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Original Article

Randomized clinical trial to assess pain and bruising in medicines administered by means of subcutaneous and intramuscular needle injection: Is it necessary to have needles changed?

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This clinical trial aimed at comparing the intensity of pain and bruising by subcutaneous and intramuscular injections using and retractable fixed syringes and needles and syringes with no needles combined, at a public hospital in Sao Paulo, for six months. We evaluated the perception of pain in case of intramuscular (n=1000) and subcutaneous injections (n=240). In subcutaneous application, bruise formation was also verified. Pain and bruising scores were higher in the group with no needles combined ($p<0.001$) and ($p<0.029$), respectively. The test power in relation to the pain scale of was 0.98. The use of retractable fixed needles is recommended in the application of subcutaneous and intramuscular injections. Clinical trial registration number: NCT01271608.

Descriptors: Pain; Hematoma; Needlestick Injuries; Injections Intramuscular; Injections Subcutaneous; Injections Intradermal; Accident Prevention; Protective Devices.

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Ensaio clínico randomizado para avaliação de dor e hematoma em administração de medicamentos por via subcutânea e intramuscular: há necessidade de troca de agulhas?

Este ensaio clínico teve como objetivo comparar a intensidade da dor e hematoma consequentes a injeções por via subcutânea e intramuscular, utilizando seringas e agulhas fixas retráteis e seringas com agulhas não conjugadas, em hospital público na cidade de São Paulo, durante seis meses. Foi avaliada a percepção da dor na injeção intramuscular (n=1.000) e na subcutânea (n=240). Na aplicação por via subcutânea, verificou-se também a formação de hematoma. A pontuação de dor e hematoma foi maior no grupo com agulhas não conjugadas (p<0,001 e p<0,029, respectivamente). O poder do teste em relação à escala de dor foi de 0,98. Recomenda-se o uso de agulha fixa retrátil na aplicação de injeções intramusculares e subcutâneas. Registro de ensaio clínico nº NCT01271608.

Descritores: Dor; Hematoma; Acidentes Perfurocortantes; Injeções Intramusculares; Injeções Subcutâneas; Injeções Intradérmicas; Prevenção de Acidentes; Dispositivos de Segurança.

Ensayo clínico aleatorio para evaluación del dolor y hematoma durante la administración de medicamentos por vía subcutánea e intramuscular: ¿Es necesario cambiar las agujas?

Este ensayo clínico tuvo como objetivo comparar la intensidad del dolor y hematoma de inyecciones por vía subcutánea e intramuscular utilizando jeringas y agujas fijas retráctiles y jeringas con agujas no conjugadas, en un hospital público en la ciudad de Sao Paulo, durante seis meses. Fue evaluada la percepción del dolor de la inyección intramuscular (n=1000) y la subcutánea (n=240). En la aplicación por vía subcutánea se verificó también la formación de hematoma. La puntuación del dolor y hematoma fue mayor en el Grupo con agujas no conjugadas (p<0,001) y (p<0,029), respectivamente. El poder de la prueba en relación a la escala de dolor fue de 0,98. Se recomienda el uso de aguja fija retráctil en la aplicación de inyecciones intramusculares y subcutáneas. Registro de ensayo clínico nº NCT01271608.

Descriptores: Dolor; Hematoma; Accidentes Perforo-Cortantes; Inyecciones Intramusculares; Inyecciones Subcutáneas; Inyecciones Intradérmicas; Prevención de Accidentes; Dispositivos de Seguridad.

Introduction

The World Health Organization (WHO) recommends the use of safety devices for intramuscular, subcutaneous and intradermal medication administration. These devices avoid equipment reuse and health professionals' contact with piercing and cutting material like needles, which increase the risk of biological accidents[1].

Between two and three million percutaneous accidents involving needles contaminated with biological material occur every year[2-3]. A North American study showed that health professionals are exposed to between 385,000 and 800,000 piercing and cutting accidents per year, involving risks of transmitting blood-borne pathogens like hepatitis B, C and HIV, among others[4]. The impact of these accidents includes emotional damage, decreased productivity at work and financial impacts for the health system[5]. Between 1995 and 2003, the National Surveillance System for Health Care Workers (NaSH) demonstrated that 26% of piercing and cutting accidents are associated with needle manipulation in patients (2,662/10,239) and 5% with needle recapping

(512/10,239). Six devices are responsible for 80% of injuries, 56% involving hollow needles and 30% hypodermal needles (5,612/18,708). Sixty-four percent of piercing and cutting accidents could be avoided. The Centers for Disease Control and Prevention (CDC) recommends that institutions establish a program to enhance a safety culture that includes the assessment of new safety devices for health professionals[6].

A systematic review on the occurrence of occupational infection by HIV in health workers in Brazil showed that the four identified cases involved nursing professionals and that contamination was due to percutaneous exposure[7].

A study on accidents involving piercing and cutting material among nursing workers, between 1985 and 2000, which analyzed 39 international and 16 Brazilian studies, appointed that the main factors associated with piercing and cutting accidents were needle handling and recapping[8].

A study conducted at a tertiary hospital between July 2003 and July 2004, involving 200 cases and 200 controls, which assessed the factors associated with percutaneous accidents in the nursing team, showed that one of the predictors was needle recapping (OR 9.48; CI 95%)[9].

In São Paulo State, Brazil, the Biological Accident Notification System (SINABIO) was created as from 1999. Out of 14,096 accidents notified until 2006 in approximately 20% of cities in the State, it was evidenced that 85.5% were percutaneous, 57.7% involved nursing professionals and 4.2% were due to needle recapping[10].

In Brazil, in 2005, Ministry of Health Decree 485 was approved, which sets standards for occupational safety and health in health establishments – NR-32[11]. This Decree established a deadline to implant safety devices for all piercing and cutting material[12]. Implanting safety devices demands tests to assess their efficacy and adequacy to their goals. Engineering of these devices should permit easy handling, passive activation and minimal changes in the usage technique[1-2,4,6].

In Brazil, intramuscular, intradermal and subcutaneous drug administration is performed, involving the exchange of the needle through which the substance is aspirated to apply the drug. These recommendations are mentioned in different technical books and are based on established practices, but are not accompanied by scientific evidence[13-15]. Most drug administration manuals do not address the need to change needles in order to apply injections[16-17].

In a literature review carried out LILACS and Medline, Pubmed and a dissertation and thesis bank, using the descriptors: "pain", "hematoma" "exchange", "intradermal injections", "subcutaneous injections", "intramuscular injections" combined with "methods", "adverse events", "prevention" and "control", studies on the theme were identified.

One study recommends changing needles after aspiring the drug to guarantee cleanliness, needle cutting, adequate caliber and length, thus avoiding pain and contact between the drug and subcutaneous tissue[18].

Other studies also recommend changing needles for injection application as good practice. These recommendations propose that, in certain situations, one should clean the needles with sterile gauze or transfer the drug to another sterile syringe before its administration[19-20]. Nevertheless, risks of contaminating the drug and equipment and accidents involving piercing and cutting material should be taken into account.

The Brazilian Diabetes Society recommends insulin preparation and application using needles combined with syringes. When administering two types of insulin, the use of needles not combined with syringes is recommended, so as to guarantee the aspiration of the correct dose[21]. The CDC does not recommend changing needles when applying vaccines[22].

Three studies cited below assessed pain or bruising, comparing the drug administration technique with or without needle changing.

The study that compared insulin administration with and without needle changing demonstrated that the diameter of the bruise did not decrease when changing needles ($p=0.87$)[23].

The trial that involved patients (n=70) who received intramuscular viscous drugs through two techniques, with and without needle changing, demonstrated results without differences in pain intensity levels measured on the numerical scale in both groups ($p<0.05$)[24].

The randomized trial that compared two groups of pediatric patients between six months and six years of age who were receiving the same volume of a double vaccination (tetanus-diphtheria) from the same laboratory through the intramuscular route was conducted during eight weeks. The same technique was used for the application, with or without needle change. In that study, 423 patients participated and 346 forms were returned (81.8%). No statistically significant differences were found in bruising levels, hardening of the site or edema in the two compared groups. Likewise, no statistically significant difference was observed in systemic effects either, including fever, vomiting, appetite loss and crying[25].

Needle changing for injection administration is a widespread practice among health professionals, without any scientific foundations. Today, syringes with retractable fixed needles are available to protect health professionals. In view of industrial and technological advances in health equipment manufacturing, research is needed on whether needle changing effectively prevents pain and bruising in case of intramuscular or subcutaneous injection administration.

Aims

To compare pain intensity using the numerical scale (0 to 10), in case of intramuscular injection and subcutaneous injection, applying retractable fixed needle syringes and the technique with needle switching;

To compare bruising after subcutaneous insulin administration, using retractable fixed needle syringes and the technique with needle switching.

Method

This randomized clinical trial was accomplished at two medical-surgical units – one medical-surgical hospitalization Unit and one Emergency Care Unit of a hospital in São Paulo City, between June 15th and November 30th 2009, after obtaining approval from the Institutional Review Board (CAAE - 0203.0.028.000-08).

The population comprised patients who were sequentially included in the study through a draft system, in which random figures in sealed and dark envelopes were used.

Sample design and size

Subcutaneous injection: the sample size was based on the expected proportion of bruising after the injection. It was expected that 40% of patients would present bruises as a result of the conventional technique and 20% when using the technique under analysis for subcutaneous applications. Setting a 5% alpha error (p=0.05) and 80% study power (20% or 0.2 beta error), 240 patients were included, 120 in each group.

Intramuscular injection: the sample size was based on the proportion of patients with moderate to intense pain. The habitual incidence level of moderate to intense pain was considered at 30% in case of needle switching, as well as an increase of up to 40% when using the retractable fixed needle syringe. Five hundred patients were included in each group.

The sample for intramuscular injection comprised 1,000 patients, 500 for each technique, and that for subcutaneous injection 240 patients, 120 for each technique.

Patients over 18 years old who agreed to participate in the study were included at one single time for the subcutaneous and intramuscular injections. The monitoring took place after reading, verifying the understanding and signing the Free and Informed Consent Term. Patients using anticoagulants or with coagulation disorders, lesions or cutaneous alterations were excluded. In the intervention group, the technique with retractable fixed needles was used to administer intramuscular and subcutaneous injections. In the control group, the conventional medication administration technique was used.

The nursing teams at both medical-surgical units were submitted to a seven-day training program on the intramuscular and subcutaneous injection application technique using retractable fixed needle syringes and the conventional technique. A nurse was exclusively hired for this function. An assessment form and the adapted numerical scale for pain assessment were used as data collection instruments[26]. On the assessment form, all study variables of interest (initials, gender, age, baseline disease, hospitalization date, medication use, body mass index, bruise size, application site, drug name and administered volume) were registered. For those patients who received the subcutaneous injections, the bruise size in millimeters was included, when present. The body mass index was verified through the following formula: weight in kilos /(height in meters)[2].

After the patient's consent, the assessment form was completed, taken from a sealed envelope, which the professional opened, after which (s)he applied the intramuscular or subcutaneous injection, using the conventional technique or retractable fixed syringe, according to the randomization. After the injection application, the patient was shown a numerical scale ranging from 0 to 10 in order to score the pain the injection application had caused. In the subcutaneous injection group, after 24 hours, the nurse measured bruise size with a millimeter ruler. Patients were included in the study until completing the necessary sample size.

Syringes and needles used

Conventional technique: for the intramuscular injection, a 5-milliliter syringe was used. After aspiring the drug with an 18G x 1.5" (40 x 1.2 mm) needle, it was disconnected from the syringe, after which a 22G x 1¼" (30 x 0.7 mm) needle was connected for the application. For the subcutaneous injection, a 1-milliliter syringe was used with 100 UI, connected with a fixed 26G x 0.5" (13 x 0.45 mm) needle.

Retractable needle technique: for the intramuscular injection, a 5-milliliter syringe was used with a retractable fixed 22G x 1½" (0.7 mm x 38 mm) needle. For the subcutaneous injection, a 1-milliliter syringe was used with 100 UI, connected with a retractable fixed 27G x ½" (0.4 x 12.7 mm) needle.

Injection application technique

Subcutaneous injection: the administered drug was insulin, according to the units prescribed to the patient. The application site was determined using an instrument to assess the body area turnover used for insulin application to patients, included in their files.

After determining the application site and performing skin antisepsis, the cutaneous fold was fixed with the non-dominant hand and the needle was introduced at a 90º angle. Without aspiration, the insulin was injected. In the conventional technique, the needle was rapidly withdrawn and the application site was slightly compressed with a swab without massaging. In the retractable needle technique, the same procedure was performed but, at the end of the application and full compression of the vial, the retractable device introduced the needle inside the body of the syringe before its removal from the subcutaneous tissue.

Intramuscular injection: the injected drugs were prescribed for the patient's treatment. The volume ranged from 1 to 4 ml. Intramuscular injections applied in the dorsal-gluteal region were assessed, as that was the body region professionals who administered medication at the Emergency Care commonly used at the institution for this type of procedure.

The gluteal region was divided in four parts and the injection was applied in the external upper quadrant. After skin antisepsis, the needle was introduced at a 90º angle. After applying the injection and removing the needle, the application site was slightly massaged. In the retractable needle technique, the same technique was performed but, at the end of the application and full compression of the vial, the retractable device introduced the needle inside the body of the syringe before it was removed from the dorsal-gluteal region.

At the medical-surgical hospitalization Unit, patients who received subcutaneous insulin were assessed. Control group patients received insulin through the conventional technique. The insulin application site was defined according to each patient's application turnover and was outlined with a specific pen for skin marking after the application. Patients were assessed 24 hours later to detect the presence of bruising at the application site.

At the Emergency Care Unit, patients who received intramuscular drugs were assessed. All drugs were applied in the patients' dorsal-gluteal region at a private room. The dorsal-gluteal region used for applying the intramuscular injections, as that was the body area standardized for this type of procedure at the institution's Emergency Care Unit.

The collected data were processed and launched in an electronic Excel® worksheet. Student's t-test was used to analyze the variables, with significance set at 5%. Thus, it was considered that differences existed between groups if $p < 0.05$.

Results

Table 1 shows the active ingredients and the volume of drugs used in intramuscular injections, applied with the conventional technique and retractable fixed needles.

Table 1 - Drugs (active ingredient) and volume applied in intramuscular injections, using the conventional and retractable fixed needle technique (n=1000)

Drug (active ingredient)*	Volume (ml)	Technique		Total
		Conventional (n=500)	Retractable fixed needle (n=500)	
Diclofenac	3	172	162	334
Tiocolchicosido	2	66	51	117
Ketoprofen	2	59	82	141
Sodium dipyrone, promethazine, adiphenine	2	46	49	95
Tenoxicam	2	36	42	78
Sodium dipyrone	2	29	18	47
Dexamethasone	2	20	16	36
Thiamin	1	15	28	43
Dimenhydrinate, pyridoxine	1	12	4	16
Promethazine	2	11	8	19
Diazepam	2	10	10	20
Ceftriaxone†	4	6	8	14

(continue...)

Table 1 - (continuation)

Drug (active ingredient)*	Volume (ml)	Technique		Total
		Conventional (n=500)	Retractable fixed needle (n=500)	
Tramadol	1	6	9	15
Betamethasone	2	4	4	8
Haloperidol	1	4	6	10
Metoclopramide	2	2	1	3
Biperiden	1	1	0	1
Teicoplanin†	4	1	1	2
Imipenem†	3	0	1	1
General total		500	500	1000

*Database of active ingredients: http://www.anvisa.gov.br/medicamentos/referencia/lmr_a.pdf.
†Flask-vial.

The administered drugs were prescribed for patient treatment at the Emergency Care Unit. Drug volume ranged between 1 and 4 ml, according to the drug or diluent used.

The comparison of volume distribution per technique, separately for each pain degree, showed that, for the total group of patients, no difference occurred in the mean pain score according to the different volumes used (p=0.364), according to Table 2. For this comparison, the Chi-Square test was used, with significance set at 5%. The results show no difference in volume distribution between the technique for any pain level.

Table 2 - Pain assessment according to volume and technique used (n=1000)

Numerical pain scale scores	Volume	Technique				p-value
		Conventional		Retractable fixed needle		
		n=500	%	n=500	%	
0	1	16	3.2	23	4.6	0.270
	2	72	14.4	104	20.8	
	3	48	9.6	82	16.4	
	4	4	0.8	1	0.2	
1	1	4	0.8	10	2.0	0.222
	2	35	7.0	28	5.6	
	3	19	3.8	16	3.2	
	4	1	0.2			
2	1	11	2.2	18	3.6	0.206
	2	59	11.8	53	10.6	
	3	38	7.6	27	5.4	
	4	1	0.2	3	0.6	
3	1	10	2.0	8	1.6	0.380
	2	24	4.8	26	5.2	
	3	18	3.6	10	2.0	
4	1	7	1.4	4	0.8	0.467
	2	18	3.6	14	2.8	
	3	16	3.2	6	1.2	
5	1	7	1.4	2	0.4	0.198
	2	24	4.8	23	4.6	
	3	21	4.2	16	3.2	
	4			2	0.4	
6	1	5	1.0			0.086
	2	9	1.8	8	1.6	
	3	1	0.2	1	0.2	
	4			2	0.4	
7	2	6	1.2	1	0.2	0.768
	3	6	1.2	2	0.4	
	4	1	0.2			

(continue...)

Table 2 - (continuation)

Numerical pain scale scores	Volume	Technique				p-value
		Conventional		Retractable fixed needle		
		n=500	%	n=500	%	
8	1	2	0.4			0.202
	2	4	0.8	2	0.4	
	3	1	0.2	3	0.6	
	4			1	0.2	
9	2	3	0.6			***
	3	2	0.4			
10	1			2	0.4	0.090
	2	5	1.0	2	0.4	
	3	2	0.4			
Total		500		500		

Table 3 shows that no statistical difference was found for the analyzed variables with regard to the compared techniques.

Table 3 - Analysis of quantitative variables according to the conventional and retractable needle syringe technique (n= 1240)

Variable	Technique		p-value
	Conventional	Retractable fixed needle	
Age			0.175
n	620	620	
Mean	45.1	46.5	
Median	43	45	
Standard deviation	19.2	18.4	
Minimum	14	14	
Maximum	92	92	
Weight			0.599
n	620	620	
Mean	71.9	72.4	
Median	70	70	
Standard deviation	15.0	15.4	
Minimum	44	40	
Maximum	120	128	
Height			0.286
n	620	620	
Mean	1.8	1.7	
Median	1.67	1.65	
Standard deviation	3.1	0.1	
Minimum	1.4	1.4	
Maximum	78	1.98	
BMI*			0.131
n	620	620	
Mean	25.8	26.3	
Median	24.8	25.8	
Standard deviation	5.0	5.2	
Minimum	16	16.3	
Maximum	44.1	43.6	

*BMI - Body Mass Index

Table 4 shows difference between the groups regarding the pain scale, evidencing that, on average, the pain score is higher in the group in which the conventional technique was used (p<0.001). Test power when comparing both groups regarding the pain scale corresponded to 0.98 when comparing the entire sample and 0.97 when comparing the intramuscular injection group, with significance set at 5%.

Table 4 - Comparison of pain in case of conventional technique and retractable needle syringe (n= 1240)

Pain	Technique		p-value
	Conventional	Retractable fixed needle	
N	620	620	<0.001
Mean	2.09	1.5	
Median	2	1	
Standard deviation	2.26	1.97	
Minimum	0	0	
Maximum	10	10	

On the average, the bruising score is higher in the patient group in which the conventional technique was used (p<0.029), according to Table 5.

Table 5 - Comparison of bruising in subcutaneous application using conventional technique and retractable needle syringe (n=240)

Bruising	Technique		p-value
	Conventional	Retractable fixed needle	
N	120	120	0.029
Mean	0.76	0.07	
Median	0	0	
Standard deviation	3.41	0.33	
Minimum	0	0	
Maximum	20	3	

Discussion

Usually, the drug aspiration needle is exchanged for another with a view to intramuscular, subcutaneous or intradermal administration. The justifications given for this practice include: muscle tissue irritation, alteration in the sharpness of the needle bevel with a consequent increase in the patient's painful sensation. Also, the risk of health professionals contaminating the aspiration needle while handling it is mentioned. These justifications are based on practices that are considered correct, without confirmatory scientific evidence. Factors like technological advances are not taken into account, which permit manufacturing material and equipment that facilitate care practices, offering safety and reducing occupational risks for health professionals.

One important reflection that is due is that aseptic handling of materials impedes drug contamination, independently of what technique is used. Professionals and institutions should join efforts for work practices to reflect this concern.

In clinical practice, the belief exists that drawing back retractable needles before removing them from the skin in case of subcutaneous injections could provoke traumas and bruising. This study, on the other hand, evidenced no major bruising when using retractable fixed needles to apply subcutaneous injections. This finding confirms that using the safety device to apply subcutaneous injections is safe to use with patients.

Initially, the researchers had planned to assess the intramuscular injection application using one single drug and volume but, after a pilot study at the Emergency Care Unit, it was observed that the time needed for data collection could turn the study unfeasible. Therefore, the decision was made to administer volumes between 1 and 4 ml for application in the dorsal-gluteal region. When comparing pain levels according to the administered volume, no changes in pain perceptions were found, neither with the conventional nor with the retractable fixed needle technique.

Training health professionals for injection application with retractable fixed needles is necessary with a view to the clarification of doubts, adequate use of available resources and protection offered by the safety device.

Other studies should be conducted on injections with retractable needles to assess their introduction in clinical practice, their impact on the reduction of accidents with piercing-cutting material, costs associated with new technologies and the production of solid health residues.

Conclusions

Technological innovations are meant to improve care quality and facilitate the execution of procedures, guaranteeing and preserving patients and health professionals' safety. The use of safety devices like syringes with retractable fixed needles is a prevention practice that guarantees compliance with NR-32, benefitting workers and health institutions.

Based on the obtained results, it can be affirmed that using syringes with retractable fixed needle safety devices neither compromise painful feelings when applying intramuscular and subcutaneous injections nor enhance the risk of bruising in case of subcutaneous applications. Thus, the use of these safety devices can be recommended in clinical practice.

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