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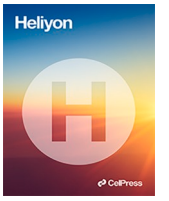

Research article

Surgical treatment of pilonidal disease - Short-term follow up results of minimally invasive pit-picking surgery versus radical excision without suturing: A prospective randomised trial

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A B S T R A C T

Background: In this study we compared the potential benefits of surgical treatments for chronic symptomatic pilonidal disease (PD) - minimally invasive pit-picking surgery and radical excision without wound suturing.
Materials and methods: A total of 100 adult patients with chronic symptomatic PD were enrolled in this study at the Kaunas Hospital of the Lithuanian University of Health Sciences. They were randomly divided into two groups: pit-picking surgery (n = 50) and radical excision with open healing (n = 50). Recurrent PD patients were not excluded. The comparison of the techniques was based on pain within the first postoperative week, failed surgery rates, and wound healing time. Additionally, pain levels at different time intervals following the treatment, analgesic consumption, and time off work, were assessed and compared.
Results: A total of 89 patients (89 %) were available for follow-up after 6 months. Pain levels the first postoperative week were significantly lower in the pit-picking group compared to the radical excision group, with median scores of 10.0 and 20.0, respectively (p = 0.002). The complete wound healing time was longer in the radical excision group (60 days) versus the pit-picking group (17 days), with a significant difference noted (p = 0.00). No significant difference was observed between the type of surgery and the rate of failed surgery, with 5 (11.9 %) cases in the pit-picking group and 4 (8.5 %) in the radical excision group.
Conclusion: Based on our short-term findings, minimally invasive pit-picking surgery is a better option regarding pain, wound healing time and failed surgery rate. In cases where this approach is not suitable, other alternatives should be contemplated, as radical surgery without wound suturing should not be employed as a treatment method for PD. Additionally, the relationship between PD and recurrence rates should be investigated further.

1. Introduction

Pilonidal disease (PD) is an inflammatory condition, which can manifest as being either acute or chronic, and ranges from minor cysts to extensive sinus formations [1]. This condition primarily affects the natal cleft of the sacrococcygeal area. The disease occurs in 26–48 cases per 100,000 population and is 2.2 times more common in men than in women [2,3].

Chronic pilonidal cyst is characterised by pain, the development of a fistula in the sacral region, and secretions. The main treatment of a chronic pilonidal cyst is surgery, with different surgical methods or modifications of these methods being used worldwide [4]. Surgical approaches can be divided into two main types: radical, where the entire cyst is excised, and minimally invasive, which

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involves partial removal of the cyst with ingrown hair follicles being removed or the cyst being opened and debrided.

Pit-picking and other minimally invasive techniques offer a significant advantage of minimal postoperative pain and shorter recovery time, allowing patients to return to work or daily activities sooner. The method is recommended by the German National Guidelines for localised PD [4]. However, it should be noted that these approaches are associated with an expected recurrence rate ranging from 4.3 % to 27 % within a timeframe of 12–120 months, and even 39.1 % after an 18-month follow-up period in a new study [4–9]. Despite the growing popularity of minimally invasive procedures, complete excision with open healing, where the postoperative wound is not sutured and left to heal in a secondary intention, remains the most commonly employed method worldwide due to its technical simplicity and ease of learning [3,4]. The major drawback of this method is prolonged wound healing and the subsequent increase in time required for recovery and return to work. The recurrence rate can vary significantly, ranging from as low as 2–6% to 15–35 %, largely due to discrepancies in patient selection and the definition of a recurrent lesion [3,4,7,10,11]. Currently, no consensus has been reached with respect to the most suitable surgical approach, as evidenced by previous studies [4,7,10,12,13].

The primary objective of the present randomised controlled trial was to compare the pain levels experienced within the initial week following two distinct surgical approaches: minimally invasive pit-picking surgery and radical excision without suturing the wound. Secondary objectives included duration of wound healing and rate of surgical failure.

2. Materials and Methods

2.1. Study protocol and patient selection

The study was a randomised, single-center trial with two groups, conducted at the Department of Surgery, Kaunas Hospital, LUHS. It took place from September 1, 2020, to February 1, 2023, when the necessary number of participants was reached. Each patient was observed for 6 months after the surgery. The study protocol was approved by the local Medical Ethics Committee, adhering to the principles of the Declaration of Helsinki, and is available at LUHS's Department of Surgery. The trial was registered in ClinicalTrials.gov with the identifier of NCT05982028. The CONSORT checklist was used when writing the report [14].

Patient inclusion criteria were the following: 1) age of 18–75 years, 2) chronic symptomatic (primary or recurrent) pilonidal cyst, 3) physical status I to III according to American Society of Anesthesiologists (ASA), 4) a signed information and informed consent form to participate in the study.

Patients were ineligible if they met any of the following criteria: 1) presented with an acute or asymptomatic cyst, 2) non-Lithuanian speakers, 3) diagnosed with cognitive, visual, auditory and locomotor system disorders, 4) significant insufficiency of kidneys, liver or cardiopulmonary system, 5) refusal to participate in the study.

Patients having met the inclusion criteria underwent surgery performed by the same group of surgeons. The type of surgical procedures was randomly determined using a computer-generated list. Block randomisation was used, resulting in an equal number of patients being assigned to each group.

2.2. Sample size

When calculating the sample size, we considered postoperative pain after 1 week as the primary endpoint. Past studies suggest an average postoperative pain score of 3.8 $\pm$ 2.4 SD using the VAS scale after radical surgery without suturing [15]. We considered a clinically significant difference between the groups when the pain in the minimally invasive surgery group was 40 % less 1 week after the procedure. To calculate the sample size of the study, the probability of the first type of error was assumed to be $\alpha = 0.01$, $\beta = 0.2$ for the second type, and the statistical power of the study = 0.8. Therefore, 38 patients per group were required. Accounting for a possible 20 % loss rate, the study aimed to include 100 patients.

2.3. Interventions

2.3.1. Preoperative procedures

Patients were placed in the prone position with their buttocks separated using tape to optimise visibility of the natal cleft area. The operative area had been shaved beforehand. All patients received preoperative antibiotic prophylaxis with a single dose of 1 g cefazolin and 500 mg metronidazole as an intravenous injection. All procedures were performed under spinal anaesthesia. In both surgical interventions, the procedure commenced with the subcutaneous administration of a 20 ml injection dose of a lidocaine HCl 1 % and epinephrine 1:100,000 in the wound area.

2.3.2. Surgical procedures

2.3.2.1. Minimally invasive pit-picking surgery. Midline pits and secondary fistula openings were probed to determine the direction and length of any associated sinus tracts, followed by an excision with a 3 or 5 mm punch biopsy needle, depending on the size of the pit. A 2 cm lateral incision was made parallel to the pilonidal cyst. The pores and the underlying tissue with the hair follicles within the sinus tracts were removed, and the cyst cavity was drained through the incision. Nonabsorbable monofilament sutures were used to close the excisional wounds of the pits and secondary fistula.

2.3.2.2. Radical surgical excision without suturing. Under the guidance of brilliant green, the cavity of the pilonidal cyst, along with the sinus tracts and fistulas, was marked. A symmetric elliptical incision was made to excise the pits and secondary fistula openings. The pilonidal cyst was removed from the healthy subcutaneous tissue and sacrococcygeal fascia using monopolar electrocautery. The wound was not sutured and was left open to heal by secondary intention.

2.3.3. Postoperative treatment and analgesia

On the day of the surgery, when the effects of spinal analgesia had subsided, participants having reported a pain score of 30 or higher on the VAS were administered pharmacologic analgesia with intramuscular (IM) injections of ketoprofenum 100 mg/2 ml.

Additional doses of ketoprofen 100 mg/2 ml were given intramuscularly (IM) to participants having reported a pain score of 30 or higher on the VAS during their postoperative hospitalisation. Patients were prescribed dexketoprofen 25 mg to take at home if the pain persisted or intensified.

Patients were provided with instructions on the dressing procedure and were instructed to continue performing the dressing with 10 % povidone-iodine solution daily at home. Patients in the pit-picking group were instructed to have stitches removed by their family doctor on the tenth postoperative day. Additionally, patients were educated on maintaining personal hygiene and preventing wound infection, particularly after defecation.

3. Assessment

3.1. Questionnaire

Participants were requested to describe their pain at specific time intervals following the surgery. These intervals included the first and second postoperative day, 1 and 2 weeks post-surgery, as well as 1, 2, and 6 months after the procedure. To assess their pain levels, patients were asked to use a visual analogue scale (VAS) ranging from 0 to 100. Additionally, patients were instructed to document the type of painkillers used and the frequency of their intake during the first week after the surgery. At 1 and 6 months after the operation, patients were requested to visit the clinic for an examination. During these visits, they were to rate their overall health and indicate the time it took for them to resume their daily activities, work, or school. Furthermore, patients were specifically asked to note the date when their wounds looked fully healed, with no discharge present. Moreover, patients were encouraged to report any issues or complications related to their wounds.

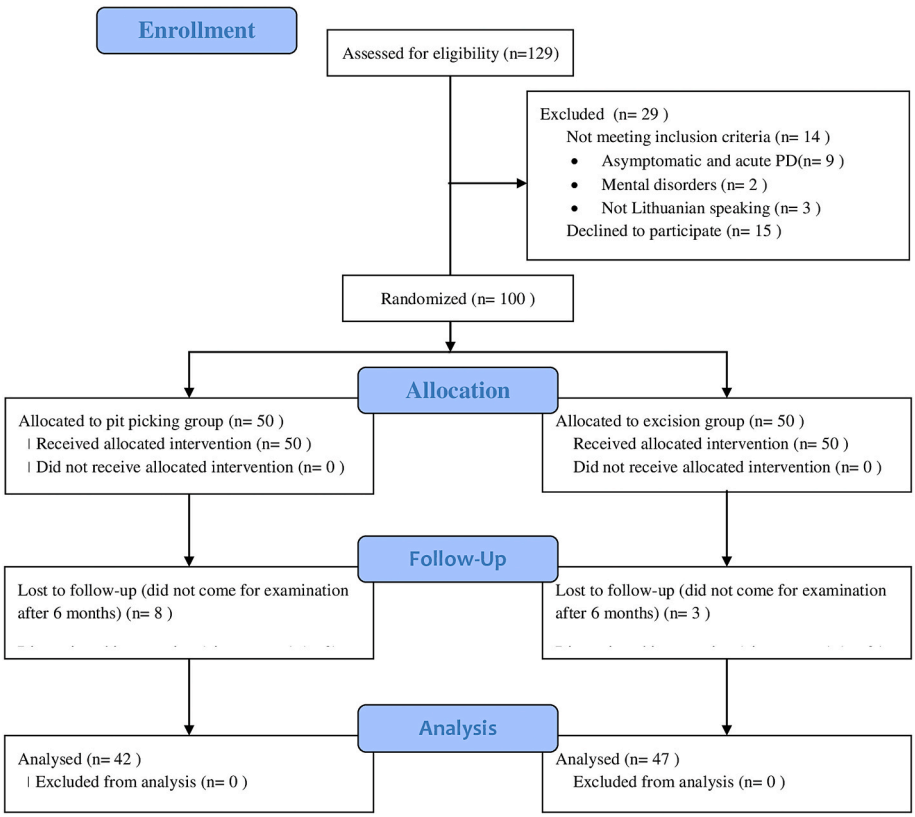

Fig. 1. Flow diagram.

3.2. Outcomes

The primary outcome was the pain score during the first week following the procedure, measured using the VAS. Secondary outcomes included duration of wound healing and the rate of failed surgery.

Given the limited duration of follow-up, any occurrence of new sinus openings or wound discharge post-complete healing was deemed a surgical failure, rather than a recurrence [3]. Typically, the excision wound should heal in 4 months. Therefore, if the healing process extended beyond this time period, it was regarded as significantly delayed wound healing or as a failure of surgery [16,17].

3.3. Statistical analysis

All statistical analyses were conducted using SPSS for Windows, version 29 (IBM Corp, Armonk, NY). The Shapiro-Wilk normality test was performed for continuous variables. Since all analysed data were found to be non-normally distributed, the Mann-Whitney *U* test was utilized to compare continuous variables with ordinal or non-normal distribution in both groups. The Pearson chi-squared test was used to analyse the relationships between categorical variables. Comparative results and other demographic characteristics in the 2 groups are presented as frequencies (percentages). Quantitative variables are presented as median (Q1–Q3). A p value of <0.05 was considered statistically significant.

4. Results

Process of enrollment is depicted in Fig. 1.

Eighty-nine patients were available for a follow-up after 6 months. Both groups exhibited similar baseline characteristics, as indicated in Table 1.

4.1. Pain and consumption of analgesics

There was no significant difference between the groups in terms of VAS pain scores on the first and second postoperative day ($p > 0.06$). However, significant differences were observed at the 1-week (median scores of 10.0 and 20.0, respectively ($p = 0.002$)), 2-week (median scores of 4.0 and 10.0, respectively ($p = 0.013$)), and 1-month intervals (median scores of 0.0 and 4.0, respectively ($p < 0.05$)), as well as at 2-months and 6-months after the procedure, with the pit-picking group experiencing significantly lower pain scores ($p < 0.01$ for each). Diagram 1 illustrates changes in pain levels at various time periods after the procedure.

The consumption of analgesics 7 days after surgery showed no significant difference between the groups ($p > 0.05$). However, a significant difference ($p = 0.03$) was observed in the number of patients using analgesics on the 6th day after the radical excision, with 1 patient (2.4 %) in the pit-picking group and 7 patients (14.9 %) in the radical excision group (Table 2). This variation should be considered incidental since there was no notable distinction observed five days prior and on the seventh day.

4.2. Wound healing, incapacity and failed surgery rate

As indicated in Table 3, the radical excision group had a longer complete wound healing time (60 days) compared to the pit-picking group (17 days), with a significant difference ($p = 0.00$). Incapacity to work was the same in both groups and was not statistically significant ($p = 0.66$).

Both groups experienced prolonged wound healing, with 1 (2.4 %) instance in the pit-picking group and 5 (10.6 %) in the radical excision group. Unhealed wounds were only observed in the radical excision group (3 instances (6.4 %)).

The rate of surgical failure was comparable between the two groups, with 5 (11.9 %) in the pit-picking group and 4 (8.5 %) in the radical excision group, and no correlation was found between the type of surgery and the rate of failed surgery ($p > 0.05$) Table 3.

Among various factors such as age, BMI, the size of a fistula, presence of a secondary opening, other medical conditions, and

Table 1
Baseline characteristics.

Baseline characteristic item	Pit-picking group (N = 42)	Excision group (N = 47)	P value
Male sex, n (%)	36 (85.7 %)	40 (85.1 %)	0.93
Age[a]	27.5 (27.14–33.91)	28 (26.80–31.79)	0.88
BMI[a]	26.98 (25.99–28.59)	26.69 (26.07–29.40)	0.51
Smoking, n (%)	23 (54.8 %)	23 (48.9 %)	0.58
Duration of symptoms, months[a]	12 (10.77–23.83)	6 (8.91–22.61)	0.60
Pain before surgery VAS[a]	2.5 (5.38–13.70)	2 (6.32–13.60)	0.89
ASA class, n (%)	I – 39 (92.9 %) II – 3 (7 %)	I – 41 (87,2 %) II – 6 (12.8 %)	0.38
Primary PC n (%)	34 (81.0 %)	34 (72.3 %)	0.34
Size of PC - cm[a]	5.2 (4.78–6.56)	5.3 (4.93–6.64)	0.83
Count of grown follicles[a]	3 (2.65–3.65)	3 (2.41–3.46)	0.17
Fistula n (%)	29 (69.0 %)	35 (74.5 %)	0.57

[a] Median (95 % Confidence interval).

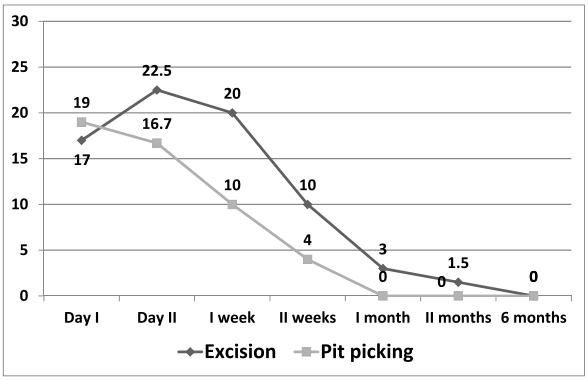

Diagram 1. Comparison of pain levels at different follow-up times after pit-picking surgery and radical excision without suturing.

Table 2
Number of patients using analgesics 7 days after surgery.

	Pit-picking group (N = 42)	Excision group (N = 47)	P value
Day of surgery	32 (76.2 %)	37 (78.7 %)	0.77
1 days after surgery	16 (38.1 %)	22 (46.8 %)	0.40
2 days after surgery	14 (29.8 %)	11 (26.2 %)	0.70
3 days after surgery	8 (19.0 %)	8 (17.0 %)	0.80
4 days after surgery	5 (11.9 %)	9 (19.1 %)	0.34
5 days after surgery	7 (16.7 %)	7 (14.7 %)	0.81
6 days after surgery	**1 (2.4 %)**	**7 (14.9 %)**	**0.03**
7 days after surgery	1 (2.4 %)	4 (8.5 %)	0.21

Table 3
Wound healing time, incapacity and recurrence rate after 6-month follow-up.

	„Pit picking“ group (N = 42)	Excision group (N = 47)	P value
Wound healing time[a]	17 (15.74–29.59)	60 (59.97–81.89)	0.00
Incapacity[a]	14.0 (10.99–18.25)	14.0 (14.46–30.45)	0.66
Prolonged wound healing The wound healed, n (%)	1 (2.4 %)	5 (10.6 %)	0.75
Prolonged wound healing Unhealed wound n (%)	0 (0.0 %)	3 (6.4 %)	0.09
Failed surgery rate, n (%)	5 (11.9 %)	4 (8.5 %)	0,59

[a] Median (95 % Confidence interval).

method of surgery, only the presence of prior recurrent PD was determined to have a statistically significant impact on the recurrence rate, with 3 (4.4 %) cases following treatment of a primary PD, compared to 6 (28.6 %) cases after treatment of a previous PD ($p = 0.01$).

Neither group exhibited significant harms or unintended effects.

5. Discussion

Various surgical and non-surgical approaches have been suggested for PD treatment. Unfortunately, neither conservative nor the most extensive surgical methods can prevent risks. Therefore, the optimal treatment for chronic symptomatic PD remains unknown [4,10,12,13,18].

Minimally invasive techniques like pit-picking offer the advantage of lower postoperative pain, shorter recovery time, increased satisfaction, and improved cosmetic outcomes [4,19]. In this randomized controlled trial comparing two methods, the pit-picking group reported significantly lower pain levels during the first week following the procedure as well as at different follow-up time intervals after the procedure, with pain scores falling below 10 as early as the 2-week mark and eventually subsiding completely. The consumption of analgesics was comparable between the 2 groups, particularly during the initial 4 days, with nonsteroidal anti-inflammatory drugs providing adequate pain relief [20]. However, the radical excision group experienced pain for a longer duration and some individuals continued to experience pain until the end of the observation period. This extended pain duration may be attributed to the longer time required for wound healing, as evidenced by previous studies [11,21]. Despite the differences in pain duration, postoperative pain after both procedures was reported to be generally mild and demonstrated no significant interference

with daily activities, being in conformity with previous research [22].

Due to a short-term follow-up time of our study, any occurrence of new sinus openings or wound discharge post-complete healing was deemed a surgical failure, rather than a recurrence [3]. The rate of surgical failure of 11.9 % observed in our trial aligns with the recurrence rates reported in previous studies, which range from 8 % to 27 % [4–6]. Radical excision with open healing continues to be widely adopted globally due to its technical simplicity and ease of learning [3,4]. The removal of a large amount of intergluteal tissue poses a higher risk of infection, leading to a prolonged secondary healing and time off-work, and a broad range of recurrence rates, spanning from 2-6% to 15–35 %, largely attributed to variations in patient selection criteria and the definition of recurrence [3,4,7,10,11]. The recurrence rate is notably high in patients undergoing excision and open healing for recurrent PD. In one study, it reached 20 % after 10 years, while in another, it peaked as high as 42 % [4,7]. Minimally invasive techniques are often preferred for PD management due to their excellent short-term outcome and seems to be an adequate treatment for patients with simple pilonidal sinus disease. However, the cumulative recurrence rate reached 23 % after 5 years and 27 % after 10 years [6,8]. A recent study indicates a notably higher recurrence rate of 39.1 % during an 18-month follow-up period [9]. Nevertheless, it's important to emphasize that a minimum of 5 years of follow-up is considered the gold standard in benchmarking pilonidal sinus surgery [17,19,23].

Alternative surgical options like the Karydakis or Limberg flap present with minimal morbidity, enabling a swift return to previous functioning and garnering high patient satisfaction [24,25]. Research on the Karydakis flap has shown recurrence rates ranging from 0 to 6 % after 10 years [4], and no significant differences between these surgical approaches were noted in further studies [26,27]. Thus, the Karydakis flap should be regarded as one of the favored off-midline procedures [4]. Additional approaches, such as the Bascom cleft lift, demonstrate an overall success rate of 96.6 % and no instances of late recurrence during a 24-month follow-up period [28]. Similar to the Karydakis flap, recurrence rate ranges from 0 to 5 % after 10 years. However, it is not widely used, likely due to difficulties stemming from challenges in comprehending the precise method of drawing the incision line [4].

Newer methods, including laser treatments and phenolisation of the sinus tract have shown promising initial outcomes in terms of reduced pain, shorter hospital stays, and improved quality of life [29–32]. Further investigations are required to assess the safety, recurrence rates and long-term effectiveness of these methods, especially taking into account the fact that phenol treatment is not approved in certain European countries due to concerns about its potential toxicity [30–33].

In addition, the absence of a comprehensive PD classification system, which enables differentiation between clinical cases suitable for conventional approaches versus minimally invasive techniques, introduces additional biases [19]. It should also be noted that studies often exclude patients with recurrent PD, leaving the link between recurrent disease and recurrence rate relatively understudied [33,34].

The study possesses certain inherent limitations, including potential memory and response biases associated with the use of the VAS score and self-assessed wound healing. Furthermore, focusing solely on pain may not fully capture the comprehensive differences between the surgical methods and their impact on patients' overall health and quality of life. While most patients reported minimal pain during the postoperative period, it is crucial to consider challenges faced by some patients in the radical excision group who had a wound located in an uncomfortable area for up to 2 months, requiring constant care and assistance from others. This could have a significant impact on both the physical and mental well-being of patients, which should be taken into account when evaluating the outcomes and overall patient experience. Moreover, the inability to resume work might have been impacted by cultural factors and the standardised duration of medical leave prescribed by family physicians.

Additionally, the study's setting itself may have influenced the outcomes. It should be noted that this was a single-centre set primarily consisting of adult participants from a homogeneous ethnic group. Including only adults excludes a substantial portion of patients who develop symptomatic PD before the age of 18. Moreover, the follow-up period was 6 months, and an additional follow-up at the 2 year mark is scheduled. To obtain more robust and generalizable results, further randomized studies with larger sample sizes and extended follow-up periods are required. These studies should compare pain levels and other factors that may influence the quality of life following different treatment approaches for pilonidal disease. By addressing these limitations, we can gain a better understanding of the effectiveness and impact of various treatment strategies on patient outcomes.

Conclusion

Based on our short-term findings, minimally invasive pit-picking surgery is a better option regarding pain, wound healing time and failed surgery rate. In cases where this approach is not suitable, other alternatives should be contemplated, as radical surgery without wound suturing should not be employed as a treatment method for PD. Additionally, the relationship between PD and recurrence rates should be investigated further.

Disclosures

Please state any sources of funding for your research - none.

This study was approved by the local Medical Ethics Committee in Lithuania, adhering to the principles of the Declaration of Helsinki. The study protocol is available at LUHS's Department of General Surgery.

Research data will be made available on request.

Research registration Unique Identifying number (UIN)

1. Name of the registry: ClinicalTrials.gov
2. Unique Identifying number or registration ID: NCT05982028.

3. Hyperlink to the specific registration: https://classic.clinicaltrials.gov/ct2/show/NCT05982028

CRediT authorship contribution statement

Edvinas Dainius: Writing – review & editing, Writing – original draft, Visualization, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Monika Karolina Vaiciute:** Writing – review & editing, Writing – original draft, Visualization. **Audrius Parseliunas:** Writing – review & editing, Methodology, Data curation. **Tadas Latkauskas:** Writing – review & editing, Methodology, Investigation. **Donatas Venskutonis:** Writing – review & editing, Supervision, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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