Original Article



Pulmonary Disorders After Injections of Hyaluronic Acid Fillers

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Abstract

Hyaluronic acid is chemically a repeating glycosaminoglycan (disaccharide of D- glucuronic acid and N-acetyl-D-glucosamine), the presence of which has been established in many human organs and tissues. In vivo, this disaccharide is produced by epithelial cells of the synovial membranes of joints. The highest level of hyaluronic acid is found in the skin. Due to their high biological compatibility, hyaluronic acid preparations are used as injectable dermal fillers in cosmetology. Hyaluronic acid is believed to promote accelerated wound healing after facial plastic surgery. In recent years, fillers based on hyaluronic acid have been used for surgical interventions on the genitals. There are separate publications on the adverse outcomes of such operations related to non-compliance with standard operating procedures, protocols of operations, and the participation of unqualified personnel. The purpose of our study is to describe the signs of complications that occurred after injections of hyaluronic acid fillers. In this paper, we have summarized the available publications on such outcomes and our own case of forensic establishment of a fatal pulmonary embolism that occurred after injections with hyaluronic acid preparations of a man's penis. The studied materials are combined into one table. A comparative analysis of these observations indicates that after injections of fillers based on hyaluronic acid, in particular in the genital area, there is a risk of developing pulmonary disorders, up to the onset of a fatal outcome.

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Introduction

Hyaluronic acid (HA) is a linear glycosaminoglycan polymer that is frequently present in the extracellular matrix of vertebrate epithelial, nervous, and connective tissues. It is synthesised in significant amounts in endothelial cells of synovial membranes of joints and is a naturally occurring

substance in many human organs and tissues. HA is especially abundant in skin¹⁻³. Being a component of the extracellular matrix, HA is involved in ion metabolism, cell division and migration along with coagulation. It is believed that due to its hygroscopic and homeostatic properties HA

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can relieve the inflammatory processes and facilitate wound healing^{4,5}. In an aqueous solution, HA turns into a viscous "lubricant"-like gel, which unfolds protein filaments and smoothes out skin wrinkles. Function of HA retain water molecules whitin cells followed skin hydrate. HA based fillers may used for multiple purpose including in plastic surgery as injectable dermal fillers for plumping up thin lips, filing in deep wrinkles and flod.

However, it is difficult to establish a causal relationship between invasive cosmetic procedures involving HA injections and pulmonary disorders. When addressing this issue within the framework of forensic medical examinations, the following possible causes of adverse outcomes caused by injections of HA- based fillers should be taken into account: surgical procedures are performed by doctors lacking the required qualifications; lack of training

Na	Authors/Year	Sex/Age	Injection location/Amount	Complaints /Time following the procedure	X-rays, CT scans	Histological studies	Brief clinical and forensic data, results of instrumental examinations	Diagnosis	Outcome
1	Hyung Joo Park, Ki Hwan Jung, Sun Young Kim, Ju- Han Lee, Jin Yong Jeong, Je Hyeong Kim / 2010	F/49	Vagina (G-spot amplification) / 5 ml	Dyspnoea, cough / on the day of injection	Diffuse bilateral "ground glass"-like shadows	Granulomatous reaction to a foreign body with multinucleated giant cells around amorphous basophilic emboli in pulmonary vessels and parenchyma	Tachypnoea; inspiratory wheezing in the lower parts of the lungs. Video-assisted thoracoscopy, lung biopsy	NTPE	Recovery
2	Rajesh Bhagat MD, Rosanna M Forteza MD, Clay B Calcote MD, William T Williams MD, Steven A Bigler MD, and Terry M Dwyer MD PhD / 2012	M / 57	Knee joint (2-sided injection into synovial tissue) / 2,5 ml	Dyspnoea, chest pain with irradiation to the right shoulder and back, cough / shortly after injection	Bilateral " ground glass"-like shadows	Respiratory bronchiolitis with multiple amorphous emboli in many pulmonary arteries composed of HA and fibrin	Tachypnoea; HR 99; SpO ₂ >95% on O ₂ . Lung biopsy	NTPE	Recovery
3	Jong Geol Jang, M.D., Kyung Soo Hong, M.D. and Eun Young Choi, M.D. / 2014	F/35	Face (forehead and right cheek area) / -	Dyspnoea, confusional state, petechiae in the upper third of the torso / 3 days after	Diffuse "ground glass"-like shadows, consolidations in both lung fields with dilatation in PA and RV	•	t°36.8; BP 150/110; HR 127; RR 28; wheezing in the lungs.	NTPE	Recovery
4	Jose F. Basora, Ricardo Fernandez, Modesto Gonzalez, Jose Adorno / 2014	M / 25	Gastrocnemius muscle /> 50 ml	Dyspnoea, dry cough / 1 day after	Diffuse bilateral "ground glass"-like shadows, consolidations, bilateral focal infiltrates	Hemosiderin-laden macrophages	HR 120; BP 11670; RR 34; SpO ₂ 84%; diffuse wheezing. Fibrobronchoscopy. BAL.	DAH NTPE	Recovery
5	Seoung Woo Han, Myung Jae Park, Seung Hyeun Lee / 2019	F/56	Vagina (vaginal wall) / 15 ml	Dyspnoea, haemoptysis / 1 day after	Diffuse "ground glass"-like shadows, consolidations	*	Tachypnoea. BP 100/60; HR 98; RR 22; SpO ₂ 89%; wheezing on both sides. BAL	DAH NTPE	Recovery
6	Yang Y, Sheng H, Gu Q, Su L, Tong H, Chen J, Qi X/ 2020	F/33	Vagina (vaginal wall) / HA (13 ml); Collagen (2 ml)	Dyspnoca, dizziness, fatigue, cough / 5-10 minutes after	Local exudation in the lower lobe of the left lung, enlargement of the right atrium and ventricle, insufficient blood flow of the lower lobe arteries; embolisation of the right lower lobe posterior basal segment.	•	Restlessness, tachypnoca, cyanosis of the lips. HR 153; RR 25; BP 86/53 on vasopressor support; SpO; 83%; bilateral moist wheezing. Ecchymoses on the vaginal mucosa. Jugular vein filling. Pulmonary angiography and three- dimensional reconstruction. Transthoracic echocardiography. No autopsy was performed.	NTPE	Fatal
7	Jiangwei Kong, TengFei Yang, XingAn Yang, Fu Zhang, XinBiao Liao, DongRi Li / 2023	F/40	Vagina (vaginal wall)/-	Pain in the lower abdomen / 2 hours after	Inflammation in the lower lobe of both lungs, especially on the right side	Extensive amorphous basophilic emboli in the small interstitial lumen vessels of both lungs, hyaline thrombi in the lumen of some pulmonary vessels along with large amounts of substances of the same type were found in the wall and small blood vessels of the vagina. Hyaluronidase cleavage and staining with alcian blue confirmed that most of the injection components were hyaluronic acid (HA)	Clinical death. Coma. HR 138; BP 92/47. Forensic autopsy reported a puncture mark of injection and submucosal haemorrhage in the vaginal wall; light-red effusion of 250 ml in the pleural cavities, severe oedema and congestion in both lungs; light-red effusion of 230 ml in the abdominal cavity.	NTPE	Fatal
8	Case in point DAH – diffuse alveolar h	M/56	Penis / -	General malaise, sweating, weakness, sleep disturbance, nausea, tremor of the limbs, pain of a "pressing nature" in the sternum area / same day	12	Foreign structureless masses (gel) with areas of organisation, hemosiderosis, productive inflammation, giant cells of foreign bodies, as well as with leukocytic reaction in the area of the root of the penis. Presence of foreign structureless masses (gel) in the lumen of numerous pulmonary vessels of different diameter	PS 110; BP 140-160/100; RR 25-27-30. Forensic autopsy reported large amount of gel in the soft issues of the root of the pensis, injection at the glans of the penis. Spectrographic study reported one of the components included in the gel is HA or sodium hyaluronate.	NTPE	Fatal

Table-1: Cases of pulmonary disorders associated with HA injections

Adverse reaction are rare^{6,7}. In cases of dissatisfaction with the results of such surgeries, forensic medical examinations commissions are appointed. They are conducted with the participation of subject matter clinical specialists to determine whether there have been violations of standard procedures along with the correctness and validity of treatment and rehabilitation.

Pulmonary disorders can occur as a result of many causes.

of medical personnel for the possibility of this type of complications taking place; rare occurrence and insufficient coverage of such cases⁸.

We have found seven reported cases of pulmonary complications caused by HA injections in the available literature⁹⁻¹⁵, detailed in Table 1. These observations are based on published articles and a case from our expert practice, listed in the table as number 8.

The analysis of the articles reviewed revealed that in 7 cases people of different ages and sexes were injected with HA, most of them were women who received injections in the vaginal wall and face. Almost identical complaints and symptoms were reported on the day of HA injection and, as an exception, 1-3 days later. Only in one case out of seven a medicolegal autopsy was performed, following histological staining of preparations from the injection site (vaginal wall) and lung; before and after hyaluronidase cleavage, it was confirmed that most of the injection components consisted of hyaluronic acid.

Therefore, the most common pulmonary disorder caused by hyaluronic acid injections after cosmetic genital surgery in women is nonthrombotic pulmonary embolism (NTPE). The only case of NTPE that had developed after a male genital surgery was a case from our own expert practice.

Case report

The body of a 56-year-old man was brought to the Bureau of Forensic Medical Examination. The forensic medical examination report indicated that the man's death was confirmed in a narcological clinic, where he had admitted himself. The day before, the man had undergone an unknown medical procedure on his penis, after which his condition deteriorated drastically. He called the ambulance team twice, and the medical personnel recommended him to go to a narcological clinic. During the examination at the narcological clinic, the patient was cooperative, lucid, and answered questions in a straightforward manner. He asked for help, was anxious, and was focused on his own poor state of health. He denied venereal diseases, HIV, head injury and tuberculosis. He had a history of alcohol abuse and heavy drinking. During the last week he had been drinking alcohol daily. The diagnosis was determined to be

a formed withdrawal syndrome with a decrease in all types of control. During examination, hyperaemia of the skin, tremor of the limbs and sweating were noted. His face was swollen, and the sclerae were injected. Vesicular breathing was audible in the lungs, heart tones were rhythmic, muted, PS 100/min. AP 160/100 mmHg. Chest X-ray and computer tomography were not performed. By morning the patient's condition worsened, he complained about weakness and pain of a "pressing nature" in the sternum area. During the examination, the patient was in a forced posture, sitting with hands resting on the bed surface. His skin was covered with sweat, visible mucous membranes were cyanotic.



Figure 1: The webbed neck of the penis.

The patient was diagnosed with respiratory arrest. Full resuscitation measures were initiated within 30 minutes. No effect was achieved and the man died. At the time of arrival of the body at the Bureau of Forensic Medical Examination, there was no clinical report on the cause of death. The possibility of death from intoxication was ruled out by the result of the forensic chemical examination: no drug substances, ethyl, methyl, propyl, butyl, amyl alcohols were found in the blood of the corpse. The penis was wrapped with a circular gauze dressing. After its removal, it was

evident that the skin of the scrotum was fused with the skin of the penis over a considerable length forming an excessive skin fold also known as the webbed neck of the penis (Fig. 1).



Figure 2: A puncture wound from an injection.

On the lower side of the glans of the penis there was a puncture wound - a site of medical injection (Fig. 2).

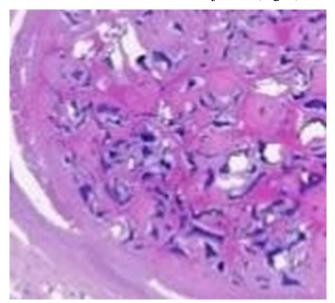


Figure 3: Gel present in the soft tissue of the penile root region. X 50

In the area of the root of the penis there were bruises of different age. The soft tissues here were enlarged in volume, with a soft-elastic consistency to the touch. The cross-section of this area revealed a concentration of a foreign jelly-like substance of pinkish-yellowish and yellow color.

Histological examination of soft tissues from the area of the root of the penis revealed signs of organization and haemosiderosis. Areas of productive inflammation with leucocytic infiltration around structureless masses of foreign bodies were visible (Fig. 3).

Histological examination of the lung tissue indicated a sharp hemorrhage, foci of edema, emphysema and dystelectasis. Foreign structureless masses (gel) were observed in the lung vessels, which were partially or completely filling their lumens (Fig. 4).

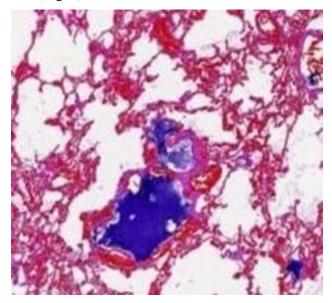


Figure 4: Gel emboli present in lung vessels. X 50

During the spectrographic examination of the foreign substance (gel) found in the penis area and a lung fragment from the corpse, it was discovered that one of the components of the investigated substance found in the soft tissues of the penis root and in the lung vessels was either hyaluronic acid as an individual compound or sodium hyaluronate. Thus, it was established that injection of HA-based filler was the cause of nonthrombotic pulmonary embolism. The diagnosis of nonthrombotic pulmonary embolism in the present case was complicated by the lack of required medical records, radiological studies and laboratory tests. The development of vascular embolization

was triggered by a wide network of venous plexuses at the site of filler injection. HA could enter the inferior vena cava system through the penile blood vessels, where venous outflow was performed by 3 drainage systems: the superficial dorsal vein system, the deep dorsal vein system, and the deep cavernous vein system. The superficial dorsal vein is formed by merging of a network of saphenous veins draining the penile skin and fascia. It extends along the dorsal surface of the penis between the Colles' fascia (the superficial vein) and the Buck's fascia (the deep vein), sometimes splitting at the root of the penis. The drainage of blood occurs in the great saphenous vein of the thigh or femoral vein (from the external iliac vein system). The deep dorsal vein drains the glans, the spongy body and the distal 2/3 of the cavernous bodies, forming a venous plexus in the area of the coronary sulcus. The emissary veins, performing the drainage of blood from the caverns, merge with the circular veins, which under the albuginea create an intrathecal plexus and merge directly or indirectly with the deep dorsal vein. Starting at the coronary sulcus, the veins are located on the dorsal surface of the penis. The deep dorsal vein passes between the cavernous bodies deeper than the Buck's fascia and merges with the prostatovesical plexus and then with the internal iliac vein system. The emissary veins in the proximal penis unite to form deep cavernous veins draining the proximal cavernous bodies and the bulbar region of the spongy body. Passing between the bulbous region of the urethra and the crura of penis, 2 to 5 deep cavernous veins merge into the internal pudendal vein of the prostatovesical plexus¹⁶ (Fig. 5).

A typical symptom of NTPE observed in such cases may be represented by an acute respiratory failure within several hours or days after HA injection.

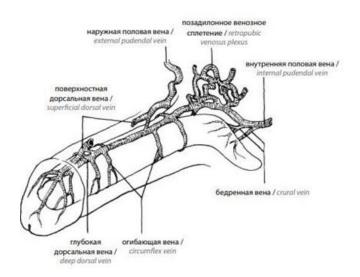


Figure 5: A schematic representation of venous outflow in the penis (according to W.D. Middleton).

Discussion

Hyaluronic acid was originally used exclusively for medical purposes in the treatment of osteoarthritis, as a replacement for joint fluid. It was also used in ophthalmological surgery in the form of injectable implants^{3,8}. With the further study of HA properties, the scope of its application expanded, making plastic surgery and cosmetology the most popular and highly demanded procedures. Side effects have hardly been reported, however, Signorini M. et al¹⁷, noted that HA injections have certain side effects such as vascular infarction, soft tissue necrosis, inflammation, pigmentation and granuloma formation. also associated with complications local reactions (subcutaneous haemorrhage, swelling, decreased or increased sensitivity, soft tissue asymmetry and fibrosis, as well as possible infection of the injection site), very few systemic complications have been described. We found few articles on the subject of complications caused by hyaluronic acid injections in the domestic literature. The study published by M. E. Sinelnikov et al. 18 lists the complications caused by

the now popular facial injections, especially in women. During filler contouring, inadvertent injection of the compound into a vessel and/or embolisation of the filler into the arterial system is characterized by soft tissue necrosis, visual impairment up to blindness and even stroke. Similarly, the publication by H. P. Takhchidi¹⁹, describes the first case of occlusion of the right posterior ciliary artery and embolic occlusion of the facial arteries in a woman caused by hyaluronic acid injection into the frontal region, where branches of the supraorbital, supratrochlear, and dorsal nasal arteries are known to be located. We have not found any cases of pulmonary complications related to HA injections in the domestic literature. Analyses of the results of different filler injections show that pulmonary embolism can occur via several mechanisms, such as excessive local tissue pressure caused by the injection of high doses of HA, local massage performed by an unlicensed practitioner, migration effects or direct intravascular injections^{8,20}.

In the case we have described, HA was injected into an area of the penis that is densely populated with vasculature, which increases the risk of embolism. Although HA filler has always been considered a static material that simply occupies space within the tissue, studies have shown that HA is osmotically active. Thus, it can also extract water from surrounding normal tissues, increasing their volume²¹. Recent studies have demonstrated that exogenous hyaluronic acid is known to bind to the receptors of all kinds of endothelial cells throughout the body, but it binds particularly strongly to the receptors of pulmonary vascular endothelium²². Thus, we can conclude that emboli diffusely accumulated in small pulmonary arteries. Also, HA can lead to the disturbance of coagulation and fibrinolysis systems, as its molecule stimulates fibroblasts, which leads to the accumulation of type I and type III collagens, in addition,

intravascular HA can interact with fibrinogen and accelerate the thrombin-induced formation of fibrin clots^{23,24}. It is impossible to ignore the fact that HA, when it enters the bloodstream, is eliminated from the liver by receptor-mediated capture and catabolism in hepatic sinusoidsat the rate of 85-90%².

The man in the above-described case suffered from chronic alcoholism with the development of alcoholic fatty hepatosis. This may have affected the metabolism of HA. According to the medical records, he consumed alcohol on the same day, after the injection. It is possible that this instance of alcohol consumption may also have affected his general condition. We have not come across any publications describing the interaction between ethanol and HA.

Conclusion

The analysis of published observations and our own practical experience allowed us to conclude that surgical interventions on genitals, through injections of hyaluronic acid-based fillers, are not as safe (as it was stated before) and may be associated with the risk of fatal pulmonary embolism. Forensic medical diagnosis in such cases is based on the results of medicolegal autopsy along with histological and spectral methods that allow identification of the foreign substance embolised from the injection site into the lungs.

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