Incidence of Complications Following Superficial Venous Interventions: Evidence from Claims Data

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BACKGROUND

- Chronic venous disease, resulting from venous reflux or obstruction, affects approximately 25 million adults in the US and can lead to pain, edema, and varicose veins[1]
- Superficial venous procedures are widely used to manage chronic venous disease to relieve symptoms and improve quality of life
- While these procedures have proven to be safe in clinical trials, real-world event rates have not been systematically studied across the different treatments

METHODS

- **Data source:** Medicare Fee-for-Service (FFS) (2018 – 2023) standard analytic files
- Patients ≥65 years old with continuous enrollment were included; the index date was defined as the first observed superficial venous procedure
- Superficial venous procedures and complications were identified with CPT and ICD-10 codes
  - In situations where there were not clear diagnosis codes for a specific complication event, a certified coder provided code combinations to best identify the event
- Procedures of interest include radiofrequency ablation, cyanoacrylate, laser, foam sclerotherapy, and adjunct procedures (sclerotherapy & phlebectomy)
- Patients were categorized into 8 groups based on single or combination procedures
- Unadjusted incidence of complications are reported for two time periods:
  - **Short term complications**: within **90** days of index procedure
  - **Long term complications:** within **6** months of index procedure

OBJECTIVE

In this retrospective observational study, we assessed the incidence of complications among patients receiving superficial venous procedures

Table 1. Incidence of complications following superficial venous procedures

		Complications				
		Short term			Long term	
Procedure type	Total Patients	Infection	Granuloma	Immune response*	Phlebitis	Death
Cyanoacrylate only	2,403	27 (1)	<11 (<0.5)	<11 (<0.5)	0 (0)	22 (0.9)
Cyanoacrylate plus	1,151	<11 (<1)	<11 (<1)	<11 (<1)	<11 (<1)	<11 (<1)
Laser only	1,487	<11 (<0.7)	<11 (<0.7)	11 (0.7)	<11 (<0.7)	<11 (<0.7)
Laser plus	1,621	<11 (<0.7)	0 (0)	<11 (<0.7)	0 (0)	<11 (<0.7))
Foam sclerotherapy	1,057	<11 (<1)	0 (0)	<11 (<1)	0 (0)	<11 (<1)
Foam sclerotherapy plus	498	<11 (<2)	0 (0)	0 (0)	0 (0)	<11 (<2)
Radiofrequency only	4,236	37 (0.9)	<11 (<0.3)	18 (0.4)	<11 (<0.3)	25 (0.6)
Radiofrequency plus	2,911	<11 (0.4)	0 (0)	11 (0.4)	0 (0)	<11 (<0.4)

Cell counts <11 were suppressed per data use agreements
*Immune response would be defined as symptoms of hypersensitivity or allergic reaction

KEY TAKEAWAY

Both short-term and long-term complications were consistently low across all the superficial venous procedure groups

RESULTS

- We identified **15,364** patients who received superficial venous procedures
- Baseline characteristics were similar across procedure groups, with the average age being 74 years old
- Complications rates were similar across procedure groups
- All long-term complications had < 11 events across groups which included deep vein thrombosis, pulmonary embolism, stroke, superficial venous thrombosis, phlebitis, and amputation
- Short term complications such as infection, granuloma and immune response also were infrequent
- Mortality rates were consistent with expectations for a Medicare population
- Results are descriptive and unadjusted for patient characteristics; causality was not evaluated

CONCLUSIONS

- Adverse events following superficial venous procedures were rare
- Findings support the favorable real-world safety profile of these interventions

REFERENCES

1. https://pmc.ncbi.nlm.nih.gov/articles/PMC7375188/#R3

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