Cohort Study

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Cholangioscopy with Spyglass DS using percutaneous transhepatic cholangiography access: a retrospective cohort study

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Background: Conventional peroral methods to visualize biliary strictures are not feasible in some patients with altered anatomy or biliary obstruction, and percutaneous transhepatic cholangioscopy can be used as an alternative procedure. This study aimed to retrospectively review the use of percutaneous transhepatic cholangiography using the SpyGlass DS technology (S-PTCS) during a 5-year period at a Danish tertiary referral centre.

Materials and methods: All patients who underwent S-PTCS at a single Danish tertiary referral centre between 2016 and 2021 were retrospectively analyzed. The visual, technical, and overall success rates of S-PTCS were analyzed, as well as the complication rate. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of S-PTCS were calculated.

Results: Twenty-two patients were included in the study. Visual, technical, and overall success of S-PTCS was achieved in 17/22, 22/22, and 21/22 patients, respectively. S-PTCS yielded a sensitivity of 83.3%, a specificity of 100%, a PPV of 100%, a NPV of 94.1%, and an accuracy of 95.4%. Complications occurred in 1/22 patients.

Conclusion: S-PTCS is a safe modality, with high success rates, high predictive values, and a low rate of complications. This study suggests that S-PTCS is an alternative to conventional methods in patients with indeterminate biliary strictures where conventional methods were unfeasible.

Keywords: Indeterminate biliary strictures, percutaneous cholangioscopy, percutaneous SpyGlass DS, SpyGlass

Introduction

Biliary strictures are caused by various disorders ranging from inflammatory strictures induced by primary sclerosing cholangitis (PSC) to strictures caused by cholangiocarcinoma. Identifying the aetiology of these strictures is often difficult, but important, as treatment is dependent on the underlying cause[1–3]. To properly treat and diagnose biliary strictures, visualization of the target area is needed, and biopsies must be taken[3,4]. Conventional methods have poor accuracy in distinguishing between benign and malignant etiologies, and diagnosing these patients presents a challenge[1,4,5].

HIGHLIGHTS

- Biliary strictures are common, and treatment depends on their cause.
- Some strictures are hard to visualize endoscopically.
- Percutaneous transhepatic cholangioscopy offers a shorter, direct route for evaluation.
- It's a safe and effective alternative for indeterminate biliary strictures.

Endoscopic retrograde pancreatography (ERCP) is the standard procedure for the treatment of biliary strictures[1] and can be further supplemented with magnetic resonance cholangiopancreatography to increase diagnostic accuracy. However, ERCP is limited by its low diagnostic sensitivity[6]. Furthermore, some difficult strictures require direct visualization of the lesions with targeted biopsies. In such cases, peroral cholangioscopy (POCS) provides an alternative when traditional ERCP is not feasible. POCS can directly visualize target lesions, obtain targeted biopsies, and is shown to be safe and useful when diagnosing indeterminate biliary strictures[1]. However, some patients have previously undergone upper gastrointestinal surgery, which can alter both duodenal and biliary anatomy. Moreover, strictures caused by PSC may be multifocal and/or positioned over the biliary confluence, which can make visualization difficult[2]. Conventional ERCP and POCS are not feasible in these patients, and another approach is required[7,8].

Percutaneous transhepatic cholangioscopy (PTCS) is an alternative, attractive procedure owing to a shorter and more straightforward route to all parts of the biliary tree. Studies have

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shown that PTCS is safe, effective, and feasible for the visualization of indeterminate biliary strictures and in cases with altered biliary anatomy[7,9–12]. In addition, the studies demonstrated high diagnostic accuracy of PTCS and reported a satisfactory rate of technical success[7,9–12].

Despite these preliminary studies, literature concerning the feasibility of PTCS using SpyGlass DS technology (S-PTCS) remains sparse. This study aimed to evaluate the use, specifically the visual and histological success, and the specificity, sensitivity, and complication rate of S-PTCS during a 5-year period at a Danish tertiary referral centre for upper gastrointestinal and hepato-pancreato-biliary surgery and transplantation.

Methods

This was a retrospective single-centre cohort study. All patients who underwent S-PTCS at a single Danish tertiary referral centre for upper gastrointestinal and hepato-pancreato-biliary surgery and transplantation, covering a population of 2.8 million inhabitants, between 2016 and 2021, were included. These patients underwent S-PTCS due to suspected stenosis or other pathologies in the bile-duct system, where conventional ERCP or peroral cholangioscopy were not feasible options. Patients were identified by searching for specific procedure codes in the hospital's local database (Endobase). Clinical patient data and information about the S-PTCS procedure were retrieved from electronic health records (Sundhedsplatformen, Epic Systems Corporation). Patient records were evaluated by TUS and discussed with MPA in unclear cases. This study was approved by The Danish Data Protection Agency (P-2021-902) and the Regional Committee for the Capital Region in Denmark (R21069569). This approval permits the extraction of specific patient data from clinical databases for research purposes without the necessity of explicit individual patient consent. This study is reported in line with the STROCCS criteria[13].

An internal/external PTC catheter was placed by an interventional radiologist using standard techniques at least 2–3 weeks before the S-PTCS procedure to allow the creation of a fibrous tract from the skin to the biliary tree. The S-PTCS procedures were performed by one of the two experienced endoscopists in conjunction with an interventional radiologist. The procedures were performed under general anaesthesia and 4.0/0.5 g of piperacillin/tazobactam was administered intravenously as a prophylactic antibiotic. The previously placed biliary drain was exchanged with a sheath (11 French sheath, 23 cm long, Cordis Corp). Two wires (0.035in × 145 cm Amplatz Super Stiff; Boston Scientific) were inserted into the tips of the duodenum. The sheath was removed and reinserted over one of the wires, and subsequently, the wire and previously placed dilatator were removed. This left the sheath for the SpyScope (Boston Scientific) and one wire as a safety wire, which also doubled as a guidance wire. Next, the SpyScope was introduced, and the biliary tract was investigated visually in a systematic manner.

Tissue biopsies were obtained by the endoscopist, if indicated, using 3-French forceps with a 4.1 mm jaw opening (SpyBite, Boston Scientific). Finally, the SpyScope was removed, and a new biliary drain was introduced (10.2-French Biliary Drainage Catheter, COOK Medical Europe Ltd.). The drain was left in place until the pathology report was received and was later removed or substituted with an internal stent depending on the clinical situation.

The main outcome of this study was the success of S-PTCS, defined as sufficient visualization of the target lesion, histological verification of the diagnosis, and absence of missed malignancy at follow-up. Visual assessment of S-PTCS was deemed successful if the visual findings corresponded to the later verified diagnosis, confirmed by histological assessment at follow-up. Technical success of S-PTCS was defined as the appropriate visualization of a target lesion and obtaining biopsies eligible for pathological evaluation. In addition, we estimated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (PPV), and accuracy of PTCS based on the information provided by visual findings and histological tissue. Furthermore, we investigated the number of days from percutaneous transhepatic catheter (PTC) placement to S-PTCS, and the number of patients with a new PTC placed to perform S-PTCS. The secondary outcome of this study was the safety of S-PTCS in terms of complications.

Statistical calculations were performed using SPSS (IBM SPSS Statistics for Windows, version 25.0). Tables were created using Microsoft Word (Microsoft Word for Windows). The data were tested for normal distribution using the Shapiro–Wilkes method. Data are presented as medians (interquartile ranges) and counts. Sensitivity, specificity, PPV, NPV, and accuracy were calculated using the MedCalc software (version 20.110).

Results

In total, 22 patients were included in the study. The baseline characteristics of the patients are shown in Table 1. Median S-PTCS procedure time was 43.5 min. Most patients (21/22) underwent S-PTCS for strictures with suspected malignancy. Detailed information on the S-PTCS procedure including indications, visual findings, histological findings, and treatment consequences (see Table 2). Perioperative visualization of the procedure can be seen in Picture 1, 2, 3, and 4.

Nine of the 22 patients had a new PTC placed to undergo S-PTCS. A median of 35 days (interquartile range 18.5–51.5) passed between PTC placement and S-PTCS. This median was calculated for 19 patients, as the specific date of PTC placement could not be found in the remaining three patients.

S-PTCS success was achieved in 21/22 patients. The combined visual and histological findings of PTCS yielded a correct diagnosis in 21/22 of the patients. In one patient, a submucosal cholangiocarcinoma was missed, and this tumour was later diagnosed in the pathology report from the patient's explanted liver.

Table 1

Baseline characteristics

Characteristic	Study population $n = 22$
Age, years, median (IQR)	57.5 (40.5–74.5)
BMI, (kg/cm^2), median (IQR)	23.8 (21.6–25.9)
Sex:	
Male, number	11
ASA score:	
1, *n*	0
2, *n*	11
3, *n*	10
4, *n*	1
S-PTCS procedure time, minutes, median (range)	43.5 (10–91)

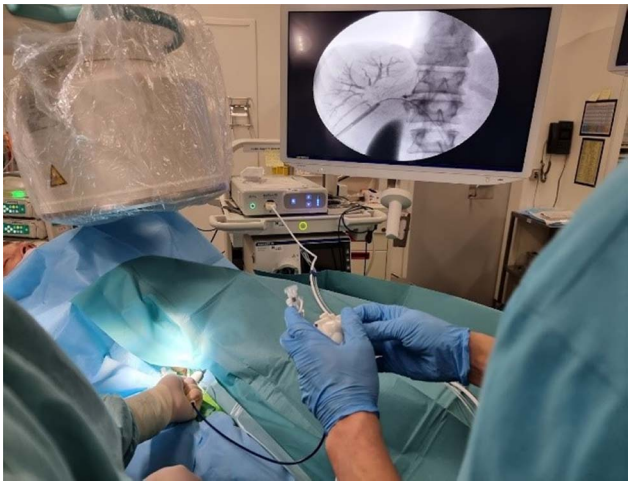
ASA, American Society of Anesthesiology; IQR, interquartile range; S-PTCS, percutaneous transhepatic cholangiography using the SpyGlass DS technology.

Table 2

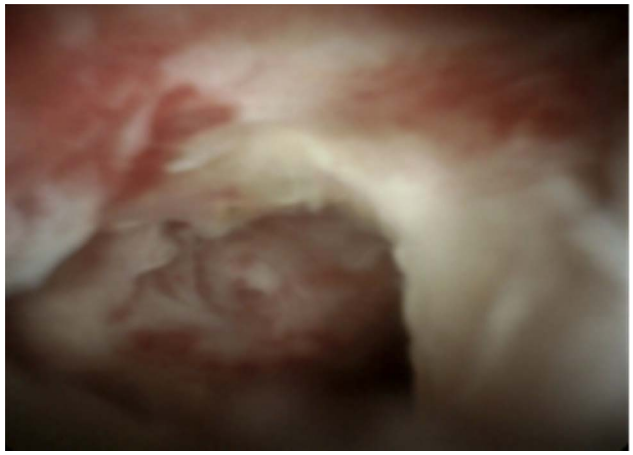
Percutaneous transhepatic cholangioscopy with SpyGlass DS

Patient number	Indication	Findings	Histopathology	Treatment consequence	Later contradictory findings (follow-up)
1	Suspected malignancy, biliary duct dilatation	Inflammation, biliary duct dilatation	Inflammation	No malignancy, follow-up MRCP in 1 year	None (4 years, 218 days)
2	Unexplained jaundice, post-liver transplant	Inflammation, ischaemic bile ducts, casts	Inflammation, bile-duct ischaemia, bile-duct atrophy	The patient condition worsens with sepsis, dies 14 days after Spy	None (deceased 6 March 2019)
3	Suspected stenosis in the distal common bile duct	No abnormal findings	No biopsies taken	Follow-up MRCP in 3 months	None (3 years, 113 days)
4	Suspected skip lesions after Whipple's operation	No abnormal findings	Inflammation	ERCP-placed stent every 3 months	None (3 years, 84 days)
5	Indeterminate biliary stricture, possible malignancy	Some slightly papillomatous tissue, otherwise normal	Inflammation	ERCP-placed stent every 3 months	None (2 years, 334 days)
6	Suspected malignancy	Stricture, polypous tissue	Inflammation, some necrotic cells	ERCP-placed stent every 3 months	None (2 years, 219 days)
7	Histological verification of malignancy pre-chemotherapy	Cancer, inflammation	Inflammation	No further treatment, a follow-up blood sample performed	None (2 years, 212 days)
8	Disprove malignancy pre-liver transplant	Inflammation	Inflammation, fibrosis	Liver transplant as planned	None (2 years, 163 days)
9	Biopsy from stricture in common bile duct for surgical strategy	Klatskin tumour, papillomatous tissue	Inflammation	Left hepatectomy instead of Whipple's operation	None (2 years, 160 days)
10	Biliary obstruction, unknown cause	Papillary tumour,	Inflammation, polypous and papillomatous tissue, a strong suspicion of adenocarcinoma	The patient was not fit for surgery, disseminated disease. The patient condition worsens and dies after many hospital admissions.	None (deceased 3 November 2020)
11	Suspected malignant stricture	Inflammation, stricture	Inflammation, ulceration, granulation tissue	No malignancy, liver transplant.	None (2 years, 135 days)
12	Suspected malignancy in a patient with PSC	PSC strictures	Inflammation, granulation tissue, ulceration	No malignancy, MRCP, then liver transplant	None (2 years, 104 days)
13	Suspected malignancy in the hepatic duct in a patient with PSC	Papillary tissue, three suspected malignant areas	Inflammation, fibrosis, ulceration	No malignancy, MRCP, then liver transplant	None (2 years, 94 days)
14	Suspected malignancy in a patient with unconfirmed PSC	Tumour tissue	High-grade dysplasia, inflammation	Chemotherapy, and stenting. The patient was not fit for surgery.	None (2 years, 58 days)
15	Suspected malignancy in a patient with PSC	Inflammation	Low-grade neoplasia, ulceration, inflammation	Liver transplant	None (1 year, 357 days)
16	Histological verification of malignancy pre-chemotherapy	Polypous tissue	Low-grade dysplasia, inflammation	Stenting, patient was not fit for surgery	None (deceased 20 June 2021)
17	Disprove malignancy in indeterminate biliary stricture with biopsy	Inflammation	Inflammation, fibrosis	MRCP, no further treatment was needed	None (1 year, 241 days)
18	Suspected malignancy in a patient with PSC	Inflammation, several strictures	High-grade dysplasia	Liver transplant and re-transplant due to complications	Missed submucosal adenocarcinoma in pathology from explanted liver
19	Evaluating biliary stricture	Inflammation	Inflammation, granulation tissue	Stenting, no further treatment needed	None (1 year, 61 days)
20	Multiple strictures in hepatic ducts	Inflammation, suspected malignant stricture	Inflammation	Operated on suspicion of malignancy alone	None (291 days)
21	Histological verification of malignancy pre-oncological treatment	Tissue suspicious of malignancy	Adenocarcinoma	Patient not fit for surgery, referred to oncology	None (250 days)
22	Histological verification of malignancy	Tissue suspicious of malignancy	Adenosquamous carcinoma	Referred to oncology	None (249 days)

ERCP, endoscopic retrograde pancreatography; MRCP, magnetic resonance pancreatography; PSC, primary sclerosing cholangitis.



Picture 1. Percutaneous transhepatic cholangioscopy with SpyGlass DS technology.



Picture 3. Suspect intraductal tissue visualized by SpyGlass DS technology.

Biopsies were taken in 21/22 procedures, and all were deemed acceptable for histological evaluation. In one patient, biopsies were not taken because of the lack of pathological findings in the visual assessment. Visual success was obtained in 17/22 patients. The findings of this study showed overall PTCS success in 21/22 patients, a sensitivity of 83.3%, a specificity of 100%, a PPV of 100%, an NPV of 94.1%, and an accuracy of 95.4%.

In 21/22 patients, no complications occurred. One patient who underwent S-PTCS in a very poor clinical condition further deteriorated clinically after S-PTCS. The patient developed cholangitis and sepsis two days after the procedure.

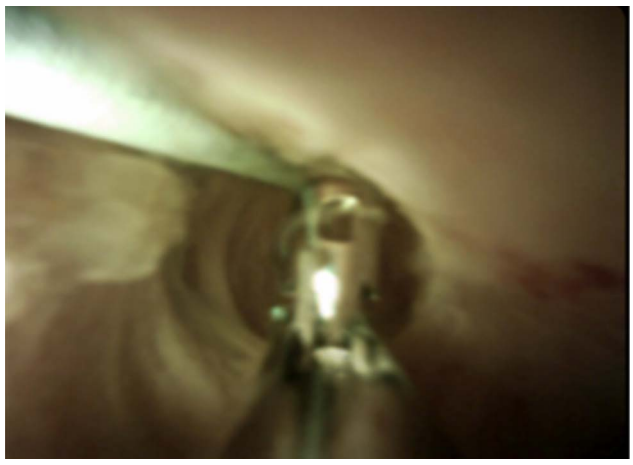
Information on the final treatment of patients in this study is shown in Table 3.

Discussion

In our study, S-PTCS was performed to diagnose indeterminate biliary strictures, for which conventional methods were impracticable. The main indication for S-PTCS in our series was suspicion of malignant strictures above the biliary confluence in patients with PSC under evaluation for liver transplantation. We found an overall S-PTCS success rate in 21/22 patients with a sensitivity of 83.3%, 100% specificity, 100% PPV, 94.1% NPV, and 95.4% accuracy of the combined visual and histological findings of the procedure. Our findings also show isolated visual success in 17/22 patients and isolated technical success in 22/22 patients.

The sensitivity results of the study are in line with a previous study of 95 patients with distal common bile-duct structures that reported 85.7% sensitivity of PTCS-guided biopsy and 74.3% sensitivity of visual PTCS findings[3]. In their study, PTCS was performed using a 5.2 mm outer diameter cholangioscope (CHF P20Q: Olympus Optical Ltd) or a 4.9 mm outer diameter cholangioscope (FCN-15X; Pentax), and biopsies were obtained with a 1.8 mm diameter forceps (FB- 19SX01, Olympus) under direct vision. The combined visual and histological assessment in their study yielded 97.1% sensitivity, 100% specificity, 100% PPV, and 98.4% NPV. Similar to our study, the study found the most precise diagnosis when combining visual and histological findings, and their findings corresponded to ours[3].

Picture 2. Normal intraductal tissue and guidewire visualized by SpyGlass DS technology.



Picture 4. Intraductal tissue and SpyBite biopsy forceps visualized by SpyGlass DS technology.

Table 3
Final treatment

Treatment	Malignant disease ($n=4$)	Benign disease ($n=18$)
ERCP[a]-placed stent ($n=4$)	0	4
Operation ($n=8$)	1	7
Oncological treatment only ($n=3$)	2[b]	1
Oncological treatment and ERCP-placed stenting ($n=1$)	0	1
No treatment ($n=6$)	1[c]	5

ERCP, endoscopic retrograde pancreatography.
[a]Endoscopic retrograde cholangiopancreatography.
[b]Patients not fit for surgery as evaluated by an anesthesiologist.
[c]Patient was not fit for any intervention; condition progressively worsened, deceased after several hospital admissions.

In another study using PTCS in 177 patients with hilar strictures, similar results were reported[14]. The authors performed PTCS with a 4.9 mm outer diameter cholangioscope (FCN-15X; Pentax, Tokyo, Japan, ECN-1530; Pentax, Japan), and reported a 76.9% sensitivity for PTCS-guided biopsy and a 56.1% sensitivity for visual PTCS findings. Combining the two methods yielded a sensitivity of 88.4%. Furthermore, PTCS also had a therapeutic role in their study through stent placement in some patients with incurable malignant hilar lesions[14].

A retrospective study of S-PTCS found favourable results in 13 patients with surgically altered anatomy[15] Eight patients had bile-duct stones, which were cleared successfully after a median of two procedures. The remaining five had biliary strictures, where biopsies confirmed adenocarcinomas with 100% accuracy. The study reported no procedure-related complications[15].

In our study, 1/22 patients experienced complications related to the procedure. The patient had S-PTCS performed in the palliative phase, and the patient's condition progressively worsened in the days leading up to the procedure. This patient developed cholangitis and sepsis 2 days after S-PTCS, which likely occurred because of instrumentation in the biliary tract. However, the patient was already in a moribund state, and S-PTCS was performed with palliative intent, which made intervention with S-PTCS the preferable option.

Similarly low rates of complications of PTCS have been reported, ranging from 3 to 10.7%[3,9,14,16]. Bleeding, perioperative pain, mild bacteremia, and cholangitis are the most common complications but rarely require intervention[3,9,14,16]. Other studies reported 0% complications; however, these studies were smaller with a limited number of patients[8,11,17–20]. In comparison, complications following POCS range from 7 to 21.4%, with cholangitis as the most common one[21–23].

The advantage of PTCS is its usability when conventional methods fail or are deemed unfeasible[12]). Although POCS can be used to acquire tissue samples, some strictures are located where they cannot be approached in a retrograde manner, as is used by both POCS and ERCP[12]. Owing to a shorter and more direct route to the biliary tree, PTCS can visualize strictures in the hepatic hilum and the far distal common bile duct, where the retrograde approach of ERCP and POCS cannot be used. Furthermore, tissue sampling can be difficult in the far distal common bile duct using ERCP and POCS, and PTCS is a viable alternative[12]. Additionally, many patients with altered anatomy of the upper gastrointestinal tract are unsuitable for the peroral approach[7,11]. In these cases, PTCS provides a safe alternative approach with demonstrated diagnostic abilities[9,19]. Conversely, the disadvantages are the more invasive and painful nature of the procedure, in addition to the waiting time from PTC to S-PTCS, with the risk of cholangitis during this period. However, it should be noted that most patients who do not have a preexisting PTC will have one place anyway for biliary drainage.

Some studies have used the S-PTCS for other indications[17,18,20]. These studies investigated the feasibility of S-PTCS for biliary stone removal and lithotripsy and reported a 100% success rate of stone removal without complications[17,18,20]. Another study of 28 patients with postsurgical altered anatomy and biliary obstruction reported a 96% success rate in treating biliary stones with S-PTCS[9]. Additionally, the authors reported 100% histopathological success in the diagnosing of ten patients with biliary strictures and 96% technical success with S-PTCS.

The strengths of this study include the relative high number of patients compared to other studies, the complete registration of data and the use of the Danish Register of Civil Registration Numbers (CPR numbers). Every citizen in Denmark is assigned an exclusive CPR number at birth that remains until death. The CPR register enables lifelong comprehensive follow-up of all patients, making registry-based studies unique in Denmark. Another strength of this study is the small risk of selection bias, as all S-PTCS procedures at our centre were registered prospectively. The main limitations of this study include the small number of included patients and the inherent limitations of conducting a retrospective cohort study with no control group or randomization. S-PTCS is a rare procedure, and to accumulate a substantial patient cohort, future research should ideally be multi-centre.

In conclusion, our study showed that S-PTCS is a safe modality, with high success rates, high predictive values, and a low rate of complications. A diagnosis and consequent treatment plan were made for 21/22 patients. S-PTCS is a good alternative to ERCP and POCS in patients with indeterminate biliary strictures and an altered biliary anatomy. For the highest diagnostic yield with this modality, visual findings must be combined with pathological results from the obtained biopsies.

Ethical approval

This study was approved by The Danish Data Protection Agency (P-2021-902) and the Regional Committee for the Capital Region in Denmark (R21069569).

Consent

In Denmark, retrospective cohort studies do not require written consent from the patient directly. We apply for permission through a data protection agency, and if we get this, we are permitted the data. This is addressed in the following sentence in the "Methods" section. "This study was approved by The Danish Data Protection Agency (P-2021-902) and the Regional Committee for the Capital Region in Denmark (R21069569)." This approval permits the extraction of specific patient data from clinical databases for research purposes without the necessity of explicit individual patient consent. As such, the study is approved for all its intentions and purposes, but I cannot.

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Author contribution

Study conception and design: T.U.S., M.P.A. Acquisition of data: T.U.S. Analysis and interpretation of data: T.U.S., Morten T., M.P.A. Drafting of the manuscript: T.U.S. Critical revision and final approval of the manuscript: T.U.S., Morten T., Mikkel T., N.S., P.N.L., M.P.A.

Conflicts of interest disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article. This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors. This is an original article, not based on previous communication with a society or meeting.

Research registration unique identifying number (UIN)

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Guarantor

Trygve Ulvund Solstad and Michael Patrick Achiam.

Data availability statement

Nothing of the sort is applicable to this article.

Provenance and peer review

Not invited.

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