Original Article

The Use of Shotblocker for Subcutaneous Injection Pain, Anxiety and Satisfaction in Chronic Spontaneous Urticaria Patients: A Randomized Controlled Trial

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Abstract

Background: In chronic diseases such as chronic spontaneous urticaria (CSU), after subcutaneous injection, problems such as pain, ecchymosis and hematoma may arise due to the injection technique.
Aim: The aim of this study was to investigate the effect of shotblocker on pain, anxiety and satisfaction levels in subcutaneous injection of CSU patients.
Methods: A randomized placebo-controlled was used for this study. Data were collected by including 90 patients out of 125 patients in Turkey. Patients were divided into three groups as intervention, control and shotblocker group.
Results: In this study; 76.7% of the patients in the shotblocker group stated that had no fear of injection, 86.7% of them had subcutaneous omalizumab injections 5 times or more, and 76.7% of them found that the injections were mildly painful. The satisfaction of the shotblocker group after injection was found to be statistically significant from the other groups. As a result of the assessment of pain and level of anxiety after injection; there was not statistically significant difference between shot blocker, placebo and control groups.
Conclusion: It is thought that shotblocker might be presented to patients as an option on account of it is easy and cost effective to use. It is recommended to support the result with further studies, since there have not been any similar study examples in subcutaneous (SC) omalizumab injection in chronic spontaneous urticaria patients.

Keywords: Chronic spontaneous urticaria, Omalizumab, Subcutaneous, Injection, Shotblocker

Introduction

Urticaria is a common, itchy, erythematous inflammatory skin disease characterized by plaque, papules and patches that may raise over the skin. Chronic urticaria is used for symptoms of urticaria lasting more than six weeks, and acute urticaria is used for symptoms that last longer than six weeks. Acute urticaria is common in young people, while chronic urticaria is seen in middle-aged women (Goncu et al., 2016;

Zuberbier et al., 2014; Tharp et al., 2019). In recent years, the definition of CSU has been proposed in studies on pathogenesis. It affects approximately 1-1.3% of the population (Zuberbier et al., 2014). Although many studies have been carried out on the aetiology and pathogenesis, the exact cause and mechanism is still unknown (Tharp et al., 2019; Greenberger, 2014).

The drug can be started in accordance with the medical board report which includes at least one of the dermatology, allergy and immunology specialist physicians in university or training hospitals. Omalizumab is a recombinant humanized monoclonal IgG antibody developed against IgE. It is administered subcutaneously at a dose of 300 mg every 28 days for 6 months; treatment is interrupted and then if symptoms persist, treatment is continued in the same way (Goncu et al., 2016; Zuberbier et al., 2014; Tharp et al., 2019). Nurses are key role in safe injection of this drug in SC injection and observation of individual responses.

Pain and anxiety are common conditions immediately after SC injection. The pain is often caused by inaccurate SC injections (Buyukyilmaz, Culha, Karaman, 2018; Celik and Khorsid, 2015). Also, injection-induced anxiety can affect the pain experienced. In these problems, the biophysical properties (Body Mass Index-BMI, SC tissue thickness) are as important as the individual's previous pain experiences. This may lead to tissue loss at the injection site subsequent injections of subcutaneously administered omalizumab every twenty-eight days and increase the stress level (Goncu et al., 2016; Zuberbier et al., 2014; Tat, 2018). It is stated in the literature that complications may be reduced significantly with appropriate technique in subcutaneous injection applications (Buyukyilmaz, Culha, Karaman, 2018; Celik, Khorsid, 2015; Sendir et al., 2015). To reduce adverse effects in SC injection application; long-term (30 seconds) SC injection should be applied without aspiration and using the airlock technique. Complications such as regional pain, ecchymosis and hematoma may occur due to inaccurate SC injection. These complications can cause anxiety in the patient and reduce their satisfaction (Buyukyilmaz, Culha, Karaman, 2018; Celik and Khorsid, 2015).

The use of nonpharmacological approaches is recommended in alleviating these undesired responses. One of these approaches "ShotBlocker (Bionix, Toledo, Ohio) was developed for subcutaneous and intramuscular injection applications. ShotBlocker is a drug-free, non-invasive plastic device that can be applied for all age groups. It simulates the smaller nerves at the injection site and briefly blocks the pain gate in the central nervous system and slows down A-delta signals. ShotBlocker is quick and easy to use, does not require any preliminary preparation, and has not been previously reported side effects. A surface of the device has a plurality of blunt spots these directly in contact with the skin. It is reported that the injection pain is reduced by applying light pressure to the contacting area with a short, non-sharp 2 mm thick blunt tip. There is a gap in the middle of the device to display the injection site and injection is applied through this gap (Zaybak and Khorshid, 2008).

In most international studies, it has been found that subcutaneous and intramuscular injection with ShotBlocker has a substantial impact on reducing pain levels (Celik and Khorsid, 2015; Drago et al., 2009; Cobb and Cohen, 2009; Sahiner Canbulat et al., 2018; Inangil and Sendir, 2020; Sivri Bilgen and Balci, 2019; Yılmaz and Alemdar, 2019). In the literature, Shotblocker intramuscular (IM) injections were examined the effects of pain in different age groups (Celik and Khorsid, 2015; Drago et al., 2009; Cobb and Cohen, 2009; Sivri Bilgen and Balci, 2019; Yılmaz and Alemdar 2019). However, in SC injection, there has been limited studies evaluating the effect of shotblocker pain and anxiety (Sahiner Canbulat et al., 2018; Inangil and Sendir, 2020). No studies were found evaluating shotblocker in CSU.

The aim of this prospective randomized controlled trial (RCT) was to examine the efficacy of shotblocker for managing SC injection pain, anxiety and satisfaction associated in chronic spontaneous urticaria patients.

The specific study questions were as follows:

1. To what extent does shotblocker use affect pain in SC omalizumab application?
2. How does the use of shotblocker in SC omalizumab application affect anxiety level?

3. What are the effects of using shotblocker on SC omalizumab application on patient satisfaction?

Methodology

Study design: A randomized was used for this study. It was conducted between June and November 2018. The CONSORT flow diagram presents the detailed research procedures as Figure 1.

The target population of the study was consisted of patients with CSU who subcutaneous omalizumab treatment at the Dermatology Clinic of one university Hospital in Istanbul. The patients were considered eligible if they were (a) communicative, (b) aged ≥ 18 years, (c) had normal BMI (reference range, 18.5-29.9 kg/m^2), (c) CSU diagnosed, (d) having regular subcutaneous omalizumab treatment, (e) having not infection, scar tissue or incision on the posterior side of both upper arms and another parenteral treatment was not applied that side, (f) having not any haematological disease.

The power analysis revealed that 90 patients who met the research criteria with a power level of 0.80, 0.05 error margin and ± 0.05 deviation were included in the study (Figure 1).

Sample size; The average difference of 1.5 units from the parameters measured in the study in each group was calculated according to the standard deviation value of 2 units. In order to find the difference between the groups, each group was calculated as 28 people (Type I error 0.05, Type II error 0.20, power 0.80).

Measurements/Instruments: As a data collection tool; data collection form, **v**isual analog scales and the state-trait anxiety inventory form TX-I (STAI) were used.

Data Collection Form: the data collection form was composed by the researchers; age, sex, education, working status, previous subcutaneous omalizumab administration status and number, fear of injections, pin-prick pain and body mass index (BMI) included in the form.

Visual Comparison Scales: in this study, Visual Analog Scales (VAS) were used in order to determine the pain and satisfaction of the administration. The scale comprise of a 10 cm long horizontal line with descriptive expressions at both ends (0 cm: no pain / no satisfaction and 10 cm on the right end: unbearable pain / very satisfied). Participants were asked to mark the pain / satisfaction level on this line.

The state-trait anxiety inventory form TX-I: STAI was developed by Spielberger et al. In 1970 to measure state (TX-I) and trait anxiety levels (TX-II), and was adapted to Turkish society in 1985 by Oner and Le Compte. The State-Trait Anxiety Scale (TX-I) used in this study is a Likert-type scale consisting of 20 questions to determine how an individual feel at a given time and under certain circumstances.

Each question has four options; 10 items are the reverse items (1,2,5,8,10,11,15,16,19 and 20), the lowest score is 20 and the highest score is 80. A higher score indicates a high level of anxiety and a lower score indicates a low level of anxiety. The average score in the previous administrations of the form ranged from 36 to 41 (Tenenbaum, Furst, & Weingarten, 1985).

Data Collection/Procedure: The participants were informed about the aim, scope, duration and method of the study by the researcher. After giving information to the participants, permission form was read and signed by the patients who agreed to participate in the study voluntarily.

Patients were divided into three groups as shotblocker, placebo and control. All SC injections were performed in the patient injection room by a registered nurse with 25 years of clinical experience. Then pain severity, anxiety, and patient satisfaction were evaluated.

Shotblocker group: Shotblocker was used by an experienced registered nurse under the researcher supervision. The injection area gripped with shotblocker was applied for 5 seconds and then injected, released after the drug administration and then the shotblocker was removed. After injection, light pressure was applied to the injection area with dry cotton.

Placebo group: The smooth surface (opposite side) of the shotblocker was placed in the injection area just before administration by an experience registered nurse and the drug was injected by holding it on the skin surface during the injection.

Control group: Subcutaneous injection was performed with normal routine clinic procedure subcutaneous drug administration steps by an experienced registered nurse and no additional method was applied. Subcutaneous injection was performed following the same steps for each patient considering that it may affect injection pain. It was applied to the upper back of the both arms for subcutaneous omalizumab, shotblocker and placebo groups were applied to the upper back of single arm at a time in urticaria patients.

The injection area was cleaned circularly with alcoholic scrub and allowed to dry. The movement of the needle in the tissue was minimized to prevent injection-induced damage by application at a 60 ° angle, 20 seconds speed. After injection, light pressure was applied to the injection site with dry cotton.

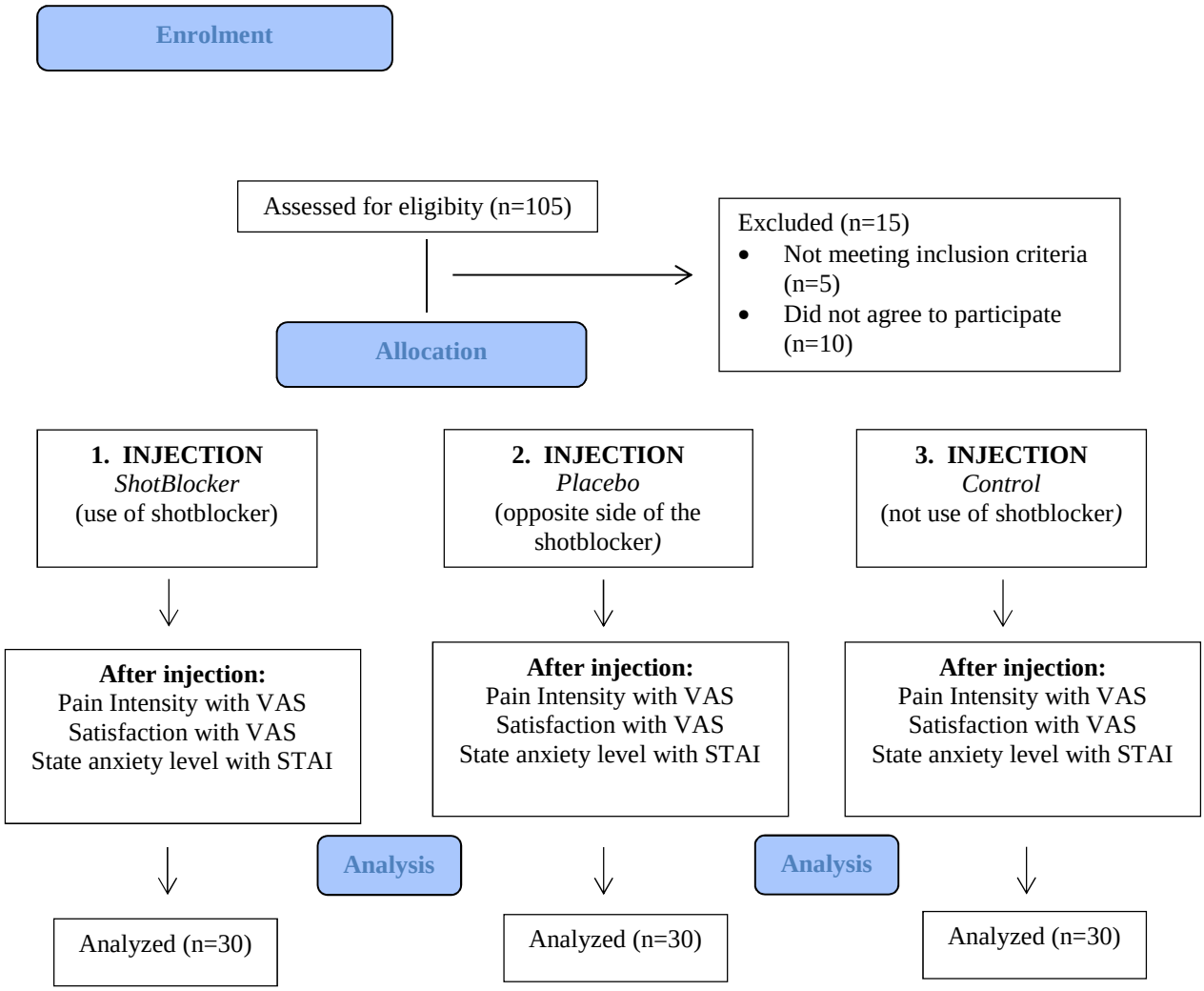

Figure 1. The CONSORT flow diagram presents the detailed research procedures
VAS= Visual Analog Scales; STAI= State-Trait Anxiety Inventory Form

Ethical considerations: In order to carry out this study, written permission from the dermatology clinic of a public hospital in Istanbul (12.06.2018) and permission from the ethics committee of the Hamidiye Non-Interventional Research Ethics Committee (46418926-050.03.04) were obtained. The participants were received an oral explanation about the research and written consent was obtained. Also, the study was registered under the number: NCT04210323.

Data analysis: Data were analysed in statistical package program. The chi-square test was used to compare socio-demographic characteristics of the individuals in the shotblocker, placebo, and control groups, and in other percent comparisons. Nonparametric tests were used for comparisons

between the groups because the data did not appropriate the normal distribution. Kruskal Wallis test was used to compare pain, satisfaction and trait anxiety levels between the groups. Results were evaluated at 95% confidence interval and p≤0.05 significance level.

Results

Shotblocker, placebo and control groups demonstrated similar characteristics from the point of research variables. There was not statistically significant difference between the groups with regard age, gender and BMI scores. In all groups of the patients participating in the study, 68.9% were female and 47.78% were obese and their mean age was 43.52 ± 13.94 (Table 1).

In this study, patients in all group stated that 78.9% of them had no fear of injection, 78.8% of them had subcutaneous omalizumab injection of 5 or more times, and 80% of them found it mildly general pin-prick pain (Table 2).

Research Question 1: Pain scores in shotblocker, placebo and control groups: Comparison of the pain scores of the three groups was given in Table 3. The mean VAS score for pain was 1.67 ± 2.38 in the shotblocker group, 1.53 ± 2.28 in the placebo group, 1.90 ± 2.45 in the control group. There was not statistically important difference between shotblocker, placebo and control groups when pain was assessed after injection (p= .733) (Table 3).

Research Question 2: Satisfaction scores in shotblocker, placebo and control groups: Comparison of patient satisfaction according to the groups was given in Table 4. The mean satisfaction score was 9.43 ± 1.22 in the shotblocker group, 8.23 ± 2.54 in the placebo group, and 8.90 ± 1.72 in the control group. The average levels of satisfaction after injection were compared; The satisfaction level of the shotblocker group from other groups was found to be statistically high (p= .049) (Table 4).

Research Question 3: State anxiety level in shotblocker, placebo and control groups: Comparison of patient state anxiety level according to the groups was given in Table 5.The mean anxiety score was 23.90 ± 4.51 in the shotblocker group, 22.16 ± 3.89 in the placebo group, and 22.56 ± 3.87 in the control group. When the state of anxiety after injection was compared between the three groups, it was determined that there was no statistically significant difference (p= .192) (Table 5).

Table 1 Characteristics of patients

Characteristics	ShotBlocker Group (n=30)	Placebo Group (n=30)	Control Group (n=30)	Total Groups	Two tailed significance
Mean of age (years)	42.60±15.19	41.63±14.40	46.33±12.05	43.52±13.94	F= 0.95 p= 0 .39
Gender					
Female	26 (86.7%)	16 (53.3%)	20 (66.7%)	62 (68.9%)	χ^2 = 7.88
Male	4 (13.3%)	14 (46.7%)	10 (33.3%)	28 (31.1%)	p= 0.019
Body Mass Index kg / m²					
Slim	1 (3.3%)	1 (3.3%)	12 (40%)	14 (15.56%)	χ^2 = 7.438
Normal weight	9 (30%)	11 (36.7%)	13 (43.3%)	33 (36.66%)	p= 0.684
Obese	20 (66.7%)	18 (60%)	5 (16.7%)	43 (47.78%)	

χ^2 = chi square

Table 2 Comparison of patients' expressions of fear of injections, number of injections and pin-prick pain

Characteristics	ShotBlocker Group (n=30)	Placebo Group (n=30)	Control Group (n=30)	Total Groups	Two tailed significance
Fear of injection					
Yes	7 (23.3%)	3 (10%)	9 (30%)	19 (21.1%)	χ^2 = 3.736
No	23 (76.7%)	27 (90%)	21 (70%)	71 (78.9%)	p= 0.154

Subcutaneous omalizumab number of injection					
1-4 times	4 (13.3%)	8 (26.7%)	7 (23.3%)	19 (21.2%)	$\chi^2 = 5.022$
5 times and above	26 (86.7%)	22 (73.3%)	23 (76.7%)	71 (78.8%)	p= 0.541
General pin-prick pain of injection					
Mild	23 (76.7%)	24 (80%)	25 (83.3%)	72 (80%)	$\chi^2 = 2.201$ p= 0.699

χ^2 = chi square

Table 3 Comparison of mean pain scores

Groups	Median VAS pain scores Min- Max	Mean VAS pain scores	Standard deviation (±)	Two tailed significance χ^2_{KW}; p
Shotblocker group (n=30)	0.50 (0 -8)	1.67	2.38	0.54; 0.76
Placebo group (n=30)	0 (0-7)	1.53	2.28	
Control group (n=30)	1 (0-9)	1.90	2.45	

χ^2_{KW} = kruskal-wallis

Table 4 Comparison of mean satisfaction scores

Groups	Median satisfaction scores	Min -max	Statistical test; χ^2_{KW}
Shotblocker group (n=30)	10*	5-10	5.764; 0.05*
Placebo group (n=30)	9.5	0-10	
Control group (n=30)	9.5	2-10	

χ^2_{KW} = kruskal-wallis, *p< 0.05

Table 5 Comparison of mean state anxiety scores

Groups	Median state anxiety scores	Min -Max	Two tailed significance χ^2_{KW}; p
Shotblocker group (n=30)	21	20-30	3.69; 0.15
Placebo group (n=30)	20	18-30	
Control group (n=30)	20	18-32	

χ^2_{KW} = kruskal-wallis

Discussion

In the literature review; No studies have been reported the use of shotblocker in subcutaneous injection in patients with CSU. However, there are international and national researches in which shotblocker was used for subcutaneous and intramuscular injections (Celik and Khorsid, 2015; Drago et al., 2009; Cobb and Cohen, 2009; Sahiner Canbulat et al., 2018; Inangil and Sendir, 2020; Sivri Bilgen and Balci, 2019; Yılmaz and Alemdar 2019).

Pain: It is stated that there may occur temporary injection site reactions such as pain, bruising, swelling, redness and pruritus at the injection area after omalizumab application (Greenberger, 2014). In most subcutaneous injection studies using shotblocker have shown significant reduction in injection pain (Sahiner Canbulat et al., 2018; Inangil and Sendir, 2020). In our study, when pain evaluation was performed after injection; it was not found meaningful difference between shotblocker, placebo and control groups (Table 3).

In a study carried by Tat (2018) in 30 patients diagnosed with CSU, as a side effect, local erythema was observed in the area where the drug was administered in only one patient and there were not any problems detected in the physical examination of the patient (Tat, 2018). In the literature review, it has been shown in many studies that omalizumab treatment is reliable in patients with CSU (Goncu et al., 2016; Tharp et al., 2019; Greenberger, 2014; Tat, 2018). Our research finding suggests that the severity of pain may decrease due to the administration of subcutaneous omalizumab injection every 28 days and for at least 6 months in CSU patients. In addition, it is also thought that the injection of SC omalizumab was administered by the nurse who specializes in dermatology and the needle tip quality used in omalizumab injection also affects this result.

Satisfaction: Patient satisfaction is the most important indicator in quality patient care, which is based on the perception of patients, which includes expectations, experience and value judgments related to the health care or medical care of the patients (Alhusban and Abualrub, 2009; Annersten and Willman, 2005). In order to determine patient satisfaction, the psychometric scale was used in our research, which is commonly used in the evaluation of subjective characteristics. The post-injection satisfaction level of shotblocker group was found to be statistically lower than other groups (Table 4). Similar results have been achieved in most of the studies using shotblocker, and the satisfaction levels of the shotblocker group were higher than other injection methods (Sahiner Canbulat et al., 2018; Inangil and Sendir, 2020). Studies estimating that shotblocker can be offered as an option to patients for reasons such as high patient satisfaction as well as ease of use and cost effectiveness.

Anxiety: State anxiety level; temporary and short-term, in the case of dealing with dangerous or threatening situations under a certain circumstance. Intense anxiety before injection can increase the severity of the pain experienced in the post-injection period. Therefore, in our study, the level of post-injection state anxiety level was examined, and it was determined that there was no statistically significant difference between the three groups (Table 5). It is thought that the result may have affected the training and care provided by the medical team in accordance with the needs of CSU patients, as well as the patients' focus on the application during the use of shotblocker. Similar to our study findings, Sahiner et al. (2018) examined shotblocker in insulin injection in children with type 1 diabetes and examined anxiety scores and found no difference between the groups (Sahiner Canbulat et al., 2018). In the study conducted by Celik and Khorshid (2015), anxiety scores were compared after intramuscular injection and there was no significant difference between the three groups (Celik and Khorsid, 2015).

Conclusion: In our study, there was no between the use of shotblocker in subcutaneous omalizumab application and level of pain and anxiety in CSU patients. Similar to the studies, it was concluded that patient satisfaction was higher in the group used shotblocker than in other groups. In addition to patient satisfaction, it is thought that this device may be offered as an option to patients for reasons such as being easy and cost-effective use.

Limitations: There were two limitations in this study. Firstly, since the study was conducted with CSU patients who applied to a single hospital and agreed to participate in the study within a certain period of time, the fact that the results can be generalized to its own universe is

an important limitation of the study. The second limitation is that prolonged SC omalizumab treatment affects the assessment of pain and anxiety.

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