The Effect of Cannula Material on The Pain of Peripheral Intravenous Cannulation in the Emergency Department: A Prospective, Randomized Controlled Study

Acil Servisteki Periferik İntravenöz Kanül Uygulamalarında, Kullanılan Kanül Materyalinin Girişim Ağrısı Üzerine Etkisi: Prospektif, Randomize Kontrollü Çalışma

Murat ÖZSARAÇ,[1] Meral DOLEK,[2] Münevver SARSILMAZ,[1] Mustafa SEVER,[3] Serkan SENER,[4] Selahattin KİYAN,[1] Aslihan YÜRÜKTÜMEN,[5] Gülbin YILMAZ[1]

[1]Department of Emergency Medicine, Ege University Medical Faculty Hospital, İzmir;
[2]Department of Emergency Medicine, Medical Park Izmir University Medical School Hospital, İzmir;
[3]Izmir Tepecik Training and Research Hospital, Emergency Service, İzmir,
[4]Department of Emergency Medicine, Acibadem University School of Medicine Hospital, İstanbul;
[5]Department of Emergency Medicine, Akdeniz University Faculty of Medicine, Antalya, all in Turkey

SUMMARY

Objectives

The present study was undertaken to compare the pain of peripheral IV cannulation (IVC) using a 20-G peripheral biomaterial PEU-Vialon cannula or the 20-G compound FEP-Teflon cannula widely used in clinical practice.

Methods

A prospective, randomized, single-blinded, controlled trial was undertaken at the ED of University Hospital. Eighty-nine noncritically ill adult patients who were receiving an IV line as part of their care were enrolled. In each case cannulas were applicated to the antecubital area. Participants rated their pain on a visual analog scale (VAS). The primary outcome was patients pain score, and the secondary outcome was the provider's perception of safety and satisfaction.

Results

The two treatment groups did not differ in age, gender or cannulation indication (p>0.05). Mean VAS was 2.80 for PEU and 3.56 for FEP (p=0.061). Mean provider safety scores were 4.84 (4 to 5) in the PEU group and 4.00 (2 to 5) in the FEP group (p=0.0001). Mean provider satisfaction of application scores were 4.65 in the PEU group and 4.56 in the FEP group (p>0.05).

Conclusions

Althogh provider safety perception is high, perception of pain has not reduced when inserting PEU-Vialon cannula compared with compound of FEP.

Key words: Analgesia; cannulation; emergency medicine; pain; pain measurement.

ÖZET

Amaç

Bu çalışma, klinik pratikte yaygın olarak kullanılan, 20-G periferik FEP-Teflon kanül ile 20-G PEU-biyomateryal Vialon kanülün, periferik IV yoldan uygulanması esnasında, hastalarda gelişen ağrıyı karşılaştırmak amacıyla yapıldı.

Gereç ve Yöntem

Çalışma bir üniversite hastanesi acil servisinde prospektif, randomize, tek kör ve kontrollü olarak yapıldı. Acile kritik olmayan şikayetler ile başvuran, genel tıbbi bakımlarının bir parçası olarak IV yoldan damar yolu açılacak, seksen dokuz erişkin hasta çalışmaya alındı. Tüm IV damar yolu açılması uygulamaları antekübital alan üzerinden yapıldı. Çalışmaya katılanların işlem esnasındaki ağrıları görsel analog skala (VAS) ile değerlendirildi.

Bulgular

İki tedavi grubunda yaş, cinsiyet veya kanülasyon göstergesi farklı değildi (p>0.05). Hastaların ortalama VAS skoru PEU kateter uygulananlar için 2.80, FEP kateter uygulananlar için 3.56 idi (p=0.061). Uygulayıcıların ortalama güvenlik algısı puanları PEU kateter uygulamaları için (4-5) 4.84, FEP kateter uygulamaları için (2-5) 4.00 olarak tespit edildi (p=0.001). Uygulayıcıların ortalama memnuniyet puanlarının; PEU kateter uygulamaları için 4.65 ve FEP için 4.56 olduğu belirlendi (p>0.05).

Sonuç

İntravenöz yoldan kateter uygulamalarında, PEU-Vialon kateterlerin, FEP-Teflon içerikli kateterler ile karşılaştırıldığında, hastalarda ağrı skorunu azaltmadığı ancak, mevcut güvenlik sağlayıcı kapaklarından dolayı, uygulayıcılarda yüksek işlem güvenliği algısı oluşturduğu belirlendi.

***Anahtar sözcükler**: Analjezi; kanülasyon; acil tıp; ağrı; ağrı ölçümü.*

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Correspondence *(İletişim):* Dr. Murat Özsaraç. Ege Üniversitesi Tıp Fakültesi Hastanesi, Acil Tıp Anabilim Dalı, Bornova, 35100 İzmir, Turkey
e-mail *(e-posta):* mozsarac@msn.com

Introduction

Insertion of Intravenous Cannulas is probably the most commonly performed invasive medical procedure in emergency department (ED). A number of strategies to minimize the pain of intravenous cannulation (IVC) for patients include; local buffered lidocaine of skin infiltration, application of topical lidocaine,[1] liposomal lidocaine,[2] prilocaine, tetracain,[3-5] diclofenac patch,[6] ibuprofen, piroxicam,[7] myolaxin[8] and ice.[9] Examples of the latter alternatives include alkane vapocoolant spray[10,11] inhaled nitrous oxide,[12,13] jet injector lidocaine,[14,15] laser-assisted anesthesia,[16,17] low-frequency ultrasound[18] and distraction tactics as valsalva[19] and cough trick,[20] with variable results. Each technique has advantages as well as limitations, especially in the ED setting. Although pain and anxiety can be reduced by pretreating with local anesthetics, it is unclear which pretreatment technique is most effective. Application of anesthetic cream is one of the most popular technique for reducing pain during IV insertion, but the utility of these creams in a busy clinical setting such as the ED is limited by their delayed onset of action.[1] As a result, clinicians have continued to seek ways to reduce the pain of IVC.[16]

The effect of the type of cannula material on the the pain of IVC has been less widely studied. Although most peripheral IVC's are made of tetrafluoroethylene-hexafluoropropylene (FEP-Teflon), catheters made of polyurethanes (PEU-Vialon) are also available (Fig. 1). A catheteter material, polyetherurethane is based on polytetramethylene ether glycol, 4.4'-diphenylmethane diiosocyanate, and 1.4-butanediol. It has a smoother microsurface, thermoplastic and more hydrophilic, makes it much more flexible than teflon at body temperature[21] (Fig. 2). The aim of this study was to compare the pain of IVC with FEP-Teflon and PEU-Vialon.

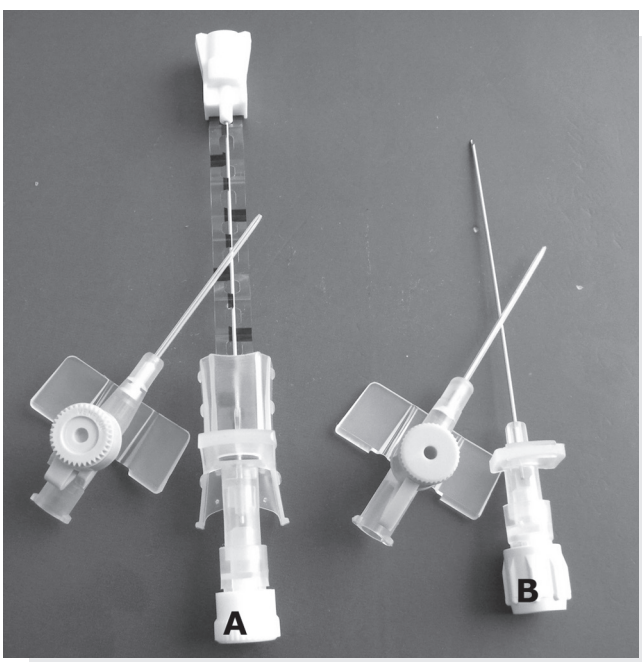


Figure 1. A. Polyurethane vialon catheter **B.** Teflon catheter.

Materials and Methods

Setting and Selection of Participants

The study was conducted at a university ED which has emergency medicine residency program with an annual patient census of approximately 100.000. This was a prospective, randomized, controlled and single-blinded study designed to compare the pain of peripheral IVC between 20-G peripheral autoguard shielded PEU-Vialon (BD-Venflon, Becton-Dickinson, UK) and 20-G compound of FEP-Teflon cannula (Bicakcilar, Turkey) widely used in clinical practice in many ED. Patients were enrolled in January 2010 to December 2010 within weekdays and working hours. Historical and demographic information were recorded on a standardized data collection form. Eligible patients were 18 to 60 years requiring acute peripheral IVC as a component of their evaluation and treatment. Participants Canadian Emergency Department Triage and Acuity Scale (CTAS) were 4.5. Patients with any type of pain and the ones that take analgesics within 24 hours were excluded from the study. Patients were also excluded if the vein has been recently used for an infusion, with abnormal skin conditions (broken skin, infection, scar, eczema or urticaria) at the site of venous puncture, chronic renal or liver disease, malignancy, stroke, mental disorder and refusal to participate the study. The study was approved by the institutional review board. Informed consent was obtained from all volunteers prior to enrollment.

We enrolled a convenience sample comprising patients who met the inclusion criteria during periods while the investigators were present in the ED (mainly 9 am to 5 pm on weekdays). Patients were assessed and managed according to

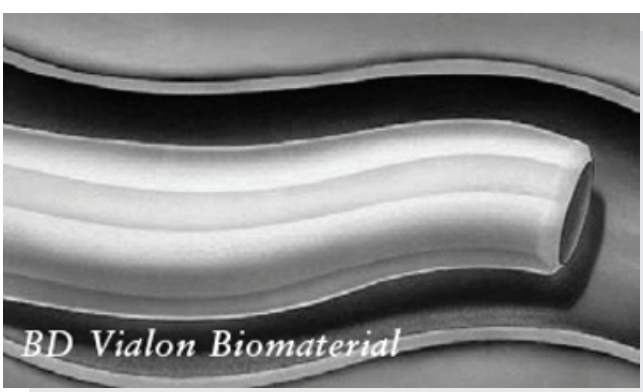
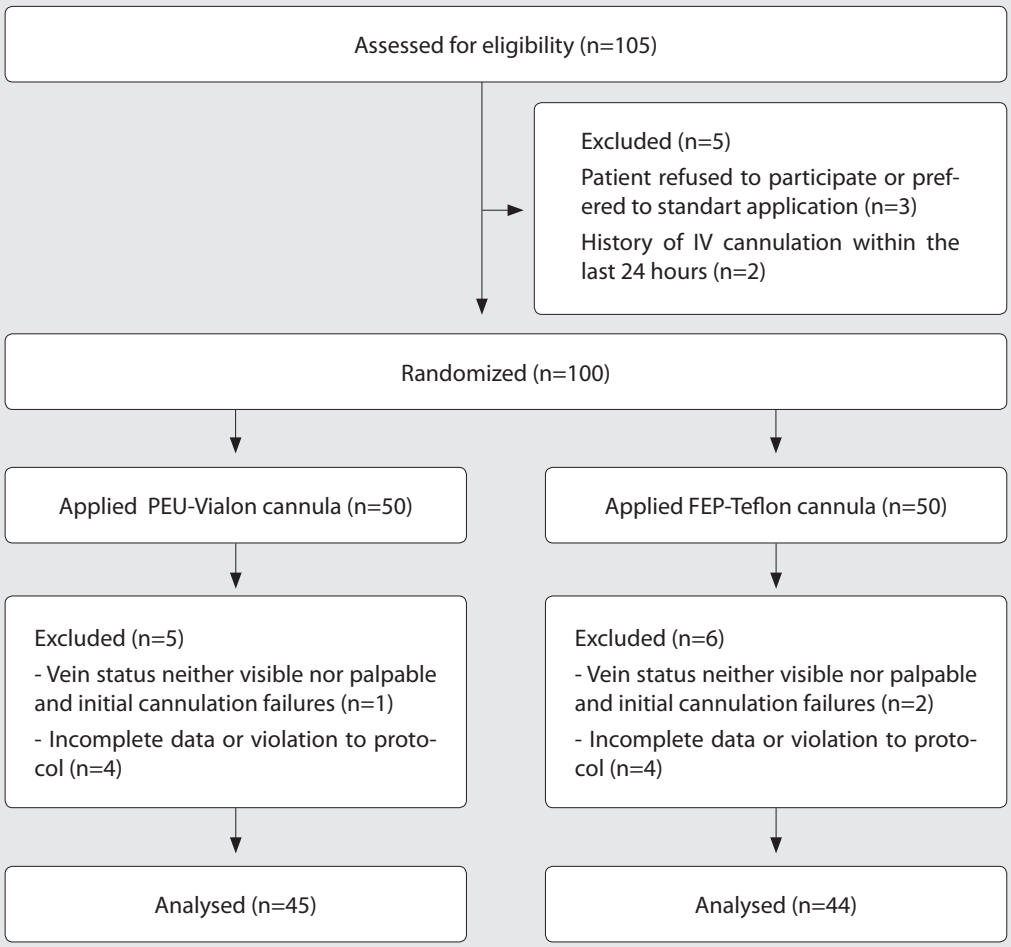


Figure 2. Flexible thermoplastic PEU-Vialon peripheral intravenous catheters.

Table 1. Flow of patients through the trial



standard practice. After informing the patients and obtaining the written informed consents, series of opaque, consecutively numbered envelopes were opened to reveal the type of canulla to be applicated to the subjects. Participating patients were randomly assigned to apply PEU or FEP. Group assignment was determined by computer generated codes, thus ensuring an equal distribution of participants. Patients were randomized by an independent pharmacy assistant. Patients were unaware of the differences between cannula. Providers had no varying prominent experience in IVC. All cannula were inserted by four independent ED nurses with similar experience in the means of working years. Vein status was evaluated as veins neither visible nor palpable, veins visible but not palpable and veins clearly visible and easily palpable. Assessments and applications were made by the provider nurses. The providers choose the IVC site, applied a tourniquet, prepared the site with isopropyl alcohol, and inserted the cannula. All peripheral cannula were inserted using strict aseptic technique and secured using a sterile transparent dressing. For this study, insertion of the cannula was limited to the antecubital fossa. In each case cannula were sited on antecubital area of approximately 10-12 cm^2, at cephalic vein, median cephalic vein or accessory cephalic vein in the forearm. We measured the time from the start of searching for an appropriate vein (after the tourniquet was applied) to successful insertion of the cannula. Successful insertion was defined as free flow of blood out of the inserted IV catheter. Likewise, we recorded the number of failed first attempts. Following venous cannulation, patients were asked whether they experienced pain. Another nurse or staff who was also blinded to group allocation, collected data and recorded perception of the pain scores as rated by patients on a visual analogue scale (VAS) 0-100 mm (0=no pain, 100=most painful). Patients whose veins could not be cannulated successfully on the first attempt were considered as initial cannulation failures and withdrawn from the study analysis. Besides the subjects vein status neither visible nor palpable were also excluded from the study analysis. After each IVC attempt, providers assessed their level of perceptions in the means of safety and satisfaction on a five-point Likert scale.

Primary outcomes were participants' ratings of the pain of IVC by PEU or FEP groups. This was the pain measured immediately after cannulation using a validated visual analog pain scale marked "most pain" at the high end.[22] Secondary outcomes were the time for successful insertion and perceptions of the providers' safety and satisfaction. The providers reported Likert scales on satisfaction (range, 1-5: 1=very dissatisfied and 5=very satisfied). Finally, they rated their overall perceptions of safety for the cannula they use on a five-point Likert scale from "not at all" to "very much". All collected data were analyzed to reduce bias against participants who partially completed the study.

Statistical Analysis

Continuous data (the severity of pain, perception of provider's safety and satisfaction) were summarized as means and 95% confidence intervals (95% CIs) and compared with Student t-test. Discrete variables (gender, vein status, clinical properties) were compared by chi-square statistics. SPSS 14.0 (SPSS Inc, Chicago, IL, U.S.A.) was used for statistical analysis. $p<0.05$ was considered as significant.

Results

A total of 105 patients were enrolled over a 12 month period. Totally 16 subjects were excluded from the study (Table 1). Mean age was 33.38±11.4 years (range of 18-59); 32 subjects (36%) were man. Groups were similar with respect to demographic and clinical characteristics (Table 2). There were no statistically significant differences in these variables between the treatment groups. The mean duration of the vascular access procedure for each treatment group was approximately 5 to 10 seconds. There was no statistically significant difference in mean procedure duration between PEU and FEP groups (p=0.685). Most IVC (97%) were successful at the first attempt. Pain scores: The mean pain score of catheter insertion on FEP group was 3.56 mm (±2.02 mm); the mean pain score for the PEU group was 2.80 mm (±1.79 mm). The difference between the mean pain scores did not reach to statistical significance when compared by using the t-test (p=.061) Satisfaction and Safety: There was no difference in the perception of providers' satisfaction between the FEP and PEU groups. However, there were remarkable difference in the perception of providers' safety between the groups (p=.000) (Table 3).

Discussion

IVC is a common procedure in the ED and it is also an uncomfortable experience for many patients.[11] Although guidelines call for multimodal management strategies for needlestick pain, compliance with recommendations is often poor in practice[23] Less than half of the medical doctors use local anesthetic for insertion of large bore intravenous cannula.

Table 2. Baseline characteristics of patients participating in the trial

Characteristic	PEU (n=45)	FEP (n=44)	p
Demographic			
Age, mean (SD), yr	33.4 (11.6)	33.2 (11.5)	0.44
Male, no. (%)	15 (37.8)	17 (34.1)	0.82
Clinical			0.08
Benign positional vertigo	15	14	
Urticaria	11	13	
Acute enteritis	13	17	
Fever	6	–	
Provider's assessment of the vein			0.52
Veins clearly visible and easily palpable	41	38	
Veins visible but not palpable	4	6	

Table 3. Comparison of Material of Intravenous Insertion

	PEU	FEP	p	t
Pain score (mean)	2.80	3.56	0.061	1.895
Perception of provider's satisfaction (mean)	4.64	4.56	0.573	-0.566
Perception of provider's safety (mean)	4.84	4.00	0.000*	-6.332

Furthermore, less than 20% of all doctors used any local anesthetic for the most commonly used cannula (20 Gauge).[24] Some reasons for caregivers overlooking a patient's pain include the subjective nature of pain and the potential for caregivers to minimize the effect, or diminish the seriousness or psychological impact, of a patient's pain.[25] Barriers to implementation of the guidelines are manifold and include a lack of knowledge among health care professionals regarding available pain assessment, as well as perceived time constraints and inconvenience for administering local anesthetics.[26] As a result, most ED patients have venous cannulation performed without any pretreatment with an anesthetic agent or device. Emergency practitioners should strive to reduce pain safely and effectively in all of their patients.[27] The ideal method for local anesthesia before IVC in the ED should be effective, fast, portable, require little training, cause no significant deviation from the usual routine, have no additional biologic or physical risks to the patient or the health care provider, and should eliminate sharps disposal and handling precautions. No commercially available modality has been shown to be as effective or faster.[14] This is the first study to assess the effect of canulla on the degree of pain experienced on IV insertion. We found PEU-Vialon cannula did not significantly reduce patients' perception of pain when compared with compound of FEP. Nociceptors are sensory end organs in the skin, muscle, joints and viscera that selectively respond to noxious or potentially tissue-damaging stimuli. An important property of nociceptors is that they sensitize. Sensitization, which typically develops as a consequence of tissue insult and inflammation, is defined as a reduction in the threshold and an increase in the magnitude of a response to noxious stimulation.[28] Future investigation could aid in elucidating the role of the produce by means of nanotechnology products of related to cannula effect on mechanical tissue inflammation. Pain perception might influenced by anxiety, underlying conditions, culture and many other factors. However, strengths of this study are the use of blinding and enrolling only patients presenting with similar symptoms other than pain. More severe complaints might be more attentive to the pain of an IV insertion. Different locations in the body are more sensitive to pain than others. Clinical pain has an emotional component not present in experimental pain.[29] Another strength of this study is the IVC applied to the same location of all patients.

Health care is one of the areas scarcely subjected to research on work-related injuries in developing countries, especially in Turkey. These injuries commonly are overlooked and neglected by health care workers in the developing countries. Needlestick injuries and sharps injuries are the most common work-related injuries in EDs, where health care is incessant for 24 hours a day, 7 days a week. %14 of all work related injuries secondary to IV catheter applications.[30] Commercially available intravenous catheters such as PEU-Violan with self-capping needles have been associated with a significant reduction in the absolute number of inadvertent needlestick injuries. Related data could not be obtained in our country. In the era of human immunodeficiency virus (HIV) and hepatitis, safety of those placing IV lines cannot be overemphasized. Universal precautions must be applied to all patients, especially in emergency care settings in which the risk of blood exposure is increased and the infection status of patients is largely unknown. The protective IV catheter safety system has a protective sleeve that encases the sharp stylet as it is retracted from the catheter.[31] An PEU-Vialon catheters used in this study, needle shield once activated, the needle tip is fully encapsulated inside the protection mechanism, which is designed to minimize the risk of injuries. This study have shown that, perceive of safety during IV insertion by protective IV catheter system.

There are a couple of limitations that need to be acknowledged and addressed regarding the present study. First this study was not placebo controlled and independent providers were not blinded as to which cannula applied. Thereby any systematic bias could not be eliminated. Severity of anxiety of participant were also not recorded. The patient severity and status were all subacute and mild; CTAS 4 or 5, however, more severely anxious participant might be more reactive of an IVC. The relatively small sample size (105 patients) and relatively small number of hours analyzed (workhours between 08:00-17:00) could limit generalizability. Study population was composed of the subjects admitted in the emergency department within working hours and weekdays which may also cause bias.

Conclusions

Althogh provider safety perception is high, perception of pain has not reduced when inserting PEU-Vialon cannula compared with compound of FEP.

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