Level of Adherence to an Extravasation Protocol Over 10 Years in a Tertiary Care Hospital

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Background: Extravasation of chemotherapy is an undesirable complication related to the administration of antineoplastic therapy. Establishing the real incidence is difficult. Because of the importance of a quick intervention after an extravasation, every hospital should have an extravasation protocol.

Objectives: The purpose of this study was to determine the degree of observance of an extravasation protocol by nursing staff and to determine extravasation incidence.

Methods: This descriptive, longitudinal, retrospective study was set in a tertiary-level hospital. The researchers reviewed 117 extravasation notification forms received by the pharmacy department during a 10-year period. Nursing actuation, particularly observance of the extravasation protocol, was analyzed.

Findings: Protocol adherence was 89%. Twelve deviations from the protocol in the application of recommended measures were detected. An antidote was used in 41 patients, and temperature measures were applied in 14 cases. Ninety-nine patients had at least one episode of reported follow-up. No cases of necrosis or skin ulcers were described, except for one patient who developed a delayed skin ulcer to vinorelbine. Drugs most frequently reported were etoposide, carboplatin, and paclitaxel. Nursing staff should be continuously trained in extravasation protocol because a rapid actuation can prevent skin lesions.

A n undesirable complication related to the administration of antineoplastic therapy is extravasation of chemotherapy. Despite being rare, it causes high concern among nursing staff and patients because of the severe consequences it may have. The term extravasation includes the unnoticed leakage or escape of a chemotherapeutic agent from a vessel into the perivascular tissue, as well as the unintentional injection of a drug into surrounding healthy tissues (Sauerland, Engelking, Wickham, & Corbi, 2006; Schrijvers, 2003). Although establishing the real incidence of extravasation is difficult, available data point to a value that ranges from 0.1%–6.5% (Alfaro-Rubio et al., 2006; Ener, Meglathery, & Styler, 2004; Gonzalez, 2013). Typically, the diagnosis of an extravasation is mainly clinical. Patients have local pain, burning sensation, swelling, or erythema (Ener et al., 2004). Patients and nursing staff must be educated to detect extravasation. Changes in drug infusion rate and absence of blood return are signs that indicate that an extravasation may have happened.

Tissue damage after an extravasation develops by different mechanisms, according to the ability of the extravasated agent to bind to DNA (Ener et al., 2004; Schulmeister, 2007). Drugs that bind to DNA enter into cells and cause rapid direct cell death. Drugs that do not bind to DNA are easily metabolized in the tissue into inactive compounds. The degree of tissue injury is lower because they are rapidly neutralized.
According to their ability to cause tissue damage, drugs are classified as vesicant, irritant, or nonvesicant (Ener et al., 2004; Gonzalez, 2013). Vesicant drugs cause the development of blisters and tissue necrosis, and irritant drugs can cause local irritation. Nonvesicant drugs rarely produce acute reactions or tissue necrosis. The classification of chemotherapeutic agents is presented in Figure 1. In addition to the drugs’ potential to cause tissue damage, the extent of tissue injury also is related to the infusion site, condition of the tissue, concentration and amount of the extravasated agent, treatment applied, and time from extravasation to initiation of the intervention (Ener et al., 2004; Sauerland et al., 2006).

The rapid instauration of treatment is mandatory because of the severe consequences that an extravasation can have on tissue integrity and patients’ quality of life. The treatment depends mainly on the ability of the drug to damage tissue (Watanabe et al., 2008). Unfortunately, information about best treatment options, including specific antidotes, is scarce. Available data come from a series of case reports, small uncontrolled trials, and studies in animals. Comparative studies in humans cannot be carried out because of chemotherapy-specific characteristics and ethical considerations. However, the use of the following antidotes is well established: hyaluronidase for the treatment of vinca alkaloid, epipodophyllotoxin, and paclitaxel extravasation; sodium thiosulfate for mechloethamine and concentrated cisplatin extravasation; and dexrazoxane and dimethyl sulfoxide for anthracycline extravasation (Ener et al., 2004; Polovich, Whitford, & Olsen, 2009). Several other drugs, such as glucocorticoids, antihistamines, sodium bicarbonate, heparin, and lidocaine, are not recommended because they are not effective in treating extravasation injuries (Schulmeister, 2007).

Because of the importance of a quick intervention after an extravasation, every hospital should have an extravasation protocol. The aim of the current study was to know the degree of observance of the extravasation protocol at the researchers’ hospital. Secondary objectives were determination of extravasation incidence and descriptive analysis of extravasation.

Established Processes

An extravasation kit is available in every area where chemotherapy administration is routinely performed at the researchers’ hospital. The kits are supplied by the pharmacy department and include an extravasation management algorithm (see Figure 2), antidotes, cold and hot packs, general nursing tools, and an extravasation notification form. When an extravasation happens, the doctor in charge is informed, an extravasation kit is opened, and the appropriate actions are made. Afterward, an extravasation notification form is completed. The notification form is filed in the patient’s medical record, and a copy is delivered to the pharmacy department to evaluate and archive. The opened kit also is returned to the pharmacy department to be replaced with a new one.

Methods

The researchers performed a descriptive, longitudinal, retrospective study, set in a tertiary-level hospital in Spain, to analyze all the information recorded and to identify strengths and weaknesses during the past 10 years. The extravasation kits were located in three areas: the chemotherapy outpatient clinic, the hospitalization wards, and with the domiciliary chemotherapy administration team.

The researchers reviewed all extravasation notification forms received by the pharmacy department from January 2003 to December 2012. Retrospective notifications of past extravasation (occurring days before the notification), recall phenomenon, and phlebitis events were excluded. Notification forms in which the patient and extravasated drug could not be identified were excluded from final analysis but considered in incidence estimation.

General information and patient demographics were recorded, including gender, age, type of cancer, chemotherapy treatment, location of the patient in the moment of extravasation (outpatient clinic, hospitalization ward, or patient residence), and nursing shift. Information regarding the extravasation sequence was reviewed as well. This included characteristics related to the administration process, including puncture point, characteristics of the vein used for administration of chemotherapy (e.g., good, thin, difficult approach, tough, weak),

<table>
<thead>
<tr>
<th>Vesicant</th>
<th>Irritant</th>
<th>Nonvesicant</th>
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<tbody>
<tr>
<td>Amsacrine</td>
<td>Oxaliplatin</td>
<td>Arsenic trioxide bortezomib</td>
</tr>
<tr>
<td>Bendamustine</td>
<td>Paclitaxel</td>
<td>Asparaginase</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Pegylated liposomal daunorubicin</td>
<td>Bortezomib</td>
</tr>
<tr>
<td>Dactinomycin</td>
<td>Pegylated liposomal doxorubicin</td>
<td>Cladribine</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>Streptozotocin</td>
<td>Clofarabine</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>Trabectedin</td>
<td>Cytarabine</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Vinblastine</td>
<td>Vinorelbine</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>Vincristine</td>
<td>Nonpegylated liposomal doxorubicin</td>
</tr>
<tr>
<td>Idarubicin</td>
<td>Vindesine</td>
<td></td>
</tr>
<tr>
<td>Mechlorethamine</td>
<td>Vinflunine</td>
<td></td>
</tr>
<tr>
<td>Mitomycin</td>
<td>Vinorelbine</td>
<td>Carboplatin</td>
</tr>
<tr>
<td>Mitoxantrone</td>
<td></td>
<td>Carmustine</td>
</tr>
<tr>
<td>Nonpegylated liposomal doxorubicin</td>
<td></td>
<td>Cyclophosphamide</td>
</tr>
</tbody>
</table>

Note. Drugs are classified according to the most serious reaction they can cause.

FIGURE 1. Classification of Cytostatic Drugs

Note. Based on information from Conde-Estévez & Mateu-de Antonio, 2012; Ener et al., 2004; Watanabe et al., 2008.
Results

During the study period, 142 notification forms were delivered to the pharmacy department. Of those, 117 were included in the study after removing the ones that did not fulfill inclusion criteria. The main reasons for exclusion were reports of phlebitis or distant lesions and notifications of past extravasation. For final analysis, another seven notification forms were excluded because the extravasated drug was not recorded and could not be identified by other means. One hundred and ten extravasation notifications were selected for final evaluation. Of those, the mean age of patients was 63.6 years, with a range of 21–85 years (see Table 1).

Adherence to the Protocol

In the current study, protocol adherence was 89%, without taking into account the use of Burow’s solution application and lack of documentation of general measures. In 81 cases (74%), the nurse applied some kind of initial or general measures, but in 28 cases (25%), it was not documented. In the notification form, the question about initial and general measures was open-ended. Therefore, a high percentage of data was not documented. The most frequent actions described were aspiration of the drug and elevation of the affected limb (percentage not available). In one patient, local pressure was applied despite it not being recommended. Twenty-seven (25%) of the cases included topical application of Burow’s solution, but this measure was not considered in the researchers’ internal protocol. An antidote was used in 41 patients (37%), and temperature measures were applied in 14 cases (13%).

The researchers found 12 deviations from the protocol in the application of recommended measures (see Table 2). In two patients, an indicated antidote was not administered. In two cases, heat or cold and an antidote were necessary, but neither was applied. However, in three patients with a reported paclitaxel extravasation, an antidote was administered although it was not included in the researchers’ protocol recommendations. In addition, in three patients, heat or cold was not applied, despite being indicated. One patient also received an antidote and heat or cold although it was unnecessary.

Incidence

Global incidence of extravasation during the study period was 117 extravasations of 213,579 doses of chemotherapy administered (0.05%). The majority of the reported extravasations (n = 102, 93%) took place at the oncology-hematology outpatient clinic; the rest of the extravasations occurred in hospital wards (n = 7, 6%). In addition, one episode of extravasation happened during a home administration of chemotherapy.

Chemotherapy Extravasation Protocol

- Notify the pharmacy department about the extravasation.
- Contact the doctor.
- Immediately use the extravasation kit according to the recommendations.
- Fill out the follow-up form.

Initial Measures

- Stop the drug infusion.
- Withdraw the infusion equipment, but not the venous catheter.
- Aspire 5–10 ml of blood through the venous catheter to extract the maximum quantity of the extravasated drug.
- Withdraw the venous catheter.
- Proceed to apply specific treatment, or go on with general measures if the drug does not require specific treatment.

Specific Treatment

- Amscarine
  - Administer six injections of 150 IU (0.5 ml) of SC hyaluronidase in the affected and surrounding area.
  - Apply dry heat for 30 minutes after the injection of hyaluronidase.

- Cisplatin, clormetin, and dacarbazine
  - Administer 2 ml of SC sodium thiosulfate molar concentration of 1/6 for every mg of extravasated drug, in several injections around the affected area.
  - Cisplatin: Administer thiosulfate only if cisplatin concentration is more than 0.4 mg/ml or if the extravasated volume is more than 20 ml.
  - Dacarbazine: Administer thiosulfate only if persistent signs of extravasation are present or if the lesion progresses after 12–24 hours.

- Etoposideb, ifosfamide, and teniposideb
  - Administer six injections of 150 IU (0.5 ml) of SC hyaluronidase in the affected and surrounding area.
  - Ifosfamide: Administer hyaluronidase only if persistent signs of extravasation are present or the lesion progresses after 12–24 hours.

- Vinblastineb, vincristineb, vindesineb, and vinorelbineb
  - Administer six injections of 150 IU (0.5 ml) of SC hyaluronidase in the affected and surrounding area.
  - Administer hyaluronidase only if persistent signs of extravasation are present or if the lesion progresses after 12–24 hours.

General Measures

- Raise the affected extremity over the height of the heart.
- Do not apply pressure at the affected area. Avoid bandages.
- Gently apply common hygienic measures. Do not clean with detergent if tissue necrosis has occurred.
- If necessary, prescribe analgesic and antibiotic treatment.
- Avoid exposure of the affected area to sunlight.
- Pharmacologic treatment with or without hot or cold treatment can be repeated if necessary after 12 and 24 hours.

DMSO—dimethyl sulfoxide; SC—subcutaneous

FIGURE 2. Chemotherapy Extravasation Protocol

Note. Based on information from Ener et al., 2004; Mateu et al., 1997; Polovich et al., 2009; Schulmeister, 2007.
Extravasation Sequence

The type of device mainly used for cytostatic administration was a short peripheral catheter, which was employed in 87 patients (78%). In six cases (5%), the patients had a long-term implantable central venous catheter. Three cases of extravasation (3%) were described in which a peripherally inserted central catheter was used. In the remaining 14 patients (13%), the kind of device used for administration was not recorded by the nurse.

The point of puncture most frequently related to an extravasation event was in the plexus arm (n = 42, 38%), forearm (n = 23, 21%), hand (n = 16, 15%), and wrist (n = 14, 13%). Nurses did not document a location in nine cases (8%). An additional six cases (5%) were not considered because of a port-a-cath administration.

In addition to the point of insertion of the catheter, another important factor that contributes to extravasation is the quality of the vein. In patients with port-a-cath administration, this question did not apply.

Extravasated Drugs

In terms of risk of tissue damage, 43 (40%) of the drugs involved in the reported extravasations were classified as vesicant and 54 (49%) as irritant. The remaining 12 (11%) were classified as nonvesicant. In one case referring to fotemustine, the risk is not clearly defined in the extravasation protocols or drug bibliography.

Twenty-four different drugs were implied in the extravasations. Drugs most frequently reported were etoposide (n = 18, 16%), carboplatin (n = 17, 15%), and paclitaxel (n = 16, 15%). In six patients (5%), the drug extravasated was not considered in the researchers’ protocol (i.e., fotemustine, oxaliplatin, pemetrexed, or temsirolimus). In those cases, the nurse consulted with the pharmacy department or doctor for actions that should be taken.

Infusion times of extravasated drugs were divided as follows: 0–30 minutes (n = 51, 46%), 31–180 minutes (n = 48, 44%), and more than 180 minutes (n = 8, 7%). In three cases (3%), this information was not reported. The quantity extravasated also was classified into three groups: volume less than 10 ml (n = 58, 53%), 10–50 ml (n = 25, 23%), and greater than 50 ml (n = 8, 7%). In 19 cases (17%), the volume extravasated was not indicated. The vein affected by the extravasation had already been used for administration of premedication drugs (mostly serum, antimetics, and corticoids) in 51 patients (46%). The remaining 59 patients (54%) did not receive premedication drugs by the same vein, or it was not documented.

Follow-Up

Ninety-nine patients (90%) who suffered an extravasation event had at least one episode of reported follow-up. The first follow-up took place during the first 24 hours after the extravasation episode in 59 patients (54%), 48–72 hours after in 20 patients (18%), and more than 72 hours after in 14 patients (13%). A second follow-up was documented in 38 patients (35%). These follow-up contacts were made by phone or a face-to-face visit. The most common symptoms described were edema, erythema, and skin toughness. No cases of necrosis or skin ulcers were described, except for in one patient, who developed a delayed skin ulcer to vinorelbine.

Discussion

In the current study, protocol adherence was high (89%). Protocol deviations only occurred in 12 extravasations (11%), but some of them could be considered serious (e.g., local pressure application at the injection site, which may cause worsening of the extravasation injury). The reasons why nurses did not follow the protocol are unknown, but several causes are probable. Some extravasations may have been mild, so the nurse may have considered applying all of the measures unnecessary. Lack of knowledge and doctors’ orders differing from the protocol could be other reasons.

In the current study, Burow’s solution was applied in 27 patients (25%), although it was not included in the protocol recommendations. Because of its astringent and antibacterial

### TABLE 1. Sample Characteristics (N = 110)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>X</th>
<th>Range</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>63.6</td>
<td>21–85</td>
</tr>
</tbody>
</table>

**Gender**
- Male: 60 (55)
- Female: 50 (46)

**Location of extravasation**
- Outpatient clinic: 102 (93)
- Hospitalization ward: 7 (6)
- Home: 1 (1)

**Nursing shift**
- Afternoon: 52 (47)
- Morning: 41 (37)
- Not identified: 17 (16)

**Type of neoplastic disease**
- Lung: 37 (34)
- Hematologic: 19 (17)
- Gynecologic: 12 (11)
- Gastrointestinal: 11 (10)
- Breast: 10 (9)
- Head and neck: 6 (6)
- Genitourinary: 4 (4)
- Sarcoma: 3 (3)
- Germinal: 2 (2)
- Melanoma: 2 (2)
- Not identified: 4 (4)

Note. Extravasations (N = 110) of 213,579 doses of chemotherapy administered.

Note. Because of rounding, percentages may not total 100.

In the current study, protocol adherence was high (89%). Protocol deviations only occurred in 12 extravasations (11%), but some of them could be considered serious (e.g., local pressure application at the injection site, which may cause worsening of the extravasation injury). The reasons why nurses did not follow the protocol are unknown, but several causes are probable. Some extravasations may have been mild, so the nurse may have considered applying all of the measures unnecessary. Lack of knowledge and doctors’ orders differing from the protocol could be other reasons.

In the current study, Burow’s solution was applied in 27 patients (25%), although it was not included in the protocol recommendations. Because of its astringent and antibacterial
properties, Burow’s solution is used to treat a number of skin conditions, such as erythema, phlebitis, and swelling (Llopis Clavijo & Baixauli Comes, 2001), and frequently is used in the researchers’ hospital. For this reason, Burow’s solution application was not considered a protocol deviation. However, the researchers cannot confirm the effectiveness of this measure.

The notification form was not complicated, but it included some open-ended questions (e.g., general measures, administered antidotes, lesion description, follow-up). In 2011, the format was changed to include more closed-ended questions in which nurses had to mark the most appropriate description. The purpose was to facilitate nurse documentation and obtain more uniform information about extravasation.

The incidence of extravasation of antineoplastic drugs injected via peripheral vein is reported to be from 0.1%–6.5% (Ener et al., 2004; Sauerland et al., 2006; Watanabe et al., 2008) and 0.3%–4.7% in implant venous access port infusions (Sauerland et al., 2006). In the current study, incidence was low, with a median of 0.05% (range = 0.02%–0.1%). One reason for the low incidence may be that the researchers’ incidence calculation includes central and peripheral administration. The use of central venous access devices (subcutaneously implanted ports or peripherally inserted central catheters) reduces but does not eliminate the risk of drug extravasation (Ener et al., 2004). Underreported extravasation also could have contributed to decreased global incidence. However, the data are similar to the data from another study (Langstein, Duman, Seelig, Butler, & Evans, 2002) that reported an extravasation incidence of 0.01%. Incidence may be decreasing because of an increase in the use of more secure devices and an increase in knowledge and awareness among healthcare professionals. The researchers’ institution is a tertiary hospital with an oncology-hematology outpatient clinic where nurses are well prepared to manage this type of medication and specially trained to detect an extravasation and act early. More than 80 chemotherapy agents are administered every day. This explains why patients in the current study did not experience severe consequences as expected. No cases of tissue necrosis were reported, and most symptoms were mild and reversible. Of note, several studies that only included paclitaxel extravasation reported higher extravasation incidence (Watanabe et al., 2008) than studies that included extravasation of several drugs. This could be related to the presence in the paclitaxel formulation of an excipient (Cremophor®), which also has vesicant properties (Stanford & Hardwicke, 2003) and could have contributed to worsening the quality of the vein.

The most frequently extravasated drugs were etoposide, carboplatin, and paclitaxel. They also are probably the most frequently administered cytotoxic drugs. During the study period, 16 cases of paclitaxel extravasation were described, which was 15% of the total drugs extravasated. This coincides with the widespread use of this agent because it is part of standard therapy for patients with breast, lung, ovarian, and other solid tumors. In early clinical studies, local tissue necrosis was not reported with paclitaxel, so it was not classified as a vesicant. However, case reports suggest that it may have vesicant properties, regardless of concentration (Stanford & Hardwicke, 2003). Therefore, it currently is classified as a vesicant in the protocol of the researchers’ hospital. In 3 of the 16 patients aforementioned, a subcutaneous drug (e.g., corticoids, hyaluronidase, dexamethasone, dexchlorpheniramine) was administered as an antidote although it was not considered in the researchers’ protocol. No consequences for the patients were identified. After a literature review, the researchers found that hyaluronidase had been applied in some cases (Dubois, Fehr, Bochtler, & Koechli, 1996) and that some guidelines and reviews recommend its use (Conde-Estévez & Mateu-de Antonio, 2012; European Society of Oncology Pharmacy, 2007). However, no recommendations about corticoid use are made. In fact, glucocorticoids have been found to be ineffective in treating extravasation injuries (Wickham, Engelking, Sauerland, & Corbi, 2006) because the mechanism of action of the injury is no longer believed to be inflammation (Langstein et al., 2002). However, in at least one study, dexamethasone was used in extravasation of vesicant drugs and no cases of necrosis were described (Watanabe et al., 2008). The researchers reviewed their extravasation protocol and included hyaluronidase application in taxane extravasation. In one patient, heat also was applied. Application of heat or cold in taxane extravasation is not a standard recommendation, but it has been used in several case reports. In one case, the use of warm compresses appeared to worsen the injury (Stanford & Hardwicke, 2003).

Most patients suffering an extravasation had altered veins. In addition, many of them had more than two negative characteristics (e.g., thin, tough, weak, difficult approach), complicating chemotherapy administration. Consequently, patients with altered veins must be more closely monitored because they are

<table>
<thead>
<tr>
<th>Drug</th>
<th>Protocol Recommendations</th>
<th>Error Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboplatin</td>
<td>Nonspecific actions</td>
<td>Local pressure application</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Nonspecific actions</td>
<td>150 IU hyaluronidase SC administered</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Topical DMSO 99% and cold application</td>
<td>DMSO 99% not applied</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>Topical DMSO 99% and cold application</td>
<td>DMSO 99% and cold not applied</td>
</tr>
<tr>
<td>Etoposide</td>
<td>150 IU hyaluronidase SC</td>
<td>150 IU hyaluronidase SC not applied</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>Nonspecific actions</td>
<td>• Hyaluronidase SC application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Dexamethasone SC application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hydrocortisone SC, hyaluronidase SC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Dexchlorpheniramine SC, and heat</td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>150 IU hyaluronidase SC and heat application</td>
<td>• Heat application not documented in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>three cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No hyaluronidase or heat applied</td>
</tr>
</tbody>
</table>

DMSO—dimethyl sulfoxide; SC—subcutaneous

TABLE 2. Deviations From the Protocol
at high risk of suffering from an extravasation. Port-a-caths can be considered to reduce this problem.

Of note, an extravasation occurred at a patient's home during administration of chemotherapy. This shows the importance of taking an extravasation kit wherever chemotherapy is administered.

**Limitations**

Owing to the current study's retrospective design, the data collected depend on the quality of data recorded in notification forms and medical records. In addition, incidence calculation depends on the rate of notification by nursing staff. In 2003, for example, the notification rate was low and incidence may be underestimated.

**Nursing Implications**

Continuing education is important for maintaining nursing staff with updated knowledge on how to proceed in case of extravasation. Nurses should be educated on how to prevent extravasation by selecting appropriate veins and types of devices for drug administration. In addition, the extravasation protocol has to be kept up to date to include new drugs, evidence, and recommendations. Because conducting clinical trials is not ethical, information is lacking about the best procedure in extravasation of new drugs. For this reason, case reports of these drugs are particularly useful. Adherence to the extravasation protocol at the researchers' hospital is high, but nursing staff must be continuously trained to improve quality of patient care.

**References**


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