Incidence of Major Complications from Embolo-Sclerotherapy of Head and Neck Vascular Malformations in a Single Specialist Center

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Disclosure of conflict of interest

None

Statement of ethical approval

This is a retrospective audit study of a prospectively collected departmental database with no patient identifiable data used; that were carried for service improvement as part of the clinical governance of the department, hence did not require institutional review board approval and informed consent. The study is registered with our local clinical governance department.

Abstract

Objective: Current data on the nature and rate of major complications for embolo-sclerotherapy (EST) of vascular malformations is scarce. However, even fewer studies focus on vascular malformations specific to the head and neck, which confer an increased specific risk of airway compromise, neurologic and ophthalmologic injury. More understanding is required surrounding the type and incidence of complications to improve treatment planning and informed consent. Therefore, this study aimed to review major complications secondary to EST of head and neck vascular malformations over a 5-year period in a single specialized multidisciplinary center for vascular anomalies.

Methods: All interventions were decided by the multi-disciplinary team. Demographic, procedural and complication data between 1st January 2013 and 31st December 2017 were prospectively documented in a dedicated database and analyzed. EST of high-flow vascular malformations (HFVM) was performed by selective catheter angiography or direct injection, and by direct injection only for low-flow vascular malformations (LFVM). Major complications were defined as any tissue or functional damage caused by direct injection, distal embolization, or tissue reaction and were decided by the multidisciplinary team.

Results: Forty-eight patients (median age of 35 years; range of 14-70 years; 18 males and 30 females) had 100 embolo-sclerotherapy procedures for head and neck vascular malformation. Of these, 14 patients had EST for HFVM and 34 patients for LFVM; total 43 and 57 procedures, respectively. Overall, 5 patients with HFVM developed major complications from EST when compared with 2 patients with LFVM (P=0.0167). Two patients required pre-emptive tracheostomy due to risk of post-operative airway compromise. Overall, seven

(14.6%) patients experienced major complication from EST. In the HFVM group, major complications from EST occurred in five patients; 4 cases of tissue ulceration and necrosis (2 needed debridement, 1 healed with resultant fibrosis that impeded speech, and 1 resolved spontaneously) and 1 post-procedural airway compromise requiring tracheostomy. Meanwhile, in the LFVM group, major complications occurred in two patients; one case of severe necrosis involving the alar cartilage, lip and cheek requiring debridement and reconstruction under plastics, and one simple cellulitis. No patients sustained stroke or vision impairment.

Conclusions: EST is relatively safe for head and neck vascular malformations in a high volume experienced center. Our major complication rate of 14.6% per patient (35.7% for HFVM; 5.9% for LFVM) or 7% per procedure (11.6% for HFVM; 3.5% LFVM) compares favorably with published data from other centers. This data will improve treatment planning and informed consent for EST for both HFVM and LFVM of the head and neck.

Keywords

Vascular malformation, arteriovenous malformation, embolo-sclerotherapy, embolization, sclerotherapy, complications.

Introduction

Embolo-sclerotherapy (EST) is widely acknowledged as a first line interventional treatment strategy for congenital vascular malformations including those involving the head and neck [1-6]. Despite being minimally invasive, EST for head and neck malformations carries significant risk of major complications including, but not limited to, airway compromise, visual impairment, stroke, tissue necrosis, contractures and nerve injury [7-9]. These complications carry significant functional, cosmetic and psychological implications for the patient affected. Despite improving care in specialist centers, up-to-date estimates of complication risk for audit and informed consent are scarce but appear considerable, as high as 63% of patients or 32% of procedures for head and neck vascular malformations [10, 11]. Recent literature focuses on high-flow vascular malformations (HFVM) and ethanol with a paucity of data for low-flow vascular malformations (LFVM) and non-ethanol agents. Therefore, this study aimed to review all major complications following EST of all head and neck vascular malformations in our specialized multidisciplinary center for vascular anomalies over a 5-year period.

Methods

This is a retrospective audit study of a prospectively collected departmental database with no patient identifiable data used; that were carried for service improvement as part of the clinical governance of the department, hence did not require institutional review board approval and informed consent. The study is registered with our local clinical governance department.

Embolo-sclerotherapy

All patients referred to our center with non-central nervous system vascular malformations underwent evaluation by the multidisciplinary team (consisting vascular surgeons,

interventional radiologists, and clinical nurse specialist) who subsequently directed decisions on intervention. All ESTs were carried out by consultant interventional radiologists and/or consultant vascular surgeons with subspecialty interest and training in treating vascular anomalies. EST was our favoured treatment for patients with rapidly growing and/or symptomatic vascular malformations, which included pain, disfigurement, pressure effect, ulceration, bleeding, coagulopathy, and cardiac failure. Patients with asymptomatic or minimally symptomatic lesions, which were stable in size, were managed conservatively. Clinically, we classified the vascular malformation into HFVM when it is an arteriovenous malformation (AVM), whereas LFVM when it is not an AVM such as venous, lymphatic, capillary or a combination of these. Pre-procedural cross-sectional imaging (i.e. computed tomography (CT) and/or magnetic resonance (MR)) was performed on all patients to aid planning. All ESTs during the study period were performed under general anaesthetics. All ESTs of HFVM were performed under selective catheter angiography and direct injection, and LFVM with direct injection only. All ESTs during this study were carried out with fluoroscopic guidance with digital subtraction angiography performed to confirm accurate position of the catheter and/or needles, and to assess the flow; either in a vascular hybrid theatre with a floor mounted C-arm or standard operating theatre with a mobile C-arm. Ultrasound was also used in some cases. ESTs were performed either with foam sclerosants (sodium tetradecyl sulfate 3% or polidocanol; mixed with air in a 1:4 ratio), ethanol, embolization coils, other substances such as Onyx™ Embolic System (Medtronic) and Gelfoam® (Pfizer), or a combination of them, and the choice of agents used was at the operator's discretion. Our preferred EST agent was foam sclerotherapy and this was purely from our own experience as there were not much evidence on this. Ethanol and coils were occasional used, often in combinations, for lesions that were perceived to be more aggressive by the operator. We always informed the patients the likelihood of repeat procedures might

be needed, especially for large lesions. ESTs were also performed at times prior to or as stage for open surgery to reduce the risk of bleeding. The majority of the ESTs were carried out as day cases and followed up in the out-patient clinic at around six to twelve weeks post-operatively.

Data Collection

Any patient who received EST treatment for a head and neck vascular malformation at our center between January 1st 2013 and December 31st 2017 was included. Demographic, anatomical, procedural, treatment outcome, complication and follow-up data collected prospectively in a dedicated database were analyzed. Major complications were defined as any tissue or functional damage caused by direct injection, distal embolization or tissue reaction. The major complications in the study were determined by our multidisciplinary team described above.

Statistical Analysis

Data was collected and analysed using Microsoft Office Excel (Redmond, Washington, USA) and GraphPad Prism 7.04 (GraphPad Sorftware, San Diego, CA). Data was presented as median and range. Proportional data was presented in percentage. Differences in the rates of major complications between subgroups were analyzed using Fisher's exact test. $P < 0.05$ was considered significant.

Results

Patients and procedures

During the study period, 48 patients had a total of 100 EST procedures for head and neck vascular malformations with a median age of 35 years (range 14-70 years); 18 (38%) males

and 30 (62%) females. In total, 14 (29%) patients had EST for HFVM and 34 (71%) for LFVM; total of 43 and 57 procedures, respectively. All the LFVM were predominant venous except four predominant lymphatic malformations. Twenty-five (9 HFVM; 16 LFVM) patients had received prior treatment including EST, surgical excision/debulking, photodynamic therapy or laser (pulsed dye or carbon dioxide) therapy either in our center, other hospitals, or both. Table 1 summarizes the embolization agents used for all the EST procedures. Meanwhile, Table 2 summarizes the anatomical distribution of the vascular malformations across the head and neck. The median number of treatments per patient for HFVM was 1 (range 1-15) and 2 (range 1-4) for LFVM. Two patients (1 HFVM; 1 LFVM) required pre-emptive tracheostomy due to risk of post-procedural airway obstruction.

Major Complications.

In total, seven patients (14.6%) sustained major complications from EST procedures of head and neck vascular malformations over 5 years (7% of total procedures). Notably no patients experienced stroke or vision loss. In the HFVM cohort, major complications from EST occurred in five patients (35.7%) or 11.6% of total procedures. There were four cases of tissue ulcerations and necrosis, and one case of airway compromise by oedema requiring tracheostomy. The major complications for the EST of the HFVM in the study were summarized in Table 3. In the LFVM group, 2 patients (5.9%) or 3.5% of total procedures experienced major complications from EST of vascular malformation; one extensive hemiface necrosis needing surgical debridement and reconstruction, and the other with cellulitis resolved with oral antibiotics. The major complications for the EST of the LFVM in the study were summarized in Table 4. The rate of major complications was significantly higher for EST of HFVM than LFVM by number of patients (P=0.0167), but not by total procedures (P=0.1362).

Discussion

This study reported a range of major complications from EST of head and neck vascular malformations including two with long term implications; 1) residual numbness causing speech impairment following EST of HFVM, and 2) functional, cosmetic, and psychological disability from extensive hemifacial necrosis requiring surgical debridement and reconstruction following EST for facial LFVM. There was a higher rate of major complications identified following EST of HFVM, compared to LFVM. The majority of complications reported in this study were due to local toxicity of the EST agents causing ulceration and necrosis. There were no events attributed to distal embolization of agent and notably no strokes, ophthalmologic or neurologic complications. Understanding the types and rates of major complication of EST for HFVM and LFVM is important to guide decision-making around treatment for both patients and clinicians.

In a single center retrospective, Jeong et al. specifically described a permanent complication rate of 8.3% (1 out of 12 patients), in a retrospective of patients undergoing ethanol EST for head and neck AVMs. This single complication was skin necrosis that healed producing a 1.5 cm scar. The authors also noted one case of skin necrosis that only resolved after surgical excision. Aside from this, all complications resolved within one month; including 2 cases of skin necrosis, one bullae formation and one patient who experienced temporary dyspnoea post-procedure[9]. In a single center retrospective, Pekkola et al. described complications in twelve out of nineteen patients (63% patients) across 14/59 EST procedures (24% procedures) for head and neck AVMs. Most complications occurred secondary to local injection of ethanol and resolved in the short term. Complications included nine cases of skin/mucosal /tissue necrosis, which all resolved, and one Horner's syndrome for a medial

canthus AVM which resolved in days. Overall, one patient sustained severe functional damage in the form of near complete monocular vision loss likely due to retinal ischemia after attempts to control a refractory mid-face AVM with arterial recruitment via the skull base [10]. McMillan et al. evaluated outcomes in 31 patients after Onyx™ of head and neck AVMs between 2007 and 2013. A total of fifteen complications were sustained over 13 EST sessions, with the commonest being infection (n=7), followed by tissue necrosis (n=4), two of whom required debridement, loss of vision (n=2) and bleeding (n=2)[11]. Su et al. carried out a retrospective single center study evaluating major complications in a cohort of 66 patients who underwent a total of 96 ethanol ESTs for infiltrating-diffuse head and neck AVMs[12]. In total, zero major complications were identified, but minor complications, encompassing skin blisters/ superficial necrosis, were encountered by sixteen out of sixty-six patients (total 24.2% patients). These healed successfully in all cases but one, which healed with obvious scar formation. Five patients also experienced post-procedural transient hemoglobinuria which resolved in hours with intravenous fluids and with no effect on renal function[13]. Kim et al. retrospectively analysed outcomes in a cohort of 42 patients with head and neck AVMs who underwent a total of 132 EST procedures using ethanol. The rate of major and minor complications was 3.8% (5/132 procedures) and 25.8% (34/132 procedures) respectively. Major complications included three cases of skin necrosis requiring skin grafting/escharotomy; one ischemic stroke manifesting as blindness, weakness and dysarthria and one case of severe periorbital swelling and orbital pressure necessitating surgical decompression. Cases of skin necrosis/bullae/discolouration that recovered with conservative treatment and ‘acceptable’ resolution, even if there was residual pigmentation or scar, were classified as minor complications; other minor complications included short-lived symptoms on the day of procedure only such as intra-operative pulmonary artery pressure increase, nerve palsy, hypoesthesia, arrhythmia, numbness and dizziness [14]. Dmytriw et al.

retrospectively identified eighty-nine patients who had undergone a total of 244 ESTs of head and neck AVMs between 1984 and 2012. Complications were classified according to transient or permanent effect; with seven patients (7.2%) and two patients (2.2%) in each group, respectively. Permanent complications included one case of vision loss and one stroke, while transient complications included five cases of post-procedural bleeding, and two cases of lingual inflammation in tongue AVMs- one which necessitated temporary intubation. The authors did not include other post-procedural side effects such as skin scaling, pruritus or paraesthesia lasting for days to weeks in their statistical analysis [15].

There is a scarcity of published data around EST for LFVM, including those with a lymphatic component. Su et al. similarly looked at treatment venous malformations of the face and neck with ethanol EST. In a cohort of sixty patients, six patients (10% patients) sustained minor complications; four cases of skin necrosis that healed with conservative care and two patients with transient facial nerve palsy that recovered completely in one to three months with corticosteroids and neurotrophic medication. Five patients also reported transient haemoglobinuria, but no renal dysfunction, that resolved with intravenous fluid supplementation [16].

Our complication rates appear comparable if not favorable to those in the literature; likely as a result of experience from working in a tertiary center with a high volume of patients and operators with a specialized interest. Therefore, it may be reasonable to recommend that EST for vascular malformations are performed in a multi-disciplinary approach with the relevant mix of skills and experience. Furthermore, a challenge we have encountered when comparing multi-center outcomes is a lack of consensus regarding the definition of complication or common guidance to stratify the severity of complications. Clearly, there is an indication to

standardize the definition of complication following EST to allow meaningful comparison between centers and improve understanding of the risks of complications. Moreover, future prospective studies with larger samples and longer follow-up should evaluate the factors that determine outcomes including with multivariate analysis.

It is also important to emphasize that this study was not designed to compare the efficacy and safety of different agents for EST. Therefore, we could not propose if a specific agent influenced the rate of major complications. There is no strong evidence in the literature to support the method of EST, and the choice and concentration of agents, hence in the authors' opinion, operator's experience and familiarity with techniques remain the most reliable determinants of clinical outcomes.[17-20] The total complication rate of ethanol EST for arteriovenous malformation has been reported to be relatively high, ranging from 10% to 52%; with absolute ethanol associated with the highest complication rates [19-25] Sclerotherapy using STS and polidocanol foam is often reported to be loss toxic than ethanol [5, 26-29]. However, all agents have potential to cause local and systemic side effects, therefore they must be used with caution and within recommended dose limits. At our center STS foam with air is our preferred agent, for both HFVM and LFVM, and has generally been very safe and effective. Our preference for foamed STS over ethanol may have influenced our relatively low major complication rates although further studies are required. Our clinical outcomes can also be attributed to our high-volume service and multidisciplinary approach which has been shown to improve outcomes in patients with congenital vascular malformations[30-31].

There were several limitations to this study. Firstly, despite being a high-volume tertiary center for vascular anomalies, our sample size of forty-eight patients was relatively small for analysis of potential risk factors. Since vascular malformation is relatively uncommon, any

larger sample size study will require a multi-center design including a registry. Secondly, despite data was collected prospectively in a database, analysing this data in retrospect still leaves scope for potential bias to occur. However, all major complications were identified and recorded prospectively in the database, hence likely to reduce the risk of potential selection bias. Finally, as previously addressed, our definition of major complication might differ from that used in other studies.

Conclusions

EST is relatively safe for head and neck vascular malformations in an experienced tertiary center. In this cohort of forty-eight patients, we found a major complication rate of 14.6% per patient (35.7% for HFVM; 5.9% for LFVM) or 7% per procedure (11.6% for HFVM; 3.5% LFVM). These rates are comparable if nor favorable to those reported in the literature. This is likely due to our high caseload, multidisciplinary approach, experienced operators and improved targeted treatment. Understanding the complications will help to instruct treatment strategies, promote safety, and improve patient consent.

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Legends for figures

Figure 1.

A 61 year old woman who developed upper lip ulceration and necrosis following ethanol sclerotherapy of the high-flow vascular (arteriovenous) malformation of the face which required surgical debridement. A. Digital subtraction angiography demonstrates the high-flow vascular malformation in the face. B. Ulceration and necrosis of the upper lip following sclerotherapy. C. End result of the face following surgical debridement and further multiple embolo-sclerotherapy procedures of the high-flow vascular malformation.

Figure 2.

A 35 year old woman who developed right lower lip and oral mucosa ulceration and necrosis following foam sclerotherapy of the right lower lip high-flow vascular (arteriovenous) malformation with sodium tetradecyl sulfate 3% which subsequently healed. A. Digital subtraction angiography demonstrates the high-flow vascular malformation in the right lower lip. B. Ulceration and necrosis of the right lower lip and oral mucosa following sclerotherapy. C. Healed ulceration and necrosis of the lower lip and oral mucosa.

Legends for tables

Table 1. Embolo-sclerotherapy agents used for high-flow and low-flow vascular malformations in this study. STS: sodium tetradecyl sulfate.

Table 2. Anatomical distribution of the vascular malformations across the head and neck treated with embolo-sclerotherapy in this study.

Table 3. Patients with major complications following embolo-sclerotheapry of high-flow vascular malformations. EST: emobolo-sclerotherapy, STS: sodium tetradecyl sulfate.

Table 4. Patients with major complications following embolo-sclerotherapy of low-flow vascular malformations. EST: embolo-sclerotherapy, STS: sodium tetradecyl sulfate.