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Indications, Outcomes, Efficacy, and Complications of Percutaneous Sclerotherapy in the Management of Hemangiomas at Kenyatta National Hospital

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ABSTRACT

Background

The effective management of hemangiomas using percutaneous sclerotherapy optimizes desired clinical outcomes and minimizes the associated complications in affected patients. Intra-lesional sclerotherapy involves injecting a sclerosing agent (such as bleomycin and sodium tetradecyl sulfate) into a lesion or the interstitial space around the lesion, causing endothelial injury, thrombosis, inflammation, scarring, and shrinkage of the lesion. Extensive literature suggests that sclerotherapy has a role in the management of hemangiomas, as demonstrated by better health outcomes and improved quality of life among affected patients.

Objectives

To evaluate the indications, outcomes, efficacy, and complications of percutaneous intra-lesional sclerotherapy in the management of hemangiomas.

Materials and methods

The study was a prospective cross-sectional study, conducted at a level 6 National Referral Hospital Interventional Radiology Unit. Patients with hemangiomas referred for intralesional sclerotherapy were treated.

Data including the indications of intra-lesional sclerotherapy, short-term outcomes, complications were collected, analyzed, and presented in percentages, graphs, pie charts, tables. Technical and clinical success rates were calculated. The efficacy of intralesional sclerotherapy was analyzed using chi-square test.

Results

A total of 20 patients with hemangiomas were treated. There were 11 females comprising 55% and 9 males comprising 45% with a male to female ratio of 1:1.2. The commonest indication for referral was pain (21.6%), followed by abnormal swelling (18.9%). Most lesions were located in the liver comprising 25%. Other locations included the hand, cheek, lower lip, lower extremities (calf, distal leg, foot, and thigh), lumbar region, posterior thoracic back region and abdomen mesenteric region. Majority of the patients had significant improvement of clinical symptoms with a p-value <0.05. Similarly, there was a statistically significant reduction in the sizes of the lesions treated with a p-value of <0.05. The technical success rate was 100% and the overall clinical success rate was 90%. Mild pain (10%), mild edema (10%) and skin discoloration (5%) were the commonest minor complications encountered, with no major complications.

Conclusion

Percutaneous intralesional sclerotherapy is a safe and efficacious treatment of hemangiomas with a high technical and clinical success rate. It should be considered as a first line of treatment for the hemangiomas.

Keywords: Hemangioma, Percutaneous sclerotherapy.

BACKGROUND

Hemangiomas are vascular malformations that result from erratic endothelial cell morphogenesis as well as disorganized vasculogenesis, causing a hemodynamically nonfunctional and dysplastic vascular network(1). The International Society for the Study of Vascular Anomalies classifies hemangiomas of infancy (infantile hemangiomas) into various patterns, including localized (focal), multifocal, segmental, and indeterminate, on the basis of clinical features. According to Kowalska et al. (2) congenital or infantile hemangiomas (strawberry marks) comprise the most common tumors benign in infancy, resulting from endothelial cell proliferation.

Hemangiomas can also occur in various locations which may include facial structures (lips, nose, forehead, orbital, etc.(3), intra-abdominal organs like liver, spleen, kidney etc, and other locations like bone, soft tissues/muscles, skin, extremities (4,5).

They may cause discomfort, bleed, or cause cosmetic disturbances therefore indicating the need for intralesional sclerotherapy to control the hemangiomas. They may also be located in anatomically challenging locations where surgical intervention may not be possible hence percutaneous sclerotherapy becomes a feasible option for therapy.

Despite conventional medical and surgical treatment options for hemangiomas, it is challenging to manage these lesions and optimize outcomes in affected patients. Thus, it is essential to examine the role of newer modalities such as percutaneous sclerotherapy in managing hemangiomas for improved health outcomes in the context of evidence-based care.

Intra-lesional sclerotherapy is a minimally invasive procedure that involves injecting a sclerosing agent into a lesion or the interstitial space around the lesion, causing endothelial injury, thrombosis, inflammation, scarring and shrinkage of the lesion. The most commonly used sclerosing agents in the management of vascular malformations include acetic acid, bleomycin, sodium tetradecyl sulfate, doxycycline, alcohol, and hypertonic saline (1). Although there is no gold standard for managing vascular malformations, bleomycin has demonstrated better therapeutic outcomes and side effect profile than other sclerosants. Most other sclerosing agents are associated with an acute inflammatory response (hypersensitivity reaction).

Hemangiomas and other vascular malformations are associated with complications such as functional impairment, ulceration, obstruction, and disfigurement. Thus, the major indications for percutaneous intra-lesional sclerotherapy in patients with hemangiomas are cosmetic improvement and symptom alleviation. Intra-lesional sclerotherapy is a safe and effective therapeutic option for managing hemangiomas and is associated with lesser post-procedural complications than radiation therapy and surgical ablation (6).

As noted above, hemangiomas are associated with multiple complications, especially if no intervention is made. Additionally, conventional therapies for hemangiomas, such as radiation therapy and surgical ablation may have sub-optimal efficacy and a poor side effect profile. Thus, percutaneous sclerotherapy is increasingly used to improve therapeutic outcomes in patients with hemangiomas (7). The goal of this study was to provide valuable insight regarding the common indications for percutaneous sclerotherapy in patients with hemangiomas, its short- term outcomes, the efficacy of the intervention, and its associated complications.

MATERIALS AND METHODS

The study was a prospective cross-sectional study, conducted at a level 6 national referral hospital, interventional radiology unit. Patients with hemangiomas referred for intralesional sclerotherapy were treated.

Data including the indications of intra-lesional sclerotherapy, short-term outcomes, complications were collected, analyzed, and presented in percentages, graphs, pie charts, tables. Technical and clinical success rates were calculated. The efficacy of intralesional sclerotherapy was analyzed using chi-square test.

Patients eligible for the study were included as per the inclusion and exclusion criteria. The inclusion criteria were patients with hemangiomas referred for percutaneous sclerotherapy and the exclusion criteria were patients who had undergone surgical or other interventions for the hemangiomas and those allergic to the sclerosant medications.

Percutaneous intralesional sclerotherapy procedure

The patient was received, consented and intravenous line placed. Vital signs were taken, and relevant pre-medications administered including pain medications, intravenous fluids.

The patient was then positioned, cleaned and draped. Sterile set with syringes, needles, and appropriate required supplies set. Lignocaine 2% was withdrawn and the required volume prepared using an appropriate dilution factor with normal saline/sterile water for injection (5- 10mls of 2% lignocaine diluted with an equal amount of 5-10mls of normal saline/sterile water for injection). The dose was maintained between 1-2mg/kg and care was taken not to exceed the maximum lignocaine dose of 5mg/kg.

The sclerosant agent was also prepared using already calculated volume depending on the lesion size/volume, with note taken not to exceed the maximum recommended dose of the sclerosant agent. The sclerosants utilized were Bleomycin (0.5-1IU/kg), 99.9% absolute alcohol (volume determined using the volume of contrast retained within the hemangioma before filling of any minor draining veins, averaging 10% of the lesion volume, and not exceeding 1ml/kg), and Sodium Tetradecyl Sulfate (STS) not more than 10mls per session. Lesion volume was calculated using three dimensions with a multiplication factor of 0.52 to give the volume.

Lignocaine was injected on the skin and advanced upto the level of the lesion, under real-time ultrasound guidance. Once the hemangioma was accessed, contrast test injection was administered under fluoroscopy to confirm the intralesional location of the needles and appropriate sclerosant volume was injected under fluoroscopic guidance. Additional needles were placed for intermediate to large hemangiomas to ensure entire coverage of the lesion. Real-time ultrasound guidance was also utilized to guide the sclerotherapy sclerosant injection process for lesions that were superficial and well visible by ultrasound.

RESULTS

A total of 20 patients were treated. 11 females (55%) and 9 males (45%) with a male to female ratio of 1:1.2. The age ranges were from 2 months to 79yrs.

The commonest indication for hemangiomas sclerotherapy was pain (21.6%), and abnormal swelling (18.9%). Others were cosmesis, pressure symptoms, proximity to critical structures, reduced general health/well-being, and non-resectable lesions respectively **(figure 1).**

Most of the hemangiomas were located in the liver (35%) followed by the hand (15%) and the rest of the hemangioma locations were 5% each. These other regions were the cheek, lower lip, lower extremities (calf, distal leg, foot, and thigh), finger, lumbar region, posterior thoracic back region, and abdomen mesenteric region.

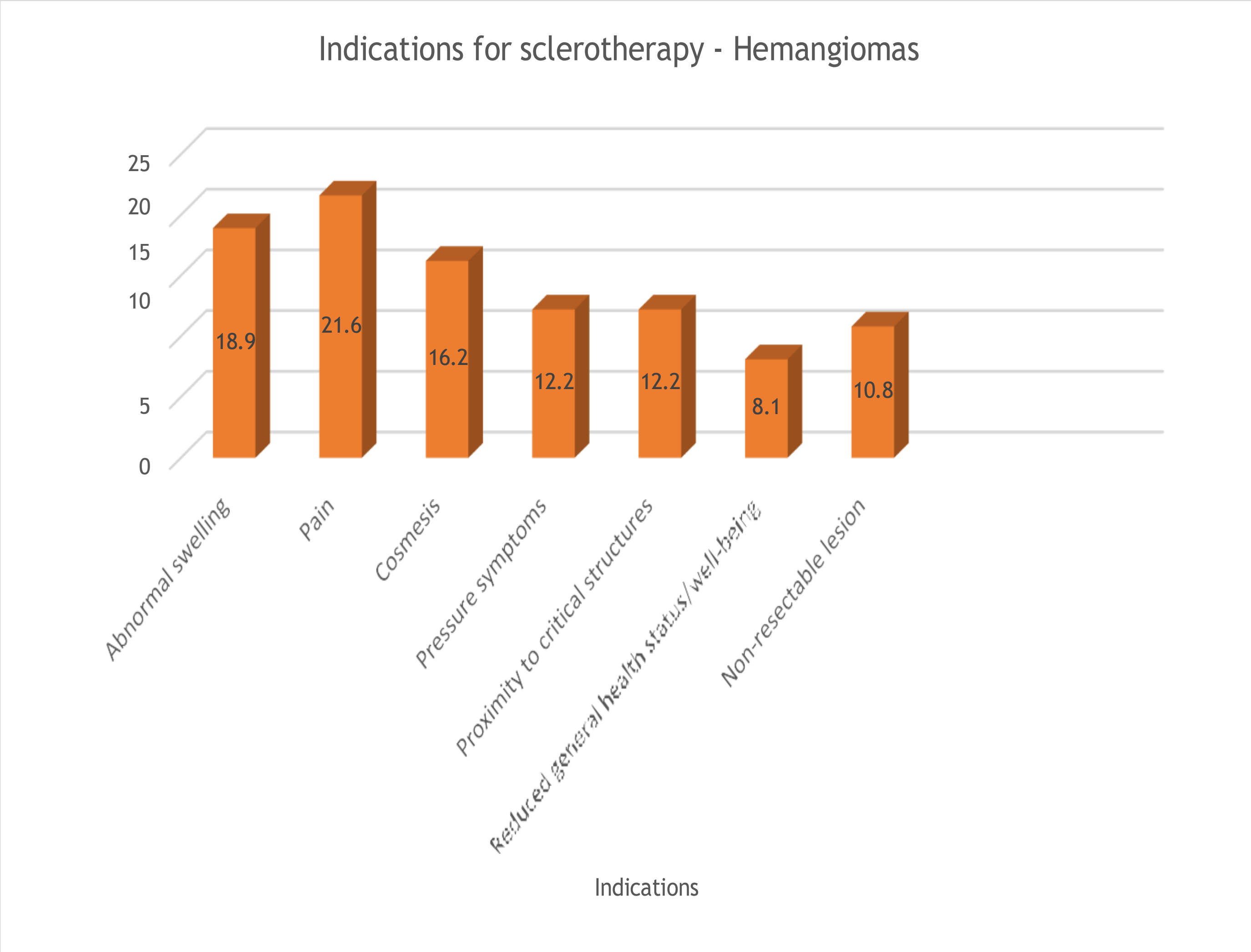

Figure 1: Indications for Sclerotherapy

Clinical response

Most patients demonstrated a significant improvement in the clinical symptoms post-sclerotherapy as demonstrated in **Figure 2**, with a reduction in pain, pressure symptoms, proximity to critical structures, and non-resectable lesions. Improvement was noted in cosmesis and general clinical health status/well-being. In all the patients treated, there was also a significant reduction in the sizes of the lesions (**Figures 3-7)**.

This clinical response to the percutaneous intralesional sclerotherapy treatment was statistically significant for both the clinical symptoms and size reduction with p-values <0.05 **(Tables 1 & 2).** The technical success rate was 100%, and the overall clinical success rate was 90%, for all the percutaneous hemangioma sclerotherapy procedures, with good post-procedure patient recovery.

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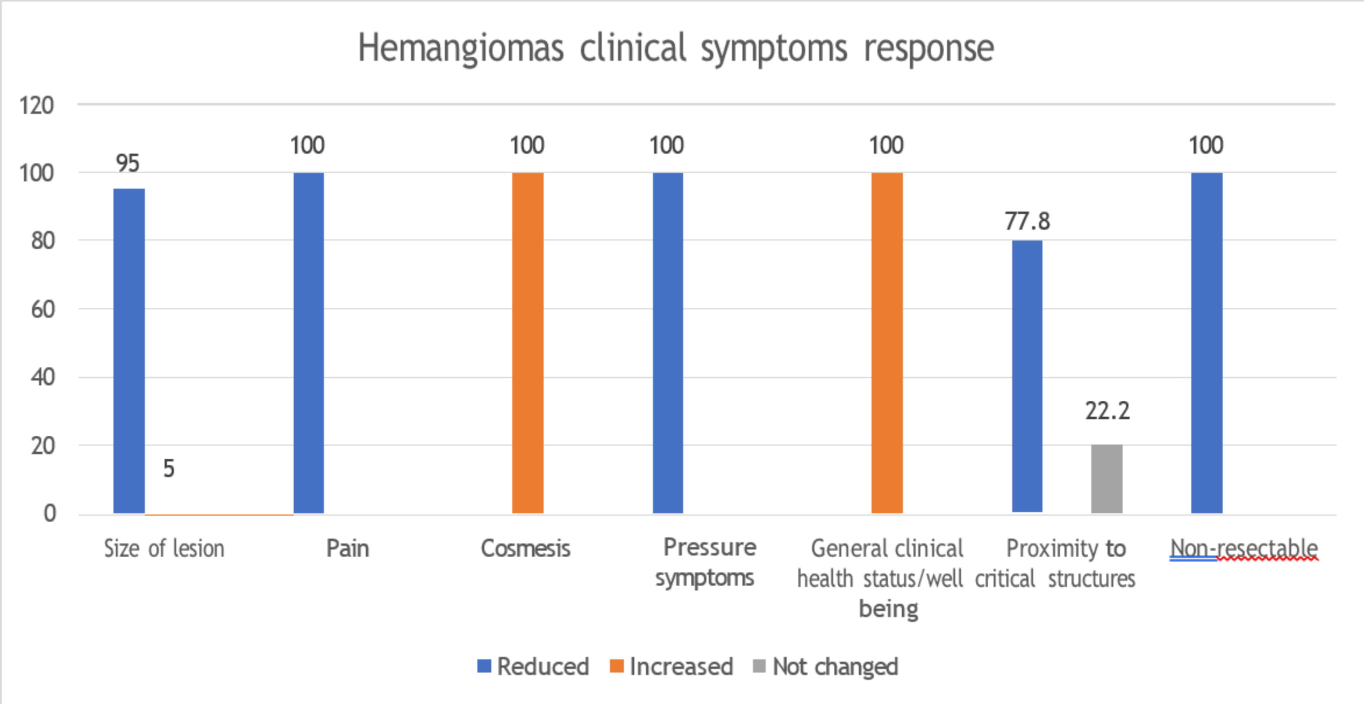

Figure 2: Bar chart showing hemangiomas treatment clinical symptom response.

Efficacy of percutaneous sclerotherapy

Percutaneous sclerotherapy demonstrated high efficacy in hemangioma treatment with a significant size reduction of the treated lesions as well as the patient symptom improvement with P values < 0.05 **(Tables 1 & 2).** This significant treatment response indicates that the percutaneous sclerotherapy procedure is therefore an efficacious treatment option for these hemangioma lesions (**Figures 3-7).**

Radiologically reduced intralesional vascularity post-treatment also reinforced the high efficacy of the percutaneous intralesional sclerotherapy for hemangiomas (**Figure 4**).

Similarly, no statistically significant association was found between the complications and the procedure, p-value > 0.05 demonstrating that percutaneous intralesional sclerotherapy for hemangiomas is a safe and efficacious procedure.

Table 1: Efficacy of clinical symptom response to percutaneous intralesional treatment of the hemangiomas.

	Hemangiomas clinical symptom response							
	Size of lesion	Pain	Cosmesis	Pressure symptoms	General clinical health status/well-being	Proximity to critical structures	Non-resectable	P-value
Reduced	19	16	0	9	0	7	8	0.0041671 *10-11
Increased	1	0	12	0	6	0	0	
Not changed	0	0	0	0	0	2	0	

The above shows that percutaneous intralesional sclerotherapy provided a statistically significant clinical improvement of symptoms after the intervention with a significant p-value of $0.0041671*10^{-11}$, thus demonstrating that percutaneous sclerotherapy is an effective and efficacious treatment method for the hemangiomas.

Table 2: Efficacy of hemangiomas size reduction response

Clinical size reduction	**Hemangiomas**	**P-value**
>90% (Complete/near complete resolution)	1	0.0005703
50-89% (Considerable/Significant reduction/marked response)	7	
21-49% (Moderate response/Partial reduction)	10	
<20% (mild response)	1	
No response/increased size	1	

The post-sclerotherapy size reduction response of the hemangiomas was statistically significant with a p-value of 0.0005703, which indicated that the percutaneous intralesional sclerotherapy intervention produced a significant size reduction response in the hemangiomas treated and therefore proves an efficacious treatment option for these lesions.

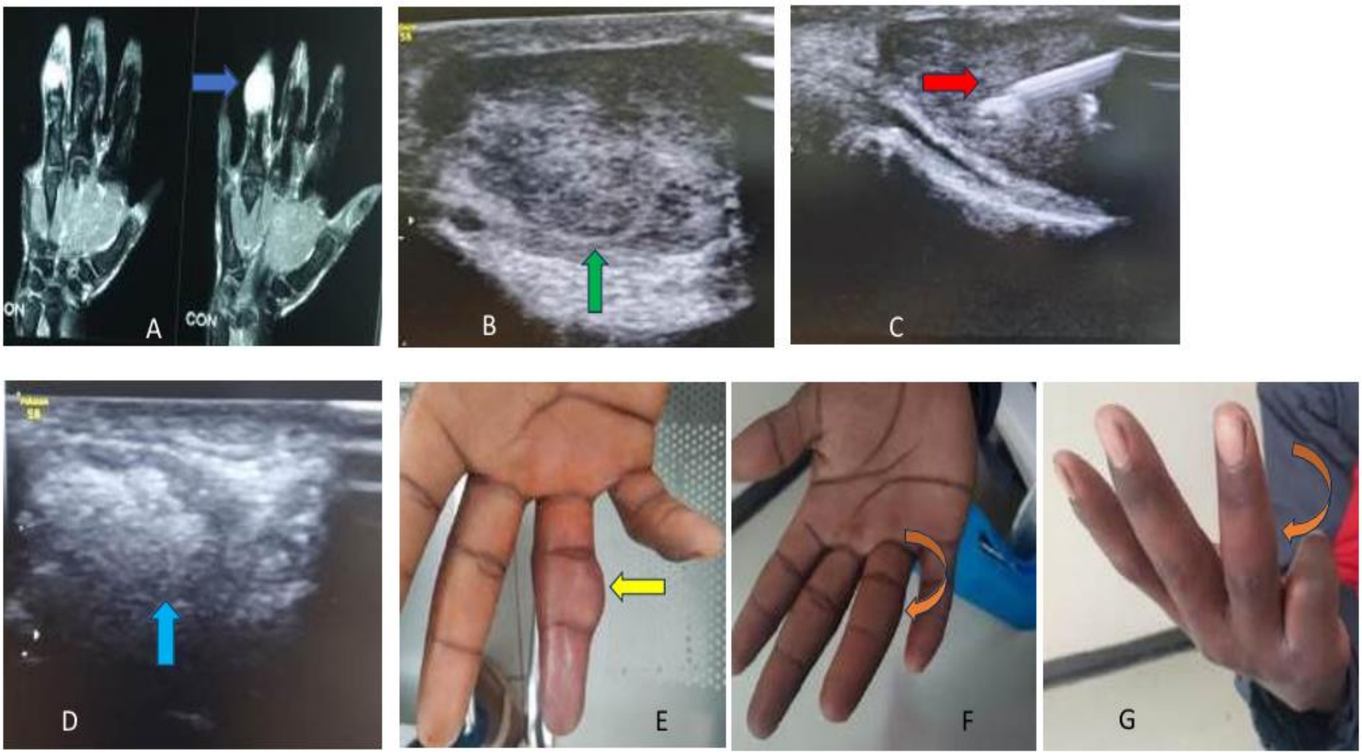

Figure 3: 19-year-old male with right 4th finger hemangioma. **A** – Contrast-enhanced hand MRI showing avidly enhancing lesion in distal right 4th finger (Blue arrow) **B** – Gray-scale ultrasound pre-sclerotherapy showing well-defined lesion with mixed echogenicity (Green arrow). **C** – Sclerotherapy access needle within the mass (Red arrow). **D** – Post-sclerotherapy gray-scale ultrasound image showing lesion entirely filled with sclerosant-air mixture, Sodium Tetradecyl Sulfate (STS) mixed with air, ratio of 4:1, 4parts air to 1 part STS (Light Blue arrow). Injection was done under real-time ultrasound guidance, with a total of 5ml STS sclerosant-air mixture. **E** – Hemangioma lesion physical appearance pre-sclerotherapy (Yellow arrow). **F & G** – Lesion resolved post-sclerotherapy (Curved orange arrows showing the initial lesion location, now resolved).

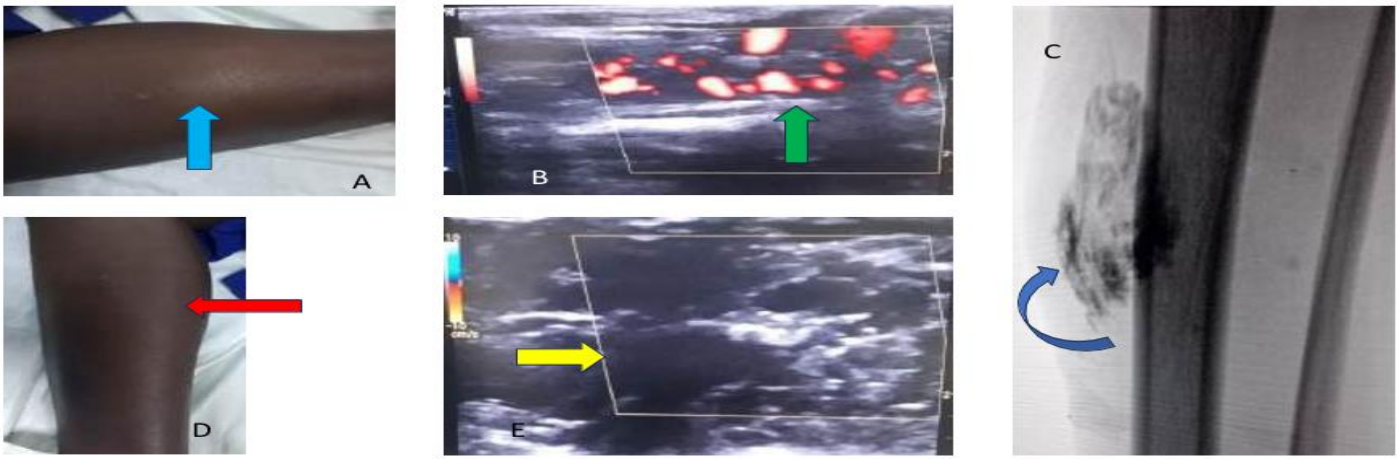

Figure 4: 15-year-old female patient with calf hemangioma. **A** – Calf hemangioma swelling pre- sclerotherapy (Light blue arrow). **B** – Colour power Doppler ultrasound demonstrating significant increased vascularity before sclerotherapy (Green arrow). **C** – Fluoroscopic spot film image demonstrating contrast during the sclerotherapy procedure where bleomycin 15IU was injected under real-time fluoroscopy mixed with contrast (Curved blue arrow). **D** – Post sclerotherapy reduction in the hemangioma one month after treatment (Red arrow). **E** – Radiological sonographic significantly reduced vascularity and size post-sclerotherapy (Yellow arrow). The above demonstrate good clinical and radiological response to bleomycin percutaneous sclerotherapy.

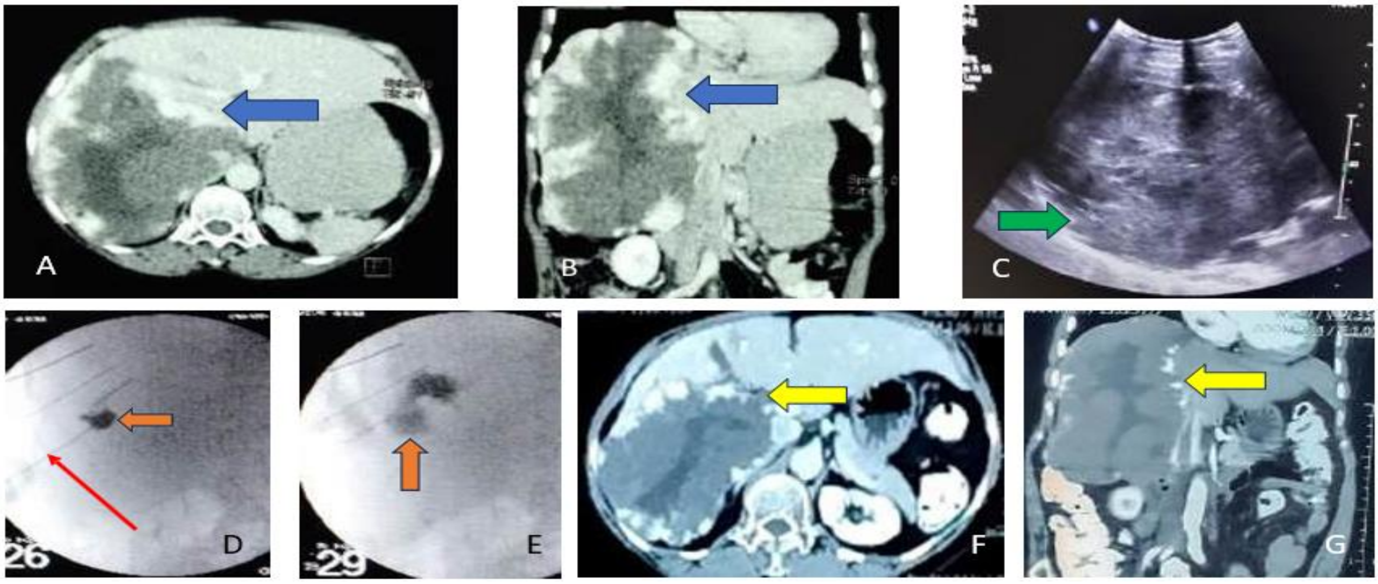

Figure 5: 61-year-old female with Giant right lobe liver hemangioma. **A & B** – Axial and coronal contrast-enhanced scans of the abdomen with large right lobe liver mass, with central hypodense regions and peripheral nodular enhancement characteristic of giant liver cavernous hemangioma. **C** – Gray-scale liver ultrasound demonstrating hyperechoic large mass with areas of hypoechogenicity in keeping with the giant liver hemangioma, pre-sclerotherapy. **D & E** – Fluoroscopic spot images demonstrating multiple access needles introduced into the mass (Red arrow) to cover the span of the mass. 45IU of Bleomycin was injected in divided doses and mixed with contrast, through the multiple access needles to cover the entire region of the mass, under real-time fluoroscopic guidance **F & G** – Axial and coronal contrast enhanced follow up CT scans demonstrating moderate size reduction of the mass as well as reduced peripheral nodular enhancement in keeping with moderate response to the bleomycin percutaneous sclerotherapy procedure. The patient’s symptoms of right upper quadrant abdominal fullness and pressure symptoms as well as pain also reduced post sclerotherapy.

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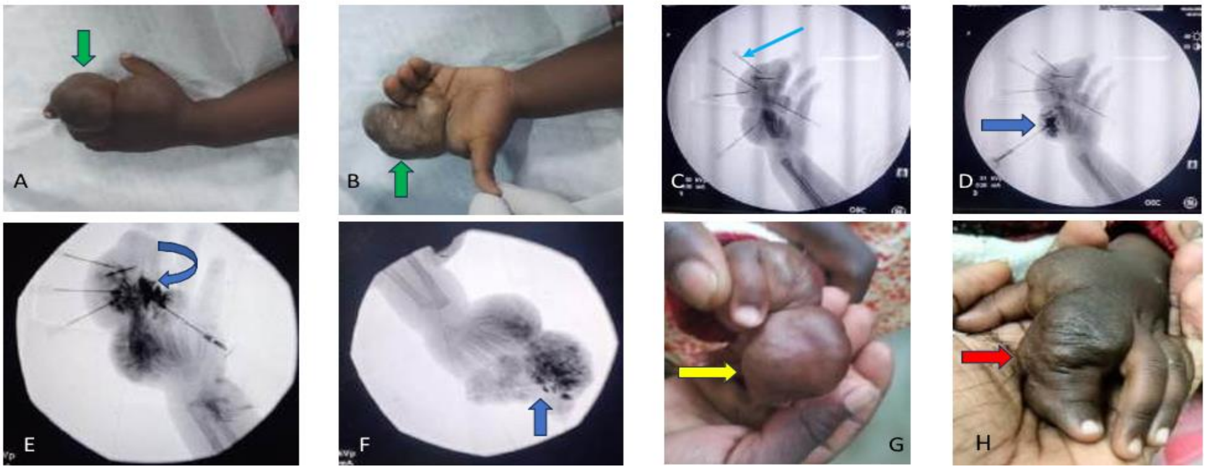

Figure 6: 8-month-old female patient with left-hand hemangioma with prominent vascular and low flow venous vessels. **A & B** – Pre-sclerotherapy physical hand images showing the hemangioma involving the index finger and dorsal thenar eminence (Green arrows). **C – F**: Fluoroscopic images depicting the sclerotherapy procedure from initial needle placement in C (Light blue arrow), followed by test contrast injection in **D** (Horizontal blue arrow), then followed by subsequent phases of Bleomycin injection (6IU) mixed with contrast in **E** (Blue curved arrow), under sedation, and **F -** after completion of the injections showing coverage of the lesion (Straight vertical blue arrow). **G** – Follow-up physical images two weeks post sclerotherapy showing mild reduction on the medial side (Yellow arrow), and **H** – One month post sclerotherapy showing moderate reduction response (Red arrow) of the hemangioma.

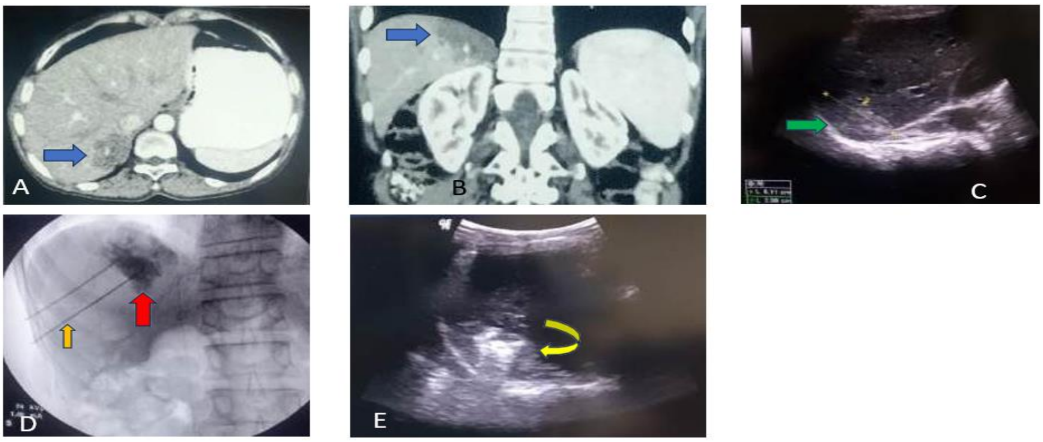

Figure 7: A 50-year-old female with right lobe liver segment 7 hemangioma, presenting with pain in the right upper quadrant region. **A** – Axial contrast-enhanced CT scan abdomen showing the segment 7 posterior right lobe liver hemangioma. **B** – Coronal contrast-enhanced CT scan abdomen showing the upper segment 7 location of the liver hemangioma. **C** – Grayscale liver ultrasound demonstrating the lesion and showing hyperechoic hemangioma, **D** – Fluoroscopic image demonstrating the contrast mixture with sclerosant (bleomycin 15IU). Hemangioma lesion opacified by the contrast mixture. **E** – Grayscale ultrasound liver image post sclerotherapy demonstrating gas within the lesion in keeping with the post-sclerotherapy injection and fills the lesion. The patient reported a significant reduction in pain after the procedure, indicating improvement in the patient's clinical symptoms.

Complications of Hemangiomas sclerotherapy.

Mild pain (Likert pain scale of 3/10) and mild edema post sclerotherapy were the commonest minor complications of hemangiomas post sclerotherapy, 10% respectively (**Figure 8)**. No severe pain was encountered.

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Skin discoloration (**Figure 9**), moderate right pleural effusion, and mild respiratory distress were each 5% **(Figure 10)**. No major complication was encountered.

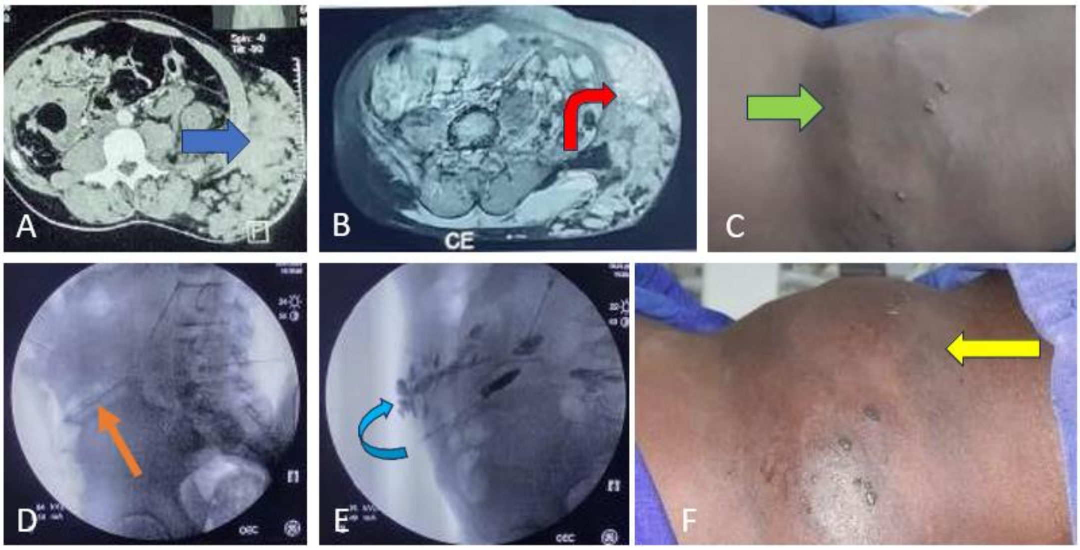

Figure 8: 16-year-old male patient with large left lumbar soft tissue hemangioma, who had mild edema, swelling post sclerotherapy injection, and mild pain. **A** – Axial contrast-enhanced CT scan arterial phase showing a large left lumbar hemangioma mass with mixed soft tissue, fat components, and prominent posterior tortuous veins (Blue arrow) **B –** Contrast-enhanced fat- suppressed MRI showing enhancing anterior segment of the hemangioma mass (Red angled arrow) and no significant posterior segment enhancement, where the prominent veins were located likely due to the slow flow within the veins. **C-** Physical appearance of the hemangioma lesion pre-sclerotherapy (Light green arrow). **D** – Fluoroscopic image demonstrating needle placement before any test contrast or sclerosant injection (Orange straight arrow). **E** – Fluoroscopic image demonstrating Sclerosant-contrast mixture injected into the hemangioma and there is flow outlining segments of the mass as well as the dilated venous channels (Curved light blue arrow). **F-** Mild edema/swelling of the hemangioma post-sclerosant injection which was a minor complication (Yellow arrow). The patient also had mild pain, and both were managed effectively with analgesic-anti-inflammatory medications. The symptoms resolved and with good post-op recovery and was later discharged from the unit with no other complaints.

Figure 9: Patient who developed 4th finger skin crusting and darkening mild complication after the hemangioma sclerotherapy procedure. Right 4th finger hemangioma skin darkening and crusting 1-week post sclerotherapy with Sodium tetradecyl sulfate (STS) (Curved blue arrow). It resolved over the next two weeks and the hemangioma resolved. No major complication was encountered.

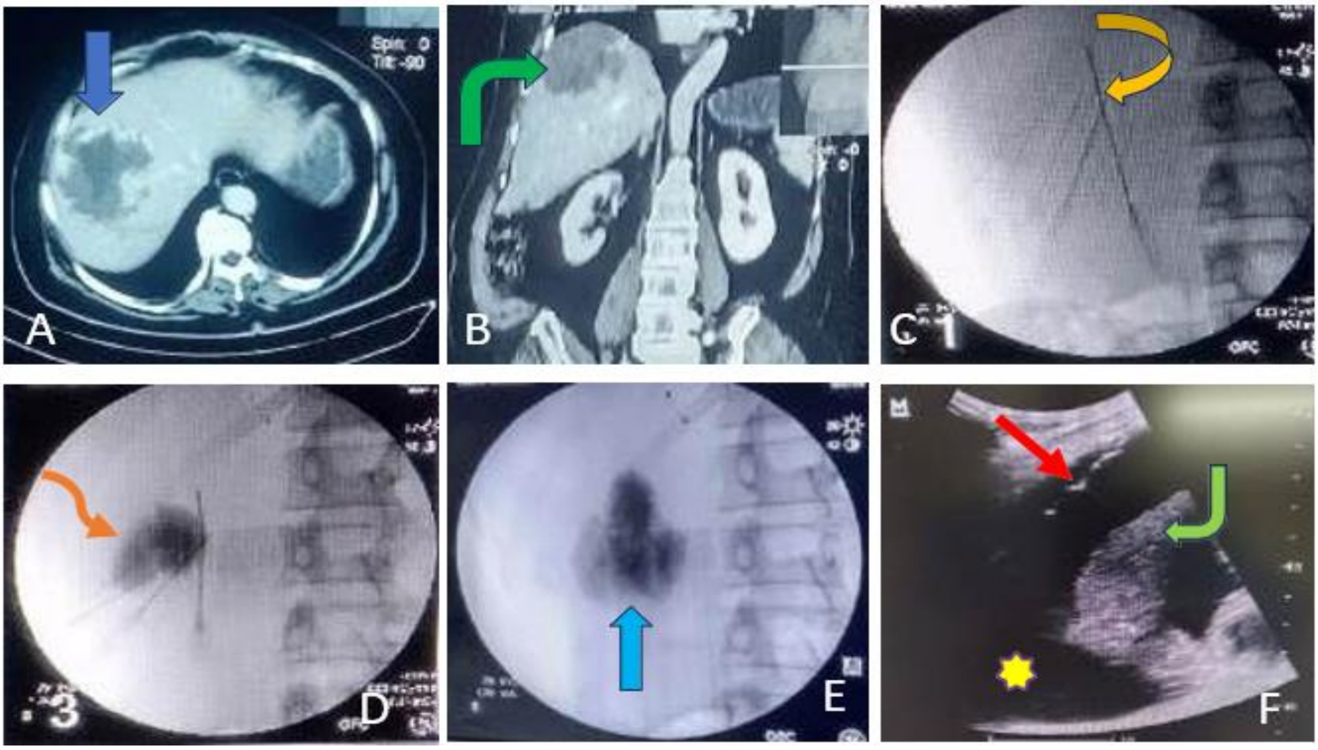

Figure 10: 40-year-old male patient with right upper lobe liver hemangioma who developed moderate right pleural effusion and mild respiratory distress post-percutaneous sclerotherapy. **A** – Axial contrast-enhanced CT scan of the abdomen showing right lobe liver mass with peripheral nodular enhancement in segments 7 and partly 8 with centripetal filling post-contrast in keeping with liver hemangioma (Blue arrow). **B** – Coronal reconstructed CT abdomen image demonstrating the mass and its proximity to the diaphragm (curved green arrow). **C** – Fluoroscopic image demonstrating the multiple gauge 22 Chiba needles placed before the injection confirming the entire coverage of the hemangioma (Curved golden arrow). **D** – Sclerosant-contrast mixture (Bleomycin 35IU+ diluted Omnipaque (350) contrast) injection started (wavy orange arrow) and the other remaining Chiba needles are still in situ. **E** – Fluoroscopic image post-injection of the sclerosant-contrast mixture confirming retention within the hemangioma and no extravasation or intravasation. **F** – Moderate right pleural effusion (yellow star) 72hrs after the percutaneous sclerotherapy procedure. It was drained successfully with a pigtail catheter (red arrow) size 10fr using trochar technique. An atelectatic right basal lung segment is also noted due to the effusion (curved light green arrow). The pleural effusion was most likely related to the post-procedure inflammatory response, and with the proximity of the diaphragm, the right pleural effusion developed. The patient improved well, the pigtail catheter was removed 48hrs later and the patient discharged thereafter with good recovery.

DISCUSSION

The majority of the patients were females (55%) compared to males, with male to female ratio of 1.1.2. This was similar to Manzano et al (6) who found more females than males at 68%. Most of the patients were in the category of 0-9 at 25%.

The most common indication of percutaneous sclerotherapy was pain accounting for 21.6%. This was followed by abnormal swelling comprising 18.9%. This was different from Winter et al (8) who found most of the sclerotherapy procedures were done for large or rapidly growing cavernous hemangiomas localized in the face region.

Patients who presented with an indication for cosmesis comprised 16.2%. Schmidt et al (7) had a higher incidence of 27.6% for patients with cosmetic disfigurement presenting for percutaneous sclerotherapy.

Most of the hemangiomas were located in the liver accounting for 25%. Hand hemangiomas were the second most predominant location at 15%.

This was different from Manzano et al (6) who found the most frequently affected region was the lower lip (52.3%), followed by the upper lip (23.8%), and this was due to the more varied anatomic locations of the hemangioma lesions in this study while Manzano et al(6) studied oral vascular malformations only.

This was different also from Ahmad et al (1) who studied hemangiomas of the head, neck and extremities, 24(68.6%) had head and neck hemangiomas, and 11 (31.4%) venous malformations in the trunk and extremities.

Majority of hemangiomas demonstrated improved clinical response to sclerotherapy treatment with symptoms reduction post-treatment. Lesion size reduced in majority of the cases. Schmidt et al (7) also demonstrated similar response rate of 88.9%.

Pain reduced in all the cases as well as improved cosmesis. Nevensy et al (9) demonstrated significant reduction in pain/discomfort and cosmetic disfigurement in patients who had veno- lymphatic and lymphatic malformations, with overall improvement by 69% and 82% respectively.

Nevesny et al.(9) examined the safety, efficacy, and midterm outcomes of percutaneous bleomycin sclerotherapy in patients with venous and lymphatic malformations. The study found a significant volume reduction of 76% in the lymphatic malformations group and 45% in the vascular malformations group. Both patient groups had significant reductions in cosmetic disfigurement, pain, and discomfort. The overall improvement in symptomatology was 69% in the vascular malformations group and 82% in the lymphatic malformations group.

The majority of the hemangiomas demonstrated moderate response at 50% (21-49% response), followed by significant/marked response at 35%(50-89%). >90% response and <20% response were each 5% respectively.

Schmidt et al (7) found an overall objective response rate of 88.9% in sclerotherapy of venous malformations of the hand. This was similar to our study.

Jan et al (10) observed complete resolution (cure) in 11 patients (36.66%), marked improvement in 17 patients (56.66%) and mild improvement in two patients (6.66%). This could be related to different lesions' responses to the sclerotherapy or technical procedure approach.

Above demonstrates high efficacy of sclerotherapy in management of the hemangiomas. Karimi et al (11) also found significant size reduction with upto 50% in 67.3% of the patients in head and neck venous malformations.

Most of the hemangiomas demonstrated significant reduced vascularity post sclerotherapy.

This was similar to Doyle et al(12) who found significantly reduced vascularity of the hemangiomas post sclerotherapy.

Percutaneous sclerotherapy of hemangiomas was found to be highly efficacious with statistically significant size reduction and symptom improvement post-treatment.

This is similar to Ahmad et al(1) who explored the safety and efficacy of percutaneous sclerotherapy in low-flow venous malformations. The study, involving 35 patients, showed that sclerotherapy alone could cause complete obliteration of vascular malformations. Most patients reported feeling much better after percutaneous sclerotherapy using bleomycin or sodium tetradecyl sulfate.

Jan et al. (10) also explored the therapeutic effects of intra-lesional bleomycin sclerotherapy for non-invasive management of low-flow vascular malformations, and reported a majority of the patients experienced either marked improvement or complete resolution.

Statistically significant radiological intralesional vascularity reduction post-sclerotherapy also reinforced the efficacy of percutaneous sclerotherapy in the management of hemangiomas.

Ayoobi Yazdi et al. (2021) (13) evaluated the role, feasibility, safety, and efficacy of percutaneous sclerotherapy with bleomycin and ethiodized oil as a promising treatment in symptomatic giant liver hemangioma. All study participants reported significant symptomatic relief and no major complications were reported after therapy.

The pooled technical success rate was 100% for all the percutaneous sclerotherapy procedures done with post-procedure good patient recovery. This was similar to Ayoobi et al (13) who had 100% technical success rate in their study.

The overall clinical success rate was at 90%. This was similar to Schmidt et al (7) found an overall objective response rate of 88.9%

Teusch et al (14) explored the effectiveness and safety of ethanol-gel sclerotherapy in the management of venous malformations. The technical success rate of ethanol-gel sclerotherapy was 100%, evidenced by clinical improvement and resolution of symptoms.

Lin et al (15) evaluated the use of ultrasound-guided percutaneous sclerotherapy versus surgical resection in the treatment of large hepatic hemangiomas. The study found that the technical success rate of intra-lesional sclerotherapy in managing hepatic hemangiomas was 100%.

Minimal minor complications were encountered and were not statistically significant. Mild pain and mild edema post-sclerotherapy were the commonest minor complications (10% respectively). This was different from Jan et al(10) who mostly had superficial ulcerations at 46.66% and hyperpigmentation at 3.33%. One patient had skin ulceration and discoloration (5%). Mild respiratory distress and moderate right pleural effusion were also 5% each. This demonstrates that percutaneous hemangiomas sclerotherapy is a safe and efficacious treatment method.

CONCLUSION

Percutaneous intralesional sclerotherapy is a safe and efficacious treatment of hemangiomas with a high technical and clinical success rate. It should be considered as a first line of treatment for hemangiomas.

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