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Effects of applications manual pressure and shotblocker to reduce needle-related pain and fear in children with type 1 diabetes mellitus

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ABSTRACT

Background: Pain and fear associated with insulin injections can cause children with type 1 diabetes mellitus to avoid insulin injections and skip doses.
Objective: To evaluate and compare pain and fear levels in children aged 6–12 years receiving subcutaneous insulin injection using the manual pressure and ShotBlocker methods.
Methods: A randomized controlled study was conducted with 90 children with type 1 diabetes who were allocated using block randomization to the manual pressure, ShotBlocker, and control groups ($n = 30$ in each group). Fear and pain levels were rated by the children, their parents, and a member of the study team immediately before and after insulin injection using the Children's Fear Scale and Wong-Baker Faces Pain Rating Scale, respectively.
Results: All groups had similar self-, parent-, and researcher-reported levels of preprocedural pain and fear ($p > 0.05$). However, pain and fear scores were lower in the manual pressure and ShotBlocker groups than in the control group after injection ($p = 0.0001$). There was no significant difference in pain and fear scores between the two intervention groups ($p > 0.05$).
Conclusion: Manual pressure and the ShotBlocker both reduced fear and pain associated with insulin injection in 6- to 12-year-old children with type 1 diabetes.
Implications for practice: Both the manual pressure and ShotBlocker methods can easily be applied in children receiving insulin injections. As manual pressure is completely cost- and equipment-free, it is a useful option to reduce pain and fear related to insulin injection.
Clinical Trial Registration Number: National Institutes of Health (NIH), ClinicalTrials.gov, NCT05789810.

Introduction

Type 1 diabetes mellitus (T1DM) is among the commonest chronic diseases in childhood (Patterson et al., 2019). Measuring and regulating blood glucose in T1DM requires repeated daily finger punctures and insulin injections, and disease management involves venous blood sampling for regular follow-up of HbA1c, blood lipid levels, and kidney and thyroid function (Göthesson et al., 2023; Pihoker et al., 2018; Samuelsson et al., 2021). Thus, invasive procedures are a part of daily life for children with T1DM (Tremolada et al., 2021), and the fear and pain associated with these procedures are also common (Cemeroğlu et al., 2015; Hanberger et al., 2021; Heinrich & Callahan, 2016; Sparapani et al., 2015). The literature data indicate that insulin injections cause significant fear and pain in children with T1DM, especially those who are newly diagnosed (Howe et al., 2011), younger children experience more fear and pain (Hanberger et al., 2021; Howe et al., 2011; McLenon & Rogers, 2019), and children's chronic pain and fear persist (Eccleston et al., 2021; Göthesson et al., 2023). The prevalence of fear related to invasive procedures in children with T1DM ranges from 9.5% to 32.7% (Heinrich & Callahan, 2016; Tremolada et al., 2021). Moreover, not only children but also their parents experience negative emotions because of these procedures (Cemeroğlu et al., 2015; Hanberger et al., 2021; Tremolada et al., 2021).

Administering insulin is the basic treatment in the management of

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T1DM in children (Rami-Merhar et al., 2019). To ensure optimal outcomes, children must comply with insulin therapy and monitor their blood glucose levels (DiMeglio et al., 2018; Sparapani et al., 2015; Tremolada et al., 2021). However, the pain and fear children with T1DM have in relation to insulin injections can lead to avoidance, skipping doses (Cemeroğlu et al., 2015; Hanberger et al., 2021; Sparapani et al., 2015), and a negative impact on diabetes self-management (Cemeroğlu et al., 2015;Göthesson et al., 2023; Hanberger et al., 2021). Children with high levels of insulin injection-related fear were reported to also have high HbA1c levels and more long-term complications (Göthesson et al., 2023; Hanberger et al., 2021). In addition to interventions to reduce insulin requirement and increase quality of life in children with T1DM, research is also focusing on methods to support diabetes self-management by reducing fear and pain during insulin injection (Canbulat Şahiner et al., 2018; Göthesson et al., 2023; Hanberger et al., 2021). Fear and pain associated with insulin injection should be treated as an important issue in pediatric diabetes management, as they negatively impact glycemic control and increase the risk of long-term complications (Göthesson et al., 2023).

Many non-pharmacological techniques have been used to reduce pain during various painful procedures in children, except for subcutaneous insulin injection. These techniques include vibration and cold application (Su et al., 2021), sweet-tasting solutions (Harrison et al., 2015), distraction (Canbulat Şahiner & Türkmen, 2019), breathing exercises (Yılmaz & Alemdar, 2019), the use of appropriate injection techniques and appropriate position (Ayinde et al., 2021; Balcı & Sivri, 2023), music therapy (Ting et al., 2022), the ShotBlocker (Sivri & Balcı, 2019; Yılmaz & Alemdar, 2019), massage (Bernstein et al., 2021), and applying manual pressure (Derya et al., 2015; Göl & Altuğ Özsoy, 2017). In the studies conducted, these techniques were reported to effectively reduce pain. Only one study investigated the effect of combined cold and vibration application and the ShotBlocker on pain and anxiety associated with subcutaneous insulin injection in children aged 6–12 years and demonstrated less pain and anxiety in both intervention groups compared to the control group (Canbulat Şahiner et al., 2018). However, most of these techniques have costs associated with the materials used (Canbulat Şahiner & Türkmen, 2019; Sivri & Balcı, 2019; Su et al., 2021; Ting et al., 2022) and cannot be applied in all settings (Balcı & Sivri, 2023; Harrison et al., 2015).

The ShotBlocker is a roughly C-shaped plastic tool with numerous short, blunt protrusions on one side. This side is applied to the skin to create sensory signal saturation surrounding the injection site, resulting in inhibition of pain signals during injection. This simple, noninvasive, drug-free method was shown to reduce pain in intramuscular (Aykanat Girgin et al., 2020; Yılmaz & Alemdar, 2019), vaccine (Cobb & Cohen, 2009), and subcutaneous insulin injections (Canbulat Şahiner et al., 2018). Manual pressure is a practical and cost-free nonpharmacological method that is easily learned and requires no equipment or preparation (Öztürk et al., 2017). Although there have been many studies using the other pain-relief methods explained above, few studies have focused on effect of manual pressure on injection-related pain in children during intramuscular injection (Derya et al., 2015; Göl & Altuğ Özsoy, 2017). There is also a gap in the literature regarding the pain-relieving efficacy of manual pressure in children with T1DM who need regular subcutaneous insulin injections.

The analgesic effect of both of these non-pharmacological techniques can be explained by the gate control mechanism. According to the gate control theory, first proposed in the 1960s by Melzack and Wall, a neural gate is controlled by the relative activity of thick and thin fibers. Thick fibers (A-beta) stimulate the substantia gelatinosa cells, inhibiting signal transmission to T cells (transmission neurons) and closing the gate to painful stimuli. Thin fibers (A-delta and C fibers) inhibit the substantia gelatinosa cells, thereby opening the gate and allowing transmission by T cells, resulting in the perception of pain (Melzack & Wall, 1965). When pressure is applied to the skin with the manual pressure and ShotBlocker techniques, it is expected that the thick fibers will stimulate the substantia gelatinosa cells, which inhibit T cells and close the gate, leading to reduced pain perception (Canbulat Şahiner et al., 2018; Chung et al., 2002; Öztürk et al., 2017).

It is important that the methods and/or equipment used to reduce fear and pain during subcutaneous insulin injection are practical, applicable in all settings, reusable, and low- or no-cost (Canbulat Şahiner et al., 2018). To our knowledge, no previous study has investigated the efficacy of applying manual pressure and the ShotBlocker in reducing pain and fear in children with T1DM during insulin administration. The current study aimed to evaluate and compare the benefits of applying manual pressure and the ShotBlocker on pain and fear during subcutaneous insulin injection in children with T1DM. The primary objective was to assess and compare the effectiveness of manual pressure and the ShotBlocker versus standard care (control) in decreasing pain levels in children. The secondary objective was to assess and compare the effectiveness of manual pressure and the ShotBlocker versus standard care (control) in decreasing children's fear levels. The results of this study may guide healthcare professionals in helping avoid negative experiences related to insulin injection, which is a key part of diabetes management in children with T1DM, and thus promote self-management in these children.

The study hypotheses were:

1) Children who have manual pressure (group 1) or the ShotBlocker (group 2) applied during subcutaneous insulin injection will have less pain (primary outcome) assessed by child, parent, and researcher than the control group.
2) Children who have manual pressure (group 1) or the ShotBlocker (group 2) applied during subcutaneous insulin injection will have less fear (secondary outcome) assessed by child, parent, and researcher than the control group.

Methods

Design and setting

This randomized controlled clinical trial (RCT) was conducted between September 2022 and February 2023 with three parallel groups in the pediatric endocrinology outpatient clinic of a training and research hospital in western Turkey. The study was registered in Clinicaltrials.gov (NCT05789810) and was designed and executed in accordance with the CONSORT guidelines (Schulz, Altman, Moher, and the CONSORT Group, 2010).

Sample and randomization

The sample comprised children 6–12 years of age who had T1DM and were receiving subcutaneous insulin injections, had cognitive and communication abilities sufficient to rate their fear and pain levels, and were willing to participate. This group was selected because children of that age are most cooperative. All participating children gave verbal consent to participate, and their families provided written consent. Children who used a continuous glucose monitoring system, had any neurodevelopmental disorder, had lipodystrophy, infection, or nerve damage at the injection site, took analgesics within the last 6 h or had an acute complication such as ketosis or hypoglycemia at the time of admission to the outpatient clinic on the day of the study, were diagnosed with Reynaud's syndrome or sickle cell anemia, or did not want to participate in the study were excluded from the sample.

Parents meeting the following inclusion criteria were eligible for participation: having normal cognitive and neurological function and verbal communication, understanding and reading Turkish, and voluntarily signing an informed consent form for participation in the study.

Children meeting the sampling criteria were allocated to one of three groups (manual pressure, ShotBlocker, and control group) by one of the researchers (İ.). The children were first grouped by sex, then assigned to

the study groups by block randomization to control for the effect of sex on pain (Bartley & Fillingim, 2013; Tran et al., 2015). First, group numbers were written on uniform pieces of paper and placed in two separate boxes for the boys and girls. The children were asked to draw from their respective boxes to ensure randomized distribution. Thus, each group comprised 15 girls and 15 boys, for a total of 30 children in each group and 90 children in the study. The CONSORT flow diagram of the participants is shown in Fig. 1.

Instruments

Child information form

Based on the relevant literature, this form was created by the researchers and included six questions about the children's sex, age, weight, diabetes duration, number of daily insulin injections, and lipodystrophy status (Canbulat Şahiner et al., 2018; Cemeroğlu et al., 2015; Hanberger et al., 2021; Howe et al., 2011). The form required approximately 5 min to complete.

Wong-Baker FACES Pain Rating Scale

The Wong-Baker FACES Pain Rating Scale (WBS) consists of six cartoon faces with expressions ranging from smiling (no pain, 0 points) to crying (worst pain, 10 points) and was developed for the assessment of pain intensity in children 3–18 years of age (Wong-Baker FACES Foundation, 2016). The WBS is shown to be valid and reliable and is frequently used with Turkish children (Canbulat Şahiner et al., 2018; Özalp Gerçeker et al., 2020; Şahiner & Bal, 2016). The children's pain scores before and after injection were rated by the children themselves, a parent, and a member of the study team who specializes in pediatric nursing.

Children's Fear Scale

This single-item scale is used for the assessment of pain-related fear in children. Like the WBS, the Children's Fear Scale (CFS) comprises a series of facial expressions ranging from no fear (0 points) to very fearful (4 points) (Gerçeker et al., 2018; McMurtry et al., 2011). The scale can be used with children 5–12 years of age to assess fear before and during a procedure (McMurtry et al., 2011). Psychometric analyses of the original and Turkish form of the scale demonstrated its validity and reliability in the evaluation of children's fear levels (Gerçeker et al., 2018). Children's fear scores before and after injection were rated by the children, their parents, and a member of the study team who specialized in pediatric nursing.

Procedure

A single researcher (İ.) evaluated all children and parents according to the inclusion criteria and informed those who met these criteria about the purpose of the study and how to use the WBS and CFS. While informing the participants, Researcher İ. showed the pictures in the WBS and CFS to the children and parents and explained what each picture and score meant. Researcher İ. is an associate professor in the public health nursing department and has clinical and research experience in the field of pain management. She obtained their verbal and written consent, then assigned the children to the study groups by block randomization as described above. Before the procedure, each child was weighed (as per routine procedure in the endocrinology outpatient clinic), and the rest of the data in the child information form was obtained by interviewing the parents.

The WBS and CFS were administered by another researcher (B.) within 5 min before insulin administration. The children, their parents, and Researcher B. gave their scores simultaneously and independently. Although Researcher B. was not blind to the interventions applied, the child, parent, and Researcher B. performed their scoring blindly from

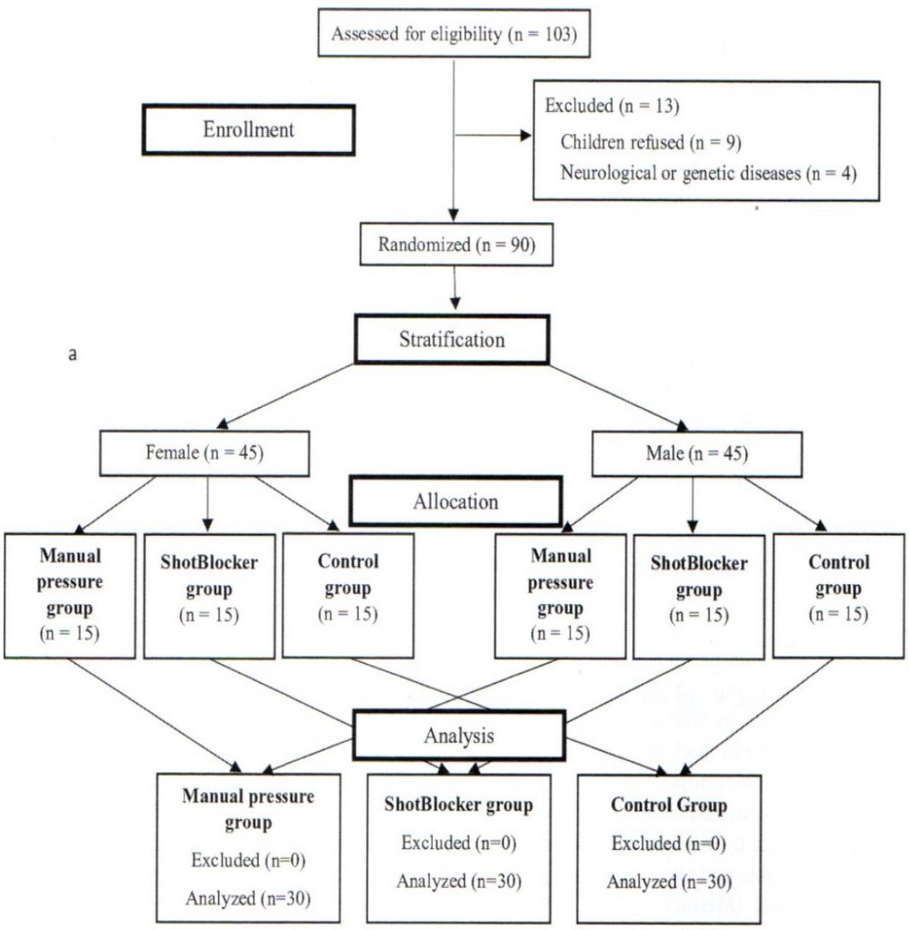

Fig. 1. Diagram showing the flow of the study participants.

each other. Researcher B. is a nurse and associate professor of pediatric nursing with research and clinical experience in pain management. The scores given independently by the three evaluators were recorded in a single form by researcher F., who is a nurse and PhD student in pediatric nursing with clinical experience in pain management in newborns and children.

In all groups, insulin injections were performed by the same expert diabetes nurse to prevent differences in practice. This diabetes nurse was working in the hospital where the study was conducted, had more than 10 years of experience caring for children with T1DM, and was not a member of the research team. The manual pressure and ShotBlocker intervention protocols were prepared in accordance with the literature prior to the study (Canbulat Şahiner et al., 2018; Chung et al., 2002; Derya et al., 2015; Yılmaz & Alemdar, 2019). Before data collection, researchers B. demonstrated the procedures to the diabetes nurse and evaluated her ability to perform them. The children, their parents, and researchers B. and F. were taken to a room in the outpatient clinic where the insulin injection would be performed.

All subcutaneous insulin injections in all groups were standardized in terms of site (left upper arm), needle thickness (32 G; 0.23 × 4 mm; Ayset, Turkey), antiseptic solution used (70% alcohol), comfortable sitting position, and the presence of the parents and the researchers (B. and F.). A single injection was assessed for each child.

Manual pressure group: Researcher F. explained to the children and parents how the manual pressure method would be implemented. The diabetes nurse pressed on the injection site with her right thumb until resistance was felt, maintained this pressure for 10 s, then immediately administered the insulin injection (Chung et al., 2002; Göl & Altuğ Özsoy, 2017).

ShotBlocker group: Researcher F. explained to the children and parents how the ShotBlocker would be used. The ShotBlocker was positioned at the insulin injection site, ensuring the protrusions on the underside of the device were in contact with the skin surface, and was held in place during the injection by the diabetes nurse. The injection was made through the opening in the middle of the device.

Control group: Researcher F. informed the children and parents that no nonpharmacological methods would be implemented before the procedure, and there was no intervention for pain and fear reduction during injection.

The children, parents, and Researcher B. completed the WBS and CFS again immediately after insulin injection, again blinded to each other's responses. Researcher F. recorded all of their scores in a single form.

Outcome measures

The primary outcome was pain levels assessed with the WBS, and secondary outcome was fear levels assessed with the CFS. The WBS and CFS were administered to the children, their parents, and Researcher B. within 5 min before and immediately after insulin administration. All ratings were done blindly to ensure that the observers did not influence each other's scores.

Ethical considerations

Local ethics committee approval was obtained (27.03.2019, 2019/97). Verbal and/or written consent was obtained from all participating children and parents after being informed about the study.

Statistical analysis

The data were evaluated using SPSS version 22 package program (significance level: $p \leq 0.05$). Kolmogorov-Smirnov and Shapiro-Wilk tests indicated non-normal data distributions. Descriptive characteristics were evaluated using number and percentage distribution, and homogeneity was assessed using chi-square analysis. Comparisons between three or more groups were made using Kruskal-Wallis H test followed by post-hoc pairwise comparisons with Bonferroni correction. Power analysis (G*Power 3.1.9.2) indicated that for an effect size of 0.36 and significance level of 0.05, a sample size of 90 would be sufficient to detect significant differences with 85% power (Faul, 2014). According to power analysis conducted at the end of the study, the power of the study was determined as 0.87 with 95% reliability, indicating an adequate sample size (Malone et al., 2016). Interobserver agreement was analyzed using intraclass correlation coefficients (ICC).

Results

The descriptive characteristics of the children in the intervention and control groups, such as age, weight, diabetes duration, and daily number of insulin injections, are summarized in Table 1. The overall mean age was 9.29 ± 1.49 years, the mean weight was 32.88 ± 6.37 kg, 80% of the children had diabetes for less than 3 years, and 94.4% received insulin 4 times a day. Statistical analyses indicated that descriptive characteristics were comparable in all three groups ($p > 0.05$; Table 1).

Mean pain scores before and after the insulin injection procedure are given in Table 2. Before the procedure, there were no statistically significant differences in mean self-, parent-, or researcher-reported pain scores among the intervention and control groups ($p > 0.05$). After the procedure, children in the ShotBlocker group had the lowest mean pain score (WBS self = 0.46 ± 0.83, parent = 0.47 ± 0.86, and researcher = 0.40 ± 0.81), followed by the manual pressure group and the control group. While the manual pressure and ShotBlocker groups showed no significant differences in mean pain scores, the control group had higher mean pain scores than the two intervention groups as rated by all three assessors, with a highly significant difference ($p = 0.001$; Table 2). There was very high agreement between the pain scores given by the children, parents, and researcher in the manual pressure, ShotBlocker, and control groups both before (ICC = 0.954, 0.955, and 0.943, respectively; $p = 0.0001$) and after (ICC = 0.966, 0.975, and 0.955, respectively; $p = 0.0001$) the insulin injection procedure.

Mean fear scores before and after insulin injection are shown in Table 3. As with pain scores, mean self-, parent-, and researcher-reported fear scores were comparable in all groups before the procedure ($p > 0.05$). After injection, the ShotBlocker group had the lowest mean fear score (CFS self = 0.23 ± 0.43, parent = 0.23 ± 0.43, and researcher = 0.30 ± 0.53), followed by the manual pressure and control groups. Again, mean fear scores from the three raters did not differ

Table 1
Comparisons of the children's descriptive characteristics by group ($n = 90$).

Characteristics	Group			Total
	Manual Pressure ($n = 30$)	ShotBlocker ($n = 30$)	Control ($n = 30$)	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Age (years)	9.30 ± 1.66	9.47 ± 1.41	9.10 ± 1.40	9.29 ± 1.49
	Kruskal-Wallis H test: h = 0.746, $p = 0.689$			
Weight (kg)	32.17 ± 7.83	33.97 ± 6.17	32.50 ± 4.82	32.88 ± 6.37
	Kruskal-Wallis H test: h = 1.64, $p = 0.44$			
Diabetes duration (years)	n %	n %	n %	N %
0–3	25 83.3	23 76.7	24 80	72 80
4–6	5 16.7	7 23.3	6 20	18 20
Total	30 100	30 100	30 100	30 100
	Chi-squared test: 0.417 $p = 0.812$			
Daily insulin injections	n %	n %	n %	N %
3	3 10	1 3.3	1 3.3	5 5.6
4	27 90	29 96.7	29 96.7	85 94.4
Total	30 100	30 100	30 100	30 100
	Chi-squared test: *$p = 0.429$			

Table 2
Comparison of pain scores before and after the insulin injection according to group (n = 90).

Evaluated by	Group			h*	p
	Manual Pressure[1] (n = 30)	ShotBlocker[2] (n = 30)	Control[3] (n = 30)		
	Mean ± SD	Mean ± SD	Mean ± SD		
	Before the procedure				
Child	0.33 ± 0.76	0.47 ± 0.86	0.40 ± 0.81	0.412	0.814
Parent	0.33 ± 0.76	0.47 ± 0.86	0.40 ± 0.81	0.412	0.814
Researcher	0.40 ± 0.97	0.53 ± 0.90	0.33 ± 0.76	1.13	0.568
	After the procedure				
Child	0.67 ± 0.96	0.46 ± 0.83	2.60 ± 1.50	34.298	0.0001[a]
Parent	0.65 ± 0.94	0.47 ± 0.86	2.67 ± 1.42	37.419	0.0001[a]
Researcher	0.73 ± 0.98	0.40 ± 0.81	2.53 ± 1.38	36.502	0.0001[a]

* Kruskal-Wallis H test.
[a] Bonferroni correction analysis showed that the control group was the group making the difference.

Table 3
Comparison of fear scores before and after the insulin injection according to groups (n = 90).

Evaluated by	Group			h*	p
	Manual Pressure[1] (n = 30)	ShotBlocker[2] (n = 30)	Control[3] (n = 30)		
	Mean ± SD	Mean ± SD	Mean ± SD		
	Before the procedure				
Child	1.33 ± 0.55	1.33 ± 0.71	1.20 ± 0.48	1.223	0.543
Parent	1.30 ± 0.60	1.33 ± 0.71	1.20 ± 0.48	0.874	0.646
Researcher	1.37 ± 0.72	1.47 ± 0.86	1.27 ± 0.58	1.035	0.596
	After the procedure				
Child	0.30 ± 0.47	0.23 ± 0.43	1.13 ± 0.01	21.271	0.0001[a]
Parent	0.27 ± 0.45	0.23 ± 0.43	1.17 ± 0.99	24.857	0.0001[a]
Researcher	0.33 ± 0.55	0.30 ± 0.53	1.17 ± 1.02	18.928	0.0001[a]

* Kruskal-Wallis H test.
[a] Bonferroni correction analysis showed that the control group was the group making the difference.

significantly between the manual pressure and ShotBlocker groups but were significantly higher in controls than in the two intervention groups ($p = 0.001$; Table 3). There was also excellent agreement between the fear ratings of the children, parents, and researcher in the manual pressure, ShotBlocker, and control groups before (ICC = 1.00, 0.966, and 0.959, respectively; $p = 0.0001$) and after (ICC = 0.917, 0.944, and 0.939, respectively; p = 0.0001) insulin injection.

Discussion

Fear and pain associated with insulin injection should be treated as an important issue in pediatric diabetes management, as they negatively impact glycemic control (Göthesson et al., 2023; Hanberger et al., 2021). In this study, manual pressure and the ShotBlocker were both effective in mitigating fear and pain associated with insulin injection in children with T1DM.

Pain was the primary outcome measure in this study. We observed lower pain scores in the intervention groups after injection (as evaluated by children, parent, and researcher) compared to the control group ($p = 0.001$), while scores were comparable in the two intervention groups ($p > 0.05$; Table 2). These findings support our primary hypothesis. The pain-relieving effects of both methods can be explained by the gate control theory, according to which interventions such as applying pressure to the skin with fingers or a tool like the ShotBlocker, rubbing, and massaging the painful area prevent the painful stimulus from reaching the central nervous system (Chung et al., 2002; Öztürk et al., 2017; Yılmaz & Alemdar, 2019). Thus, manual pressure and the ShotBlocker are believed to act by a similar analgesic mechanism, stimulating thinner, faster conducting nerves to close the gate and temporarily block pain signals.

There is evidence in the literature that manual pressure alleviates pain in intramuscular and vaccine injections in adults (Barnhill et al., 1996; Chung et al., 2002). In addition, studies conducted in different pediatric age groups showed that manual pressure was effective in reducing pain during intramuscular (Derya et al., 2015) and vaccine (Göl & Altuğ Özsoy, 2017) injections. However, there are no studies demonstrating the analgesic effect of manual pressure in children with T1DM who require regular subcutaneous insulin injections. Our findings in this study showed that manual pressure is a simple, practical, safe, free, and easily taught/learned method than can mitigate the pain of insulin injection in children. The ShotBlocker has been previously reported to reduce pain during intramuscular injections (Aykanat Girgin et al., 2020; Drago et al., 2009; Sivri & Balcı, 2019; Yılmaz & Alemdar, 2019), venous blood sampling (Sivri et al., 2022), and immunization (Çağlar et al., 2017). As in our study, Canbulat Şahiner et al. (2018) examined the impact of the ShotBlocker on pain levels in children aged 6–12 years with T1DM receiving insulin injections and found that this method effectively reduced pain.

The prevalence of fear related to invasive procedures in children with T1DM ranges from 9.5% to 32.7% (Heinrich & Callahan, 2016; Tremolada et al., 2021). Fear was reported to be another important factor in pain perception, with feelings of fear and anxiety said to open the gate and lead to greater pain (Sparks, 2001). Subsequent studies have also pointed to a positive relationship between fear and pain levels (Twycross, 2009; Young, 2005). Therefore, we also assessed injection-related fear in this study as a secondary outcome. Our results showed that fear scores (evaluated by child, parent, researcher) after insulin injection were lower in the manual pressure and ShotBlocker groups compared to the control group ($p = 0.001$), while the intervention groups had comparable scores ($p > 0.05$; Table 3). This indicates that both interventions effectively reduced fear associated with insulin injection. Therefore, our second hypothesis was also supported. The ShotBlocker was previously reported to reduce fear scores during intramuscular injections (Aykanat Girgin et al., 2020; Yılmaz & Alemdar, 2019) and venous blood collection (Sivri et al., 2022). In addition, Canbulat Şahiner et al. (2018) observed the ShotBlocker was effective in reducing anxiety in children receiving insulin injections. Although the literature indicates that applying the ShotBlocker reduces fear during various painful procedures, studies on the use of manual pressure in pediatric age groups did not evaluate the effect of this intervention on fear (Derya et al., 2015; Göl & Altuğ Özsoy, 2017). Our study demonstrated that manual pressure to the injection site can also alleviate fear in children with T1DM who require regular subcutaneous insulin injections.

Considering that the pain and fear children with T1DM have in relation to insulin injections can lead to avoidance, skipping doses (Cemeroğlu et al., 2015; Hanberger et al., 2021; Sparapani et al., 2015), and a negative impact on diabetes self-management (Cemeroğlu et al.,

2015; Göthesson et al., 2023; Hanberger et al., 2021), the current research findings are important in terms of reducing levels of insulin injection-related pain and fear to potentially prevent long-term complications. These two methods can be easily used with children receiving multiple daily insulin injections to maintain glycemic control. We believe that manual pressure is an especially useful option for this purpose because it is a simple technique that can be applied by the child in any setting and is cost-free.

Practice implications

Manual pressure and the ShotBlocker both reduced procedural fear and pain in children with T1DM during insulin injection. Further studies should evaluate the effectiveness of these methods in younger children and different cultural groups. As older children with T1DM also self-administer insulin, future studies may also investigate the effects of children's use of manual pressure and ShotBlocker during insulin self-administration.

Limitations

An important limitation of this study is that it was not double-blind, so the study team knew the group assignments of the children. However, the participating children, parents, and a member of the study team independently rated the children's fear and pain, which should mitigate researcher bias. Another potential limitation of this trial is the use of self-report instruments. However, the scales used in the study have been shown to be valid and reliable and are frequently utilized in pain studies. The high agreement between self-reported and parent- and researcher-reported scores in both scales also points to the reliability of our results.

Conclusions

Our findings indicate that both manual pressure and the ShotBlocker were effective in relieving the fear and pain associated with insulin injection in children with T1DM. Both of these methods can be used to reduce children's fear and pain related to insulin injections.

Ethical statement

The study was approved by the ethics committee of a State University in Turkey (27.03.2019, 2019/97).

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Contributions

Design: BAG, İG, DG, HK.
Data Collection: BAG, İG, FÇ, HK.
Data Analysis: BAG, İG, DG, FÇ, HK.
Manuscript writing: BAG, İG, DG, HK, FÇ.

CRediT authorship contribution statement

Burcu Aykanat Girgin: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Visualization, Supervision. **İlknur Göl:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Visualization, Supervision. **Duygu Gözen:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Visualization, Supervision. **Fatma Çarikçi:** Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Visualization, Supervision. **Heves Kirmizibekmez:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Visualization, Supervision.

Declaration of Competing Interest

The authors declare no conflicts of interest.

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