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Observational Studies

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Interventional pathway in the management of refractory post cholecystectomy pain (PCP) syndrome: a 6-year prospective audit in 60 patients

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Abstract

Objectives: Post cholecystectomy pain syndrome can affect over a third of patients undergoing laparoscopic cholecystectomy. Acute exacerbations can result in recurrent emergency admission with excessive healthcare utilization. Standard surgical management appears to focus on visceral aetiology. Abdominal myofascial pain syndrome is a poorly recognised somatic pathology that can cause refractory pain in this cohort. It develops as a result of trigger points in the abdominal musculature. The report describes the pathophysiology and a novel interventional pathway in the management of post cholecystectomy pain secondary to abdominal myofascial pain syndrome.

Methods: The prospective longitudinal audit was performed at a tertiary pain medicine clinic in a university teaching hospital. Over a six-year period, adult patients with refractory abdominal pain following laparoscopic cholecystectomy were included in a structured interventional management pathway. The pathway included two interventions. Intervention I was a combination of abdominal plane blocks and epigastric port site trigger injection with steroids. Patients who failed to report durable relief (>50% pain relief at 12 weeks) were offered pulsed radiofrequency treatment to the abdominal planes (Intervention II). Outcomes included

patient satisfaction, change in opioid consumption and impact on emergency visits.

Results: Sixty patients who failed to respond to standard management were offered the pathway. Four patients refused due to needle phobia. Fifty-six patients received Intervention I. Failure rate was 14% (8/56). Forty-eight patients (48/56, 86%) reported significant benefit at 12 weeks while 38 patients reported durable relief at 24 weeks (38/56, 68%). Nine patients received Intervention II and all (100%) reported durable relief. Emergency admissions and opioid consumption were reduced.

Conclusions: Abdominal myofascial pain syndrome is a poorly recognised cause of post cholecystectomy pain. The novel interventional management pathway could be an effective solution in patients who fail to benefit from standard management.

Keywords: abdominal myofascial pain syndrome; abdominal pain; ACNES; post cholecystectomy syndrome; pulsed radiofrequency treatment.

Introduction

Laparoscopic cholecystectomy is considered the gold standard in the management of symptomatic gallstone disease [1]. Recurrent and persistent pain following laparoscopic cholecystectomy is termed post cholecystectomy pain (PCP) syndrome [2]. It can affect over a third of patients [3, 4]. PCP syndrome can cause significant distress affecting quality of life and exacerbations often result in emergency admissions with excess healthcare costs [5, 6]. Established aetiologies can be broadly divided into extra-biliary and intra-biliary where organic and functional biliary pathologies have detailed management strategies (Table 1) [7, 8]. In many cases, an organic pathology cannot be identified and persistent pain remains unexplained and challenging to manage [2, 8]. Anterior cutaneous nerve entrapment syndrome (ACNES) is

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listed as a potential cause of PCP syndrome [7-9]. In ACNES, there is localised tenderness at the lateral edge of rectus abdominis muscle [10]. However, ACNES does not adequately explain the epigastric and the right upper quadrant pain, which is often seen in patients with PCP. Chronic pain arising from myofascial structures in the abdomen is termed abdominal myofascial pain syndrome (AMPS) [11]. It is a poorly recognised cause of chronic abdominal pain with distinct features that differentiates it from ACNES [11-14]. In addition, there is robust pathophysiological rationale for the development of AMPS in this cohort. The underlying pathology is the presence of trigger points in abdominal musculature, which induces abnormal function [11, 15]. Abdominal trigger points can arise from muscle trauma, underlying visceral inflammation (phenomenon of viscerosomatic convergance) or a combination of both [11, 15]. The authors present the first report on a novel management pathway in sixty patients with PCP who failed to respond to standard surgical interventions and detail the underlying pathophysiology.

Methods

Adult patients, who were diagnosed with refractory PCP syndrome under the care of a single physician (GN) based in a tertiary pain medicine service, were included in an on-going prospective longitudinal audit. The Audit was registered with the Clinical Audit Safety and Effectiveness (CASE 7125), University Hospitals of Leicester NHS Trust, UK [11]. As it was an audit, ethical review was not required.

Surgeons working in a hepatopancreaticbiliary unit at a University Hospital referred the patients who failed to respond to standard surgical management. Standard management of PCP included ultrasound scan, upper gastrointestinal endoscopy, computed tomography (CT) scan of the abdomen, magnetic resonance cholangiopancreatography (MRCP), endoscopic retrograde cholangiopancreatography (ERCP) with or without stent insertion to rule out extra biliary and biliary pathologies. Patients underwent hepatobiliary iminodiacetic acid (HIDA) scan if sphincter of Oddi dysfunction (SODS) was suspected

Table 1: Potential causes of post cholecystectomy pain syndrome [7, 8].

Structural	Functional
Retained stones	Irritable bowel syndrome
Papillary fibrosis	Biliary sphincter disorder
Biliary stricture	Functional dyspepsia
Chronic pancreatitis	Functional biliary-type pain
Peptic ulcer	Gastroparesis
Mesenteric ischaemia	
GORD	
ACNES	
Fatty liver disease Bile acid malabsorption	

GORD, gastro-oesophageal reflux disease; ACNES, anterior cutaneous nerve entrapment syndrome.

and if present, were managed with endoscopic sphincterotomy. Patients with gastritis received a course of proton pump inhibitor. Amitriptyline, codeine, tramadol, and oral morphine were prescribed for analgesia. The pain physician reviewed the patient on the ward (emergency admission) or in the outpatient clinic.

Clinical diagnosis of PCP secondary to AMPS [11]

- Type of pain: Constant dull and deep achy pain with intermittent sharp stabbing flare-ups.
- Site(s) of Pain: Right upper quadrant (RUQ), Epigastrium, Umbilicus.
- Radiation of pain: Right flank (RUQ pain), subcostal margins (Epigastric pain) or the groin (umbilical pain).
- Aggravating factors for Pain: Eating, activity, bowel movement.
- Presence of potential risk factors (Table 2).
- On examination:
 - Abdomen is soft with tender trigger points in upper abdomen, usually associated with port scars. Trigger point is a hyperirritable spot within a taut band of skeletal muscle that is painful on compression and can give rise to referred pain and motor dysfunction [11].
 - Positive Carnett's sign. Carnett's sign is a physical examination finding where the abdominal pain increases on tensing the abdominal wall muscles [11].
 - Allodynia could be present over the port scar(s).
- Investigations including imaging, endoscopy and biochemistry do not reveal on going visceral inflammation
- Poor response to opioids (codeine, tramadol and oral morphine). Once AMPS was clinically diagnosed, the patients were provided with a possible diagnosis and were given reassurance that there could be an organic cause for their pain.

The objective was to identify whether the novel management pathway could confirm the diagnosis of AMPS and provide therapeutic benefit at 12-and 24-weeks following treatment. Patients were given detailed information on the technique, potential risks and the objectives of offering a novel pathway. All patients provided written consent for their annonymised data to be used for analysis and for publication in a peer reviewed journal.

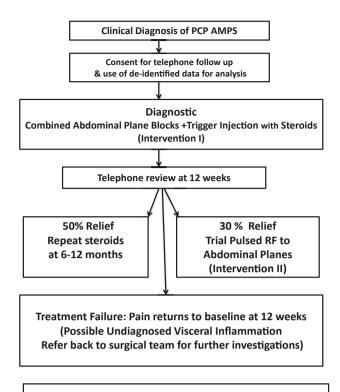
Interventional management pathway

This pathway included two interventions (Figure 1).

Table 2: Potential risk factors in the development of post cholecystectomy pain (PCP) syndrome [11, 16-20].

Non-specific	Specific
Female gender	Pancreatitis (gall stone, post ERCP)
Young age	Biliary leak (gall bladder perforation)
Pre-existing anxiety	Gastritis
Pre-existing depression	GORD
Pain at other sites	Recurrent cholecystitis
Obesity	Port site infection
	Poorly controlled postoperative pain

GORD, gastro-oesophageal reflux disease; ERCP, endoscopic retrograde cholangiopancreatography.



Once the durable treatment is identified, Repeat at 7-12 months

Figure 1: Flow chart of the interventional management pathway in patients with refractory postcholecystectomy pain (PCP) syndrome.

Intervention I: Combined abdominal plane blocks (APB) and epigastric trigger point injections (TPI) with depot methylprednisolone.

Abdominal plane blocks included ultrasound guided subcostal transversus abdominis plane (STAP) block and transmuscular quadratus lumborum plane (TQL) block [21, 22]. APB was chosen according to the site of pain presentation.

- Epigastric pain with radiation to subcostal margins (Epigastric Pain): Bilateral STAP blocks [21].
- Right upper quadrant (RUQ) pain with radiation to the right flank (RUQ pain): Combined bilateral STAP blocks + Right TQL block [21, 22].

Trigger point injections were performed into the epigastric port site: Zone 1 of rectus abdominis muscle (medial end of the rectus muscle just below the xiphisternum) on either side was injected [11]. TPI into lateral or umbilical ports were avoided due to increased risk of prolonged post procedural flare-up in pain [21].

Patients received a total of 100 mg depot methylprednisolone and 36 mL of 0.25% levo-bupivacaine. A telephone review was performed at 12 weeks and 24 weeks following the intervention. Brief pain inventory (BPI) and Hospital Anxiety and Depression Scale (HADS) questionnaires were completed at baseline (pre-procedure) and at 12 and 24 weeks following the intervention.

- If the patient reported >50% pain relief at 12 week, the Intervention I was repeated (Figure 1).
- If the patient reported 30% pain relief at 12-week follow-up, they were booked for Intervention II.

Intervention II: Pulsed radiofrequency treatment to bilateral subcostal TAP planes and if indicated, the transmuscular quadratus lumborum plane on the right side [23]. Pulsed radiofrequency (PRF) treatment was performed under real-time ultrasound guidance using an in-plane approach. A 20-gauge radiofrequency straight cannula with a 10 mm tip (Neuro Therm, Wilmington, MA, USA) was used. PRF treatment was initiated with a RF generator (Neuro Therm, Wilmington, MA, USA) using the following parameters: voltage output 60 V; 5 Hz frequency; 5 ms pulses in a 1 s cycle; impedance range between 150 and 450 ohm and 42-degree Celsius plateau temperature. PRF was performed for 9 min following saline hydro-dissection of the fascial plane. Subsequently, 10 mL of 0.25% levobupivacaine was injected into each plane. Patients completed two questionnaires (BPI and HADS) at baseline, 12 and 24 week post procedure.

Definition of outcomes

- In the audit, clinically significant pain relief was defined using the 'Pain at its worst in the last 24 h' construct in the Brief Pain Inventory Short Form (BPI SF) questionnaire. This 11-point pain intensity Numerical Rating Scale (NRS) has been found to have the strongest relationship with the pain interference scale [24, 25].
- Following the IMMPACT recommendations (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials), a 2-point change (30%) at 12 weeks post-treatment was considered as a successful intervention providing clinically significant pain relief [24].
- A 4-point change (50%) at 12-week and a 2-point change (30%) at 24-week follow-up post-treatment was considered as durable pain relief [11, 25, 26].
- Treatment failure was defined as absence of pain relief at 12-week review following interventional treatment.

Data collected included age, gender, duration of pain, site of pain, patient satisfaction with the management pathway, complications from the interventional treatments, ability to maintain employment and reduction in opioid consumption (oral morphine equivalent) at 24-week

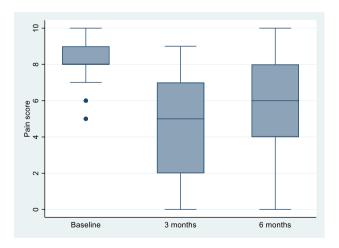


Figure 2: 'Worst pain score at 24 h' baseline, 12 weeks and 24 weeks for post cholecystectomy pain (PCP) patients who received combined abdominal plane block (APB) + trigger point injections (TPI) with steroid (n=56).

follow-up post interventional treatment. Treatment outcomes included failure rate, clinically significant pain relief, durable pain relief, and any reduction in emergency admission at 12 months post intervention.

Statistical analysis of the results was performed using Stata version 13.1 (Statacorp LC, Texas) statistical package for Windows (Microsoft Corp.). The paired t-test was used to compare baseline pain NRS to NRS at each follow up period (12 weeks and 24 weeks). The paired t-test was used for HADS scores at baseline and at 24-week follow-up. The Wilcoxon matched-pairs test was used for opioid consumption at baseline and at 24-week follow-up. Differences were considered significant for p<0.05.

Missing data was imputed using the last-observation-carried-forward' method.

Results

Over a six-year period, 60 patients with refractory PCP syndrome were referred to the physician. The patients had undergone extensive investigations to rule out a visceral pain generator. All patients showed clinical characteristics of AMPS and were offered the novel pathway. Four patients refused to trial the interventional treatment(s) due to needle phobia. Demographic characteristics are detailed in Table 3.

Combined US guided APB + TPI with steroids (intervention I)

Fifty-six patients received combined US guided APB and epigastric port site TPI with steroids (Table 3). In 32 patients (32/56, 57%) who reported epigastric pain, bilateral combined STAP block and epigastric TPI was performed. Twentyone patients (24/56, 43%) reporting RUQ pain received an additional TQL block on the right side (Figure 2).

Forty-eight patients (48/56, 86%) reported clinically significant pain relief at 12 weeks, out of which 38 patients (38/56, 68%) reported durable pain relief at 24-week followup (Table 5).

Eight patients failed to report any benefit from Intervention I (8/56, 14%). Subsequent investigations revealed previously undiagnosed or new onset visceral inflammation [gastritis (5/8), pancreatitis (1/8), hepatitis with cirrhosis (1/8) and irritable bowel syndrome (1/8)].

Pulsed radiofrequency of abdominal planes (intervention II)

Nine patients who reported clinically significant pain relief at 12-week follow up underwent intervention 2 (pulsed RF to abdominal planes). All nine patients (100%) reported >50%

Table 3: Demographic data, patient satisfaction scores, number of potential risk factors, recurrent hospital admission and employment data in patients with AMPS who underwent interventional treatment.

Demographics	n=60
Age, years (mean ± SD)	45.2 ± 15.1
Gender, n, %	
Male	12 (20%)
Female	48 (80%)
Potential risk factors, n, %	
None	1 (2%)
1	3 (5%)
2	14 (23%)
3	25 (42%)
4	15 (25%)
5	2 (3%)
Recurrent hospital admission, n, %	
Yes	30 (50%)
No	30 (50%)
Admission post entry into pathway	6 (10%)
Duration, years (median [P25, P75])	3 (1, 5)
Employment, n, %	
Employed	32 (54%)
Unemployed	17 (28%)
Retired	11 (18%)
Satisfaction, n, %	
Excellent	34 (57%)
Good	14 (23%)
Fair	1 (2%)
Poor	6 (10%)
LFU	1 (2%)
Did not receive intervention	4 (6%)

LFU, lost to follow up.

pain relief at 24-week follow up. At subsequent clinic follow up, seven patients reported analgesia lasting 12 months. The analgesic benefit and duration of relief was reproduced following repeat PRF treatment in all nine patients.

Emergency admission

Thirty patients (30/60, 50%) were admitted with acute exacerbation and received treatment during in-patient stay. All had a history of at least one emergency hospital visit in the last 12 months prior to Intervention 1. Only six patients (6/60, 10%) required further hospital visit(s) since the initiation of treatment pathway.

Opioid consumption

Forty-five patients (45/56, 80%) were on opioid medication before the initiation of treatment pathway. At 24 weeks post intervention, 15 patients (15/45, 33%) had discontinued

opioids consumption (Table 4). The dose of opioid at baseline (median [1QR]) was 60 mg [20, 80] and the change at 24 weeks following an effective intervention was 10 mg [0, 30]. The change (median [95% CI]) was -30 [-40, -20], p-value < 0.001.

Risk factors for PCP syndrome

One or more potential risk factors were present in 98% (55/56) of the patients (Table 3). Pre-existing anxiety was the commonest risk factor and was the present in 75% of patients who completed the HADS questionnaire (36/48).

Complications

Complications from Intervention I (depot methylprednisolone) comprised of post-procedural flare-up in pain lasting 1-2 weeks (34/56, 61%), weight gain (3/56, 5%), mood disturbance (5/56, 9%) and injection site infection (1/56, 2%). Complication from Intervention II (PRF) included postprocedural flare-up in pain lasting 2 weeks (6/9, 66%). All patients were advised on the possibility of a post-procedural flare-up in pain that could last up to two weeks. The flare-up was actively managed with oral non-steroidal anti-inflammatory medication (NSAIDS), topical NSAIDS, and application of heat. An additional short (1-2 week) course of oral morphine was prescribed in patients with inadequately controlled pain.

Missing data imputed using 'last-observation-carriedforward' method was utilised in seven patients.

Discussion

The authors present the first report on a novel pathway in the management of refractory PCP syndrome. PCP syndrome can affect over a third of patients undergoing laparoscopic

Table 4: Percentage change in opioid consumption at 24 weeks following interventional treatment(s) of AMPS.

Oral morphine equivalent	n (56)
100% reduction	15
>50% reduction	15
25–49% reduction	6
No change	5
Increase in dose	1
Not on opioids	11
Data not available	3

cholecystectomy [7, 8]. Current practice places undue emphasis on surgical pathologies as the likely cause of PCP syndrome, with patients undergoing extensive investigations that ultimately lead to substantial healthcare utilisation (Table 1) [8]. While abdominal wall pain is listed as a potential culprit, it is often undiagnosed and poorly managed [11]. As a result, patients with acute exacerbations have recurrent hospital admissions with additional resource consumption [5, 6]. A common but unrecognised cause of abdominal wall pain is AMPS, which can occur after laparoscopic surgery [11–13].

Pathophysiology of PCP secondary to AMPS

The underlying pathology in AMPS is the presence of trigger points in abdominal musculature, which induces abnormal function [11, 15]. In patients undergoing laparoscopic cholecystectomy, AMPS can result from a combination of two pathophysiological processes [11, 16, 17]. The initial stage is the development of viscerosomatic convergance (VSC) occurring from the underlying inflammation in the gallbladder and biliary tree. VSC is a well-recognised physiological phenomenon that can cause central and peripheral sensitisation in susceptible individuals [11, 15, 17, 27–29]. As a result, the pain generator can move from the inflamed viscera to the overlying abdominal muscle [11, 15, 17]. Presence of pre-existing anxiety, depression, obesity, poorly controlled postoperative pain and persistent pain at other sites are well-recognised risk factors for triggering central sensitisation [11, 16, 18]. In patients without pre-existing risk factors, concomitant gastritis or gastro-oesophageal reflux disease (GORD), development of recurrent cholecystitis, gallstone pancreatitis or gallbladder perforation with biliary leak could augment central sensitisation. When patients with pre-existing central sensitisation undergo surgery, insertion of laparoscopic ports can cause trauma to the abdominal muscles that are sensitised by VSC [11, 16, 17]. The combination of VSC and port site trauma can result in the development of AMPS. In addition, patients who have persistent pain after laparoscopic cholecystectomy often undergo ERCP to identify suspected biliary pathology. The incidence of post ERCP pancreatitis (PEP) is between 10 and 40% [19, 20]. Pancreatitis can exacerbate central sensitisation (VSC) thereby increasing the risk for development of AMPS. In patients with a history of pancreatitis, management of chronic abdominal pain tends to focus on visceral pain despite negative imaging and biochemistry [11, 30]. In this report, 98% of patients had at least one risk factor and 57% patients had more than two risk factors (Table 3).

Pattern of pain presentation in PCP

We have identified two common patterns of pain presentation in PCP. They include epigastric pain radiating to the subcostal margins (epigastric pain) and right upper quadrant pain radiating to the right flank (RUQ pain). Both correspond to laparoscopic port sites. The authors recommend that the initial intervention with steroids should target the specific pattern for optimal analgesia. Subcostal TAP block provides dermatomal cover to the upper abdomen that extends from the xiphisternum to the umbilicus anteriorly (thoracic dermatome T6-T10). However, it does not cover the anterolateral abdominal wall where the two lateral ports are usually sited [31]. On the other hand, transmuscular quadratus lumborum block covers the anterolateral abdominal wall although the sensory block may not extend to the epigastric region [32].

Rationale for combined procedure

In an initial cohort of patients with PCP syndrome, TPI with steroids led to significant post procedural flare-up with transient analgesia [21]. One likely explanation is the high prevalence of anxiety disorder in this cohort, which is a known risk factor for prolonged postprocedural flare-up [21]. Baseline HADS questionnaire was completed by 48 patients (48/56, 86%) in this series and 75% (36/48) had abnormal anxiety scores.

Thereafter, bilateral STAP blocks were trialled, which provided analgesic benefit for 6-12 weeks. When the combination of APB and epigastric TPI (Intervention I) was performed, the patients reported durable pain relief with limited post-procedural flare-up (Table 5). The success of the combined procedure implies both central (neurogenic) and peripheral (myogenic) sensitisation may be at play. The absence of refractory pain in the umbilical port site, which is the largest port scar, seen in this cohort reinforces the above hypothesis that PCP may involve a neurogenic component in addition to myogenic trigger (muscle trauma) in its pathogenesis [33, 34].

Pulsed radiofrequency treatment to the abdominal planes provided durable relief in all nine patients. At subsequent pain clinic review, a majority of patients reported sustained analgesia effect lasting 12 months. The PRF treatment could not be performed in a larger cohort of patients because of reprioritization of clinical care as a result of the coronavirus pandemic.

Table 5: 'Worst pain at 24 h' scores and HADS scores at baseline and at 24 weeks post treatment in PCP patients (n=56).

Variable	Baseline	24 weeks	Change from baseline	p- Value
	$\text{Mean} \pm \text{SD}$	$\text{Mean} \pm \text{SD}$	Mean (95% CI)	
HADS				
Anxiety (n=48)	11.2 ± 4.8	7.1 ± 4.9	-4.1 (-5.4, -2.8)	<0.001
Depression (n=48)	9.9 ± 4.2	6.5 ± 4.8	-4.2 (-3.5, -2.3)	< 0.001
Pain scores				
APB + TPI steroids	8 0.3 ± 1.2	5.7 ± 2.6	-2.5 (-3.2, -1.9)	< 0.001
(n=56)				
APB PRF (n=9)	8.7 ± 0.9	3.9 ± 2.0	-4.8 (-6.4, -3.2)	<0.001

HADS, hospital anxiety depression scale; PCP, post cholecystectomy syndrome; AMPS, abdominal myofascial pain syndrome; APB, abdominal plane block; TPI, trigger point injection; PRF, pulsed radiofrequency.

Emergency admission

Patients with PCP can suffer protracted flare-up in pain, which is often unresponsive to medications including opioids. Poorly controlled exacerbations cause significant distress and anxiety leading to recurrent emergency visits [5, 35]. A visceral pathology remains elusive despite extensive investigations. The absence of an organic pathology leaves the physician and the patients in a challenging situation [8, 30]. A diagnosis of functional abdominal pain syndrome (FAPS) is not uncommon in this scenario [30]. Thirty patients (30/56, 54%) had recurrent emergency admissions in a 12-month period prior to a diagnosis of AMPS. At 12-months post intervention, only six patients (6/30, 20%) showed further emergency visit(s). The interventional pathway not only provided significant improvement in pain and mood but also reduced emergency attendance (Table 5). Prompt diagnosis and effective interventional management of acute exacerbations in patients with AMPS has shown to result in substantial healthcare saving [30].

In the surgical ward, PCP patients are often managed as having visceral abdominal pain syndrome (VAPS). It is unsurprising that most patients are prescribed opioid medications despite their poor efficacy. Patients in this report demonstrated significant reduction in opioid consumption at 24 weeks post effective intervention (Table 4).

Limitations

The authors are aware of the limitations of this open label, observational, single centre audit in a small cohort of patents. In the UK, there are over 600,000 laparoscopic cholecystectomies performed annually [8]. However, the literature is scarce on identifying a somatic aetiology for PCP syndrome as well as detailing an effective management strategy. The authors present the first report on the management of a complex condition with good patient outcomes.

In conclusion, abdominal myofascial pain syndrome appears to be a common but unrecognised cause of PCP syndrome [11, 15]. The results of this prospective audit show that the combination of ultrasound guided abdominal plane blocks and epigastric trigger point injections can provide durable pain relief, improvement in mood, reduction in opioid consumption, and prevention of recurrent emergency admission. Further research is required to confirm the therapeutic benefit of pathway.

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Conflict of interest: The authors state no conflict of interest. **Informed consent**: The author states that written informed consent was obtained from the patient.

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