Original Research

Pregnancy Success After Hysteroscopic Sterilization Reversal

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OBJECTIVE: To evaluate the effectiveness of hysteroscopic sterilization reversal by assessing pregnancy rates and identifying surgical complications.

METHODS: All patients at a single center undergoing elective reversal of hysteroscopic sterilization for fertility were followed from January 2009 to May 2014. Eligible patients met prespecified criteria for outpatient surgery. Patients underwent outpatient reversal using a transverse suprapubic abdominal incision with tubouterine implantation performed with either bilateral cornual or single transverse posterior-fundal uterine incisions. Patients were evaluated on postoperative day 1, called the following day, and e-mailed at 2 weeks and 12 months. Pregnancy outcomes were assessed through a 12-month questionnaire and self-reporting using an Internet-based patient portal. Univariate analysis of patient and operative characteristics was performed.

RESULTS: Seventy patients underwent bilateral tubouterine implantation and completed at least 12 months of follow-up. All surgeries were outpatient without any immediate operative complications. Four patients had complications between 2 and 30 days, none requiring extended hospitalization. Women who became pregnant were younger (mean age 34 years) than those who did not become pregnant (mean age 38 years). Twenty-five patients (36%, 95% confidence interval [CI] 25–47%) reported a total of 31 naturally conceived pregnancies. Twenty-seven percent (19/70, 95% CI 17–37%) of those undergoing surgery subsequently reported live births. A single pregnancy complication of postpartum hemorrhage after cesarean delivery requiring transfusion was reported; no ectopic pregnancies were reported.

CONCLUSION: Hysteroscopic sterilization can be reversed using tubouterine implantation and both pregnancy and live birth rates are promising.

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Transcervical hysteroscopic tubal sterilization was first approved as a method for female sterilization in 2001. In comparison to other tubal sterilization procedures, transcervical hysteroscopic sterilization can be performed in an office setting without the need for general anesthesia. This newer method of tubal sterilization is becoming more prevalent with approximately 750,000 units sold worldwide from 2001 to 2014.

Women who regret transcervical hysteroscopic sterilization and desire to conceive have two options: in vitro fertilization or tubouterine implantation. Successful pregnancy resulting from in vitro fertilization after hysteroscopic tubal sterilization has been described.[1,2] Historically, proximal fallopian tube occlusion affecting the interstitial portion of the fallopian tube has been surgically corrected with tubouterine implantation. Since surgical correction of proximal tubal occlusion was first described in the late 19th century,[3] other case series have followed and have demonstrated conception rates ranging from 13 to 56%.[4,5]

Our group has previously described women who have had live births after outpatient tubouterine implantation for correction of hysteroscopic sterilization using either silicone intratubal microinserts or metallic intratubal microinserts.[6,7] The objective of this article is to document the effectiveness of hysteroscopic sterilization reversal by assessing pregnancy

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Dr. Monteith is the Medical Director and owner of Chapel Hill Tubal Reversal Center. Chapel Hill Tubal Reversal Center is a fee-for-service surgical center dedicated to corrective tubal surgery. The study on the effectiveness of hysteroscopic sterilization reversal was performed at this surgical center. The other authors did not report any potential conflicts of interest.

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rates and identifying surgical complications in a case series of patients undergoing outpatient surgical reversal of hysteroscopic sterilization.

MATERIALS AND METHODS

This study is a retrospective analysis of an uncontrolled case series of patients who underwent surgical reversal of hysteroscopic tubal sterilization at a single outpatient surgical center from January 2009 to May 2014. The surgical center exclusively provides female sterilization reversal, and tubouterine implantation to correct interstitial tubal occlusion is the standard of care at this surgical center. Description of this analysis was submitted to the Copernicus Group institutional review board and was determined to be exempt.

Patients requesting surgery underwent telephone interviews and completed questionnaires at the time of scheduling to screen for medical conditions that may increase the risk of elective, outpatient surgery. They submitted medical records of their sterilization procedures and were screened for surgical considerations that would warrant exclusion. Exclusion criteria for the outpatient surgical center included body mass index (calculated as weight (kg)/[height (m)]^2) higher than 37; anemia (hemoglobin less than 10 mg/dL); significant cardiopulmonary or renal disease; thrombophilias; infection with human immunodeficiency virus; active hepatitis B or C infections; postmenopausal status; and current use of anticoagulant medications. Patients undergoing tubouterine implantation were counseled regarding the alternative treatment of in vitro fertilization, the risks of ectopic pregnancy after tubal surgery, and the associated risk of uterine rupture during pregnancy or delivery.[8] Prospective patients were informed that early pregnancy management was not provided by the surgical center. Patients were advised to follow up with their local physicians and to have early pregnancy monitoring with serial serum measurements of human chorionic gonadotropin (hCG) and endovaginal ultrasonography when serum hCG levels were higher than 1,500 milli-international units.

Inclusion criteria for this analysis were patients who had undergone uncomplicated hysteroscopic tubal occlusion procedures previously, expressed the desire to conceive, and who had undergone bilateral tubouterine implantation for the reversal procedure at the surgical center with at least 12 months of follow-up. Exclusion criteria include those who had additional tubal occlusive procedures after hysteroscopic sterilization, prior endometrial ablation, or unilateral tubal implantation. Because the pregnancy rate after tubouterine implantation is cycle-dependent and additive over time, the authors choose to focus the analysis on patients who had at least 12 months of follow-up after surgery. A 12-month follow-up period provides a more accurate estimate of conception rates after surgical correction of tubal sterilization, and this follow-up time period is consistent with other published reports.[9,10]

Tubouterine implantation was performed by two surgeons (C.W.M. and G.S.B.) as outpatient procedures. All surgeries were performed under general laryngeal mask anesthesia using a single, transverse laparotomy incision placed 2 cm above the pubic symphysis. The length of the incision was determined by the operating surgeon and was based on the amount of surgical exposure anticipated to facilitate surgery but minimize postoperative pain. Skin incisions were not measured but ranged from 5 to 10 cm in length. Patients received 40 mL of 0.25% bupivacaine with epinephrine 1:200,000 injected into the rectus fascia to assist with postoperative pain control. A Collin uterine forceps was used to manipulate the uterus and minimize blood loss by providing extrinsic uterine compression. Avascular areas were identified in the broad ligaments, openings created with electrodissection, and a uterine tourniquet using 1-0 monofilament suture was placed around the lower uterine segment and vessels for additional hemostasis. Using sharp dissection with a scalpel, each fallopian tube was transected at the tubouterine junction and the microinsert devices were removed intact when possible with traction and sharp dissection. Patency of each distal tubal segment was confirmed by the free flow of saline using a 22-gauge angiocatheter inserted into the isthmic section of the dissected fallopian tube. A double-armed 3-0 absorbable monofilament was placed into the proximal isthmic tubal muscularis of each transected fallopian tube.

Tubouterine implantation was performed using either a single posterior transverse uterine incision made at the level of the uterine ovarian ligaments or bilateral cornual wedge incisions made in the area where the previous isthmic sections of the fallopian tube were located. The decision on which type of uterine incision to use for tubouterine implantation was made by the surgeon at the time of surgery. Transfundal incisions were chosen when surgical exposure and hemostasis were felt to be adequate and transcornual incisions were chosen when surgical exposure and hemostasis were felt to be less than adequate. Each needle of the double-armed suture was placed into the uterine cavity under direct visualization and through full-thickness myometrium. Tension was placed on each arm of the double-armed

suture and the fallopian tubes were drawn into the uterine cavity. Each 3-0 absorbable monofilament was tied against the serosal layer of the myometrium. The intramural portion of each fallopian tube was anchored against the intramural myometrium using several interrupted sutures of 3-0 absorbable monofilament. The tubouterine incision(s) were closed with 3-0 absorbable monofilament. Estimated blood loss and immediate operative complications were recorded at the time of surgery.

Patients were observed in recovery for 1–2 hours, provided oral pain medication to take as needed, and after demonstrating the ability to void spontaneously, they were discharged to a local hotel with an adult chaperone. Patients returned to the office on postoperative day 1 for evaluation before returning home. Patients were contacted for a telephone interview on postoperative day 2. Patients were advised to contact the surgical center with complications or unanticipated visits to their local physician within the first 30 days of surgery and to wait for 6 weeks before attempting to conceive. Patients were e-mailed at 2 weeks to assess for complications. At 12 months, patients who did not report pregnancy were e-mailed requesting information regarding unreported complications, pregnancies, and pregnancy outcomes. Delayed postoperative complications were defined as any unplanned visit to their local doctor or emergency department within 30 days of surgery.

Patients were asked to self-report pregnancies and pregnancy outcomes using a pregnancy reporting system accessible through the web site of the surgical center. When patients reported a pregnancy through the web site, information requested included: the first day of the last menstrual period; date of positive pregnancy test; estimated due date; and use of assisted reproductive technology, either ovulation assistance or in vitro fertilization. When births were reported, the following information was confirmed: date of birth, neonate gender, and newborn weight at delivery. Comment boxes on each report allowed respondents to enter additional information. Pregnancy was defined as any positive urine or blood hCG test performed by the patient or their local physician. The e-mailed 12-month questionnaires inquired about the outcome of any previously reported pregnancy, a pregnancy that may not have been reported previously, or both. Patients were not sent 12-month questionnaires if they reported either ongoing pregnancies or birth. Information was recorded in a database designed specifically for follow-up of patients undergoing sterilization reversal. Database entry was performed by nursing staff and was confirmed by the lead investigator by comparison with the patient's electronic record before data analysis.

Univariate analysis of patient and operative characteristics was performed using means, medians, and distributions; when appropriate, frequencies were reported for categorical variables. All analyses were completed using Stata 13.

RESULTS

From January 2009 to May 2014, 142 patients underwent outpatient surgery to correct hysteroscopic tubal occlusion. Of these, 38 patients did not desire pregnancy and requested removal of intratubal microinserts because of abnormal symptoms experienced after intratubal microinserts were inserted. These patients had removal of intratubal microinserts and concomitant bilateral tubal occlusive procedures. Nine patients desired pregnancy but had unilateral tubouterine implantation procedures. Of these nine patients, four had unilateral tubouterine implantations only and five had combined unilateral tubouterine implantation and unilateral tubotubal anastomosis. Of the four patients who had unilateral tubouterine implantations only, two had uterine adhesions secondary to previous cesarean delivery, which prevented bilateral tubouterine implantation, one had a surgically absent contralateral fallopian tube, and one had congenital absence of the contralateral fallopian tube. Five patients had unilateral failure of intratubal microinserts after hysteroscopic sterilization and required unilateral tubal sterilization to complete their sterilization procedures. These five patients required combined unilateral tubotubal implantation and unilateral tubotubal anastomosis to reverse their sterilization procedures. The remaining 95 patients underwent bilateral tubouterine implantation. Of these patients, 25 had less than 12 months of follow-up and 70 patients had completed at least 12 months of follow-up and they served as the study cohort (Fig. 1).

Characteristics of the entire study population who underwent bilateral hysteroscopic sterilization reversal for restored fertility are shown in Table 1 (n=95). The most relevant characteristics include a mean age of 37 years old (standard deviation [SD] 5.1); median parity 2 children (range 0–5 children); 21 patients (22%) had undergone at least one cesarean delivery before sterilization; and the mean 92 (97%) of patients were sterilized using metallic intratubal microinserts and 3% using silicone intratubal microinserts. Body mass index was 26 (SD 4.6).

Regarding operative characteristics, the procedures' mean duration 88 minutes (SD 18) and the median estimated blood loss was 75 mL (range 5–325

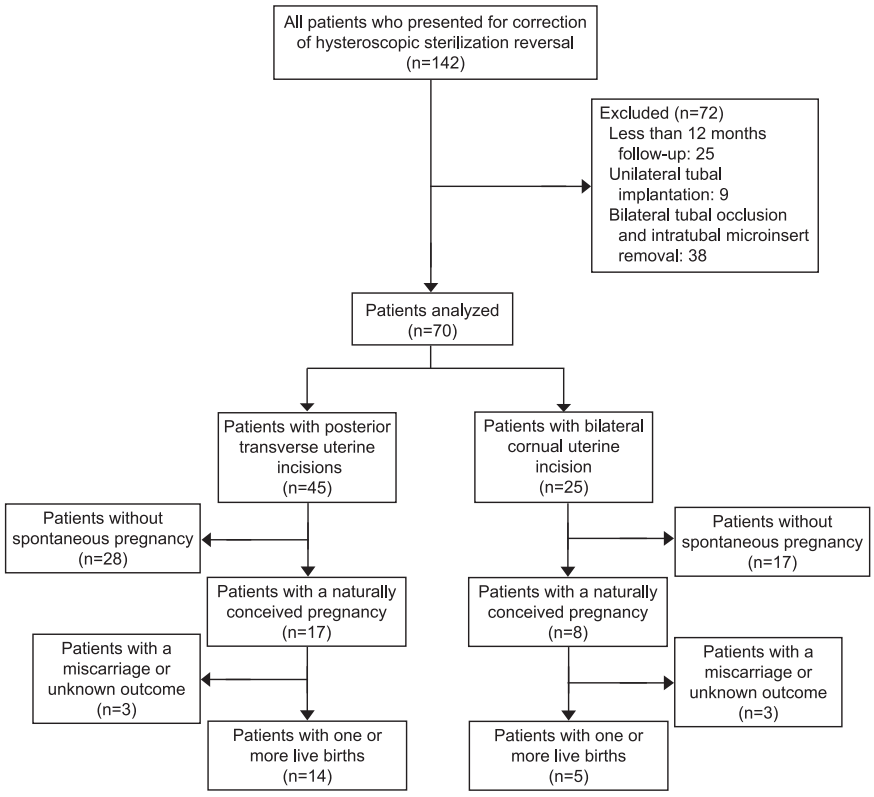

Fig. 1. Flowchart of patients who presented for hysteroscopic sterilization reversal and pregnancy outcome by uterine incision type.
Monteith. Pregnancy After Hysteroscopic Sterilization. Obstet Gynecol 2014.

with a right-skewed distribution). No patient experienced an immediate operative complication (ie, blood transfusion or injury to adjacent organ) or required hospitalization.

Eighty-four patients (88%) were reached at the time of the 2-day surgery follow-up call. E-mailed questionnaire response rates for 2 weeks and 12 months were 63 (66%) and 58 (61%), respectively. Four patients (4%) reported delayed complications within 30 days of surgery. One patient presented to the emergency department on postoperative day 3 with a chief complaint of fever and was diagnosed with a superficial surgical site infection, culture positive for pseudomonas, which was treated successfully with oral antibiotics only. A second patient presented to her local doctor with a chief complaint of abdominal pain on postoperative day 4, who was found at laparoscopy to have 100 mL of hemoperitoneum but no active bleeding. She was discharged without the need for a blood transfusion. A third patient presented to the emergency department with a chief complaint of vaginal bleeding on postoperative day 12 that required no treatment. The fourth patient presented with a chief complaint of pelvic pain to her local emergency department on postoperative day 22 and was diagnosed with an ovarian cyst not requiring intervention.

Table 2 contains pregnancy rates and outcomes for the 70 patients who had at least 12 months after surgery to attempt pregnancy and who served as the cohort for analysis. Of this cohort, 25 (36%, 95% confidence interval [CI] 25–47%) reported becoming pregnant with five of these women becoming pregnant twice (a total of 31 pregnancies). All pregnancies reported were the result of natural conception. Among the 31 pregnancies, 20 (65%, 95% CI 48–82%) were live births, eight (26%, 95% CI 11–41%) were miscarriages, two (7%, 95% CI 0–16%) were ongoing, and one (3%, 95% CI 0–9%) was an unknown outcome at the time of this publication submission. One patient had two live births as a result of two separate pregnancies. For all pregnancies recorded, the median number of weeks from date of surgery to first positive pregnancy test was 17 weeks (range 5–82 weeks). There were no reported ectopic pregnancies, uterine ruptures, or hysterectomies. One patient reported a pregnancy complication after receiving a blood transfusion for prolonged bleeding after cesarean delivery. She was hospitalized for 4 days and no further treatment was required.

Of the 25 patients with less than 12 months of follow-up, six patients reported seven pregnancies. Of the seven pregnancies, one was a live birth, four were

Table 1. Characteristics of the Observational Group Who Underwent Bilateral Hysteroscopic Sterilization Reversal

Characteristic	Patients Undergoing Outpatient Bilateral Tubouterine Implantation (n=95)
Patient-related	
Age (y)	37±5.1
Parity before sterilization	2 (0–5)
Prior cesarean delivery	21 (22)
BMI (kg/m^2)	26±4.6
Smoking history	31 (33)
Time between sterilization and reversal (y)	4.3±2.0
Operative	
Sterilization type	
Essure	92 (97)
Adiana	3 (3)
Uterine incision	
Posterior transverse	49 (52)
Bilateral cornual	46 (48)
Operative time (min)	88±18
Estimated blood loss (mL)	75 (5–325)
Surgical complications	
Immediate	0
Delayed	4 (4)
Time after surgery to first positive urine pregnancy test (wk)	17 (9–88)

BMI, body mass index.
Data are mean±standard deviation, median (range), or n (%).

ongoing and intrauterine, one was a miscarriage of an intrauterine pregnancy, and one was an ectopic pregnancy treated with methotrexate. Of the four patients who underwent unilateral implantation only, no patient reported pregnancy. Of the five patients who underwent combined unilateral implantation and unilateral tubotubal anastomosis, three patients reported pregnancy. Two of these pregnancies were the result of natural conception and one pregnancy was the result of in vitro fertilization. All three pregnancies resulted in live births without complications. Of all patients who underwent laparotomy for tubouterine implantation (n=104), 33 patients reported natural pregnancy. The pregnancy rate for all patients who underwent laparotomy for tubouterine implantation was 32% (33/104, 95% CI 24–41%).

Characteristics of the patients with at least 12 months of follow-up (n=70) are reported by pregnancy status in Table 3. As a result of the small size of this case series, and the absence of a priori power calculations, statistical testing was not performed by pregnancy status. Select characteristics of women with more than 12 months of follow-up are presented in Table 4 by the two uterine incisions performed at time of tubal reversal, posterior transverse, or bilateral cornual. Statistical testing was not performed as a result of the small sample size and retrospective analysis; however, there are no clinically significant differences by uterine incision type.

Table 2. Pregnancy Rates and Outcomes of Patients Who Completed 12 Months or More of Follow-Up

Pregnancy Outcomes	Patients With 12 Mo or More of Follow-up After Surgery (n=70)
Patients reporting pregnancy	25 (36)
Total pregnancies reported	31
Pregnancy outcome, n	
Live birth	20
Miscarriage	8
Ongoing	2*
Unknown	1
Pregnancy complication	1†

Data are n (%) or n.
* Second pregnancy in patient whose first pregnancy resulted in a liveborn neonate.
† Prolonged bleeding after cesarean delivery requiring transfusion.

Table 3. Demographics and Medical History of Those With 12 Months or More of Follow-Up by Pregnancy Status

Characteristic	Patients Who Reported 1 or More Pregnancy, With 12 Mo or More of Follow-up (n=25)	Patients Not Reporting Pregnancy, With 12 Mo or More of Follow-Up (n=45)
Age (y)	34±4.6	38±5.0
Parity	2 (2, 3)	2 (2, 3)
BMI (kg/m^2)	25±3.5	26±4.3
Smoker (past or current)	8 (32)	16 (36)
Prior cesarean delivery	1 (4)	12 (27)
Operative time (min)	91±22.0	91±16
Estimated blood loss (mL)	75 (40, 150)	75 (40, 100)
Uterine incision		
Posterior transverse	17 (68)	28 (62)
Bilateral cornual	8 (32)	17 (38)

BMI, body mass index.
Data are mean±standard deviation, median (interquartile range), or n (%).

Table 4. Pregnancy Rates, Demographics, and Medical History of Those With 12 Months or More of Follow-Up by Sterilization Reversal Uterine Incision Type

Characteristic	Patients With Posterior Transverse Incisions, 12 Mo or More Since Surgery (n=45)	Patients With Bilateral Cornual Incisions, 12 Mo or More Since Surgery (n=25)
Patients with 1 or more pregnancy	17 (38)	8 (32)
Patients with 1 or more live birth	14 (31)	5 (20)
Age (y)	36±5.2	37±4.9
BMI (kg/m^2)	26±3.9	27±4.3
Smoker	15 (34)	9 (36)
Prior cesarean delivery	7 (16)	6 (24)
Operative time (min)	96±19	82±15
Estimated blood loss (mL)	75 (50, 125)	60 (30, 100)

BMI, body mass index.
Data are n (%), mean±standard deviation, or median (interquartile range).

DISCUSSION

This case series demonstrates tubouterine implantation is feasible, allows for restoration of fertility, and can provide patients an alternative to in vitro fertilization treatment. Among those with at least 12 months of follow-up, the pregnancy rate was observed to be 36% (25/70, 95% CI 25–47%) and the live birth rate was 27% (19/70, 95% CI 17–37%). As evident by the five patients who became pregnant more than once and the one patient who had two live births, a significant benefit of tubouterine implantation for reversal of hysteroscopic sterilization is patients do not require cycle-dependent medical treatment for subsequent pregnancy attempts.

Patients who regret transcervical hysteroscopic sterilization and desire more children have limited options. They can elect to have surgical reversal of their sterilization or undergo in vitro fertilization treatment. Although small case series of successful pregnancy after in vitro fertilization treatment with tubal microinsert devices in situ do exist, the authors were unable to find any larger published studies investigating what effects in situ tubal microinserts may have on in vitro fertilization treatment success.[1,2] Moreover there is limited understanding of what risks in situ tubal microinserts may pose during pregnancy.

We limited our study cohort to those patients who underwent bilateral tubouterine implantation and had at least 12 months to attempt pregnancy because this group provides a more accurate evaluation of the effectiveness of bilateral tubouterine implantation in allowing natural conception. We excluded patients who had unilateral implantation alone because these patients may require more time to acquire pregnancy or may have less chance of pregnancy should the one-sided repair heal with closure. Patients who underwent simultaneous unilateral tubouterine implantation and unilateral tubotubal anastomosis were excluded because tubotubal anastomosis has been historically associated with a higher pregnancy rate than has tubouterine implantation and including these pregnancies may have artificially increased the pregnancy rate of the entire study cohort.

Although formal statistical testing was not performed, those who became pregnant were younger (mean age of 34 years, SD 4.6) compared with those who did not become pregnant (mean age of 38 years, SD 5). In general, younger women have higher fecundity when compared with older women. Age may be an important point when counseling patients who are considering tubouterine implantation to restore fertility.

Previous cesarean delivery was significantly associated with failure to achieve pregnancy. Patients who had previous cesarean delivery seemed to have more limited surgical exposure and technically more difficult implantation procedures. Although tubouterine implantation seemed more challenging in this group of patients, no statistically significant differences in patient body mass index, total operative times, or estimated blood loss were observed among patients with previous cesarean delivery than when compared with those without previous cesarean delivery. Bilateral cornual uterine incisions were often chosen for patients who had limited surgical exposure. Although a trend toward increased pregnancy success was observed in patients who underwent tubouterine implantation using transverse uterine incisions when compared with bilateral cornual incisions, the groups were too small for meaningful statistical comparison.

The greatest contribution of this analysis is the size of this case series, because previous reports of successful hysteroscopic sterilization reversals have been limited to individual case reports. Limitations include that these findings are from a clinical observational cohort with no experimental design. The operative procedures were performed by two experienced surgeons, so the results may not be applicable to surgeons who are unfamiliar with tubouterine

implantation. Women entering this cohort were restricted to comply with the screening criteria of an outpatient surgical center; therefore, results may not be replicable with a more obese and medically complicated cohort. A significant limitation of our study is all outcomes relied on patient self-reporting and pregnancy and complication rates may not have been accurately reported. As a result of our study design, evaluation of delivery complications was limited.

A committee opinion by the American Society for Reproductive Medicine supports the benefit of microsurgical tubal reanastomosis for the treatment of tubal sterilization because tubal reanastomosis is more cost-effective and has a significantly higher cumulative pregnancy rate compared with in vitro fertilization. In this same committee opinion, the American Society for Reproductive Medicine states tubal implantation for correction of proximal tubal occlusion has been relegated to historic interest, because it is associated with very low success rates and risk of cornual rupture in pregnancy.[11] Although the frequency of tubouterine implantation has decreased since the advent of assisted reproductive technology, this case series demonstrates successful pregnancy after tubouterine implantation is feasible and a historical surgical procedure may have a role in the successful reversal of a newer form of tubal sterilization.

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