadjusted RR (95% CI)	P value ^a
Age (y)			.44
<30	16 (57)	1.10 (0.75–1.59)	
30–34	49 (52)	1.00	
35–39	66 (59)	1.13 (0.88–1.45)	
40–44	25 (52)	1.00 (0.72–1.39)	
45+	18 (67)	1.28 (0.92–1.78)	
Total no. of sperm at first SA			<.0001
<1 $ imes$ 10 ⁶ /mL	58 (75)	2.44 (1.67–3.56)	
1–19 $ imes$ 10 6 /mL	95 (58)	1.88 (1.28–2.74)	
≥20 × 10 ⁶ /mL	21 (31)	1.00	
Vas occlusion technique			.11
Cautery and FI on prostatic end	5 (56)	1.02 (0.56–1.85)	
Cautery and FI on testicular end	16 (84)	1.55 (1.24–1.93)	
Ligation with clips and excision	153 (54)	1.00	
Interval vasectomy-first SA (wk)			.006
≤13 ^b	86 (65)	2.24 (1.28–3.95)	
14–20	79 (54)	1.86 (1.05–3.30)	
>20	9 (29)	1.00	
Note: $FI = fascial interposition: SA = seme$	n analysis.		

Note: FI = fascial interposition; SA = semen analysis.

^a P value from Wald chi-square calculated by logistic regression including all variables presented in the table.

 $^{\rm b}$ Mean \pm SD interval between vasectomy and first SA: 10 \pm 2 weeks.

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6 (54.5%) and persistence of motile sperm in 5 (45.5%), all with a sperm count of $\geq 1 \times 10^{6}$ /mL, including 2 with $\geq 20 \times 10^{6}$ /mL.

DISCUSSION

This study shows that delayed vasectomy success might be achieved in more than half of the men presenting with motile sperm at the time of their first semen analysis, as long as vasectomy is repeated only if motile sperm persist ≥ 6 months after the initial vasectomy or if the sperm count with motile cells remains similar or increases over subsequent semen analyses. To our knowledge, this is the first study estimating the frequency of delayed success of vasectomy when motile sperm are present at the time of the first semen analysis. Although no previous study has been designed to evaluate the extent of this phenomenon, it has been believed that most recanalizations eventually closed or scarred down (18, 19). A few cases of delayed success after observation of motile sperm 2 months or more after vasectomy have also been reported (3-5, 12, 13, 18). However, a study on such a large sample of men with motile sperm at the time of the first postvasectomy semen analysis is unique.

Possible physiopathologic processes by which recanalization occurs have been described (20-24), but the exact mechanism remains unclear. After vasectomy, various tissues and cells, including connective tissue, spermatozoa, blood cells, smooth muscle tissues, and epithelial cells, tend to create connecting bridges between the two cut ends of the vas deferens. Some are fibrous scars showing no or minimal signs of inflammation, whereas others, such as vasitis nodosa and granuloma, are mostly inflammatory.

Vasitis nodosa is due to the proliferation of epithelial cells from the testicular stump through the scar tissue creating bundles of tortuous microtubules of various sizes, some filled with spermatozoa, trying to connect the two lumens of the vas cut ends (25). This phenomenon is often referred to as Medusa's head (26, 27). Vasitis nodosa might lead to sperm granuloma when microtubules of epithelial cells erode through the scar tissue and adventitia, causing extravasation of spermatozoa (25). Sperm granuloma resulting from sperm leakage are also observed when the testicular end is intentionally left open during vasectomy (28).

Inflammatory processes, however, do not seem to be necessary to foster recanalization. Scattered foci of epithelial cells trapped in the scar tissues might also proliferate to create a network of microtubules through the connecting tissue in the absence of vasitis nodosa or granuloma (24). Whichever mechanism might be active, one or more of these tubules might eventually reconstitute the lumen between the two stumps of the cut vas. It is believed that any recanalization process usually takes place early, within 3 to 4 weeks after the vasectomy (6, 7). Delayed success implies that recanalization eventually occludes (6).

We observed that the probability of delayed success increased when the first semen analysis had been performed ≤ 13 weeks after vasectomy and the sperm count was lower. The association between delayed success and interval between vasectomy and first semen analysis with motile sperm suggests that long-standing recanalizations are less prone to subsequent spontaneous occlusion and vasectomy success. Similarly, the association with sperm count suggests that larger patency of the micro-epithelial tubule(s) within the connecting tissues prevents delayed success.

There was no significant association between delayed vasectomy success and the vas occlusion surgical technique performed. The probability of delayed success was >50% with all three techniques performed in this study. However, as observed in other studies (3, 4), the risk of observing motile sperm at the time of the first semen analysis after vasectomy—and thus the risk of failure—varies widely according to the occlusion technique performed. The proportion of men with motile sperm at the time of the first semen analysis in our study was higher with the ligation with clips technique (318 of 3,171 [10.0%]) than with thermal cautery with fascial interposition on the testicular end (20 of 450 [4.4%]). In turn, it was higher than thermal cautery with fascial interposition on the prostatic end (9 of 1,839 [0.5%]).

The higher proportion of men with motile sperm with the fascial interposition on the testicular end technique compared with fascial interposition on the prostatic end might be explained by the fact that a clip was applied on the cauterized prostatic vas, thus shortening the length of the cauterized segment and reducing the efficacy of cautery. Our results tend to support the recommendations of some investigators (29, 30) to avoid the use on the vas of any type of ligature, such as suture material and metal clips. They argue that ligating the muscular wall of the vas leads to necrosis of the stump distal to the suture and increases the risk of recanalization.

Many studies have shown a greater risk of vasectomy failure with vas ligation with metal clips or suture material compared with occlusion techniques with thermal cautery and fascial interposition (31). Adopting a more effective occlusion technique decreases the risk of recanalization but does not completely eliminate it. Thus, any surgeon eventually must decide whether to repeat a vasectomy. Our findings provide evidence regarding the overall probability and prognostic factors of delayed vasectomy success (and failure), which should help the process of shared decision making between the physician and his or her patient (32).

Our study also suggests that men with motile sperm at the time of the first semen analysis can be safely advised to stop back-up contraception as soon as one subsequent semen analysis shows azoospermia or a very low number ($\leq 0.1 \times$

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10⁶/mL) of nonmotile sperm. Patients still should be aware that vasectomy is never 100% effective. In our study, two men whose last semen analysis done in the course of standard care showed azoospermia had motile sperm in their recent semen analysis done as part of the study. Without long-term serial semen analysis it is not possible to say whether these men had persistent early recanalization with transient occlusion or recurrence of recanalization-a late recanalization-after many months or years of occlusion. Nevertheless, none of these men reported a pregnancy, and their fertility potential with sperm count of 3.90×10^6 /mL and 0.10×10^{6} /mL is very low. Based on the World Health Organization study on the contraceptive efficacy of IM injection of testosterone, the pregnancy rate with sperm count in the range of $0.1-3.0 \times 10^{6}$ /mL is 8.1 (95% CI 2.2–20.7) per 100 person-years (33).

One strength of our study is that we were able to contact almost all eligible men. Only four (1.3%) men were lost to follow-up, and the questionnaire was completed by 95.5% of the men with no repeat vasectomy according to our records. A limitation of our study is that more than two thirds of the men contacted did not submit an additional semen sample, even though the possibility of failure was explained. In these cases we were able to determine their final vasectomy status on the basis of the questionnaire and the medical records.

Our study has other limitations. First, men who had a repeat vasectomy based on our criteria—a similar or increasing number of motile sperm in subsequent semen analyses or persistence of motile sperm 6 months after vasectomy could have reached azoospermia if we had waited longer after the vasectomy. A more conservative approach might have resulted in a higher probability of delayed vasectomy success.

Second, not all men had a similar length of follow-up. Shorter follow-up times could have biased the results toward overestimating success. Data collection, however, was performed approximately 7 years, on average, after vasectomy (range, 1.5–13 years), a sufficiently long time for assessing contraceptive success. Moreover, men with the shortest follow-up had vas occlusion performed with thermal cautery and fascial interposition on the prostatic end, the occlusion technique that appears to be the most effective (31).

Third, our conclusions were based on combining both confirmed and probable successes. This could overestimate delayed postvasectomy success. However, because stringently established confirmed success was observed in 42% of all participants, excluding probable success would not modify our conclusions. Fourth, this study has been conducted in patients from a single provider practice and its results might not be applicable to other settings. The use of various occlusion techniques nonetheless supports generalizability of its results.

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sectomy semen analysis. The decision to repeat vasectomy should not rely on a single semen analysis showing motile sperm. Repeating vasectomy only if the number of motile sperm is increasing in subsequent semen analyses or if motile sperm persist for >26 weeks after vasectomy seems to be a safe and acceptable approach.

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