Ultrasound-guided abdominal wall infiltration *versus* freehand technique in anterior cutaneous nerve entrapment syndrome (ACNES): randomized clinical trial

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Abstract

Background: The optimal technique of abdominal wall infiltration for chronic abdominal wall pain due to anterior cutaneous nerve entrapment syndrome (ACNES) is unknown. The aim of this study was to compare pain reduction after an abdominal wall anaesthetic injection by use of an ultrasound-guided technique (US) or given freehand (FH).

Methods: In this multicentre non-blinded randomized trial, adult patients with ACNES were randomized (1:1) to an US or a FH injection technique. Primary outcome was the proportion of injections achieving a minimum of 50 per cent pain reduction on the Numeric Rating Scale (range 0–10) 15–20 min after abdominal wall infiltration ('successful response'). Secondary outcomes were treatment efficacy after 6 weeks and 3 months, and the influence of the subcutaneous tissue thickness on treatment outcome.

Results: Between January 2018 and April 2020, 391 injections (US = 192, FH = 199) were administered in 117 randomized patients (US = 55, FH = 62; 76.0 per cent female, mean age 45 years). The proportion of successful responses did not significantly differ immediately after the injection regimen (US 27.1 per cent *versus* FH 33.2 per cent; P = 0.19) or after 3 months (US 29.4 per cent *versus* FH 30.5 per cent; P = 0.90). Success was not determined by subcutaneous tissue thickness.

Conclusion: Pain relief following abdominal wall infiltration by a US or FH technique in ACNES is similar and not influenced by subcutaneous tissue thickness.

Registration number: Dutch Clinical Trial Register NL8465.

Introduction

Chronic abdominal wall pain due to the anterior cutaneous nerve entrapment syndrome (ACNES) is an under-recognized source of chronic abdominal pain[1]. The incidence of ACNES is unknown, but up to 30 per cent of patients with chronic abdominal pain may actually have abdominal wall pain[2,3]. ACNES is possibly caused by entrapped or compromised cutaneous intercostal nerve endings (T7–T12)[4]. Once diagnosed, a stepwise treatment strategy, including abdominal wall infiltration at tender points (TPs), pulsed radiofrequency, or removal of terminal nerve end branches (neurectomy) at the level of the rectus abdominis muscle fascia, offers relief in most patients[5,6].

The optimal technique of abdominal wall infiltration is unknown. Some prefer an ultrasound (US)-guided technique, whereas others rely on personal experience using a freehand (FH) technique[7–13]. In earlier randomized trials, FH TP infiltration (TPI) with 5–10 ml of 1 per cent lidocaine was used[5,6,9,14]. However, an often-recurring criticism from reviewers was a presumed suboptimal mode of administration. Randomized trials comparing different techniques of local anaesthetic injection in the treatment of chronic abdominal wall pain, including ACNES, are unavailable.

The primary aim of this study was to compare patient-reported pain reduction after local anaesthetic injection of abdominal wall TPs by use of an US-guided or a FH technique in patients with ACNES. The hypothesis was that US-guided TPI is more effective than FH TPI.

Methods
Design

This Dutch multicentre parallel non-blinded randomized controlled trial was conducted between January 2018 and April 2020 at SolviMáx, Center of Excellence for Chronic Abdominal Wall and Groin Pain, a surgical subdivision of Máxima Medical Center, Eindhoven, and at the Laurentius Hospital, Roermond. The

surgical departments of both hospitals have considerable experience, over several years, in the treatment of chronic abdominal wall pain syndromes, including ACNES[15]. The local Medical Ethics Committee of Máxima Medical Center approved the study design, protocol, and informed consent procedure (N16.171). All patients provided written informed consent before enrolment. This trial was designed and reported according to the CONSORT guidelines[16] and was registered in the Dutch Clinical Trial Register (NL8465).

Participants

Patients were recruited at the outpatient departments of both hospitals. Criteria for the diagnosis of ACNES are, according to previous publications[5,9]:

- Predictable site of abdominal tenderness with a small (< 2 cm) area of maximal intensity (the TP) situated within the lateral boundaries of the rectus abdominis muscle,
- The presence of somatosensory skin disturbances such as altered cool sensation, hypoaesthesia, or hyperaesthesia covering the TP,
- Intense pain while squeezing the abdominal wall skin covering the TP (pinch test),
- Tenderness increased by abdominal muscle tensing using Carnett's test.

Only adult patients (18 years and above) suffering from unilateral ACNES were eligible for inclusion. Exclusion criteria were recent intra-abdominal pathology; other abdominal wall pathology such as a tumour, hernia, or endometriosis; entrapment syndrome due to scar tissue or surgical nerve injury; lidocaine allergy; earlier treatment for ACNES; bilateral or multiple TPs; pregnancy; or an inability to complete follow-up. Diagnosis, treatment, and study plan were discussed in a shared decision environment.

Randomization, blinding, and treatment allocation

Randomization on a patient-level was performed by means of a sealed-envelope system. The content of the envelopes was determined using computer-generated randomization, with an allocation ratio of 1:1. There was no stratification. After informed consent, the next consecutive envelope was opened by the physician and the patient was offered the allocated treatment regimen. There was no reuse of envelopes. Blinding was not possible.

Interventions

The TP was marked with a pen with a patient in supine position. If allocated to the US-guided technique, needle advancement towards the anterior rectus fascia was visualized using multi-Hertz linear transducers (12 L-RS probe, frequency range 6–13 MHz (LOGIQ e; GE Healthcare, Shanghai, China); probe L4–15, frequency range 4-15 MHz (MyLabSigma; Esaote, Genoa, Italy)). Injection of 8–10 ml of 1 per cent lidocaine occurred once the correct position of the needle tip just underneath the anterior sheath of the rectus abdominal muscle was attained.

If a patient was allocated to the FH technique, the injection was administered as reported previously[9,14]. In short, the needle was inserted at the TP and penetrated the anterior sheath as subjectively experienced by a characteristic 'plop'. If attempted aspiration of the plunger did not yield blood, the volume was injected. Injections were administered by three physicians and a

physician assistant; all specializing in ACNES management. They were all familiar and experienced with the FH technique and were extensively trained in the US technique before the start of this study.

Each study patient was scheduled for a regimen of four injections at two-week intervals. If a patient subjectively experienced sufficient pain reduction at an evaluation, consecutive injections were aborted. Patients who reported an unsatisfactory result after this 6-week injection regimen were offered alternative treatment options in a step-up approach starting with pulsed radiofrequency, and, if unsuccessful, an anterior neurectomy[5,6]. If appropriate, a shared decision could be made to discontinue the pulsed radiofrequency treatment.

Measurements and outcomes

Baseline characteristic such as pain aetiology, duration of the pain, and a five-item verbal rating score were obtained from the electronic patient files. Thickness of the subcutaneous tissue was measured using US in all patients prior to the first injection. At subsequent injections, this information was not used again by the practitioner. Subcutaneous tissue thickness was defined as the distance (mm) between skin and the anterior rectus fascial sheath.

The primary outcome was the proportion of successful injections yielding a minimum of a 50 per cent reduction in pain perception in relation to all administered injections. To determine pain reduction, levels were scored immediately before and 15–20 min after injection using a numeric rating scale (range 0–10).

Secondary outcomes were efficacy at 6 weeks and 3 months after the injection regimen measured using a 4-point patient satisfaction score as previously reported[17]:

(1) I am very satisfied (greater than 95 per cent pain reduction);
(2) I am satisfied. I occasionally experience some pain (50 per cent or greater pain reduction);
(3) I have improved but experience some pain on a regular basis (less than 50 per cent pain reduction);
(4) The treatment did not change my pain level or made my pain worse.

Outcomes 1 and 2 were termed successful, whereas outcomes 3 and 4 were considered unsuccessful. Furthermore, the influence of subcutaneous tissue thickness on success at 3 months after the treatment regimen was determined.

Sample size and analysis

Sample size calculation was based on an inferiority design with an alternative hypothesis that US TPI is more effective than FH. Based on earlier experience reporting a 30 per cent immediate success rate per TPI with a FH technique, the proportion of successful FH injections was determined to be 0.30[14]. Conversely, the proportion of successful US injections was set as 0.45. This percentage was arbitrarily chosen on the basis of a minimal clinically relevant difference of 15 per cent between both groups. Considering a two-sided 5 per cent significance level (α) and an 80 per cent power (1-β), 160 injections per group were required. Based on a database of over 1000 patients with ACNES, it was calculated that patients who were successfully treated with abdominal wall infiltrations required an average of three TPIs per patient[15]. Therefore, 108 patients were required to achieve 320 injections. Allowing for a 10 per cent dropout rate and a 10 per cent underestimation, the intention was to recruit 130 patients. It

Primary outcome

There was an equal success rate after both injection techniques (US 27.1 per cent, FH 33.2 per cent; P = 0.190). Not every patient received four injections. Causes for interrupting the injection regimen, apart from insufficient pain reduction, were loss of confidence or a wish for an alternative treatment strategy. The percentages of patients experiencing a minimum of 50 per cent pain reduction following an injection at the various time points of the injection regimen per treatment group are shown in Table 2. Complications were minor (temporary increased pain, haematoma, nausea, and/or dizziness) and did not differ between groups (US 11 per cent, FH 14 per cent; P = 0.449).

Secondary outcome

Pain reduction at 6 weeks and 3 months after the final injection was similar between groups (US 38.2 and 29.1 per cent, FH 37.1 and 29.0 per cent (P = 0.904 and P = 0.994, respectively); Table 3). The number of required injections leading to success (50 per cent or greater pain reduction) was also not significantly different (median: US = 3, FH = 2; P = 0.486). After the first injection, six patients (two in the US group and four in the FH group) had persistent sufficient (50 per cent or greater) pain reduction. The proportion of sufficient pain reduction increased after each consecutive injection. Fig. 2 illustrates the cumulative beneficial effect of this repeated injection regimen.

The 3-month outcome was neither associated with injection technique nor influenced by subcutaneous tissue thickness (Fig. 3). Also, logistic regression analysis showed that subcutaneous tissue thickness did not predict treatment outcome (odds ratio 0.99, 95 per cent confidence interval 0.948–1.030).
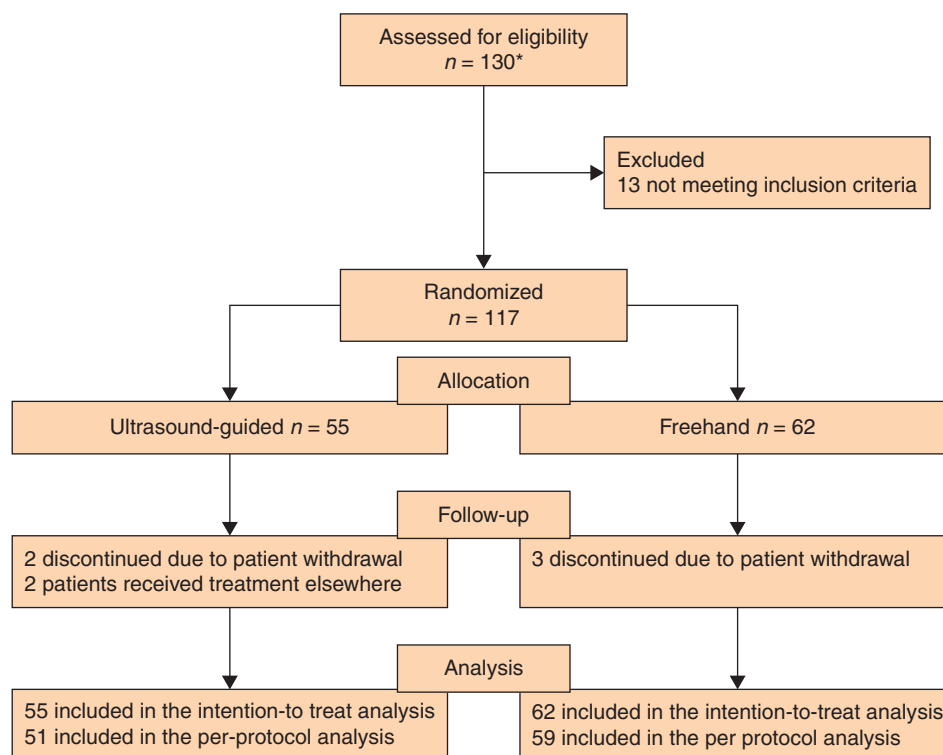
was estimated that the Laurentius Hospital would include 20 patients and the Máxima Medical Center 110 patients.

Baseline characteristics of continuous variables were depicted as mean and standard deviation if parametric, and median and range if non-parametric. Categorical variables were presented as count and percentage. Differences in primary outcome were analysed on an intention-to-treat (ITT) basis using the Pearson χ^2 test. Secondary outcome analysis was done on an ITT and per-protocol (PP) basis using Pearson χ^2 test for categorical variables, or the Mann–Whitney U test for non-parametric variables. Logistic regression analysis determined the effect of subcutaneous tissue thickness on treatment outcome after 3 months. A p-value $\leq$ 0.05 was considered statistically significant. Data analysis was performed using SPSS® version 22 for Windows (IBM, Armonk, New York, USA).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Results

Between January 2018 and April 2020, a total of 130 potentially eligible patients were approached for this study, of which 13 patients did not meet study criteria (Fig. 1). Therefore, 117 patients were randomized. Seven were lost to follow-up (US four patients, FH three patients) due to withdrawal of consent or receiving treatment elsewhere. Thus, 117 patients were included in the ITT analysis (US 55 patients, FH 62 patients) and 110 patients in the PP analysis (US 51 patients, FH 59 patients). A total of 391 injections (US 192, FH 199) were administered in these 110 patients. Table 1 shows baseline characteristics per study group.

Fig. 1 Flow diagram of patients with ACNES undergoing abdominal wall infiltration using an ultrasound-guided or freehand injection technique

*Number of patients per participating hospital, Máxima Medical Center (*n* = 110) and Laurentius Hospital (*n* = 20).

Table 1 Baseline characteristics of patients undergoing abdominal wall infiltration using ultrasound-guided or freehand injection technique (intention-to-treat analysis)

	Ultrasound-guided ($n = 55$)	Freehand ($n = 62$)
Age, years*	48.2 (15)	42.3 (15.8)
Female sex	43 (78)	46 (74)
Height, metres*	1.7 (0.10)	1.7 (0.1)
Weight, kg*	76.0 (16.2)	79.7 (14.8)
BMI, kg/m²*	26.1 (4.7)	27.4 (5.0)
Subcutaneous tissue thickness, mm*	20.1 (9.7)	22.9 (11.0)
Aetiology		
Spontaneous	35 (63.6)	43 (69.4)
Abdominal surgery	13 (23.6)	15 (24.2)
Pregnancy	1 (1.8)	2 (3.2)
Trauma	2 (3.6)	0 (0)
After flu	1 (1.8)	0 (0)
Other	3 (5.5)	2 (3.2)
Duration of pain prior to enrolment, months†	12.0 (1–216)	10 (1–300)
NRS (0–10)†	6.0 (2–10)	6 (0–9)
VRS		
0 = no pain	0 (0)	0 (0)
1 = very mild	4 (7.3)	5 (8.1)
2 = mild	9 (16.4)	12 (19.4)
3 = moderate	29 (52.7)	24 (38.7)
4 = severe	12 (21.8)	19 (30.6)
5 = excruciating	1 (1.8)	2 (3.2)
Abdominal wall pain location		
Right upper quadrant	8 (14.5)	11 (17.7)
Right lower quadrant	20 (36.4)	33 (53.2)
Left upper quadrant	5 (9.1)	8 (12.9)
Left lower quadrant	22 (40.0)	10 (16.1)

*Data are mean (s.d.), †median (range), or n (%). BMI, body mass index; NRS, numerical rating scale (pain level: 0 = absent; 10 = unbearable); VRS, verbal rating scale.

Table 2 Proportion of patients with ACNES experiencing ≥ 50 per cent pain reduction 15–20 min after an injection using two different techniques of abdominal wall administration

	Ultrasound-guided	Freehand	P-value
First injection = week 0	14/55 (25.5)	24/62 (38.7)	0.126
Second injection = week 2	13/51 (25.5)	19/53 (35.9)	0.253
Third injection = week 3	14/45 (31.1)	14/46 (30.4)	0.944
Fourth injection = week 4	11/41 (26.8)	9/38 (23.7)	0.748
Total	52/192 (27.1)	66/199 (33.2)	0.190

Data are n (%). ACNES, anterior cutaneous nerve entrapment syndrome.

Table 3 Proportion of patients with ACNES experiencing a persistent pain reduction (≥ 50 per cent) following an injection regimen

	Ultrasound-guided	Freehand	P-value
At 6 weeks, ITT ($n = 117$)	21/55 (38.2)	23/62 (37.1)	0.904
At 6 weeks, PP ($n = 110$)	20/51 (39.2)	23/59 (39.0)	0.980
At 3 months, ITT ($n = 117$)	16/55 (29.1)	18/62 (29.0)	0.994
At 3 months, PP ($n = 110$)	15/51 (29.4)	18/59 (30.5)	0.900

Data are n (%). ACNES, anterior cutaneous nerve entrapment syndrome; ITT, intention-to-treat; PP, per-protocol.

Discussion

The aim of the present study in patients with ACNES was to compare the proportion of patients demonstrating adequate pain relief after an US-guided or FH TPI using a local anaesthetic agent. The findings indicate that approximately one in three patients experience a minimum of 50 per cent pain reduction after 15–20 min, with a similar efficacy after 6 weeks and 3 months, regardless of the technique used. A final overall 30 per cent success rate is consistent with previously published data[9,14,17].
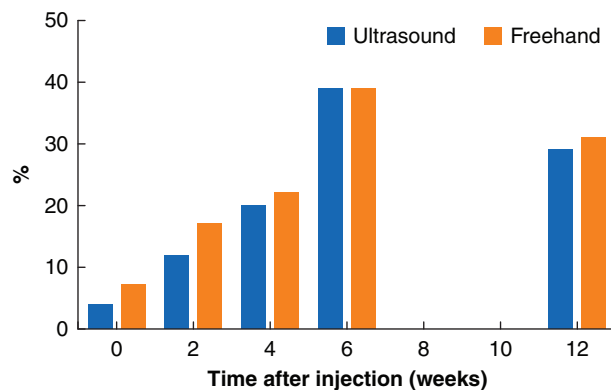
Fig. 2 Cumulative percentage of patients experiencing a persistent ≥ 50 per cent pain reduction after 1–4 abdominal wall infiltrations

It may seem intuitive to assume that US-guided TPI is superior to a 'blind' FH TPI. However, the available literature is scarce and mainly based on retrospective case series. Alnahhas *et al.* reported that over a third of 120 patients with chronic abdominal wall pain had a significant improvement after US-guided TPI, but efficacy was not better than after FH TPI[7]. Kanakarajan *et al.* performed US-guided TPI in nine patients, and four had a minimum of 50 per cent persisting pain reduction after 12 weeks[11]. Weum and de Weerd used US for perforator-guided injections in 15 patients by localizing the perforator vessels at the point of maximal tenderness in the abdominal wall. It was concluded that the technique enables precise drug deposition at the location of the entrapped nerve[13]. Earlier trials from the group undertaking the current study were performed by FH TPI only, with an overall success rate of one in three patients[5,6,9,14]. Interestingly, this 30 per cent TPI efficacy was again found in the present ACNES population, regardless of the technique used.
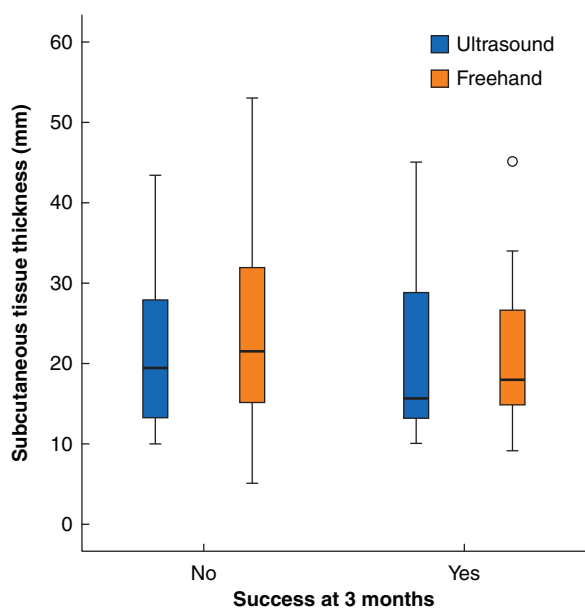
Fig. 3 Relation between subcutaneous tissue thickness and treatment outcome at 3 months per injection technique group

○ is defined as an outlier.

A potential advantage of US guidance is its safety as anatomical structures may be visualized[8,10–12]. The possibility of inadvertently entering the peritoneal cavity has been mentioned as a potential risk of a FH TPI. Weum and Weerd registered no specific complications in nine patients by using US guidance[13]. In the present study there were no major complications or complications related to penetration of the peritoneal cavity such as bowel perforation. In addition, the present minor complication rate of FH injections is low, possibly due to under-reporting. An earlier study reported an up to 34 per cent minor complication rate[14]. Untoward events usually included a temporary increased local tenderness, haematoma at the injection site, or, occasionally, nausea and dizziness. However, these complications may also occur after US TPI as illustrated by the present study. The authors have never encountered a case of peritoneal cavity or clinically evident viscus penetration in over 5000 injections. It is concluded that a FH method for TPI in ACNES is a safe technique.

The possible influence of subcutaneous tissue thickness, or its correlated body mass index (BMI), on TPI efficacy is largely unclear. It is conceivable that obese patients, having a subcutaneous tissue layer that is thicker than the needle length, are prone to having an inaccurate drug deposition. During a FH TPI, penetration of the needle tip through the rectus fascia is often sensed by the administrator, although this phenomenon may become less clear with a thicker fat layer. Some have reasoned that non-response after FH injection is due to inaccurate drug deposition[18]. A subfascial drug deposition is mandatory, as dictated by Applegate and Buckwater's theory[4]. In the present study, US was used to facilitate an accurate subfascial needle position, whereas other studies using US focused on the position of neurovascular bundle for accurate drug administration[8,10–13]. Nevertheless, the present study demonstrates that neither subcutaneous tissue thickness nor BMI are factors predicting TPI outcome. This finding may imply that deposition of drug depot, whether subfascially or more superficially, is possibly irrelevant regarding its

anaesthetic effect. It is hypothesized that a more superficial drug placement will invade the area around the entrapped nerve due to the amount of volume (8–10 ml). Remarkably, this is contradictory to the theory of Applegate and Buckwater[4]. Therefore, the relevance of drug deposition could be tested in a future trial comparing subfascial with prefascial anaesthetic drug deliverance; the outcome may have consequences for first line treatment. Surely, if depth of drug deposition does not matter, any family physician can perform a FH TPI for ACNES, thus largely decreasing second-line treatment delay.

There are some reasons to favour a FH technique over US guidance. A FH TPI is inexpensive, simple, quick, and always accessible, compared to US. However, US may be a good tool for gaining confidence in performing local injections, due to the immediate feedback of correct needle tip placement. Therefore, US can be seen as part of a learning curve for performing the FH TPI. Nevertheless, the FH TPI is a safe and effective alternative for general practitioners and various specialists who do not always have access to an US device.

A potential flaw of the present study is that subcutaneous tissue measurement and TPI were performed by the same physician. Another potential weakness could be that the US frequency was not predefined; however, optimal visualization was preferred on the basis of individualized frequencies that likely did not influence study outcome. Patient-level randomization was chosen over injection-level randomization to avoid patient response bias and to evaluate the overall treatment effect of repeated injections. Moreover, the power analysis may be criticized as the success rate of US TPI was arbitrary. Nevertheless, the results of this study are rather in favour of the FH technique, and therefore it is unlikely that the inclusion of more patients would have led to confirmation of the hypothesis that US is better. Also, the inferiority design could be criticized in favour of a non-inferiority design. However, fewer injections per group were required using a non-inferiority approach, so it is not likely that this alternative design would have led to another study outcome. A subanalysis on the treating centre was not performed owing to the difference in number of included patients (as expected at the outset of the trial), but both centres have extensive experience in diagnosing and treating patients with ACNES. The administration of relatively large volumes (8–10 ml) of local anaesthetic is a potential limitation as an inaccurate drug deposition may be mimicked, particularly when the fluid is subfascially deposited and distribution is widespread, potentially affecting more structures. Nevertheless, side effects with smaller or somewhat larger volumes are considered similar. Consequently, the standard use of 8–10 ml is reasonable.

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