

## Conventional endoscopic retrograde cholangiopancreatography vs the Olympus V-scope system

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### Abstract

**AIM:** To compare the new Olympus V-scope (VS) to conventional endoscopic retrograde cholangiopancreatography (ERCP).

**METHODS:** Forty-nine patients with previous endoscopic papillotomy who were admitted for interventional ERCP for one of several reasons were included in this single-centre, prospective randomized study. Consecutive patients were randomized to either the VS group or to the conventional ERCP group. ERCP-naïve patients who had not undergone papillotomy were excluded. The main study parameters were interventional examination time, X-ray time and dose, and premedication dose (all given below as the median, range) and were investigated in addition to each patient's clinical outcome and complications. Subjective scores to assess each procedure were also provided by the physicians and endoscopy assistants who carried out the procedures. A statistical analysis was carried out using the Wilcoxon rank-sum test.

**RESULTS:** Twenty-five patients with 50 interventions were examined with the VS ERCP technique, and 24 patients with 47 interventions were examined using the conventional ERCP technique. There were no significant differences between the two groups regarding the age, sex, indications, degree of ERCP difficulty, or interventions performed. The main study parameters in the VS group showed a nonsignificant trend towards a shorter interventional examination time (29 min, 5-50 min vs 31 min, 7-90 min,  $P = 0.28$ ), shorter X-ray time (5.8 min, 0.6-14.1 min vs 6.1 min, 1.6-18.8 min,  $P = 0.48$ ), and lower X-ray dose (1351 cGy/m<sup>2</sup>, 159-5039 cGy/m<sup>2</sup> vs 1296 cGy/m<sup>2</sup>, 202.2-6421 cGy/m<sup>2</sup>,  $P = 0.34$ ). A nonsignificant trend towards fewer adverse events occurred in the VS group as compared with the conventional ERCP group (cholangitis: 12% vs 16%,  $P = 0.12$ ; pain: 4% vs 12.5%,  $P = 0.33$ ; post-ERCP pancreatitis: 4% vs 12.5%,  $P = 0.14$ ). In addition, there were no statistically significant differences in assessment by the physicians and endoscopy assistants using subjective questionnaires.

**CONCLUSION:** ERCP using the short-guidewire V-system did not significantly improve ERCP performance or patient outcomes, but it may reduce and simplify the ERCP procedure in difficult settings.

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**Key words:** Endoscopic retrograde cholangiopancreatography; Short guidewire endoscopic retrograde cholangiopancreatography system; X-ray protection; V-scope; Bile duct stenosis

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## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex diagnostic and therapeutic approach that is used to identify and treat various hepatobiliary and pancreatic diseases. ERCP is a time-consuming, expensive, and laborious method that requires the patient to be exposed to substantial doses of premedication, contrast medium, and X-rays, especially when difficult cannulation of the papilla, biliary, or pancreatic ducts or strictures occurs and/or difficult interventions are performed<sup>[1-5]</sup>. Thus, future advances to simplify the technical process of ERCP, reduce known ERCP risks for the patient, and reduce the time and effort of the physician for this procedure, as well as attempts to reduce costs, are important issues given the restricted financial resources of hospitals regarding radiation protection, hygiene, and the need for greater patient safety<sup>[5-10]</sup>.

With the release of a specialised side-viewing endoscope from Olympus [V-scope (VS)], which contains a specialised elevator lever with a V-groove in combination with the use of a specialised short guidewire system and a V-holder, further optimization of the entire ERCP process appears possible. The VS, including the V-groove of the elevator lever and the V-holder and its dedicated guidewires, was constructed to help the endoscopist secure the guidewire at a particular visible length during accessory exchange. This allows the physician to perform a guidewire or accessory exchange by him/herself and may thus lead to quicker instrumentation when working with or without assistance<sup>[11-14]</sup>. In addition, the availability of a specialised short guidewire (2.6 m in length) and corresponding accessories promises to improve guidewire handling during ERCP and to increase hygienic aspects of ERCP, and it may also reduce the efforts of physicians and assistants<sup>[12-14]</sup>.

To analyse this procedure systematically, we performed a randomized prospective pilot trial to explore and document whether clinical, practical, and subjective improvements occur in daily ERCP practice when using the VS and its dedicated guidewire system as compared with conventional ERCP (without a VS, usually using long guidewires of 4.0-4.5 m in length). The main objectives were to evaluate the parameters of interventional examination time, X-ray time and dose, premedication dose, and interventions. In addition, subjective scores from physicians and endoscopy assistants were obtained to provide information about practical handling, hygienic aspects, and the convenience of this new ERCP method at a tertiary care university medical centre.

## MATERIALS AND METHODS

### Patient population

From June to October, 2007, 49 consecutive patients who were admitted to the Department of Medicine 1 of the University Erlangen-Nuremberg for interventional ERCP were included in this ERCP pilot trial if they

**Table 1 Patient characteristics and indications for endoscopic retrograde cholangiopancreatography**

	ERCP with V-scope/V-system	Conventional ERCP
Examinations (n)	25	24
Age, median (range), yr	57 (33-83)	57 (19-96)
Sex (male/female)	8/17	8/16
Hepaticolithiasis	4	5
Biliary strictures (benign/malignant)	7 (4/3)	5 (4/1)
Chronic pancreatitis	12	12
Pancreatic tumour	2	2

ERCP: Endoscopic retrograde cholangiopancreatography.

had a previous endoscopic papillotomy and had one or more of the following conditions choledocholithiasis or hepaticolithiasis, malignant or benign bile duct stenosis, and chronic pancreatitis or pancreatic tumour. In addition, patients agreed to participate in this pilot trial with randomization to one ERCP technique, the collection of prospective scientific documentation, and the evaluation of their clinical and ERCP findings. Patient characteristics and indications for interventional ERCP are given in Table 1. All patients gave informed consent to participate and agreed to the collection of scientific documentation of the examination results. This clinical study was carried out in accordance with the Helsinki declaration.

Because cannulation of native papilla, papillotomy, and potential treatment of its associated risks may require a substantial amount of time, ERCP-naïve patients without papillotomy were excluded from this study, as were patients with coagulation disorders, septic cholangitis, or severe cardiovascular or pulmonary disease or who were pregnant<sup>[5,9,15,16]</sup>.

Informed consent to participate in this practice study was obtained the evening before the scheduled ERCP. Thirty minutes before the scheduled ERCP procedure, patients were randomized either to ERCP using the VS and its dedicated (short) guidewire system (VS group) or to conventional ERCP.

### ERCP and interventions

ERCP in the VS group was performed with the commercially available Olympus side-viewing VS (TJF160 VR; Olympus, Hamburg, Germany), which contains a modified elevator lever with a V-groove and a specialised fixable guidewire system. The V-groove of the elevator lever induces an increased angle of articulation in the VS and allows complete locking of a specialised guidewire for use with the VS<sup>[13,14,17]</sup>. This guidewire consists of a linear guide and a flexible hydrophilic tip (5 cm in length) combined with a long, stiff nitinol wire (0.35 mm in diameter, 2.6 or 4.2 m in length); both the linear guide and the nitinol wire have endoscopically visible markings at 5 cm (Olympus). In addition, a V-holder, which attaches to the working channel of the VS, allows the physician, in conjunction with securing the guidewire with the newly constructed V-elevator, to perform changes of instru-

ments and accessories (*e.g.*, appropriate baskets, balloons, papillotomes, *etc.*; Olympus) with or without assistance. This procedure accelerates instrumentation and may reduce X-ray time because of endoscopically visible control of the fixed guidewire<sup>[13,14,17]</sup>.

ERCP in the conventional ERCP group was performed with a side-viewing duodenoscope (Olympus TJF160) and typical 4.0- to 4.8-m-long guidewires (Terumo radifocus guidewire, flexible hydrophilic; Terumo Corporation, Leuven, Belgium; straight green guidewire, Teflon coated; Dispomedica, Hamburg, Germany; tracer metro wire guide; Aqua Coat Tip, Cook Ireland Ltd., Limerick, Ireland) and corresponding accessories (catheters, bougies, baskets, balloons, *etc.*)<sup>[1,2,18-20]</sup>. Exchange of instruments was performed conventionally, and only if necessary, using fluoroscopy with the endoscopist pressing down the elevator lever and carefully withdrawing the instrument, while the assistant tried to retain the position of the guidewire in the cannulated area.

In brief, interventional ERCP in both groups was performed using the following steps: first prosthesis extraction (if necessary for exchange), cannulation of the papilla, visualization of the biliary system or pancreatic ducts with contrast medium (Peritrac 300/60%; Dr. Köhler Chemie GmbH, Alsbach Hähnlein, Germany), radiological documentation of pathological findings in two radiological axes, selective cannulation of pathologically changed biliary or pancreatic ducts using appropriate guidewires, performance of one or more interventions (*e.g.*, bougienage, concrement extraction, prosthesis insertion, *etc.*), and radiological and endoscopic documentation of results.

Of note, the interventional examination time for ERCP did not include insertion of the side-viewing duodenoscope down to the papilla or extraction of the endoprosthesis. To appropriately determine the effects of VS-guided ERCP, the interventional examination time was defined as the start of the ERCP once the side-viewing endoscope had been appropriately positioned in front of the papilla. Timing was started with a stopwatch once the cannulation catheter had been introduced to the working channel of the endoscope for the first time. The interventional examination time ended when the last intervention (endoprosthesis insertion, stone extraction, *etc.*) was completed and the final endoscopic photograph for documentation had been taken. Withdrawal of the endoscope from the patient was not included in the interventional examination time.

X-ray time and dose of each ERCP procedure from the first cannulation until the entire procedure and the final intervention had been finished were automatically registered and documented with the multifunctional digital Axiom artis fluoroscope (AXIOM Artis MP, Siemens, Munich, Germany) for each patient.

ERCPs were performed by two experienced investigators with > 10 years experience in gastrointestinal endoscopy, each of whom had performed more than 1500 ERCPs. Before the start of the trial, both investigators and the endoscopy assistants underwent 2 mo of

learning and training to become familiar with the VS and its fixable guidewire system. During this learning phase, each investigator performed more than 20 VS ERCPs. From this training phase, it became clear that handling, time requirements, radiological or endoscopic control of intrahepatically or intrapancreatically placed guidewires, and the method of performing instrument exchange had to be learned and require repeated training to improve skills and perhaps to reduce intervention times. From the team of endoscopy assistants, four individuals, each with experience of > 1000 ERCPs, were involved in this prospective randomised study.

Physicians and assistants completed the study documents immediately after the end of the ERCP and independently gave subjective scores (0-10, best to worst) in terms of “overall performance of ERCP”, “difficulty of ERCP” and “hygienic performance”. “Overall performance of ERCP” concerned global assessment of the course of the entire ERCP process. “Difficulty of ERCP” was described as the degree of interventional technical difficulty of the ERCP. “Hygienic performance” concerned whether the guidewire or accessories exchange was perfectly hygienic and whether guidewires contacted the patient’s face or head, were ever outside the covered sterile working area, *etc.*

Premedication was achieved in most patients with midazolam/pethidine and in younger patients with high levels of anxiety or in patients with high consumption of alcohol with propofol/pethidine. Conscious sedation was administered and monitored by a second physician who was responsible for analgo-sedation and documentation of all findings relevant to the study. All patients received continuous measurement of cutaneous oxygen saturation, pulse, blood pressure, and adequate oxygen supply during ERCP, which was performed in the prone position.

Cost analysis was also performed for each ERCP case for all consumables used during the study. The institutional costs for the side-viewing endoscopes and personnel costs for training purposes were not included in this analysis.

### Statistical analysis

Statistical analysis was done using SPSS (SPSS for Windows Version 16.0.2, Ehningen, Germany) with descriptive statistics (median and range) for all parameters and performance of the Wilcoxon rank-sum test (*U* test). The statistical hypothesis was that use of the Olympus VS and its fixable guidewire system in the VS group would make ERCP faster (interventional examination time), reduce the X-ray time and dose, and reduce the premedication dose. Additional statistical descriptions are provided for subjective scores describing the convenience and performance of each ERCP procedure given by the endoscopists and the assistants.

## RESULTS

Table 2 list all objective and subjective parameters used to



**Table 2 Objective and subjective score results from comparison of endoscopic retrograde cholangiopancreatography using the V-scope with conventional endoscopic retrograde cholangiopancreatography**

	ERCP with V-scope/V-system	Conventional ERCP	P value
<b>Objective results</b>			
Total interventions (n)	50	47	
Bougienage bile ducts	7	6	
Bougienage pancreas	2	8	
Endoprosthesis insertion	24	16	
Extraction of biliary concretions	10	9	
Extraction of pancreatic concretions	3	3	
Bile duct biopsy	1	0	
Nasobiliary catheter	1	2	
Partial guidewire dislocation	1	3	
Loss of guidewire	1	0	
Examination time (min), median (range)	29 (5–50)	31 (7–90)	0.28
X-ray time (min), median (range)	5.87 (0.6–14.15)	6.12 (1.67–18.85)	0.48
X-ray dose (cGy/m <sup>2</sup> ), median (range)	1351 (159–5039.2)	1296 (202.3–6421)	0.34
<b>Premedication dose (mg), median (range)</b>			
Midazolam	7 (0–11.5)	6.75 (0–11.5)	0.33
Pethidine	100 (0–200)	100 (0–200)	0.48
Propofol	0 (0–720)	0 (0–490)	0.42
Diazepam	0 (0–10)	0 (0–15)	0.33
<b>Adverse events (n patients, % of each group)</b>			
Abdominal pain >24 h without inflammation	1 (4)	3 (12.5)	0.59
Cholangitis <sup>1</sup>	3 (12)	4 (16.7)	0.77
Post-ERCP pancreatitis <sup>2</sup>	1 (4)	3 (12.5)	0.59
Perforation	0	0	
<b>Subjective score results</b>			
<b>Endoscopy assistants (n = 4), median (range)</b>			
Overall performance of ERCP	3 (1–8)	2 (1–7)	0.51
Hygienic aspects of ERCP	3 (1–6)	3 (1–7)	0.33
<b>Endoscopists (n = 2), median (range)</b>			
Overall performance of ERCP	3 (1–8)	3 (1–7)	0.47
Position to papilla	3 (1–7)	4 (1–7)	0.29
Difficulty of ERCP, median (range)	2 (1–2)	2 (1–3)	0.49

<sup>1</sup>Cholangitis was diagnosed by post-procedural elevation of inflammatory markers in conjunction with an intermittent increase in cholestatic enzymes and/or bilirubin, or subfebrile/febrile temperatures after endoscopic retrograde cholangiopancreatography (ERCP). Cholangitis was mild, and cases resolved within a median of 8 d (range, 2–10 d);

<sup>2</sup>Post-ERCP pancreatitis was diagnosed by elevation of lipase (more than twofold of the upper normal value) and the presence of abdominal pain after ERCP. These patients had mild pancreatitis, and cases resolved after a median of 4 d (range, 2–7 d).

compare ERCP in the VS group and in the conventional group.

Age, indications, and the number and difficulty of interventions were not different between the VS group and the control group. Although the median interventional examination time was 2 min shorter in the VS group (29 min *vs* 31 min), the difference was not statistically significant.

Similarly, the median X-ray time and dose, as well as the premedication dose, were nearly the same in both groups. Interestingly, fewer adverse events were seen in the VS group, but this difference was also not statistically significant, perhaps because of the low number of cases (Table 2).

Subjective assessment scores by physicians and endoscopy assistants concerning “overall performance of ERCP” also did not reveal any significant differences between the VS group and the conventional ERCP group. Scores were also the same for “hygienic aspects of the ERCP” as assessed by the assistants.

Individual cost analysis of the ERCP materials and accessories used during the ERCP study revealed no significant difference in consumables used. Accessories used in the VS group amounted to 349 EUR (range, 44–673 EUR), and costs in the conventional ERCP group were 335 EUR (range, 135–604 EUR).

## DISCUSSION

ERCP is a resource-intensive, complex, interventional, multi-step endoscopic-radiologic procedure for the treatment of various biliary and pancreatic diseases<sup>[1–5,19–22]</sup>. However, performance of ERCP, whether it results in therapeutic success or technical failure, harbours a known risk of side effects for the patient (*e.g.*, cholangitis, post-ERCP pancreatitis, analgo-sedation-induced complications, *etc.*), including a radiation risk, which the endoscopy team also experiences. ERCP requires the substantial use of fluoroscopy and expensive materials (balloons, guidewires, *etc.*), and technical success is often accompanied by substantial time and physical efforts on the part of the endoscopist and his/her team of assistants. Thus, further innovations are currently being studied to make ERCP safer for patients, to reduce X-ray dose and premedication, and to simplify the technical ERCP process<sup>[2–6,9,17,21]</sup>.

One possible future approach for a more convenient and perhaps safer, faster, and easier ERCP procedure may be the use of specialized fixable (short) guidewire systems as compared with the use of conventional long guidewires (4.0–4.5 m), which require longer exchange times. Several studies have been published using prototype VSs and prototype linear guidewires that demonstrated shorter accessory exchange times and a reduced need for guidewire adjustments<sup>[13,14,17,23]</sup>. However, the benefit of the use of this Olympus V-system with respect to the overall ERCP outcome, interventional examination time, and fluoroscopy requirements has not been completely evaluated in daily ERCP practice. Thus, in an effort to optimize ERCP quality and hospital costs in a high-volume ERCP centre, an investigator-driven, prospective, randomized pilot trial was performed to explore whether the use of the Olympus VS and its dedicated guidewire system significantly improves the outcome of patients undergoing ERCP or reduces intervention time, fluoroscopy, or the endoscopists' and assistants' work, handling, and efforts.

This prospective, single-centre study did not, how-

ever, reveal any statistically significant differences between ERCP using the V-system and conventionally performed ERCP in terms of interventional examination time, fluoroscopy, analgo-sedation requirements, or subjective assessments obtained from the endoscopists and the endoscopy assistants. Interestingly, interventional examination time was somewhat shorter in the VS group (29 min) than in the control group (31 min), despite the need to perform additional endoprosthesis insertions in the VS group (Table 2), raising the question of whether the study population was too small to observe significant differences. Alternatively, this result may merely reflect the high quality and training status of the individuals who carry out conventional ERCP at a high-volume tertiary ERCP centre (> 1000 ERCPs per year).

Joyce *et al.*<sup>[17]</sup>, in a previous multicentre comparative trial, also did not demonstrate any significant effect of the V-system on ERCP examination time or on fluoroscopy time, although they did demonstrate significant benefits of the V-system when particular individual ERCP working steps were analysed, such as the median exchange time of accessories or the need for guidewire repositioning. Combined with our findings, these data show that a possible improvement in one single working step in ERCP (*e.g.*, exchange of accessories) is not necessarily coupled with an improvement or reduction in the entire examination or fluoroscopy time, especially when varying degrees of case difficulties are being treated by various experienced endoscopists<sup>[5,7,11-14,17,24]</sup>. However, the real benefit of V-system-guided ERCP may become relevant when the high interindividual variation in ERCP complexity and the different experiences of endoscopists are compensated for in an appropriate follow-up study protocol in which one patient is examined by the same investigator during follow-up interventions, such as endoprosthesis replacement, stone extraction, *etc.*, using both ERCP techniques. Such a stratified study protocol that would compare both ERCP techniques performed by one endoscopist on the same patient with the same therapeutic indication promises to better demonstrate whether a real benefit exists concerning interventional examination time and possibly other ERCP parameters including quality or outcome findings when using the V-system.

This small, prospective, randomized, single-centre pilot ERCP study in routine patients showed that several other uncontrolled factors during ERCP intervention influenced the examination time and radiation requirements more than the proposed time saving that is attributed to the V-system<sup>[11-14,17-19,21,25,26]</sup>. Thus, from the experience gained during the use of the VS and its short guidewire system, it became apparent that the V-system may be helpful in individual cases with repetitive interventions and several instrument changes (*e.g.*, multiple stenting, numerous stone extractions), but these impressions have not yet been objectively proven with a corresponding interventional ERCP study.

Although previous studies dealing with the use of the V-system have focused primarily on technical aspects and

time requirements of single ERCP working steps<sup>[14,15,17]</sup>, this prospective pilot trial also documented all adverse events and analgo-sedation requirements in each group. Interestingly, in the VS group, the frequency of adverse events in terms of abdominal pain lasting longer than 24 h, cholangitis, and post-ERCP pancreatitis was not significantly different as compared with that of the conventional ERCP group. However, the tendency of fewer instances of post-ERCP pancreatitis in the VS group raises the question of whether the completely fixed guidewire within the pancreatic duct reduces mechanical irritation of the pancreatic tissue, which may be a cause of an inflammatory response during conventional ERCP. This unexpected observation warrants further prospective studies, because post-ERCP pancreatitis is still a major adverse event following ERCP procedures<sup>[4,16,18,19]</sup>.

Cost evaluation of the consumables used in each case revealed that both ERCP techniques have nearly the same cost to the hospital according to Germany University prices. This analysis does not favour the exclusive use of only one ERCP technique.

In addition, evaluation of the subjective assessment scores from endoscopists and the endoscopy assistants also demonstrated no advantage of the V-system as compared with the conventional ERCP technique. The overall performance of ERCP and the hygienic aspects of ERCP were similar in the VS group and in the conventional group, although working with shorter guidewires may be more convenient for the personnel than longer guidewires<sup>[12-15,17]</sup>. However, as discussed above, these results may be related to the high training status of the personnel at our high-volume ERCP centre and to the fact that performing a safe and effective bougienage within the biliary system or pancreas requires the use of the long linear guidewire (4.2 m), which may have influenced the judgement of the personnel. Subjective assessment may vary according to the training status of the endoscopy team, which would preclude the translation of these results to low-volume endoscopy hospitals.

In conclusion, this prospective ERCP trial using the VS and V-system did not show a significant advantage of this dedicated short guidewire system at a high-volume ERCP centre as compared with the conventional ERCP technique. The real value of this V-system in ERCP practice requires further investigation in follow-up interventional studies that compensate for interindividual variation in both patients and endoscopists. Studies should be performed in low-volume endoscopy centres as well.

## ACKNOWLEDGMENTS

ERCP materials were provided by Olympus, Hamburg, Germany.

## COMMENTS

### Background

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex and cost-intensive diagnostic and therapeutic approach for the identification and

treatment of hepatobiliary and pancreatic disorders. To simplify this method, many new endoscopic techniques and instruments are currently being developed. In this pilot study, authors compared the new Olympus V-Scope (VS) system with the normal Olympus duodenoscope in patients admitted for interventional ERCP.

### Research frontiers

The new VS system with its specialized fixable guidewire system (Olympus TJF160 VR) was evaluated and compared to the conventional ERCP technique (Olympus TJF160) with respect to the interventional examination time, X-ray time and dose, premedication dose, frequency of adverse events, handling in daily routine, and cost effectiveness.

### Innovations and breakthroughs

Although detailed parameters of the ERCP technique and the outcomes were carefully assessed, no statistically significant differences were found between ERCPs performed with the VS and V-system and those performed using the conventional ERCP technique. Objective parameters such as interventional examination time and X-ray dose, outcome parameters such as adverse events, and subjective assessment scores by the endoscopy personnel were all similar in both ERCP technique groups. However, the study group was small, various levels of ERCP difficulty were included, and the results may have been influenced by the high-level training status of the personnel at our high-volume ERCP centre.

### Applications

Regarding the fairly small number of patients, this study was designed as a pilot study to provide preliminary results concerning future study parameters for sample size estimations, outcome parameters and cost assessments. In further studies with a larger number of patients, the potential benefits of the Olympus V-system may be better evaluated when including only one or two defined ERCP indications and by including endoscopists who examine the same patient during follow-up and use both ERCP techniques.

### Terminology

ERCP: A diagnostic and therapeutic tool for selective radiographic illustration of the biliary tract and pancreatic ducts that enables important interventions such as endoprosthesis insertion for drainage, stone extraction, or tumour palliation *via* short or long guidewire techniques. The Olympus side-viewing VS contains a modified elevator lever with a V-groove, which allows the use of short guidewires that can be fixed. However, these potential advantages have not yet been shown to improve the technical aspects of ERCP instrumentation, patient outcomes, or adverse events.

### Peer review

This pilot study carefully assessed several outcomes and technical and subjective parameters of both ERCP techniques. Perhaps because of the small number of patients, no significant differences were demonstrated between ERCP using the V-system technique and conventional ERCP. The results obtained may be used for sample size calculation for a larger, more definitive study with more homogeneous ERCP indications.

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