Activating a Protocol for Prevention, Management and Follow up of Dermal Filler Injection Related Vascular Occlusion (A Clinical Audit)

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Abstract
With the increased demand for dermal filler injections, more complications and adverse events are reported. Vascular occlusion is one of the most serious complications. The need urges to adopt a powerful protocol to manage such cases. The private practice I am working for has six branches in the middle east. I tried to investigate if there were any vascular occlusion incidences through the last three years. Four cases without sufficient details were found. A protocol was adopted from a scientific reference to deal with similar cases properly. A re-audit was done after six months to test the efficiency of the suggested protocol.

Keywords
Dermal, Filler, Vascular, Occlusion, Code: Pale

1. Introduction
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2. Audit Methodology

With the increased demand for dermal filler injections, more complications and adverse events are reported. Vascular occlusion is one of the most serious complications that can lead to deformity, blindness and other catastrophic events. The need urges to adopt a powerful protocol to manage such cases.

Assessing current situation in our six practice branches, according our knowledge, there have been at least four cases of dermal filler associated vascular occlusion in the last three years. Management was individually variable from a doctor to another. Cases were not properly documented.

Current literature has been reviewed and a discussion started to establish a protocol for immediate management and follow up of filler injection induced vascular occlusion accidents. First audit was done in November, 2019. A re-audit has been done after six months.

Dominguez et al. [1] was chosen to be the main reference for our management protocol. Certain actions need to be taken to prevent filler injection induced vascular occlusion accidents.

3. Action Plan and Recommendations

3.1. Prevention

1) Informed consent including all possible complications
2) Proper explanation of all aspects of the procedure to the patient
3) Take history thoroughly
4) Always take photos before
5) Know your anatomy (dangerous zones) (Figure 1)
6) Use cannula when possible
7) Take your time while injecting
8) Always aspirate and wait

3.2. Management

1) Detect/diagnose the incidence (blanching, severe pain, vasovagal shock, …)
2) Calm yourself and the patient down
3) Call colleagues for help by activating (code: pale) on the public address (PA) system.
4) Implement the protocol as detailed in the steps below and Table 1. Table 2.
5) Document and report the incidence as soon as your patient is stable.

3.3. Protocol Steps

1) Immediately stop the procedure and all injections.
2) For HA dermal fillers, inject hyaluronidase in and around the injection site.
3) Massage topical nitroglycerin paste 2% into the affected area.
4) Massage and apply warm compresses to affected area to increase vasodilation.
5) Start patient on a course of methylprednisolone.
Figure 1. Dangerous zones for accidental dermal filler injection associated vascular occlusion [1].

Table 1. Suggested treatment protocol for acute facial volumization-related arterial occlusion [1].

| Therapy                | Dose, Route, and Duration of Therapy                                                                                                                                 |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Antibiotics and Antivirals | Penicillin 500 mg twice daily, cephalosporin 500 mg four times daily, or clindamycin 150 mg four times daily. Acyclovir 800 mg five times daily. Continue until area has epithelialized. |
| Nitroglycerin paste 2% | Apply immediately around injection site and zone of ischemia for 5 minutes. Reapply for 5 minutes every 1 - 2 h while in the ED, but for no longer than 24 h due to development of drug tolerance. |
| Corticosteroids        | Oral prednisone 60 mg daily for 4 d, or methylprednisolone dose pack for 6 d.                                                                                                                                                   |
| Enoxaparin             | 30 mg subcutaneously every 12 h for 7 - 14 d or until area has normal arterial blood flow; do not give in combination with acetylsalicylic acid aspirin.                                                                          |
| Acetylsalicylic acid aspirin | 325 mg orally once daily for 7 - 14 d; do not give in combination with enoxaparin.                                                                                                                                     |
| Esomeprazole           | 40 mg daily for 5 d.                                                                                                                                                                                                           |
| Phosphodiesterase type 5 inhibitors | Oral sildenafil 100 mg, tadalafil 20 mg, or vardenafil 100 mg daily for 7 - 14 d or until area has normal arterial blood flow.                                                                                                       |
| Hyperbaric oxygen      | Begin treatment daily as soon as possible, with continued treatment at 3 atmospheres for 45 minutes daily until the area has epithelialized.                                                                                     |
6) Administer subcutaneous enoxaparin (if not giving acetylsalicylic acid aspirin [ASA]).
7) Administer ASA (unless contraindications exist and if not giving enoxaparin).
8) When giving ASA, administer an antacid to prevent gastritis/esophagitis.
9) Administer a phosphodiesterase type 5 inhibitor.
10) Administer prophylactic antibiotic and antiviral therapy.
11) Consult plastic surgery, ophthalmology, and neurology services.
12) Initiate hyperbaric oxygen therapy, when indicated [1].

A box/container containing the protocol hard copy and the medications will be available in each clinic for any possible incidents. A nurse will be responsible for its availability and checking the expiry dates.

A correspondence will be started with the purchasing department to supply the box/container components. We will provide them with the generic and suggested brand names available in the national pharmaceutical market (Table 3).

### 3.4. Pitfalls

1) Don’t give Low Molecular Weight Heparin (LMWH) and Acetylsalicylic Acid (ASA) together

#### Table 2. Consultations to consider for patients with acute facial volumization-related arterial occlusion [1].

| Signs and Symptoms       | Recommendation                                              |
|--------------------------|--------------------------------------------------------------|
| Ophthalmic/ocular        | Consult ophthalmology services immediately if patient has any ocular pain, visual defects or disturbances. |
| Neurological             | Consult neurology services immediately if patient has any signs or symptoms of cerebral ischemia. |
| Plastic/dermatological   | Consult plastic surgery services for continued care.         |

#### Table 3. Generic and brand names examples available in Saudi pharmaceutical market of the medications enlisted in the suggested protocol.

| Generic name                      | Brand name example (in Saudi market according to SFDA website) |
|-----------------------------------|---------------------------------------------------------------|
| Hyaluronidase                     | PBSerum Drain Plus (Hyaluronidase PB3000) (300 units/ml)      |
| Amoxicillin/Clavulanic acid       | Klavox/Augmentin 1000 mg (tablet)                             |
| Acyclovir                         | Zovirax 800 mg (tablet)                                      |
| Glyceryl Trinitrite               | Nitroderm TTS-10 System 50 mg/patch (patch)                  |
| Prednisone                        | Predone 20 mg (tablet)                                       |
| Enoxaparin Sodium                 | Clexane 60 MG/0.6ML (Inj)                                   |
| Acetylsalicylic acid              | ALKA-SELTZER 324 mg (tablet)                                 |
| Esomeprazole                      | Nexium 40 mg (tablet)                                        |
| Phosphodiesterase type 5 inhibitor| Viagra 100 mg (tablet)                                       |
| Sodium Thiosulfate                | Marketed as a generic. Can be used to dissolve Calcium Hydroxyapatite dermal filler [2] [3] [4]. |
2) Don’t give Acetylsalicylic Acid (ASA) without Proton Pump Inhibitor (PPI) coverage.

3) Check warm compresses on your own skin first. Patient may get burned without feeling under topical anesthesia.

4. First Re-Audit and Closure after 6 Months (June, 2020)

Case Presentation

Introduction
During the last six months, two incidences of dermal filler injection related vascular occlusion occurred.

The previously suggested protocol was followed immediately. Code: pale was activated and the case was managed accordingly. Cases made full recovery as seen in diagram 2, 3 and 4.

Case 1
1) Present History
27-year-old female sought our clinical advice for filler injection on the nose. 0.6 cc of Hyaluronic acid dermal filler was injected on the dorsum and tip. Aspiration was done during injection: negative. Patient did not produce any signs or symptoms immediately e.g. blanching, collapse or pain. However, she contacted the clinic after 48 hours complaining of severe redness and pain. Blisters started to show after 4 days of injection. Protocol was applied and code: pale was activated as previously shown in the main audit.

2) Outcome
Progress of the case till full recovery was achieved (Figure 2).

Case 2
1) Present History
28-year-old female sought our clinical advice for filler injection on the chin. 1.5 cc of Calcium Hydroxyapatite dermal filler was injected on the chin mixed with 0.5 cc Lidocaine 2%. Aspiration was done during injection: negative. Patient did not produce any signs or symptoms immediately e.g. blanching, collapse or pain. However, she contacted the clinic after less than 48 hours complaining of severe pain and blisters. Protocol was applied and code: pale was activated as previously shown in the main audit.

2) Outcome
Progress of the case till full recovery was achieved (Figure 3 and Figure 4).

5. Discussion

With the increased demand for dermal filler injections, more complications and adverse events are reported. Vascular occlusion is one of the most serious complications. The need urges to adopt a powerful protocol to manage such cases. Precautions can be taken to minimize dermal filler injection associated vascular occlusion incidences. However, they are still not uncommon. Proper and prompt
Figure 2. An example of post dermal filler injection vascular occlusion. 0.6 cc of Hyaluronic acid dermal filler was injected on the dorsum and tip of the nose. 1: 4 days post injection. 2, 3: 6 days post injection. Hyaluronidase injected, 4: 8 days post injection. 5: 10 days post injection. 6: 12 days post injection. 7: 14 days post injection. 8, 9: full recovery 3 weeks post injection.

Figure 3. An example of post dermal filler injection vascular occlusion. 1.5 cc of Calcium Hydroxyapatite dermal filler was injected on the chin mixed with 0.5 cc Lidocaine 2%. (A) (B) 2 days after procedure, Hyaluronidase injected, ((C), (D)) 3 days after procedure, Hyaluronidase injected again, (E) 4 days after procedure, (F) 5 days after procedure, (G) 6 days after procedure, (H) 7 days after procedure, (I) 8 days after procedure.
management is crucial to handle such cases aiming at full recovery. In both cases
detailed before, vascular occlusion happened, on the nose in case 1 and on the
chin in case 2, despite taking all precautions. Immediate response using the
treatment protocol led to full recovery in both cases.

6. Conclusion

The protocol showed efficiency in dealing with one case that was recorded dur-
ing the first six months after starting the audit. Our future plan is to review,
embed, sustain and spread the protocol, then re-audit again after 6 months.

Informed Consent

The author certifies that informed consents were properly taken from both pa-
tients involved in the series to use their photos anonymously.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this pa-
per.

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